COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED	___ (Y/N)
ADOPTED AS AMENDED	___ (Y/N)
ADOPTED W/O OBJECTION	___ (Y/N)
FAILED TO ADOPT	___ (Y/N)
WITHDRAWN	___ (Y/N)
OTHER	_____

Committee/Subcommittee hearing bill: Appropriations Committee
Representative Chaney offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. This act may be cited as the "Prescription Drug Reform Act."

Section 2. Subsection (29) is added to section 499.005, Florida Statutes, to read:

499.005 Prohibited acts.—It is unlawful for a person to perform or cause the performance of any of the following acts in this state:

(29) Failure to accurately complete and timely submit reportable drug price increase forms, reports, and documents as required by s. 499.026 and rules adopted thereunder.

Section 3. Subsection (16) is added to section 499.012, Florida Statutes, to read:

499.012 Permit application requirements.—

(16) A permit for a prescription drug manufacturer or a nonresident prescription drug manufacturer is subject to the requirements of s. 499.026.

Section 4. Section 499.026, Florida Statutes, is created to read:

499.026 Notification of manufacturer prescription drug price increases.—

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

(a) "Course of therapy" means the recommended daily dose units of a prescription drug pursuant to its prescribing label for 30 days or the recommended daily dose units of a prescription drug pursuant to its prescribing label for a normal course of treatment which is less than 30 days.

(b) "Manufacturer" means a person holding a prescription drug manufacturer permit or a nonresident prescription drug manufacturer permit under s. 499.01.

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

(d) "Reportable drug price increase" means, for a prescription drug with a wholesale acquisition cost of at least

$100 for a course of therapy before the effective date of an increase:

1. Any increase of 15 percent or more of the wholesale acquisition cost during the preceding 12-month period; or

2. Any cumulative increase of 30 percent or more of the wholesale acquisition cost during the preceding 3 calendar years. In calculating the 30 percent threshold, the manufacturer must base the calculation on the wholesale acquisition cost in effect at the end of the 3-year period as compared to the wholesale acquisition cost in effect at the beginning of the same 3-year period.

(e) "Wholesale acquisition cost" means, with respect to a prescription drug or biological product, the manufacturer's list price for the prescription drug or biological product to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates, or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological product pricing data.

(2) On the effective date of a manufacturer's reportable drug price increase, the manufacturer must provide notification of each reportable drug price increase to the department on a form prescribed by the department. The form must require the manufacturer to specify all of the following:

(a) The proprietary and nonproprietary names of the prescription drug, as applicable.

(b) The wholesale acquisition cost before the reportable drug price increase.

(c) The dollar amount of the reportable drug price increase.

(d) The percentage amount of the reportable drug price increase from the wholesale acquisition cost before the reportable drug price increase.

(e) Whether a change or an improvement in the prescription drug necessitates the reportable drug price increase.

(f) If a change or an improvement in the prescription drug necessitates the reportable drug price increase as reported in paragraph (e), the manufacturer must describe the change or improvement.

(g) The intended uses of the prescription drug.

This subsection does not prohibit a manufacturer from notifying other parties, such as pharmacy benefit managers, of a drug price increase before the effective date of the drug price increase.

(3) By April 1 of each year, each manufacturer shall submit a report to the department on a form prescribed by the department. The report must include all of the following:

(a) A list of all prescription drugs affected by a reportable drug price increase during the previous calendar year and both the dollar amount of each reportable drug price increase and the percentage increase of each reportable drug price increase relative to the previous wholesale acquisition cost of the prescription drug. The prescription drugs must be identified using their proprietary names and nonproprietary names, as applicable.

(b) If more than one form has been filed under this section for previous reportable drug price increases, the percentage increase of the prescription drug from the earliest form filed to the most recent form filed.

(c) The intended uses of each prescription drug listed in the report and whether the prescription drug manufacturer benefits from market exclusivity for such drug.

(d) The length of time the prescription drug has been available for purchase.

(e) A listing of the factors contributing to each reportable drug price increase. As used in this section, the term "factors" means any of the following: research and development; manufacturing costs; advertising and marketing; whether the drug has more competitive value; an increased rate of inflation or other economic dynamics; changes in market dynamics; supporting regulatory and safety commitments; operating patient assistance and educational programs; rebate

increases, including any rebate increase requested by a pharmacy benefit manager; Medicaid, Medicare, or 340B Drug Pricing Program offsets; profit; or other factors. An estimated percentage of the influence of each listed factor must be provided to equal 100 percent.

(f) A description of the justification for each factor referenced in paragraph (e) must be provided with such specificity as to explain the need or justification for each reportable drug price increase. The department may request additional information from a manufacturer relating to the need or justification for any reportable drug price increase before approving the manufacturer's report.

(g) Any action that the manufacturer has filed to extend a patent report after the first extension has been granted.

(4)(a) The department shall submit all forms and reports submitted by manufacturers to the Agency for Health Care Administration, to be posted on the agency's website pursuant to s. 408.062. The agency may not post on its website any of the information provided pursuant to paragraph (2)(f), paragraph (3)(f), or paragraph (3)(g) which is marked as a trade secret. The agency shall compile all information from the forms and reports submitted by manufacturers and make it available upon request to the Governor, the President of the Senate, and the Speaker of the House of Representatives.

(b) Except for information provided pursuant to paragraph (2)(f), paragraph (3)(f), or paragraph (3)(g), a manufacturer may not claim a public records exemption for a trade secret under s. 119.0715 for any information required by the department under this section. Department employees remain protected from liability for release of forms and reports pursuant to s. 119.0715(4).

(5) The department, in consultation with the Agency for Health Care Administration, shall adopt rules to implement this section.

(a) The department shall adopt necessary emergency rules pursuant to s. 120.54(4) to implement this section. If an emergency rule adopted under this section is held to be unconstitutional or an invalid exercise of delegated legislative authority and becomes void, the department may adopt an emergency rule pursuant to this section to replace the rule that has become void. If the emergency rule adopted to replace the void emergency rule is also held to be unconstitutional or an invalid exercise of delegated legislative authority and becomes void, the department must follow the nonemergency rulemaking procedures of the Administrative Procedure Act to replace the rule that has become void.

(b) For emergency rules adopted under this section, the department need not make the findings required under s.

120.54(4)(a). Emergency rules adopted under this section are also exempt from:

1. Sections 120.54(3)(b) and 120.541. Challenges to emergency rules adopted under this section are subject to the time schedules provided in s. 120.56(5).

2. Section 120.54(4)(c) and remain in effect until replaced by rules adopted under the nonemergency rulemaking procedures of the Administrative Procedure Act.

Section 5. Paragraph (a) of subsection (10) of section 624.307, Florida Statutes, is amended, and paragraph (b) of that subsection is republished, to read:

624.307 General powers; duties.—

(10)(a) The Division of Consumer Services shall perform the following functions concerning products or services regulated by the department or office:

1. Receive inquiries and complaints from consumers.

2. Prepare and disseminate information that the department deems appropriate to inform or assist consumers.

3. Provide direct assistance to and advocacy for consumers who request such assistance or advocacy.

4. With respect to apparent or potential violations of law or applicable rules committed by a person or an entity licensed by the department or office, report apparent or potential violations to the office or to the appropriate division of the

department, which may take any additional action it deems appropriate.

5. Designate an employee of the division as the primary contact for consumers on issues relating to sinkholes.

6. Designate an employee of the division as the primary contact for consumers and pharmacies on issues relating to pharmacy benefit managers. The division must refer to the office any consumer complaint that alleges conduct that may constitute a violation of part VII of chapter 626 or for which a pharmacy benefit manager does not respond in accordance with paragraph (b).

(b) Any person licensed or issued a certificate of authority by the department or the office shall respond, in writing, to the division within 20 days after receipt of a written request for documents and information from the division concerning a consumer complaint. The response must address the issues and allegations raised in the complaint and include any requested documents concerning the consumer complaint not subject to attorney-client or work-product privilege. The division may impose an administrative penalty for failure to comply with this paragraph of up to $2,500 per violation upon any entity licensed by the department or the office and $250 for the first violation, $500 for the second violation, and up to $1,000 for the third or subsequent violation upon any individual licensed by the department or the office.

Section 6. Subsection (1) of section 624.490, Florida Statutes, is amended to read:

624.490 Registration of pharmacy benefit managers.—

(1) As used in this section, the term "pharmacy benefit manager" has the same meaning as in s. 626.88 ~~means a person or entity doing business in this state which contracts to administer prescription drug benefits on behalf of a health insurer or a health maintenance organization to residents of this state.~~

Section 7. Subsections (1) and (5) of section 624.491, Florida Statutes, are amended to read:

624.491 Pharmacy audits.—

(1) A pharmacy benefits plan or program as defined in s. 626.8825 ~~health insurer or health maintenance organization~~ providing pharmacy benefits ~~through a major medical individual or group health insurance policy or a health maintenance contract, respectively,~~ must comply with the requirements of this section when the pharmacy benefits plan or program ~~health insurer or health maintenance organization~~ or any person or entity acting on behalf of the pharmacy benefits plan or program ~~health insurer or health maintenance organization~~, including, but not limited to, a pharmacy benefit manager as defined in s. 626.88 ~~s. 624.490(1)~~, audits the records of a pharmacy licensed under chapter 465. The person or entity conducting such audit must:

(a) Except as provided in subsection (3), notify the pharmacy at least 7 calendar days before the initial onsite audit for each audit cycle.

(b) Not schedule an onsite audit during the first 3 calendar days of a month unless the pharmacist consents otherwise.

(c) Limit the duration of the audit period to 24 months after the date a claim is submitted to or adjudicated by the entity.

(d) In the case of an audit that requires clinical or professional judgment, conduct the audit in consultation with, or allow the audit to be conducted by, a pharmacist.

(e) Allow the pharmacy to use the written and verifiable records of a hospital, physician, or other authorized practitioner, which are transmitted by any means of communication, to validate the pharmacy records in accordance with state and federal law.

(f) Reimburse the pharmacy for a claim that was retroactively denied for a clerical error, typographical error, scrivener's error, or computer error if the prescription was properly and correctly dispensed, unless a pattern of such errors exists, fraudulent billing is alleged, or the error results in actual financial loss to the entity.

(g) Provide the pharmacy with a copy of the preliminary audit report within 120 days after the conclusion of the audit.

(h) Allow the pharmacy to produce documentation to address a discrepancy or audit finding within 10 business days after the preliminary audit report is delivered to the pharmacy.

(i) Provide the pharmacy with a copy of the final audit report within 6 months after the pharmacy's receipt of the preliminary audit report.

(j) Calculate any recoupment or penalties based on actual overpayments and not according to the accounting practice of extrapolation.

(5) A pharmacy benefits plan or program ~~health insurer or health maintenance organization~~ that, under terms of a contract, transfers to a pharmacy benefit manager the obligation to pay a pharmacy licensed under chapter 465 for any pharmacy benefit claims arising from services provided to or for the benefit of an insured or subscriber remains responsible for a violation of this section.

Section 8. Subsection (1) of section 626.88, Florida Statutes, is amended, and subsection (6) is added to that section, to read:

626.88 Definitions.—For the purposes of this part, the term:

(1) "Administrator" means ~~is~~ any person who directly or indirectly solicits or effects coverage of, collects charges or premiums from, or adjusts or settles claims on residents of this state in connection with authorized commercial self-insurance

funds or with insured or self-insured programs which provide life or health insurance coverage or coverage of any other expenses described in s. 624.33(1); ~~or~~ any person who, through a health care risk contract as defined in s. 641.234 with an insurer or health maintenance organization, provides billing and collection services to health insurers and health maintenance organizations on behalf of health care providers; or a pharmacy benefit manager. The term does not include~~, other than~~ any of the following ~~persons~~:

(a) An employer or wholly owned direct or indirect subsidiary of an employer, on behalf of such employer's employees or the employees of one or more subsidiary or affiliated corporations of such employer.

(b) A union on behalf of its members.

(c) An insurance company which is either authorized to transact insurance in this state or is acting as an insurer with respect to a policy lawfully issued and delivered by such company in and pursuant to the laws of a state in which the insurer was authorized to transact an insurance business.

(d) A health care services plan, health maintenance organization, professional service plan corporation, or person in the business of providing continuing care, possessing a valid certificate of authority issued by the office, and the sales representatives thereof, if the activities of such entity are

limited to the activities permitted under the certificate of authority.

(e) An entity that is affiliated with an insurer and that only performs the contractual duties, between the administrator and the insurer, of an administrator for the direct and assumed insurance business of the affiliated insurer. The insurer is responsible for the acts of the administrator and is responsible for providing all of the administrator's books and records to the insurance commissioner, upon a request from the insurance commissioner. For purposes of this paragraph, the term "insurer" means a licensed insurance company, health maintenance organization, prepaid limited health service organization, or prepaid health clinic.

(f) A nonresident entity licensed in its state of domicile as an administrator if its duties in this state are limited to the administration of a group policy or plan of insurance and no more than a total of 100 lives for all plans reside in this state.

(g) An insurance agent licensed in this state whose activities are limited exclusively to the sale of insurance.

(h) A person appointed as a managing general agent in this state, whose activities are limited exclusively to the scope of activities conveyed under such appointment.

(i) An adjuster licensed in this state whose activities are limited to the adjustment of claims.

(j) A creditor on behalf of such creditor's debtors with respect to insurance covering a debt between the creditor and its debtors.

(k) A trust and its trustees, agents, and employees acting pursuant to such trust established in conformity with 29 U.S.C. s. 186.

(l) A trust exempt from taxation under s. 501(a) of the Internal Revenue Code, a trust satisfying the requirements of ss. 624.438 and 624.439, or any governmental trust as defined in s. 624.33(3), and the trustees and employees acting pursuant to such trust, or a custodian and its agents and employees, including individuals representing the trustees in overseeing the activities of a service company or administrator, acting pursuant to a custodial account which meets the requirements of s. 401(f) of the Internal Revenue Code.

(m) A financial institution which is subject to supervision or examination by federal or state authorities or a mortgage lender licensed under chapter 494 who collects and remits premiums to licensed insurance agents or authorized insurers concurrently or in connection with mortgage loan payments.

(n) A credit card issuing company which advances for and collects premiums or charges from its credit card holders who have authorized such collection if such company does not adjust or settle claims.

(o) A person who adjusts or settles claims in the normal course of such person's practice or employment as an attorney at law and who does not collect charges or premiums in connection with life or health insurance coverage.

(p) A person approved by the department who administers only self-insured workers' compensation plans.

(q) A service company or service agent and its employees, authorized in accordance with ss. 626.895-626.899, serving only a single employer plan, multiple-employer welfare arrangements, or a combination thereof.

(r) Any provider or group practice, as defined in s. 456.053, providing services under the scope of the license of the provider or the member of the group practice.

(s) Any hospital providing billing, claims, and collection services solely on its own and its physicians' behalf and providing services under the scope of its license.

(t) A corporation not for profit whose membership consists entirely of local governmental units authorized to enter into risk management consortiums under s. 112.08.

A person who provides billing and collection services to health insurers and health maintenance organizations on behalf of health care providers shall comply with the provisions of ss. 627.6131, 641.3155, and 641.51(4).

(6) "Pharmacy benefit manager" means a person or an entity doing business in this state which contracts to administer prescription drug benefits on behalf of a pharmacy benefits plan or program as defined in s. 626.8825. The term includes, but is not limited to, a person or an entity that performs one or more of the following services on behalf of such plan or program:

(a) Pharmacy claims processing.

(b) Administration or management of a pharmacy discount card program and performance of any other service listed in this subsection.

(c) Managing pharmacy networks or pharmacy reimbursement.

(d) Paying or managing claims for pharmacist services provided to covered persons.

(e) Developing or managing a clinical formulary, including utilization management or quality assurance programs.

(f) Pharmacy rebate administration.

(g) Managing patient compliance, therapeutic intervention, or generic substitution programs.

(h) Administration or management of a mail-order pharmacy program.

Section 9. Present subsections (3) through (6) of section 626.8805, Florida Statutes, are redesignated as subsections (4) through (7), respectively, a new subsection (3) and subsection (8) are added to that section, and subsection (1) and present subsection (3) of that section are amended, to read:

626.8805 Certificate of authority to act as administrator.—

(1) It is unlawful for any person to act as or hold himself or herself out to be an administrator in this state without a valid certificate of authority issued by the office pursuant to ss. 626.88-626.894. A pharmacy benefit manager that is registered with the office under s. 624.490 as of June 30, 2023, may continue to operate until January 1, 2024, as an administrator without a certificate of authority and is not in violation of the requirement to possess a valid certificate of authority as an administrator during that timeframe. To qualify for and hold authority to act as an administrator in this state, an administrator must otherwise be in compliance with this code and with its organizational agreement. The failure of any person, excluding a pharmacy benefit manager, to hold such a certificate while acting as an administrator shall subject such person to a fine of not less than $5,000 or more than $10,000 for each violation. A person who, on or after January 1, 2024, does not hold a certificate of authority to act as an administrator while operating as a pharmacy benefit manager is subject to a fine of $10,000 per violation per day. By January 15, 2024, the office shall submit to the Governor, the President of the Senate, and the Speaker of the House of Representatives a report detailing whether each pharmacy benefit manager operating

in this state on January 1, 2024, obtained a certificate of authority on or before that date as required by this section.

(3) An applicant that is a pharmacy benefit manager must also submit all of the following:

(a) A complete biographical statement on forms prescribed by the commission.

(b) An independent background report as prescribed by the commission.

(c) A full set of fingerprints of all of the individuals referenced in paragraph (2)(c) to the office or to a vendor, entity, or agency authorized by s. 943.053(13). The office, vendor, entity, or agency, as applicable, shall forward the fingerprints to the Department of Law Enforcement for state processing, and the Department of Law Enforcement shall forward the fingerprints to the Federal Bureau of Investigation for national processing in accordance with s. 943.053 and 28 C.F.R. s. 20.

(d) A self-disclosure of any administrative, civil, or criminal complaints, settlements, or discipline of the applicant, or any of the applicant's affiliates, which relate to a violation of the insurance laws, including pharmacy benefit manager laws, in any state.

(e) A statement attesting to compliance with the network requirements in s. 626.8825 beginning January 1, 2024.

(4)(a) ~~(3)~~ The applicant shall make available for inspection by the office copies of all contracts relating to services provided by the administrator to insurers or other persons using the services of the administrator.

(b) An applicant that is a pharmacy benefit manager shall also make available for inspection by the office:

1. Copies of all contract templates with any pharmacy as defined in s. 465.003; and

2. Copies of all subcontracts to support its operations.

(8) A pharmacy benefit manager is exempt from fees associated with the initial application and the annual filing fees in s. 626.89.

Section 10. Section 626.8814, Florida Statutes, is amended to read:

626.8814 Disclosure of ownership or affiliation.—

(1) Each administrator shall identify to the office any ownership interest or affiliation of any kind with any insurance company responsible for providing benefits directly or through reinsurance to any plan for which the administrator provides administrative services.

(2) Pharmacy benefit managers shall also identify to the office any ownership affiliation of any kind with any pharmacy which, either directly or indirectly, through one or more intermediaries:

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

(b) Shares common ownership with a pharmacy benefit manager holding a certificate of authority issued under this part; or

(c) 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.

(3) A pharmacy benefit manager shall report any change in information required by subsection (2) to the office in writing within 60 days after the change occurs.

Section 11. Section 626.8825, Florida Statutes, is created to read:

626.8825 Pharmacy benefit manager transparency and accountability.—

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

(a) "Adjudication transaction fee" means a fee charged by the pharmacy benefit manager to the pharmacy for electronic claim submissions.

(b) "Affiliated pharmacy" means a pharmacy 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.

(c) "Brand name or generic effective rate" means the contractual rate set forth by a pharmacy benefit manager for the reimbursement of covered brand name or generic drugs, calculated using the total payments in the aggregate, by drug type, during the performance period. The effective rates are typically calculated as a discount from industry benchmarks, such as average wholesale price or wholesale acquisition cost.

(d) "Covered person" means a person covered by, participating in, or receiving the benefit of a pharmacy benefits plan or program.

(e) "Direct and indirect remuneration fees" means price concessions that are paid to the pharmacy benefit manager by the pharmacy retrospectively and that cannot be calculated at the point of sale. The term may also include discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, upfront payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits from manufacturers, pharmacies, or similar entities.

(f) "Dispensing fee" means a fee intended to cover reasonable costs associated with providing the drug to a covered person. This cost includes the pharmacist's services and the overhead associated with maintaining the facility and equipment necessary to operate the pharmacy.

(g) "Effective rate guarantee" means the minimum ingredient cost reimbursement a pharmacy benefit manager guarantees it will pay for pharmacist services during the applicable measurement period.

(h) "Erroneous claims" means pharmacy claims submitted in error, including, but not limited to, unintended, incorrect, fraudulent, or test claims.

(i) "Group purchasing organization" means an entity affiliated with a pharmacy benefit manager or a pharmacy benefits plan or program which uses purchasing volume aggregates as leverage to negotiate discounts and rebates for covered prescription drugs with pharmaceutical manufacturers, distributors, and wholesale vendors.

(j) "Incentive payment" means a retrospective monetary payment made as a reward or recognition by the pharmacy benefits plan or program or pharmacy benefit manager to a pharmacy for meeting or exceeding predefined pharmacy performance metrics as related to quality measures, such as Healthcare Effectiveness Data and Information Set measures.

(k) "Maximum allowable cost appeal pricing adjustment" means a retrospective positive payment adjustment made to a pharmacy by the pharmacy benefits plan or program or by the pharmacy benefit manager pursuant to an approved maximum allowable cost appeal request submitted by the same pharmacy to dispute the amount reimbursed for a drug based on the pharmacy benefit manager's listed maximum allowable cost price.

(l) "Monetary recoupments" means rescinded or recouped payments from a pharmacy or provider by the pharmacy benefits plan or program or by the pharmacy benefit manager.

(m) "Network" means a group of pharmacies that agree to provide pharmacist services to covered persons on behalf of a pharmacy benefits plan or program or a group of pharmacy benefits plans or programs in exchange for payment for such services. The term includes a pharmacy that generally dispenses outpatient prescription drugs to covered persons.

(n) "Network reconciliation offsets" means a process during annual payment reconciliation between a pharmacy benefit manager and a pharmacy which allows the pharmacy benefit manager to offset an amount for overperformance or underperformance of contractual guarantees across guaranteed line items, channels, networks, or payors, as applicable.

(o) "Participation contract" means any agreement between a pharmacy benefit manager and pharmacy for the provision and

reimbursement of pharmacist services and any exhibits, attachments, amendments, or addendums to such agreement.

(p) "Pass-through pricing model" means a payment model used by a pharmacy benefit manager in which the payments made by the pharmacy benefits plan or program to the pharmacy benefit manager for the covered outpatient drugs are:

1. Equivalent to the payments the pharmacy benefit manager makes to a dispensing pharmacy or provider for such drugs, including any contracted professional dispensing fee between the pharmacy benefit manager and its network of pharmacies. Such dispensing fee would be paid if the pharmacy benefits plan or program was making the payments directly.

2. Passed through in their entirety by the pharmacy benefits plan or program or by the pharmacy benefit manager to the pharmacy or provider that dispenses the drugs, and the payments are made in a manner that is not offset by any reconciliation.

(q) "Pharmacist" has the same meaning as in s. 465.003.

(r) "Pharmacist services" means products, goods, and services or any combination of products, goods, and services provided as part of the practice of the profession of pharmacy as defined in s. 465.003 or otherwise covered by a pharmacy benefits plan or program.

(s) "Pharmacy" has the same meaning as in s. 465.003.

(t) "Pharmacy benefit manager" has the same meaning as in s. 626.88.

(u) "Pharmacy benefits plan or program" means a plan or program that pays for, reimburses, covers the cost of, or provides access to discounts on pharmacist services provided by one or more pharmacies to covered persons who reside in, are employed by, or receive pharmacist services from this state.

1. The term includes, but is not limited to, health maintenance organizations, health insurers, self-insured employer health plans, discount card programs, and government-funded health plans, including the Statewide Medicaid Managed Care program established pursuant to part IV of chapter 409 and the state group insurance program pursuant to part I of chapter 110.

2. The term excludes such a plan or program under chapter 440.

(v) "Rebate" means all payments that accrue to a pharmacy benefit manager or its pharmacy benefits plan or program client or an affiliated group purchasing organization, directly or indirectly, from a pharmaceutical manufacturer, including, but not limited to, discounts, administration fees, credits, incentives, or penalties associated directly or indirectly in any way with claims administered on behalf of a pharmacy benefits plan or program client.

(w) "Spread pricing" is the practice in which a pharmacy benefit manager charges a pharmacy benefits plan or program a different amount for pharmacist services than the amount the pharmacy benefit manager reimburses a pharmacy for such pharmacist services.

(x) "Usual and customary price" means the amount charged to cash customers for a pharmacist service exclusive of sales tax or other amounts claimed.

(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:

(a) Use a pass-through pricing model, remaining consistent with the prohibition in paragraph (3)(c).

(b) Exclude terms that allow for the direct or indirect engagement in the practice of spread pricing unless the pharmacy benefit manager passes along the entire amount of such difference to the pharmacy benefits plan or program as allowable under paragraph (a).

(c) Ensure that funds received in relation to providing services for a pharmacy benefits plan or program or a pharmacy are received by the pharmacy benefit manager in trust for the

pharmacy benefits plan or program or pharmacy, as applicable, and are used or distributed only pursuant to the pharmacy benefit manager's contract with the pharmacy benefits plan or program or with the pharmacy or as otherwise required by applicable law.

(d) Require the pharmacy benefit manager to pass 100 percent of all prescription drug manufacturer rebates, including nonresident manufacturer rebates, received to the pharmacy benefits plan or program, if the contractual arrangement delegates the negotiation of rebates to the pharmacy benefit manager, for the sole purpose of offsetting defined cost sharing and reducing premiums of covered persons. Any excess rebate revenue after the pharmacy benefit manager and the pharmacy benefits plan or program have taken all actions required under this paragraph must be used for the sole purpose of offsetting copayments and deductibles of covered persons. This paragraph does not apply to contracts involving Medicaid managed care plans.

(e) Include network adequacy requirements that meet or exceed the Medicare Part D program standards for convenient access to network pharmacies set forth in 42 C.F.R. s. 423.120, and that:

1. Do not limit a network to solely include affiliated pharmacies;

2. Require a pharmacy benefit manager to offer a provider contract to licensed pharmacies physically located on the physical site of providers that are:

a. Within the pharmacy benefits plan's or program's geographic service area and that have been specifically designated as essential providers by the Agency for Health Care Administration pursuant to s. 409.975(1)(a);

b. Designated as a Cancer Center of Excellence under s. 381.925, regardless of the pharmacy benefits plan's or program's geographic service area;

c. Organ transplant hospitals, regardless of the pharmacy benefits plan's or program's geographic service area;

d. Hospitals licensed as specialty children's hospitals as defined in s. 395.002; or

e. Regional perinatal intensive care centers as defined in s. 383.16(2), regardless of the pharmacy benefits plan's or program's geographic service area.

Such provider contracts must be solely for the administration of covered prescription drugs, including biological products, that are administered through infusions, intravenously injected, inhaled during a surgical procedure, or a covered parenteral drug, as part of onsite outpatient care;

3. Do not require a covered person to receive a prescription drug by United States mail, common carrier, local

courier, third-party company or delivery service, or pharmacy direct delivery unless the prescription drug cannot be acquired at any retail pharmacy in the pharmacy benefit manager's network for the covered person's pharmacy benefits plan or program. This subparagraph does not prohibit a pharmacy benefit manager from operating mail order or delivery programs on an opt-in basis at the sole discretion of a covered person, provided the covered person is not penalized, such as through the imposition of a higher cost-sharing obligation or a lower allowed-quantity limit, for choosing not to opt in to the mail order or delivery programs; and

4. Prohibit requiring a covered person to receive pharmacist services from an affiliated pharmacy or an affiliated health care provider for the in-person administration of covered prescription drugs; offering or implementing pharmacy networks that require or provide a promotional item or an incentive, defined as anything other than a reduced cost-sharing amount or enhanced quantity limit allowed under the benefit design for a covered drug, to a covered person to use an affiliated pharmacy or an affiliated health care provider for the in-person administration of covered prescription drugs; or advertising, marketing, or promoting an affiliated pharmacy to covered persons. Subject to the foregoing, a pharmacy benefit manager may include an affiliated pharmacy in communications to covered persons regarding network pharmacies and prices, provided that

the pharmacy benefit manager includes information, such as links to all nonaffiliated network pharmacies, in such communications and that the information provided is accurate and of equal prominence. This subparagraph may not be construed to prohibit a pharmacy benefit manager from entering into an agreement with an affiliated pharmacy to provide pharmacist services to covered persons.

(f) Prohibit the ability of a pharmacy benefit manager to condition participation in one pharmacy network on participation in any other pharmacy network or penalize a pharmacy for exercising its prerogative not to participate in a specific pharmacy network.

(g) Prohibit a pharmacy benefit manager from instituting a network that requires a pharmacy to meet accreditation standards inconsistent with or more stringent than applicable federal and state requirements for licensure and operation as a pharmacy in this state. However, a pharmacy benefit manager may specify additional specialty networks that require enhanced standards related to the safety and competency necessary to meet the United States Food and Drug Administration's limited distribution requirements for dispensing any drug that, on a drug-by-drug basis, requires extraordinary special handling, provider coordination, or clinical care or monitoring when such extraordinary requirements cannot be met by a retail pharmacy. For purposes of this paragraph, drugs requiring extraordinary

special handling are limited to drugs that are subject to a risk evaluation and mitigation strategy approved by the United States Food and Drug Administration and that:

1. Require special certification of a health care provider to prescribe, receive, dispense, or administer; or

2. Require special handling due to the molecular complexity or cytotoxic properties of the biologic or biosimilar product or drug.

For participation in a specialty network, a pharmacy benefit manager may not require a pharmacy to meet requirements for participation beyond those necessary to demonstrate the pharmacy's ability to dispense the drug in accordance with the United States Food and Drug Administration's approved manufacturer labeling.

(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. 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:

(a) At the time of adjudication for electronic claims or the time of reimbursement for nonelectronic claims, the pharmacy benefit manager shall provide the pharmacy with a remittance,

including such detailed information as is necessary for the pharmacy or pharmacist to identify the reimbursement schedule for the specific network applicable to the claim and which is the basis used by the pharmacy benefit manager to calculate the amount of reimbursement paid. This information must include, but is not limited to, the applicable network reimbursement ID or plan ID as defined in the most current version of the National Council for Prescription Drug Programs (NCPDP) Telecommunication Standard Implementation Guide, or its nationally recognized successor industry guide. The commission shall adopt rules to implement this paragraph.

(b) The pharmacy benefit manager must ensure that any basis of reimbursement information is communicated to a pharmacy in accordance with the NCPDP Telecommunication Standard Implementation Guide, or its nationally recognized successor industry guide, when performing reconciliation for any effective rate guarantee, and that such basis of reimbursement information communicated is accurate, corresponds with the applicable network rate, and may be relied upon by the pharmacy.

(c) A prohibition of financial clawbacks, reconciliation offsets, or offsets to adjudicated claims. A pharmacy benefit manager may not charge, withhold, or recoup direct or indirect remuneration fees, dispensing fees, brand name or generic effective rate adjustments through reconciliation, or any other monetary charge, withholding, or recoupments as related to

discounts, multiple network reconciliation offsets, adjudication transaction fees, and any other instance when a fee may be recouped from a pharmacy. This prohibition does not apply to:

1. Any incentive payments provided by the pharmacy benefit manager to a network pharmacy for meeting or exceeding predefined quality measures, such as Healthcare Effectiveness Data and Information Set measures; recoupment due to an erroneous claim, fraud, waste, or abuse; a claim adjudicated in error; a maximum allowable cost appeal pricing adjustment; or an adjustment made as part of a pharmacy audit pursuant to s. 624.491.

2. Any recoupment that is returned to the state for programs in chapter 409 or the state group insurance program in s. 110.123.

(d) A pharmacy benefit manager may not unilaterally change the terms of any participation contract.

(e) Unless otherwise prohibited by law, a pharmacy benefit manager may not prohibit a pharmacy or pharmacist from:

1. Offering mail or delivery services on an opt-in basis at the sole discretion of the covered person.

2. Mailing or delivering a prescription drug to a covered person upon his or her request.

3. Charging a shipping or handling fee to a covered person requesting a prescription drug be mailed or delivered if the pharmacy or pharmacist discloses to the covered person before

the mailing or delivery the amount of the fee that will be charged and that the fee may not be reimbursable by the covered person's pharmacy benefits plan or program.

(f) The pharmacy benefit manager must provide a pharmacy, upon its request, a list of pharmacy benefits plans or programs in which the pharmacy is a part of the network. Updates to the list must be communicated to the pharmacy within 7 days. The pharmacy benefit manager may not restrict the pharmacy or pharmacist from disclosing this information to the public.

(g) The pharmacy benefit manager must ensure that the Electronic Remittance Advice contains claim level payment adjustments in accordance with the American National Standards Institute Accredited Standards Committee, X12 format, and includes or is accompanied by the appropriate level of detail for the pharmacy to reconcile any debits or credits, including, but not limited to, pharmacy NCPDP or NPI identifier, date of service, prescription number, refill number, adjustment code, if applicable, and transaction amount.

(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 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 12. Section 626.8827, Florida Statutes, is created 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:

(1) Prohibit, restrict, or penalize in any way a pharmacy or pharmacist from disclosing to any person any information that the pharmacy or pharmacist deems appropriate, including, but not limited to, information regarding any of the following:

(a) The nature of treatment, risks, or alternatives thereto.

(b) The availability of alternate treatment, consultations, or tests.

(c) The decision of utilization reviewers or similar persons to authorize or deny pharmacist services.

(d) The process used to authorize or deny pharmacist services or benefits.

(e) Information on financial incentives and structures used by the pharmacy benefits plan or program.

(f) Information that may reduce the costs of pharmacist services.

(g) Whether the cost-sharing obligation exceeds the retail price for a covered prescription drug and the availability of a more affordable alternative drug, pursuant to s. 465.0244.

(2) Prohibit, restrict, or penalize in any way a pharmacy or pharmacist from disclosing information to the office, the Agency for Health Care Administration, Department of Management Services, law enforcement, or state and federal governmental officials, provided that the recipient of the information represents it has the authority, to the extent provided by state or federal law, to maintain proprietary information as confidential; and before disclosure of information designated as confidential, the pharmacist or pharmacy marks as confidential any document in which the information appears or requests confidential treatment for any oral communication of the information.

(3) Communicate at the point-of-sale, or otherwise require, a cost-sharing obligation for the covered person in an amount that exceeds the lesser of:

(a) The applicable cost-sharing amount under the applicable pharmacy benefits plan or program; or

(b) The usual and customary price, as defined in s. 626.8825, of the pharmacist services.

(4) Transfer or share records relative to prescription information containing patient-identifiable or prescriber-identifiable data to an affiliated pharmacy for any commercial purpose other than the limited purposes of facilitating pharmacy reimbursement, formulary compliance, or utilization review on behalf of the applicable pharmacy benefits plan or program.

(5) Fail to make any payment due to a pharmacy for an adjudicated claim with a date of service before the effective date of a pharmacy's termination from a pharmacy benefit network unless payments are withheld because of fraud on the part of the pharmacy or except as otherwise required by law.

(6) Terminate the contract of, penalize, or disadvantage a pharmacist or pharmacy due to a pharmacist or pharmacy:

(a) Disclosing information about pharmacy benefit manager practices in accordance with this act;

(b) Exercising any of its prerogatives under this part; or

(c) Sharing any portion, or all, of the pharmacy benefit manager contract with the office pursuant to a complaint or a

query regarding whether the contract is in compliance with this act.

(7) Fail to comply with the requirements in s. 626.8825 or s. 624.491.

Section 13. Section 626.8828, Florida Statutes, is created to read:

626.8828 Investigations and examinations of pharmacy benefit managers; expenses; penalties.—

(1) The office may investigate administrators who are pharmacy benefit managers and applicants for authorization as provided in ss. 624.307 and 624.317. The office shall review any referral made pursuant to s. 624.307(10) and shall investigate any referral that, as determined by the Commissioner of Insurance Regulation or his or her designee, reasonably indicates a possible violation of this part.

(2)(a) The office shall examine the business and affairs of each pharmacy benefit manager at least biennially. The biennial examination of each pharmacy benefit manager must be a systematic review for the purpose of determining the pharmacy benefit manager's compliance with all provisions of this part and all other laws or rules applicable to pharmacy benefit managers and must include a detailed review of the pharmacy benefit manager's compliance with ss. 626.8825 and 626.8827. The first 2-year cycle for conducting biennial reviews begins January 1, 2025. By January 15, 2026, and each January 15

thereafter, the office shall submit to the Governor, the President of the Senate, and the Speaker of the House of Representatives a report summarizing the results of the prior year's examinations which includes detailed descriptions of any violations committed by each pharmacy benefit manager and detailed reporting of actions taken by the office against each pharmacy benefit manager for such violations. Beginning with the 2027 report, and every 2 years thereafter, the report must document the office's compliance with the examination timeframe requirements as provided in this paragraph. The office must specify the number and percentage of all examination completed within the timeframe.

(b) The office also may conduct additional examinations as often as it deems advisable or necessary for the purpose of ascertaining compliance with this part and any other laws or rules applicable to pharmacy benefit managers or applicants for authorization.

(c) If a referral made pursuant to s. 624.307(10) reasonably indicates a pattern or practice of violations of this part by a pharmacy benefit manager, the office must begin an examination of the pharmacy benefit manager or include findings related to such referral within an ongoing examination.

(d) Based on the findings of an examination that a pharmacy benefit manager or an applicant for authorization has exhibited a pattern or practice of knowing and willful

violations of s. 626.8825 or s. 626.8827, the office may, pursuant to chapter 120, order a pharmacy benefit manager to file all contracts between the pharmacy benefit manager and pharmacies or pharmacy benefits plans or programs and any policies, guidelines, rules, protocols, standard operating procedures, instructions, or directives that govern or guide the manner in which the pharmacy benefit manager or applicant conducts business related to such knowing and willful violations for review and inspection for the following 36-month period. Such documents are public records and are not trade secrets or otherwise exempt from s. 119.07(1). As used in this section, the term:

1. "Contracts" means any contract to which s. 626.8825 is applicable.

2. "Knowing and willful" means any act of commission or omission which is committed intentionally, as opposed to accidentally, and which is committed with knowledge of the act's unlawfulness or with reckless disregard as to the unlawfulness of the act.

(e) Examinations may be conducted by an independent professional examiner under contract to the office, in which case payment must be made directly to the contracted examiner by the pharmacy benefit manager examined in accordance with the rates and terms agreed to by the office and the examiner. The commission shall adopt rules providing for the types of

independent professional examiners who may conduct examinations under this section, which types must include, but need not be limited to, independent certified public accountants, actuaries, investment specialists, information technology specialists, or others meeting criteria specified by commission rule. The rules must also require that:

1. The rates charged to the pharmacy benefit manager being examined are consistent with rates charged by other firms in a similar profession and are comparable with the rates charged for comparable examinations.

2. The firm selected by the office to perform the examination has no conflicts of interest which might affect its ability to independently perform its responsibilities for the examination.

(3) In making investigations and examinations of pharmacy benefit managers and applicants for authorization, the office and such pharmacy benefit manager are subject to all of the following provisions:

(a) Section 624.318, as to the conduct of examinations.

(b) Section 624.319, as to examination and investigation reports.

(c) Section 624.321, as to witnesses and evidence.

(d) Section 624.322, as to compelled testimony.

(e) Section 624.324, as to hearings.

(f) Any other provision of chapter 624 applicable to the investigation or examination of a licensee under this part.

(4)(a) A pharmacy benefit manager must maintain an accurate record of all contracts and records with all pharmacies and pharmacy benefits plans or programs for the duration of the contract, and for 5 years thereafter. Such contracts must be made available to the office and kept in a form accessible to the office.

(b) The office may order any pharmacy benefit manager or applicant to produce any records, books, files, contracts, advertising and solicitation materials, or other information and may take statements under oath to determine whether the pharmacy benefit manager or applicant is in violation of the law or is acting contrary to the public interest.

(5)(a) Notwithstanding s. 624.307(3), each pharmacy benefit manager and applicant for authorization must pay to the office the expenses of the examination or investigation. Such expenses include actual travel expenses, a reasonable living expense allowance, compensation of the examiner, investigator, or other person making the examination or investigation, and necessary costs of the office directly related to the examination or investigation. Such travel expenses and living expense allowances are limited to those expenses necessarily incurred on account of the examination or investigation and shall be paid by the examined pharmacy benefit manager or

applicant together with compensation upon presentation by the office to such pharmacy benefit manager or applicant of such charges and expenses after a detailed statement has been filed by the examiner and approved by the office.

(b) All moneys collected from pharmacy benefit managers and applicants for authorization pursuant to this subsection shall be deposited into the Insurance Regulatory Trust Fund, and the office may make deposits from time to time into such fund from moneys appropriated for the operation of the office.

(c) Notwithstanding s. 112.061, the office may pay to the examiner, investigator, or person making such examination or investigation out of such trust fund the actual travel expenses, reasonable living expense allowance, and compensation in accordance with the statement filed with the office by the examiner, investigator, or other person, as provided in paragraph (a).

(6) In addition to any other enforcement authority available to the office, the office shall impose an administrative fine of $5,000 for each violation of s. 626.8825 or s. 626.8827. Each instance of a violation of such sections by a pharmacy benefit manager against each individual pharmacy or prescription benefits plan or program constitutes a separate violation. Notwithstanding any other provision of law, there is no limitation on aggregate fines issued pursuant to this

section. The proceeds from any administrative fine shall be deposited into the General Revenue Fund.

(7) Failure by a pharmacy benefit manager to pay expenses incurred or administrative fines imposed under this section is grounds for the denial, suspension, or revocation of its certificate of authority.

Section 14. Section 626.89, Florida Statutes, is amended to read:

626.89 Annual financial statement and filing fee; notice of change of ownership; pharmacy benefit manager filings.—

(1) Each authorized administrator shall annually file with the office a full and true statement of its financial condition, transactions, and affairs within 3 months after the end of the administrator's fiscal year or within such extension of time as the office for good cause may have granted. The statement must be for the preceding fiscal year and must be in such form and contain such matters as the commission prescribes and must be verified by at least two officers of the administrator.

(2) Each authorized administrator shall also file an audited financial statement performed by an independent certified public accountant. The audited financial statement must ~~shall~~ be filed with the office within 5 months after the end of the administrator's fiscal year and be for the preceding fiscal year. An audited financial statement prepared on a consolidated basis must include a columnar consolidating or

combining worksheet that must be filed with the statement and must comply with the following:

(a) Amounts shown on the consolidated audited financial statement must be shown on the worksheet;

(b) Amounts for each entity must be stated separately; and

(c) Explanations of consolidating and eliminating entries must be included.

(3) At the time of filing its annual statement, the administrator shall pay a filing fee in the amount specified in s. 624.501 for the filing of an annual statement by an insurer.

(4) In addition, the administrator shall immediately notify the office of any material change in its ownership.

(5) A pharmacy benefit manager shall also notify the office within 30 days after any administrative, civil, or criminal complaints, settlements, or discipline of the pharmacy benefit manager or any of its affiliates which relate to a violation of the insurance laws, including pharmacy benefit laws in any state.

(6) A pharmacy benefit manager shall also annually submit to the office a statement attesting to its compliance with the network requirements of s. 626.8825.

(7) The commission may by rule require all or part of the statements or filings required under this section to be submitted by electronic means in a computer-readable form

compatible with the electronic data format specified by the commission.

Section 15. Subsection (5) is added to section 627.42393, Florida Statutes, to read:

627.42393 Step-therapy protocol.—

(5) This section applies to a pharmacy benefit manager acting on behalf of a health insurer.

Section 16. Subsections (2), (3), and (4) of section 627.64741, Florida Statutes, are amended to read:

627.64741 Pharmacy benefit manager contracts.—

(2) In addition to the requirements of part VII of chapter 626, a contract between a health insurer and a pharmacy benefit manager must require that the pharmacy benefit manager:

(a) Update maximum allowable cost pricing information at least every 7 calendar days.

(b) Maintain a process that will, in a timely manner, eliminate drugs from maximum allowable cost lists or modify drug prices to remain consistent with changes in pricing data used in formulating maximum allowable cost prices and product availability.

~~(3) A contract between a health insurer and a pharmacy benefit manager must prohibit the pharmacy benefit manager from limiting a pharmacist's ability to disclose whether the cost-sharing obligation exceeds the retail price for a covered~~

~~prescription drug, and the availability of a more affordable alternative drug, pursuant to s. 465.0244.~~

~~(4) A contract between a health insurer and a pharmacy benefit manager must prohibit the pharmacy benefit manager from requiring an insured to make a payment for a prescription drug at the point of sale in an amount that exceeds the lesser of:~~

~~(a) The applicable cost-sharing amount; or~~

~~(b) The retail price of the drug in the absence of prescription drug coverage.~~

Section 17. Subsections (2), (3), and (4) of section 627.6572, Florida Statutes, are amended to read:

627.6572 Pharmacy benefit manager contracts.—

(2) In addition to the requirements of part VII of chapter 626, a contract between a health insurer and a pharmacy benefit manager must require that the pharmacy benefit manager:

(a) Update maximum allowable cost pricing information at least every 7 calendar days.

(b) Maintain a process that will, in a timely manner, eliminate drugs from maximum allowable cost lists or modify drug prices to remain consistent with changes in pricing data used in formulating maximum allowable cost prices and product availability.

~~(3) A contract between a health insurer and a pharmacy benefit manager must prohibit the pharmacy benefit manager from limiting a pharmacist's ability to disclose whether the cost-~~

~~sharing obligation exceeds the retail price for a covered prescription drug, and the availability of a more affordable alternative drug, pursuant to s. 465.0244.~~

~~(4) A contract between a health insurer and a pharmacy benefit manager must prohibit the pharmacy benefit manager from requiring an insured to make a payment for a prescription drug at the point of sale in an amount that exceeds the lesser of:~~

~~(a) The applicable cost-sharing amount; or~~

~~(b) The retail price of the drug in the absence of prescription drug coverage.~~

Section 18. Paragraph (e) is added to subsection (46) of section 641.31, Florida Statutes, to read:

641.31 Health maintenance contracts.—

(46)

(e) This subsection applies to a pharmacy benefit manager acting on behalf of a health maintenance organization.

Section 19. Subsections (2), (3), and (4) of section 641.314, Florida Statutes, are amended to read:

641.314 Pharmacy benefit manager contracts.—

(2) In addition to the requirements of part VII of chapter 626, a contract between a health maintenance organization and a pharmacy benefit manager must require that the pharmacy benefit manager:

(a) Update maximum allowable cost pricing information at least every 7 calendar days.

(b) Maintain a process that will, in a timely manner, eliminate drugs from maximum allowable cost lists or modify drug prices to remain consistent with changes in pricing data used in formulating maximum allowable cost prices and product availability.

~~(3) A contract between a health maintenance organization and a pharmacy benefit manager must prohibit the pharmacy benefit manager from limiting a pharmacist's ability to disclose whether the cost-sharing obligation exceeds the retail price for a covered prescription drug, and the availability of a more affordable alternative drug, pursuant to s. 465.0244.~~

~~(4) A contract between a health maintenance organization and a pharmacy benefit manager must prohibit the pharmacy benefit manager from requiring a subscriber to make a payment for a prescription drug at the point of sale in an amount that exceeds the lesser of:~~

~~(a) The applicable cost-sharing amount; or~~

~~(b) The retail price of the drug in the absence of prescription drug coverage.~~

Section 20. (1) This act establishes requirements for pharmacy benefit managers as defined in s. 626.88, Florida Statutes, including, without limitation, pharmacy benefit managers in their performance of services for or otherwise on behalf of a pharmacy benefits plan or program as defined in s. 626.8825, Florida Statutes, which includes coverage pursuant to

Titles XVIII, XIX, or XXI of the Social Security Act, 42 U.S.C. ss. 1395 et seq., 1396 et seq., and 1397aa et seq., known as Medicare, Medicaid, or any other similar coverage under a state or Federal Government funded health plan, including the Statewide Medicaid Managed Care program established pursuant to part IV of chapter 409, Florida Statutes, and the state group insurance program pursuant to part I of chapter 110, Florida Statutes.

(2) This act is not intended, nor may it be construed, to conflict with existing, relevant federal law.

(3) If any provision of this act or its application to any person or circumstances is held invalid, the invalidity does not affect other provisions or applications of this act which can be given effect without the invalid provision or application, and to this end the provisions of this act are severable.

Section 21. For the 2023-2024 fiscal year, the sum of $980,705 in recurring funds and $146,820 in nonrecurring funds from the Insurance Regulatory Trust Fund are appropriated to the Office of Insurance Regulation, and 10 full-time equivalent positions with associated salary rate of 644,877 are authorized, for the purpose of implementing this act.

Section 22. This act shall take effect July 1, 2023.

T I T L E A M E N D M E N T

Remove everything before the enacting clause and insert:
An act relating to prescription drugs; providing a short title; amending s. 499.005, F.S.; specifying additional prohibited acts related to the Florida Drug and Cosmetic Act; amending s. 499.012, F.S.; providing that prescription drug manufacturer and nonresident prescription drug manufacturer permitholders are subject to specified requirements; creating s. 499.026, F.S.; defining terms; requiring certain drug manufacturers to notify the Department of Business and Professional Regulation of reportable drug price increases on a specified form on the effective date of such increase; providing requirements for the form; providing construction; requiring such manufacturers to submit certain reports to the department by a specified date each year; providing requirements for the reports; authorizing the department to request certain additional information from the manufacturer before approving the report; requiring the department to submit the forms and reports to the Agency for Health Care Administration to be posted on the agency's website; prohibiting the agency from posting on its website certain submitted information that is marked as a trade secret; requiring the agency to compile all information from the submitted forms and reports and make it available to the Governor and the Legislature upon request; prohibiting manufacturers from claiming a public records exemption for trade secrets for certain information provided in such forms or

reports; providing that department employees remain protected from liability for releasing the forms and reports as public records; authorizing the department, in consultation with the agency, to adopt rules; providing for emergency rulemaking; amending s. 624.307, F.S.; requiring the Division of Consumer Services of the Department of Financial Services to designate an employee as the primary contact for consumer complaints involving pharmacy benefit managers; requiring the division to refer certain complaints to the Office of Insurance Regulation; amending s. 624.490, F.S.; revising the definition of the term "pharmacy benefit manager"; amending s. 624.491, F.S.; revising provisions related to pharmacy audits; amending s. 626.88, F.S.; revising the definition of the term "administrator"; defining the term "pharmacy benefit manager"; amending s. 626.8805, F.S.; providing a grandfathering provision for certain pharmacy benefit managers operating as administrators; providing a penalty for certain persons who do not hold a certificate of authority to act as an administrator on or after a specified date; requiring the office to submit a report detailing specified information to the Governor and the Legislature by a specified date; providing additional requirements for pharmacy benefit managers applying for a certificate of authority to act as an administrator; exempting pharmacy benefit managers from certain fees; amending s. 626.8814, F.S.; requiring pharmacy benefit managers to identify certain ownership affiliations to

the office; requiring pharmacy benefit managers to report any change in such information to the office within a specified timeframe; creating s. 626.8825, F.S.; defining terms; providing requirements for certain contracts between a pharmacy benefit manager and a pharmacy benefits plan or program; requiring pharmacy benefits plans and programs, beginning on a specified date, to annually submit a certain attestation to the office; providing requirements for certain contracts between a pharmacy benefit manager and a participating pharmacy; requiring the Financial Services Commission to adopt rules; specifying requirements for certain administrative appeal procedures that such contracts with participating pharmacies must include; requiring pharmacy benefit managers to submit reports on submitted appeals to the office every 90 days; creating s. 626.8827, F.S.; specifying prohibited practices for pharmacy benefit managers; creating s. 626.8828, F.S.; authorizing the office to investigate administrators that are pharmacy benefit managers and certain applicants; requiring the office to review certain referrals and investigate them under certain circumstances; providing for biennial reviews of pharmacy benefit managers; requiring the office to submit an annual report of its examinations to the Governor and the Legislature by a specified date; providing requirements for the report, including specified additional requirements for the biennial reports; authorizing the office to conduct additional

examinations; requiring the office to conduct an examination under certain circumstances; providing procedures and requirements for such examinations; defining the terms "contracts" and "knowing and willful"; providing that independent professional examiners under contract with the office may conduct examinations of pharmacy benefit managers; requiring the commission to adopt specified rules; specifying provisions that apply to such investigations and examinations; providing recordkeeping requirements for pharmacy benefit managers; authorizing the office to order the production of such records and other specified information; authorizing the office to take statements under oath; requiring pharmacy benefit managers and applicants subjected to an investigation or examination to pay the associated expenses; specifying covered expenses; providing for collection of such expenses; providing for the deposit of certain moneys into the Insurance Regulatory Trust Fund; authorizing the office to pay examiners, investigators, and other persons from such fund; providing administrative penalties; providing grounds for administrative action against a certificate of authority; amending s. 626.89, F.S.; requiring pharmacy benefit managers to notify the office of specified complaints, settlements, or discipline within a specified timeframe; requiring pharmacy benefit managers to annually submit a certain attestation statement to the office; amending s. 627.42393, F.S.; providing that certain step-therapy

protocol requirements apply to a pharmacy benefit manager acting on behalf of a health insurer; amending ss. 627.64741 and 627.6572, F.S.; conforming provisions to changes made by the act; amending s. 641.31, F.S.; providing that certain step-therapy protocol requirements apply to a pharmacy benefit manager acting on behalf of a health maintenance organization; amending s. 641.314, F.S.; conforming a provision to changes made by the act; providing legislative intent, construction, and severability; providing appropriations and authorizing positions; providing an effective date.