A bill to be entitled

An act relating to prescription drugs; providing a short title; amending s. 499.005, F.S.; providing 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 drug price increases on a specified date; providing requirements for the form to be used for such notification; providing construction; requiring such manufacturers to submit reports to the department by a specified date each year; providing requirements for the reports; 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 manufacturers from claiming a public records exemption for trade secrets for any information provided in such forms and reports; providing that department employees remain protected from liability for releasing the forms and reports as public records; requiring 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 of the division 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. 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; providing additional requirements for pharmacy benefit managers applying for a certificate of authority to act as administrators; exempting pharmacy benefit managers from certain fees; amending s. 626.8814, F.S.; requiring pharmacy benefit managers to identify certain ownership interests and 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 and for certain contracts between a pharmacy benefit manager and a participating pharmacy; providing reporting requirements for pharmacy benefits plans and programs; creating s. 626.8827, F.S.; providing 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; requiring biennial examinations of pharmacy benefit managers; providing procedures and requirements for such examinations; providing reporting requirements; authorizing the office to conduct additional examinations; defining the terms "contract" and "knowing and willful"; 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 certain applicants subjected to an investigation or examination to pay the associated expenses associated; specifying covered expenses; providing for the deposit 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 conducting examination or investigation out of such trust fund; providing fines; providing grounds for administrative action against a pharmacy benefit manager's 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 pharmacy benefit managers 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; amending s. 624.491, F.S.; conforming a cross-reference; providing legislative intent, construction, and severability; providing an appropriation; providing an effective date.

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

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 drug price increase forms and reports as required under this part 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) "Drug price increase" means a prescription drug with a wholesale acquisition cost that is more than $40 for a course of therapy and that is increased by more than 10 percent by the manufacturer. In calculating the 10 percent threshold, the manufacturer includes the proposed increase and the cumulative increases that occurred within the previous 24 months before the effective date of the increase.

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

(d) "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.

(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 date a manufacturer drug price increase becomes effective, the manufacturer must provide notification of the 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 drug price increase.

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

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

(e) A statement regarding whether a change or improvement in the prescription drug necessitates the drug price increase. If so, the manufacturer must describe the change or improvement.

(f) 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. A report is not deemed to be submitted until approved by the department. At a minimum, the report must include all of the following:

(a) A list of all prescription drugs affected by a drug price increase during the previous calendar year and both the dollar amount of each drug price increase and the percentage increase of each drug price increase relative to the previous wholesale acquisition cost of the prescription drug. The prescription drugs shall 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 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 complete description of the factors contributing to each drug price increase. The factors must be provided with such

specificity as to explain the need or justification for each drug price increase. The department may request additional information from a manufacturer relating to the need or justification of any drug price increase before accepting the manufacturer's report.

(f) 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.

(b) 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 under 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 shall 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 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 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. 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)<u>;</u> ~~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<u>; or a pharmacy benefit manager. The term does not include</u>~~, 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 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 entity that performs one or more of the following services:

(a) Pharmacy claims processing.

(b) Administration or management of pharmacy discount card programs.

(c) Managing pharmacy networks or pharmacy reimbursements.

(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.

Section 8. Subsections (4), (5), and (6) of section 626.8805, Florida Statutes, are renumbered as subsections (5), (6), and (7), respectively, subsections (1) and (3) are amended, and subsection (8) is added to that section, 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.

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

(a) A complete biographical statement on a form prescribed by the commission, an independent investigation report, and fingerprints obtained pursuant to chapter 624, of all of the individuals referred to in paragraph (2)(c).

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

(c) 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 9. 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 interest or affiliation of any kind with

any pharmacy which, 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 10. 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" mean a fee charged by a pharmacy benefit manager to a 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, 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. These costs include the pharmacist 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 claim" means a pharmacy claim submitted in error, including, but not limited to, an unintended, incorrect, fraudulent, or test claim.

(i) "Incentive payment" means a retrospective monetary payment made as a reward or recognition by a 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 the Healthcare Effectiveness Data and Information Set measures.

(j) "Maximum allowable cost appeal pricing adjustment" means a retrospective positive payment adjustment made to a pharmacy by the pharmacy benefits plan or program or 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.

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

(l) "Network" means a pharmacy or group of pharmacies that agree to provide pharmacist services to covered persons on behalf of a pharmacy benefits plan or program or 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 or dispenses particular types of prescription drugs, provides pharmacist services to particular types of covered persons, or dispenses prescriptions in particular health care settings, including networks of specialty, institutional, or long-term care facilities.

(m) "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 payers, as applicable.

(n) "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.

(o) "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. 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 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.

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

(q) "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.

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

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

(t) "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. The term includes, but is not limited to, health maintenance organizations, health insurers, self-insured employer 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 established pursuant to part I of chapter 110.

(u) "Rebate" means all payments that accrue to a pharmacy benefit manager or its pharmacy benefits plan or program client, 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.

(v) "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.

(w) "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.—

(a) 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 apply to pharmacist services on or after January 1, 2024, between a pharmacy benefit manager and a pharmacy benefits plan or program must:

1. Use a pass-through pricing model and comply with the prohibition in paragraph (3)(c).

2. 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 the pricing difference to the pharmacy benefits plan or program as authorized in subparagraph 1.

3. 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.

4. Require the pharmacy benefit manager to pass 100 percent of all prescription drug manufacturer, 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 subparagraph must be used for the sole purpose of offsetting copayments and deductibles of covered persons. This subparagraph does not apply to contracts involving Medicaid managed care plans.

5. 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:

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

b. Require a pharmacy benefit manager to offer a provider contract to licensed pharmacies physically located on the physical site of providers within the pharmacy benefits plan's or program's geographic service area which have been specifically designated as essential providers by the Agency for Health Care Administration pursuant to s. 409.975(1)(a), and Florida cancer hospitals that meet the criteria in s. 409.975(1)(b), regardless of the pharmacy benefits plan's or

program's geographic service area, solely for the administration or dispensing of covered prescription drugs, including biological products, that are administered through infusions, intravenously injected, or inhaled during a surgical procedure, or covered parenteral drugs, as part of onsite outpatient care;

c. 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. This sub-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; or

d. Prohibit a requirement for 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 incentivize 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.

6. 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 right not to participate in a specific pharmacy network.

7. 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.

8. At a minimum, require the pharmacy benefit manager or pharmacy benefits plan or program to annually provide an updated formulary listing of covered prescription drugs to a covered person at least 60 days before the commencement of a plan year.

9. Prohibit the pharmacy benefit manager or pharmacy benefits plan or program from removing a covered prescription drug from its formulary for the duration of a plan year, unless 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.

10. Allow the addition of covered prescription drugs to the formulary of the pharmacy benefit manager or pharmacy benefits plan or program during a plan year.

(b) 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, which applies to pharmacist services on or after January 1, 2024, between a pharmacy benefit manager and 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 must 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 identification or plan identification 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 office 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) The pharmacy benefit manager may not recoup direct or indirect remuneration fees, dispensing fees, brand name or generic effective rate adjustments through reconciliation, or any other monetary recoupments as related to discounts, financial clawbacks, multiple network reconciliation offsets, adjudication transaction fees, and any other instance when a fee

may be recouped from a pharmacy. For purposes of this paragraph, the terms "financial clawbacks" and "reconciliation offsets" do not include:

1. Any incentive payments provided by the pharmacy benefit manager to a network pharmacy for meeting or exceeding predefined quality measures such as the 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 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.

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

(e) 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.

(f) The pharmacy benefit manager must ensure that the electronic remittance advice contains claim level payment

adjustments in accordance with the American National Standards Institute's Accredited Standards Committee X12 format and must include or be accompanied by appropriate level of detail for the pharmacy to reconcile any debits or credits, including, but not limited to, the NCPDP pharmacy identification number or National Provider Identifier, date of service, prescription number, refill number, adjustment code if applicable, and transaction amount.

(g) The pharmacy benefit manager must 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 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 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 that 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.

5. If the drug with the national drug code provided by the pharmacy benefit manager is not available below the acquisition cost to the pharmacy or pharmacist from the pharmaceutical wholesaler from whom the pharmacy or pharmacist purchases the majority of drugs for resale, the pharmacy benefit manager must adjust the maximum allowable cost pricing information above the acquisition cost to the pharmacy or pharmacist and permit the

pharmacy or pharmacist to reverse and rebill each claim affected by the pharmacy's or pharmacist's inability to procure the drug at a cost that is equal to or less than the previously challenged maximum allowable cost.

6. The pharmacy benefit manager shall report to the office every 90 days the total number of appeals received and denied in the preceding 90-day period for each specific drug appealed pursuant to this paragraph.

Section 11. Section 626.8827, Florida Statutes, is created to read:

626.8827 Pharmacy benefit manager prohibited practices.—In addition to any 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 or risks from treatment, or alternatives thereto.

(b) The availability of alternative treatments, consultations, or tests.

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

(d) The process that is used to authorize or deny pharmacist services or pharmacy 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, in accordance with 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, the Department of Management Services, a law enforcement officer, or a state or federal government official, provided that the recipient of the information has the authority, to the extent provided by state or federal law, to maintain proprietary information as confidential; and provided that, before the disclosure of information designated as confidential, the pharmacist or pharmacy marks as confidential any document in which the information appears or the pharmacist or pharmacy 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 actual fraud on the part of the pharmacy or 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 part;

(b) Exercising any of its rights 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 complies with this part.

(7) Fail to comply with the requirements of s. 626.8825.

Section 12. 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 under ss. 624.307 and 624.317 administrators that are pharmacy benefit managers and applicants for authorization to become pharmacy benefit managers. The office must review any referral made pursuant to s. 624.307(10) and must investigate any referral that, as determined by the Commissioner of Insurance Regulation or the commissioner's 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 this part and 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 July 1, 2023. By January 1 of the year following a 2-year cycle, the office must deliver to the Governor, the President of the Senate, and the Speaker of the House of Representatives a report summarizing the results of the biennial examinations during the most recent 2-year cycle 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.

(b) The office may also conduct additional examinations as often as it deems advisable or necessary for the purpose of determining compliance with this part and 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 conduct 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 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 order a pharmacy benefit manager or applicant pursuant to chapter 120 to file all contracts between the pharmacy benefit manager, or applicant, 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. "Contract" means any contract to which s. 626.8825 applies.

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 with the office, in which case payment shall 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.

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

(a) Section 624.318, relating to the conduct of examinations and investigations, access to records, correction of accounts, and appraisals.

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

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

(d) Section 624.322, relating to compelled testimony and

immunity from prosecution.

(e) Section 624.324, relating to hearings.

(f) Section 624.34, relating to fingerprinting.

(g) 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 contracts 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 any 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 must include actual travel expenses; reasonable living expense allowance; compensation of the examiner, investigator, or other person conducting such examination or investigation; and necessary costs of the office directly related to the examination or investigation. Such travel expenses and living

expense allowance shall be 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, investigator, or other person conducting the examination or investigation 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 other person conducting the 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 conducting such examination or investigation, 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 either section 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 under this subsection. The proceeds from any administrative fine imposed under this subsection 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 13. 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 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 15 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) ~~(5)~~ 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 14. 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 15. Subsection (5) of section 627.64741, Florida Statutes, is renumbered as subsection (3), and subsection (2), present subsection (3), and subsection (4) of that section 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 16. Subsection (5) of section 627.6572, Florida Statutes, is renumbered as subsection (3), and subsection (2), present subsection (3), and subsection (4) of that section 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 17. Subsection (5) of section 641.314, Florida Statutes, is renumbered as subsection (3), and subsection (2), present subsection (3), and subsection (4) of that section 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 18. Subsection (1) of section 624.491, Florida Statutes, is amended to read:

624.491 Pharmacy audits.—

(1) A 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 health insurer or health maintenance organization or any person or entity acting on behalf of the 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.

Section 19. (1) This act establishes requirements for pharmacy benefit managers as defined in s. 624.490, 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 providing coverage pursuant to Title XVIII, Title XIX, or Title XXI of the Social Security Act, 42 U.S.C. ss. 1395 et seq., 42 U.S.C. ss. 1396 et

seq., or 42 U.S.C. ss. 1397aa et seq., known as Medicare, Medicaid, or state child health plans, respectively, 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 established pursuant to part I of chapter 110, Florida Statutes.

(2) This act is not intended, and may not be construed, to conflict with existing relevant federal law.

(3) If any provision of this act or its application to any person or circumstance 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 20. The sum of $1.5 million in recurring funds is appropriated from the General Revenue Fund to the Office of Insurance Regulation to implement this act.

Section 21. This act shall take effect July 1, 2023.