By Senator Rodriguez

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A bill to be entitled An act relating to prescription drug price transparency; providing a short title; amending s. 465.003, F.S.; defining the terms "pharmacy benefit manager" and "pharmacy benefit management services"; creating s. 465.203, F.S.; defining terms; authorizing specified pharmacies and pharmacists to contract with pharmacy benefit managers; prohibiting pharmacy benefit managers from engaging in certain practices; requiring pharmacy benefit managers to allow payors access to specified records, data, and information; requiring pharmacy benefit managers to disclose and report specified information to the payor; requiring certain income and financial benefits to be passed through to payors; requiring pharmacy benefit managers to allow the Department of Financial Services access to specified records, data, and information; requiring the department to investigate certain violations; providing penalties; providing that specified violations are subject to the Florida Deceptive and Unfair Trade Practices Act; providing applicability; creating s. 499.0284, F.S.; defining terms; requiring prescription drug manufacturers to annually report certain information to the Department of Business and Professional Regulation by a specified date; requiring the department to publish the reported information on its website; specifying circumstances under which prescription drug manufacturers are required to report certain information to the department; prescribing the

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contents of such reports; requiring the department to publish the reports on its website within a specified timeframe; authorizing the department to adopt rules; amending s. 624.490, F.S.; conforming provisions to changes made by the act; creating s. 624.491, F.S.; defining terms; requiring pharmacy benefit managers to submit annual reports to the Office of Insurance Regulation by a specified date; prescribing the contents of such reports; prohibiting the annual reports from disclosing certain information; requiring the office to publish the data from the annual reports on its website by a specified date; prohibiting the office from publishing the data in a manner that may disclose certain information; authorizing the Financial Services Commission to adopt rules; creating s. 627.42385, F.S.; defining terms; requiring group health plans, health insurers, and certain pharmacy benefit managers to base plan beneficiaries' and insureds' coinsurance obligations for certain prescription drugs on specified drug prices; providing applicability; prohibiting such group health plans, health insurers, and pharmacy benefit managers from revealing specified information; requiring such entities to protect such information and impose the confidentiality protections on other entities; providing penalties; requiring the department to investigate certain violations; providing construction; amending ss. 627.64741, 627.6572, and 641.314, F.S.; conforming provisions to changes made

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by the act; providing requirements for contracts; requiring pharmacy benefit managers to allow insurers, health maintenance organizations, and payors access to specified records, data, and information; requiring pharmacy benefit managers to disclose and report specified information to the insurer, health maintenance organization, or payor; requiring the department to investigate certain violations; providing penalties; providing applicability; creating ss. 627.64745, 627.65725, and 641.262, F.S.; defining the terms "specialty drug" and "utilization management"; requiring insurers issuing individual and group health insurance policies, and health maintenance organizations, respectively, to annually submit reports to the office by a specified date; prescribing the contents of such reports; prohibiting such reports from disclosing certain information; requiring the office to publish data from the reports on its website by a specified date; prohibiting the office from publishing the data in a manner that may disclose certain information; authorizing the commission to adopt rules; amending ss. 409.9201, 458.331, 459.015, 465.014, 465.015, 465.0156, 465.016, 465.0197, 465.022, 465.023, 465.1901, 499.003, and 893.02, F.S.; conforming cross-references; providing an effective date.

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

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

Section 2. Section 465.003, Florida Statutes, is amended to read:

465.003 Definitions.—As used in this chapter, the term:

- (1) "Administration" means the obtaining and giving of a single dose of medicinal drugs by a legally authorized person to a patient for her or his consumption.
 - (3) $\frac{(2)}{(2)}$ "Board" means the Board of Pharmacy.
- (9) "Consultant pharmacist" means a pharmacist licensed by the department and certified as a consultant pharmacist pursuant to s. 465.0125.
- (10) (4) "Data communication device" means an electronic device that receives electronic information from one source and transmits or routes it to another, including, but not limited to, any such bridge, router, switch, or gateway.
 - $(11) \frac{(5)}{(5)}$ "Department" means the Department of Health.
- (12) (6) "Dispense" means the transfer of possession of one or more doses of a medicinal drug by a pharmacist to the ultimate consumer or her or his agent. As an element of dispensing, the pharmacist shall, prior to the actual physical transfer, interpret and assess the prescription order for potential adverse reactions, interactions, and dosage regimen she or he deems appropriate in the exercise of her or his professional judgment, and the pharmacist shall certify that the medicinal drug called for by the prescription is ready for transfer. The pharmacist shall also provide counseling on proper drug usage, either orally or in writing, if in the exercise of her or his professional judgment counseling is necessary. The

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actual sales transaction and delivery of such drug shall not be considered dispensing. The administration shall not be considered dispensing.

- (13) (7) "Institutional formulary system" means a method whereby the medical staff evaluates, appraises, and selects those medicinal drugs or proprietary preparations which in the medical staff's clinical judgment are most useful in patient care, and which are available for dispensing by a practicing pharmacist in a Class II or Class III institutional pharmacy.
- (14) (8) "Medicinal drugs" or "drugs" means those substances or preparations commonly known as "prescription" or "legend" drugs which are required by federal or state law to be dispensed only on a prescription, but shall not include patents or proprietary preparations as hereafter defined.
- (17) (9) "Patent or proprietary preparation" means a medicine in its unbroken, original package which is sold to the public by, or under the authority of, the manufacturer or primary distributor thereof and which is not misbranded under the provisions of the Florida Drug and Cosmetic Act.
- (18) "Pharmacist" means any person licensed pursuant to this chapter to practice the profession of pharmacy.
- (19)(11)(a) "Pharmacy" includes a community pharmacy, an institutional pharmacy, a nuclear pharmacy, a special pharmacy, and an Internet pharmacy.
- 1. The term "community pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis.
 - 2. The term "institutional pharmacy" includes every

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location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility, hereinafter referred to as "health care institutions," where medicinal drugs are compounded, dispensed, stored, or sold.

- 3. The term "nuclear pharmacy" includes every location where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold. The term "nuclear pharmacy" does not include hospitals licensed under chapter 395 or the nuclear medicine facilities of such hospitals.
- 4. The term "special pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold if such locations are not otherwise defined in this subsection.
- 5. The term "Internet pharmacy" includes locations not otherwise licensed or issued a permit under this chapter, within or outside this state, which use the Internet to communicate with or obtain information from consumers in this state and use such communication or information to fill or refill prescriptions or to dispense, distribute, or otherwise engage in the practice of pharmacy in this state. Any act described in this definition constitutes the practice of pharmacy as defined in subsection (23) (13).
- (b) The pharmacy department of any permittee shall be considered closed whenever a Florida licensed pharmacist is not present and on duty. The term "not present and on duty" shall not be construed to prevent a pharmacist from exiting the prescription department for the purposes of consulting or responding to inquiries or providing assistance to patients or customers, attending to personal hygiene needs, or performing

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any other function for which the pharmacist is responsible, provided that such activities are conducted in a manner consistent with the pharmacist's responsibility to provide pharmacy services.

- (20) "Pharmacy benefit manager" means an entity that performs pharmacy benefit management services for a health plan, a health plan sponsor, a health plan provider, a health insurer, or any other payor. The term does not include a provider as defined in s. 641.19, a physician as defined in s. 458.305, or an osteopathic physician as defined in s. 459.003.
- (21) "Pharmacy benefit management services" means services that:
- (a) Are provided, directly or through another entity, to a health plan, a health plan sponsor, a health plan provider, a health insurer, or any other payor, regardless of whether the services provider and the health plan, health plan sponsor, health plan provider, health insurer, or other payor are related or associated by ownership, common ownership, organization, or otherwise.
- (b) Include the procurement of prescription drugs to be dispensed to patients and the administration or management of prescription drug benefits, including, but not limited to, any of the following:
 - 1. A mail service pharmacy or a specialty pharmacy.
- 2. Claims processing, retail network management, or payment of claims to pharmacies for dispensing drugs.
- 3. Clinical or other formulary or preferred-drug-list development or management.
 - 4. Negotiation, administration, or receipt of rebates,

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discounts, payment differentials, or other incentives, to include particular drugs in a particular category or to promote the purchase of particular drugs.

- 5. Patients' compliance, therapeutic intervention, or generic substitution programs.
 - 6. Disease management.
- 7. Drug use review, step-therapy protocol, or prior authorization.
- 8. Adjudication of appeals or grievances related to prescription drug coverage.
 - 9. Contracts with network pharmacies.
 - 10. Control of the cost of covered prescription drugs.
- (22) (12) "Pharmacy intern" means a person who is currently registered in, and attending, a duly accredited college or school of pharmacy, or who is a graduate of such a school or college of pharmacy, and who is duly and properly registered with the department as provided for under its rules.
- (23) (13) "Practice of the profession of pharmacy" includes compounding, dispensing, and consulting concerning contents, therapeutic values, and uses of any medicinal drug; consulting concerning therapeutic values and interactions of patent or proprietary preparations, whether pursuant to prescriptions or in the absence and entirely independent of such prescriptions or orders; and conducting other pharmaceutical services. For purposes of this subsection, "other pharmaceutical services" means the monitoring of the patient's drug therapy and assisting the patient in the management of his or her drug therapy, and includes review of the patient's drug therapy and communication with the patient's prescribing health care provider as licensed

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under chapter 458, chapter 459, chapter 461, or chapter 466, or similar statutory provision in another jurisdiction, or such provider's agent or such other persons as specifically authorized by the patient, regarding the drug therapy. However, nothing in this subsection may be interpreted to permit an alteration of a prescriber's directions, the diagnosis or treatment of any disease, the initiation of any drug therapy, the practice of medicine, or the practice of osteopathic medicine, unless otherwise permitted by law. "Practice of the profession of pharmacy" also includes any other act, service, operation, research, or transaction incidental to, or forming a part of, any of the foregoing acts, requiring, involving, or employing the science or art of any branch of the pharmaceutical profession, study, or training, and shall expressly permit a pharmacist to transmit information from persons authorized to prescribe medicinal drugs to their patients. The practice of the profession of pharmacy also includes the administration of vaccines to adults pursuant to s. 465.189 and the preparation of prepackaged drug products in facilities holding Class III institutional pharmacy permits.

(24) (14) "Prescription" includes any order for drugs or medicinal supplies written or transmitted by any means of communication by a duly licensed practitioner authorized by the laws of the state to prescribe such drugs or medicinal supplies and intended to be dispensed by a pharmacist. The term also includes an orally transmitted order by the lawfully designated agent of such practitioner. The term also includes an order written or transmitted by a practitioner licensed to practice in a jurisdiction other than this state, but only if the pharmacist

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called upon to dispense such order determines, in the exercise of her or his professional judgment, that the order is valid and necessary for the treatment of a chronic or recurrent illness. The term "prescription" also includes a pharmacist's order for a product selected from the formulary created pursuant to s. 465.186. Prescriptions may be retained in written form or the pharmacist may cause them to be recorded in a data processing system, provided that such order can be produced in printed form upon lawful request.

- (15) "Nuclear pharmacist" means a pharmacist licensed by the department and certified as a nuclear pharmacist pursuant to s. 465.0126.
- (5)(16) "Centralized prescription filling" means the filling of a prescription by one pharmacy upon request by another pharmacy to fill or refill the prescription. The term includes the performance by one pharmacy for another pharmacy of other pharmacy duties such as drug utilization review, therapeutic drug utilization review, claims adjudication, and the obtaining of refill authorizations.
- $\underline{(2)}$ "Automated pharmacy system" means a mechanical system that delivers prescription drugs received from a Florida licensed pharmacy and maintains related transaction information.
- (8) "Compounding" means combining, mixing, or altering the ingredients of one or more drugs or products to create another drug or product.
- (16) (19) "Outsourcing facility" means a single physical location registered as an outsourcing facility under the federal Drug Quality and Security Act, Pub. L. No. 113-54, at which sterile compounding of a drug or product is conducted.

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(7)(20) "Compounded sterile product" means a drug that is intended for parenteral administration, an ophthalmic or oral inhalation drug in aqueous format, or a drug or product that is required to be sterile under federal or state law or rule, which is produced through compounding, but is not approved by the United States Food and Drug Administration.

- (4)(21) "Central distribution facility" means a facility under common control with a hospital holding a Class III institutional pharmacy permit that may dispense, distribute, compound, or fill prescriptions for medicinal drugs; prepare prepackaged drug products; and conduct other pharmaceutical services.
- $\underline{(6)}$ "Common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, contract, or otherwise.
- Section 3. Section 465.203, Florida Statutes, is created to read:
 - 465.203 Pharmacy benefit managers.-
 - (1) As used in this section, the term:
 - (a) "Affiliate" means a pharmacy:
- 1. In which a pharmacy benefit manager, directly or indirectly, has an investment, financial interest, or ownership interest; or
- 2. The ownership of which is shared, directly or indirectly, with a pharmacy benefit manager.
- 317 (b) "Covered individual" means a member, participant,
 318 enrollee, contract holder, policyholder, or beneficiary of a
 319 payor.

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(c) "Make a referral" means any of the following:

- 1. To order, direct, or influence, orally or in writing, a covered individual to use an affiliate, including by sending messages to the covered individual through electronic mail, a cellular telephone, or a facsimile machine, or by making telephone calls.
- 2. To offer or implement plan designs that require a covered individual to use an affiliate.
- 3. To target a covered individual or a prospective patient with advertisement, marketing, or promotion of an affiliate, including by placing a specific pharmacy name on an insurance card or health plan card supplied to the covered individual.
- (d) "Maximum allowable cost" means the per-unit amount that a pharmacy benefit manager reimburses a pharmacy or pharmacist for a generic drug, brand name drug, specialty drug, biological product, or other prescription drug, excluding dispensing fees, before the application of copayments, coinsurance, and other cost-sharing charges, if any.
- (e) "Maximum allowable cost list" means a listing of generic drugs, brand name drugs, specialty drugs, biological products, or other prescription drugs or other methodology used directly or indirectly by a pharmacy benefit manager to set the maximum allowable costs for the drugs.
- (f) "Payor" means a health plan, a health plan sponsor, a health plan provider, a health insurer, or any other payor that uses pharmacy benefit management services in this state.
- (g) "Spread pricing" means the practice by a pharmacy benefit manager of charging or claiming from a payor an amount that is more than the amount the pharmacy benefit manager paid

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to the pharmacy or pharmacist who filled the prescription or who provided the pharmacy services.

- (2) A pharmacy or pharmacist licensed or registered under this chapter who has a pharmacy permit and is in good standing with the Board of Pharmacy may contract directly or indirectly with a pharmacy benefit manager within 30 days after filing an application with the pharmacy benefit manager, without a probation period, an exclusion period, or minimum inventory requirements.
- (3) A pharmacy benefit manager may not do any of the following:
 - (a) Conduct or participate in spread pricing in this state.
- (b) Charge a pharmacy or pharmacist a fee related to the adjudication of a claim, including, without limitation, a fee for:
 - 1. The submission of a claim;
- 2. The enrollment or participation in a retail pharmacy network; or
- 3. The development or management of claims processing services or claims payment services related to participation in a retail pharmacy network.
- (c) Prohibit a pharmacy or pharmacist from providing to a covered individual or a covered individual's caregiver information regarding the pricing of a prescription drug and whether the cost-sharing obligation to the covered individual exceeds the retail price of the prescription in the absence of prescription drug coverage or from selling to a covered individual or a covered individual's caregiver a more affordable alternative drug.

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(d) Penalize or remove from a pharmacy network or plan a pharmacy or pharmacist for providing to a covered individual or a covered individual's caregiver information regarding the pricing of a prescription drug and whether the cost-sharing obligation to the covered individual exceeds the retail price of the prescription in the absence of prescription drug coverage or for selling to a covered individual or a covered individual's caregiver a more affordable alternative drug.

- (e) Deny a pharmacy or pharmacist the opportunity to participate in a pharmacy network at the preferred participation status even though the pharmacy or pharmacist is willing to accept, as a condition of the preferred participation status, the terms and conditions that the pharmacy benefit manager has established for other pharmacies that are in a pharmacy network at the preferred participation status and that are not owned in whole or in part by the pharmacy benefit manager.
- (f) Impose registration or permit requirements for a pharmacy or accreditation standards or recertification requirements for a pharmacist which are inconsistent with, more stringent than, or in addition to federal and state requirements for licensure as a pharmacy or pharmacist in this state.
- (g) Pay or reimburse a pharmacy or pharmacist an amount for a drug, product, or pharmacy service in the state which is:
- 1. Less than the amount the pharmacy benefit manager reimburses a pharmacy benefit manager affiliate for providing the same drug, product, or pharmacy service in this state;
- 2. Less than the actual cost incurred by the pharmacy or pharmacist for providing the drug, product, or pharmacy service in this state; or

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3. Different from the combined maximum allowable cost and dispensing fees for a drug. The dispensing fees must be at least equal to the fees for service set by the Agency for Health Care Administration.

- (h) Retroactively deny, hold back, or reduce reimbursement for a covered service claim after paying a claim, unless the original claim was submitted fraudulently.
- (i) Prohibit a pharmacy or pharmacist from providing information regarding drug pricing, contract terms, or drug reimbursement rates to a member of the Legislature.
- (j) Remove a pharmacy or pharmacist from a pharmacy network or plan or otherwise engage in any action to retaliate against a pharmacy or pharmacist for providing information regarding drug pricing, contract terms, or drug reimbursement rates to a member of the Legislature.
 - (k) Engage in the practice of the profession of pharmacy.
- (1) Engage in the practice of medicine as defined s.

 458.305 or the practice of osteopathic medicine as defined in s.

 459.003.
 - (m) Make a referral.
- (n) Publish or otherwise reveal information regarding the actual amount of rebates, discounts, payment differentials, concessions, reductions, or any other incentives that the pharmacy benefit plan receives on a product-, manufacturer-, or pharmacy-specific basis. The pharmacy benefit manager shall protect such information as a trade secret and shall impose the confidentiality protections on any vendor or third-party entity performing services on behalf of the pharmacy benefit manager that has access to rebate, discount, payment differential,

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concession, reduction, or any other incentive information.

- (4) A payor shall have access to all financial and utilization records, data, and information used by the pharmacy benefit manager in relation to the pharmacy benefit management services provided to the payor.
 - (5) A pharmacy benefit manager shall:
- (a) Disclose in writing to the payor any activity, policy, practice, contract, or arrangement of the pharmacy benefit manager which directly or indirectly presents conflicts of interest with the pharmacy benefit manager's relationship with, or fiduciary duty or obligation to, the covered individuals and the payor.
- (b) Report quarterly to the payor any income resulting from pricing discounts, rebates of any kind, inflationary payments, credits, clawbacks, fees, grants, chargebacks, reimbursements, or other financial benefits received by the pharmacy benefit manager from any person or entity. The pharmacy benefit manager shall ensure that such income and financial benefits are passed through in full, at least quarterly, to the payor to reduce the cost of prescription drugs and pharmacy services to covered individuals.
- (6) The Department of Financial Services shall have access to all financial and utilization records, data, and information used by pharmacy benefit managers in relation to pharmacy benefit management services provided to payors in this state.

 The department shall investigate any alleged violation of this section.
- (7) (a) A pharmacy benefit manager that violates this section is liable for a civil fine of \$10,000 for each violation

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and may have its registration revoked by the Department of Financial Services.

- (b) A violation of this section which is committed or performed with such frequency as to indicate a general business practice is subject to the Florida Deceptive and Unfair Trade Practices Act under part II of chapter 501.
- (8) This section applies to contracts entered into or renewed on or after January 1, 2021.

Section 4. Section 499.0284, Florida Statutes, is created to read:

- <u>499.0284 Prescription drug manufacturers; disclosure of</u> drug pricing information; reports.—
 - (1) As used in this section, the term:
- (a) "Prescription drug" has the same meaning as defined in this part, but is limited to prescription drugs intended for human use.
- (b) "Prescription drug manufacturer" means a person or entity permitted under this part to manufacture or distribute prescription drugs in this state.
- (c) "Prompt pay" means a discount offered in exchange for early payment of an invoice.
- (d) "Wholesale acquisition cost" means the list price of the prescription drug which the manufacturer charged 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 drug pricing data sources.
 - (2) (a) By January 15 of each year, each prescription drug

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manufacturer manufacturing or distributing prescription drugs in this state shall submit to the department a report of its

wholesale acquisition cost information for all United States

Food and Drug Administration-approved drugs the manufacturer sold in or into this state during the previous calendar year.

- (b) The department shall publish on its website the wholesale acquisition cost information it receives pursuant to paragraph (a). The link to this information must be prominently displayed and easily accessible on the home page of the department's website.
- (c) A prescription drug manufacturer shall report to the department when the price of a drug it manufactures increases by 40 percent or more during the preceding 3 years or by 15 percent in the preceding calendar year, if the wholesale acquisition cost of the drug was at least \$100 for a 30-day supply before the effective date of the increase. The manufacturer shall submit such report to the department within 30 days after the effective date of the increase. The report must include all of the following:
 - 1. The name of the drug.
 - 2. Whether the drug is a brand name or generic equivalent.
- 3. The effective date of the change in wholesale acquisition cost.
- 4. Aggregate, company-level research and development costs for the most recent year for which final audit data is available.
- 5. The name of each of the manufacturer's prescription drugs approved by the United States Food and Drug Administration in the previous 3 calendar years.

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6. The name of each of the manufacturer's prescription drugs that lost patent exclusivity in the United States in the previous 3 calendar years.

- 7. A statement regarding the factors, if any, that caused the increase in the wholesale acquisition cost and an explanation of each factor's impact on the cost.
- (d) The quality and types of information and data which a prescription drug manufacturer submits to the department under paragraph (c) must be consistent with the quality and types of information and data which the manufacturer includes in the manufacturer's annual consolidated report to the United States Securities and Exchange Commission or in any other public disclosure.
- (e) The department shall publish on its website a report provided under paragraph (c) within 60 days after receiving it.
- $\underline{\mbox{ (f)}}$ The department may adopt rules to implement this section.

Section 5. 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" means an a person or entity that performs pharmacy benefit management services for a health plan, a health plan sponsor, a health plan provider, a health insurer, or any other payor that uses pharmacy benefit management services 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. The term does not include a provider as defined in s. 641.19, a

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physician as defined in s. 458.305, or an osteopathic physician as defined in s. 459.003. As used in this subsection, the term "pharmacy benefit management services" means services that:

- (a) Are provided, directly or through another entity, to a health plan, a health plan sponsor, a health plan provider, a health insurer, or any other payor, regardless of whether the services provider and the health plan, health plan sponsor, health plan provider, health insurer, or other payor are related or associated by ownership, common ownership, organization, or otherwise.
- (b) Include the procurement of prescription drugs to be dispensed to patients and the administration or management of prescription drug benefits, including, but not limited to, any of the following:
 - 1. A mail service pharmacy or a specialty pharmacy.
- 2. Claims processing, retail network management, or payment of claims to pharmacies for dispensing drugs.
- 3. Clinical or other formulary or preferred-drug-list development or management.
- 4. Negotiation, administration, or receipt of rebates, discounts, payment differentials, or other incentives, to include particular drugs in a particular category or to promote the purchase of particular drugs.
- 5. Patients' compliance, therapeutic intervention, or generic substitution programs.
 - 6. Disease management.
- 7. Drug use review, step-therapy protocol, or prior authorization.
 - 8. Adjudication of appeals or grievances related to

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20201682 37-00392A-20 581 prescription drug coverage. 582 9. Contracts with network pharmacies. 10. Control of the cost of covered prescription drugs. 583 584 Section 6. Section 624.491, Florida Statutes, is created to 585 read: 586 624.491 Pharmacy benefit managers; reports.-587 (1) As used in this section, the term: 588 (a) "Enrollee" means an individual insured under an 589 individual or group health insurance policy or a subscriber as defined in s. 641.19. 590 591 (b) "Health insurance" has the same meaning as in s. 592 624.603. (c) "Health insurer" means an authorized insurer as defined 593 594 in s. 624.03 providing health insurance or a health maintenance 595 organization as defined in s. 641.19. 596 (d) "Pharmacy benefit manager" means a person or entity 597 registered with the office under s. 624.490 to contract on 598 behalf of a health insurer to administer prescription drug 599 benefits to residents of this state. 600 (e) "Prescription drug" has the same meaning as in s. 601 499.003, but is limited to prescription drugs intended for human 602 use. (f) "Prescription drug manufacturer" means a person or 603 604 entity permitted under part I of chapter 499 to manufacture or distribute prescription drugs in this state. 605 606 (2) By February 1 of each year, each pharmacy benefit 607 manager shall submit a report to the office including all of the

(a) The aggregated rebates, fees, price protection

following information for the previous calendar year:

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payments, and any other payments collected from prescription drug manufacturers; and

- (b) The aggregated dollar amount of rebates, fees, price protection payments, and any other payments collected from prescription drug manufacturers which were:
- 1. Passed on to the health insurers or the enrollees, at the point of sale of the prescription drug; or
 - 2. Retained by the pharmacy benefit manager as revenue.
- (3) A report submitted under this section must not disclose the identity of a specific health insurer or enrollee, the price charged for a specific prescription drug or class of prescription drugs, or the amount of any rebate or fee provided for a specific prescription drug or class of prescription drugs.
- (4) By May 1 of each year, the office shall publish on its website the combined aggregated data from all reports it received under this section for that year. The data from the reports may not be published in a manner that would disclose or tend to disclose any health insurer's proprietary or confidential information.
- $\underline{\mbox{(5)}}$ The commission may adopt rules to implement this section.
- Section 7. Section 627.42385, Florida Statutes, is created to read:
 - 627.42385 Coinsurance obligations for prescription drugs.-
 - (1) As used in this section, the term:
- (a) "Coinsurance" means, with respect to prescription drug coverage under a group health plan or health insurance coverage, a payment obligation of a plan beneficiary or an insured that is based on a percentage of the specified cost of a prescription

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drug, which may be up to 100 percent of that cost.

(b) "Deductible" means the payment obligation of a group health plan beneficiary or a health insurance coverage insured before the plan or coverage will pay any portion of the cost of prescription drug coverage.

- (c) "Health insurer" has the same meaning as provided in s. 627.42392.
- (d) "List price" means the manufacturer's price for a drug for wholesalers or direct purchasers in this country, not including any rebate, discount, payment differential, concession, or reduction 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 pricing data.
- (e) "Net price" means the price of a drug paid by a group health plan or a health insurer, or a pharmacy benefit manager performing pharmacy benefit management services for a group health plan or a health insurer, after all rebates, discounts, payment differentials, concessions, and reductions in price have been applied to the list price.
- (f) "Pharmacy benefit manager" has the same meaning as provided in s. 465.003.
- (g) "Pharmacy benefit management services" has the same meaning as provided in s. 465.003.
- (h) "Prescription drug" has the same meaning as provided in s. 409.9201.
- (2) Unless otherwise expressly provided in this section, a group health plan or a health insurer offering group or individual health insurance coverage, or a pharmacy benefit

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manager performing pharmacy benefit management services for a group health plan or a health insurer, shall base a plan beneficiary's or an insured's coinsurance obligation for a prescription drug covered by the plan or coverage on the net price, and not the list price, of the drug.

- (3) (a) Subsection (2) applies to a prescription drug benefit if a plan beneficiary or an insured is required to pay a deductible with respect to such benefit and if the plan beneficiary or insured:
- 1. Has not yet satisfied the deductible under the plan or coverage; or
- 2. Has another coinsurance obligation with respect to such benefit under the plan or coverage.
- (b) Subsection (2) does not apply if, with respect to the dispensed quantity of a prescription drug, the net price and list price of the drug are different by not more than 1 percent.
- (4) In complying with this section, a group health plan or a health insurer, or a pharmacy benefit manager performing pharmacy benefit management services for a group health plan or a health insurer, may not publish or otherwise reveal information regarding the actual amount of rebates, discounts, payment differentials, concessions, or reductions in price that the plan, health insurer, or pharmacy benefit plan receives on a product-, manufacturer-, or pharmacy-specific basis. The plan, health insurer, or pharmacy benefit manager shall protect such information as a trade secret and shall impose the confidentiality protections on any vendor or third party performing health care or pharmacy administrative services on behalf of the plan, health insurer, or pharmacy benefit manager

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that have access to rebate, discount, payment differential, concession, or reduction information.

- (5) A group health plan, health insurer, or pharmacy benefit manager that violates any provision of this section is liable for a civil fine of \$10,000 for each violation and may be required to discontinue the issuance or renewal of the plan or health insurance coverage or the provision of pharmacy benefit management services, as applicable.
- (6) The department shall investigate any alleged violation of this section.
- (7) This section does not prevent a group health plan, health insurer, or pharmacy benefit manager from requiring a copayment for any prescription drug if such copayment is not tied to a percentage of the cost of the drug.
- Section 8. Present subsection (5) of section 627.64741, Florida Statutes, is redesignated as subsection (10), new subsections (5) through (9) are added to that section, and subsection (1) and present subsection (5) are amended, to read:
 - 627.64741 Pharmacy benefit manager contracts.-
 - (1) As used in this section, the term:
- (a) "Maximum allowable cost" means the per-unit amount that a pharmacy benefit manager reimburses a <u>pharmacy or pharmacist</u> for a <u>generic drug, brand name drug, specialty drug, biological product, or other prescription drug, excluding dispensing fees, <u>before prior to</u> the application of copayments, coinsurance, and other cost-sharing charges, if any.</u>
- (b) "Maximum allowable cost list" means a listing of generic drugs, brand name drugs, specialty drugs, biological products, or other prescription drugs or other methodology used

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directly or indirectly by a pharmacy benefit manager to set the maximum allowable costs for the drugs.

- (c) "Payor" means a health plan, a health plan sponsor, a health plan provider, or any other payor that uses pharmacy benefit management services in this state.
- (d) (b) "Pharmacy benefit manager" means an a person or entity that performs pharmacy benefit management services for doing business in this state which contracts to administer or manage prescription drug benefits on behalf of a health insurer or payor to residents of this state. The term does not include a provider as defined in s. 641.19, a physician as defined in s. 459.003.
- (e) "Pharmacy benefit management services" means services
 that:
- 1. Are provided, directly or through another entity, to a health insurer or payor, regardless of whether the services provider and the health insurer or payor are related or associated by ownership, common ownership, organization, or otherwise.
- 2. Include the procurement of prescription drugs to be dispensed to patients and the administration or management of prescription drug benefits, including, but not limited to, any of the following:
 - a. A mail service pharmacy or a specialty pharmacy.
- b. Claims processing, retail network management, or payment of claims to pharmacies for dispensing drugs.
- c. Clinical or other formulary or preferred-drug-list development or management.
 - d. Negotiation, administration, or receipt of rebates,

37-00392A-20 20201682 755 discounts, payment differentials, or other incentives, to include particular drugs in a particular category or to promote 756 757 the purchase of particular drugs. 758 e. Patients' compliance, therapeutic intervention, or 759 generic substitution programs. 760 f. Disease management. 761 g. Drug use review, step-therapy protocol, or prior 762 authorization. 763 h. Adjudication of appeals or grievances related to 764 prescription drug coverage. i. Contracts with network pharmacies. 765 766 j. Control of the cost of covered prescription drugs. 767 (5) A contract between a health insurer or payor and a 768 pharmacy benefit manager must require the maximum allowable cost 769 list to include: 770 (a) Average acquisition cost, including national average 771 drug acquisition cost. 772 (b) Average manufacturer price. 773 (c) Average wholesale price. 774 (d) Brand effective rate or generic effective rate. 775 (e) Discount indexing. 776 (f) Federal upper limits. 777 (q) Wholesale acquisition cost. 778 (h) Any other item that a pharmacy benefit manager or a 779 health insurer or payor may use to establish reimbursement rates 780 to a pharmacist or pharmacy for filling prescriptions or 781 providing other pharmacy services. 782 (6) A health insurer that uses pharmacy benefit management

services or a payor shall have access to all financial and

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utilization records, data, and information used by the pharmacy benefit manager in relation to the pharmacy benefit management services provided to the health insurer or payor.

- (7) A pharmacy benefit manager shall:
- (a) Disclose in writing to the health insurer that uses pharmacy benefit management services or to the payor any activity, policy, practice, contract, or arrangement of the pharmacy benefit manager which directly or indirectly presents conflicts of interest with the pharmacy benefit manager's relationship with, or fiduciary duty or obligation to, the insureds and the health insurer or payor.
- (b) Report quarterly to the health insurer or payor any income resulting from pricing discounts, rebates of any kind, inflationary payments, credits, clawbacks, fees, grants, chargebacks, reimbursements, or other financial benefits received by the pharmacy benefit manager from any person or entity. The pharmacy benefit manager shall ensure that such income and financial benefits are passed through in full, at least quarterly, to the health insurer or payor to reduce the cost of prescription drugs and pharmacy services to the insureds.
- (8) The department shall investigate any alleged violation of this section.
- (9) (a) A pharmacy benefit manager that violates any provision of this section is liable for a civil fine of \$10,000 for each violation and may have its registration revoked by the department.
- (b) A violation by a pharmacy benefit manager of any provision of this section which is committed or performed with

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prescription drugs.

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attributable to prescription drugs.

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814 subject to the Florida Deceptive and Unfair Trade Practices Act 815 under part II of chapter 501. 816 (10) (5) This section applies to contracts entered into or 817 renewed on or after January 1, 2021 July 1, 2018. 818 Section 9. Section 627.64745, Florida Statutes, is created 819 to read: 820 627.64745 Health insurers; prescription drug spending 821 reports.-822 (1) As used in this section, the term: (a) "Specialty drug" means a prescription drug on a health 823 824 insurer's formulary which is also covered under Medicare Part D 825 and exceeds the specialty tier cost threshold established by the 826 federal Centers for Medicare and Medicaid Services. (b) "Utilization management" means a set of formal 827 828 techniques designed to monitor the use of or evaluate the 829 medical necessity, appropriateness, efficacy, or efficiency of 830 health care services, procedures, or settings. 831 (2) By February 1 of each year, each health insurer shall 832 submit to the office a report including all of the following 833 information across all health insurance policies for the 834 preceding calendar year:

such frequency as to indicate a general business practice is

(d) The percentage of specialty drugs with utilization

(b) The percentage of any increase in annual net spending

(c) The percentage of any increase in premiums which was

(a) The names of the 25 most frequently prescribed

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management requirements prescribed.

- (e) Any premium reductions that were attributable to specialty drug utilization management.
- (3) A report submitted under this section must not disclose the identity of a specific health insurance policy or the price charged for a specific prescription drug or class of prescription drugs.
- (4) By May 1 of each year, the office shall publish on its website aggregated data from all reports it received under this section for that year. The data from the reports may not be published in a manner that would disclose or tend to disclose any health insurer's proprietary or confidential information.
- (5) The commission may adopt rules to implement this section.

Section 10. Present subsection (5) of section 627.6572, Florida Statutes, is redesignated as subsection (10) and amended, a new subsection (5) and subsections (6) through (9) are added to that section, and subsection (1) is amended, to read:

627.6572 Pharmacy benefit manager contracts.-

- (1) As used in this section, the term:
- (a) "Maximum allowable cost" means the per-unit amount that a pharmacy benefit manager reimburses a <u>pharmacy or pharmacist</u> for a <u>generic drug, brand name drug, specialty drug, biological product, or other prescription drug, excluding dispensing fees, <u>before prior to</u> the application of copayments, coinsurance, and other cost-sharing charges, if any.</u>
- (b) "Maximum allowable cost list" means a listing of generic drugs, brand name drugs, specialty drugs, biological

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products, or other prescription drugs or other methodology used directly or indirectly by a pharmacy benefit manager to set the maximum allowable costs for the drugs.

- (c) "Payor" means a health plan, a health plan sponsor, a health plan provider, or any other payor that uses pharmacy benefit management services in this state.
- (d) (b) "Pharmacy benefit manager" means an a person or entity that performs pharmacy benefit management services for doing business in this state which contracts to administer or manage prescription drug benefits on behalf of a health insurer or payor to residents of this state. The term does not include a provider as defined in s. 641.19, a physician as defined in s. 459.003.
- (e) "Pharmacy benefit management services" means services
 that:
- 1. Are provided, directly or through another entity, to a health insurer or payor, regardless of whether the services provider and the health insurer or payor are related or associated by ownership, common ownership, organization, or otherwise.
- 2. Include the procurement of prescription drugs to be dispensed to patients and the administration or management of prescription drug benefits, including, but not limited to, any of the following:
 - a. A mail service pharmacy or a specialty pharmacy.
- <u>b. Claims processing, retail network management, or payment</u> of claims to pharmacies for dispensing drugs.
- $\underline{\text{c. Clinical or other formulary or preferred-drug-list}}$ development or management.

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d. Negotiation, administration, or receipt of rebates, discounts, payment differentials, or other incentives, to include particular drugs in a particular category or to promote the purchase of particular drugs.

- e. Patients' compliance, therapeutic intervention, or generic substitution programs.
 - f. Disease management.
- g. Drug use review, step-therapy protocol, or prior authorization.
- h. Adjudication of appeals or grievances related to prescription drug coverage.
 - i. Contracts with network pharmacies.
 - j. Control of the cost of covered prescription drugs.
- (5) A contract between a health insurer or payor and a pharmacy benefit manager must require the maximum allowable cost list to include:
- (a) Average acquisition cost, including national average drug acquisition cost.
 - (b) Average manufacturer price.
 - (c) Average wholesale price.
 - (d) Brand effective rate or generic effective rate.
 - (e) Discount indexing.
 - (f) Federal upper limits.
 - (g) Wholesale acquisition cost.
- (h) Any other item that a pharmacy benefit manager or a health insurer or payor may use to establish reimbursement rates to a pharmacist or pharmacy for filling prescriptions or providing other pharmacy services.
 - (6) A health insurer that uses pharmacy benefit management

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services or a payor shall have access to all financial and utilization records, data, and information used by the pharmacy benefit manager in relation to the pharmacy benefit management services provided to the health insurer or payor.

- (7) A pharmacy benefit manager shall:
- (a) Disclose in writing to the health insurer that uses pharmacy benefit management services or the payor any activity, policy, practice, contract, or arrangement of the pharmacy benefit manager which directly or indirectly presents conflicts of interest with the pharmacy benefit manager's relationship with, or fiduciary duty or obligation to, the insureds and the health insurer or payor.
- (b) Report quarterly to the health insurer or payor any income resulting from pricing discounts, rebates of any kind, inflationary payments, credits, clawbacks, fees, grants, chargebacks, reimbursements, or other financial benefits received by the pharmacy benefit manager from any person or entity. The pharmacy benefit manager shall ensure that such income and financial benefits are passed through in full, at least quarterly, to the health insurer or payor to reduce the cost of prescription drugs and pharmacy services to the insureds.
- (8) The department shall investigate any alleged violation of this section.
- (9) (a) A pharmacy benefit manager that violates any provision of this section is liable for a civil fine of \$10,000 for each violation and may have its registration revoked by the department.
 - (b) A violation by a pharmacy benefit manager of any

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provision of this section which is committed or performed with such frequency as to indicate a general business practice is subject to the Florida Deceptive and Unfair Trade Practices Act under part II of chapter 501.

(10) (5) This section applies to contracts entered into or renewed on or after January 1, 2021 July 1, 2018.

Section 11. Section 627.65725, Florida Statutes, is created to read:

627.65725 Health insurers; prescription drug spending reports.—

- (1) As used in this section, the term:
- (a) "Specialty drug" means a prescription drug on a health insurer's formulary which is also covered under Medicare Part D and exceeds the specialty tier cost threshold established by the federal Centers for Medicare and Medicaid Services.
- (b) "Utilization management" means a set of formal techniques designed to monitor the use of or evaluate the medical necessity, appropriateness, efficacy, or efficiency of health care services, procedures, or settings.
- (2) By February 1 of each year, each health insurer shall submit to the office a report including all of the following information across all group health insurance policies for the preceding calendar year:
- (a) The names of the 25 most frequently prescribed prescription drugs.
- (b) The percentage of any increase in annual net spending for prescription drugs.
- (c) The percentage of any increase in premiums which was attributable to prescription drugs.

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(d) The percentage of specialty drugs with utilization management requirements prescribed.

- (e) Any premium reduction that was attributable to specialty drug utilization management.
- (3) A report submitted under this section must not disclose the identity of a specific health insurance policy or the price charged for a specific prescription drug or class of prescription drugs.
- (4) By May 1 of each year, the office shall publish on its website aggregated data from all reports it received under this section for that year. The data from the reports may not be published in a manner that would disclose or tend to disclose any health insurer's proprietary or confidential information.
- (5) The commission may adopt rules to implement this section.

Section 12. Section 641.262, Florida Statutes, is created to read:

- 641.262 Health maintenance organizations; prescription drug spending reports.—
 - (1) As used in this section, the term:
- (a) "Specialty drug" means a prescription drug on a health maintenance organization's formulary which is also covered under Medicare Part D and exceeds the specialty tier cost threshold established by the federal Centers for Medicare and Medicaid Services.
- (b) "Utilization management" means a set of formal techniques designed to monitor the use of or evaluate the medical necessity, appropriateness, efficacy, or efficiency of health care services, procedures, or settings.

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(2) By February 1 of each year, each health maintenance organization shall submit to the office a report including all of the following information across all health maintenance contracts for the preceding calendar year:

- (a) The names of the 25 most frequently prescribed prescription drugs.
- (b) The percentage of any increase in annual net spending for prescription drugs.
- (c) The percentage of any increase in premiums which was attributable to prescription drugs.
- (d) The percentage of specialty drugs with utilization management requirements prescribed.
- (e) Any premium reduction that was attributable to specialty drug utilization management.
- (3) A report submitted under this section must not disclose the identity of a specific health maintenance contract or the price charged for a specific prescription drug or class of prescription drugs.
- (4) By May 1 of each year, the office shall publish on its website aggregated data from all reports it received under this section for that year. The data from the reports may not be published in a manner that would disclose or tend to disclose any health maintenance organization's proprietary or confidential information.
- (5) The commission may adopt rules to implement this section.

Section 13. Present subsection (5) of section 641.314, Florida Statutes, is redesignated as subsection (10) and amended, a new subsection (5) and subsections (6) through (9)

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are added to that section, and subsection (1) is amended, to read:

- 641.314 Pharmacy benefit manager contracts.-
- (1) As used in this section, the term:
- (a) "Maximum allowable cost" means the per-unit amount that a pharmacy benefit manager reimburses a <u>pharmacy or pharmacist</u> for a <u>generic drug, brand name drug, specialty drug, biological product, or other prescription drug, excluding dispensing fees, <u>before prior to</u> the application of copayments, coinsurance, and other cost-sharing charges, if any.</u>
- (b) "Maximum allowable cost list" means a listing of generic drugs, brand name drugs, specialty drugs, biological products, or other prescription drugs or other methodology used directly or indirectly by a pharmacy benefit manager to set the maximum allowable costs for the drugs.
- (c) "Payor" means a health plan, a health plan sponsor, a health plan provider, or any other payor that uses pharmacy benefit management services in this state.
- (d) (b) "Pharmacy benefit manager" means an a person or entity that performs pharmacy benefit management services for doing business in this state which contracts to administer or manage prescription drug benefits on behalf of a health maintenance organization or payor to residents of this state.

 The term does not include a provider as defined in s. 641.19, a physician as defined in s. 458.305, or an osteopathic physician as defined in s. 459.003.
- (e) "Pharmacy benefit management services" means services
 that:
 - 1. Are provided, directly or through another entity, to a

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health maintenance organization or payor, regardless of whether the services provider and the health maintenance organization or payor are related or associated by ownership, common ownership, organization, or otherwise.

- 2. Include the procurement of prescription drugs to be dispensed to patients and the administration or management of prescription drug benefits, including, but not limited to, any of the following:
 - a. A mail service pharmacy or a specialty pharmacy.
- b. Claims processing, retail network management, or payment of claims to pharmacies for dispensing drugs.
- c. Clinical or other formulary or preferred-drug-list development or management.
- d. Negotiation, administration, or receipt of rebates, discounts, payment differentials, or other incentives, to include particular drugs in a particular category or to promote the purchase of particular drugs.
- <u>e. Patients' compliance, therapeutic intervention, or</u> generic substitution programs.
 - f. Disease management.
- g. Drug use review, step-therapy protocol, or prior authorization.
 - h. Adjudication of appeals or grievances related to prescription drug coverage.
 - i. Contracts with network pharmacies.
- j. Control of the cost of covered prescription drugs.
- 1100 (5) A contract between a health maintenance organization or
 1101 payor and a pharmacy benefit manager must require the maximum
 1102 allowable cost list to include:

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1103 (a) Average acquisition cost, including national average 1104 drug acquisition cost.

- (b) Average manufacturer price.
- (c) Average wholesale price.
- (d) Brand effective rate or generic effective rate.
- (e) Discount indexing.

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- (f) Federal upper limits.
- (g) Wholesale acquisition cost.
- (h) Any other item that a pharmacy benefit manager or a health maintenance organization or payor may use to establish reimbursement rates to a pharmacist or pharmacy for filling prescriptions or providing other pharmacy services.
- (6) A health maintenance organization that uses pharmacy benefit management services or a payor shall have access to all financial and utilization records, data, and information used by the pharmacy benefit manager in relation to the pharmacy benefit management services provided to the health maintenance organization or payor.
 - (7) A pharmacy benefit manager shall:
- (a) Disclose in writing to the health maintenance organization that uses pharmacy benefit management services or the payor any activity, policy, practice, contract, or arrangement of the pharmacy benefit manager which directly or indirectly presents conflicts of interest with the pharmacy benefit manager's relationship with, or fiduciary duty or obligation to, the subscribers and the health maintenance organization or payor.
- (b) Report quarterly to the health maintenance organization or payor any income resulting from pricing discounts, rebates of

to the subscribers.

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any kind, inflationary payments, credits, clawbacks, fees,
grants, chargebacks, reimbursements, or other financial benefits
received by the pharmacy benefit manager from any person or
entity. The pharmacy benefit manager shall ensure that such
income and financial benefits are passed through in full, at
least quarterly, to the health maintenance organization or payor
to reduce the cost of prescription drugs and pharmacy services

- (8) The department shall investigate any alleged violation of this section.
- (9) (a) A pharmacy benefit manager that violates any provision of this section is liable for a civil fine of \$10,000 for each violation and may have its registration revoked by the department.
- (b) A violation of any provision of this section which is committed or performed with such frequency as to indicate a general business practice is subject to the Florida Deceptive and Unfair Trade Practices Act under part II of chapter 501.
- (10) (5) This section applies to contracts entered into or renewed on or after January 1, 2021 July 1, 2018.

Section 14. Paragraph (a) of subsection (1) of section 409.9201, Florida Statutes, is amended to read:

409.9201 Medicaid fraud.

- (1) As used in this section, the term:
- (a) "Prescription drug" means any drug, including, but not limited to, finished dosage forms or active ingredients that are subject to, defined in, or described in s. 503(b) of the Federal Food, Drug, and Cosmetic Act or in s. 465.003 s. 465.003(8), s. 499.003(17), s. 499.007(13), or s. 499.82(10).

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The value of individual items of the legend drugs or goods or services involved in distinct transactions committed during a single scheme or course of conduct, whether involving a single person or several persons, may be aggregated when determining the punishment for the offense.

Section 15. Paragraph (pp) of subsection (1) of section 458.331, Florida Statutes, is amended to read:

458.331 Grounds for disciplinary action; action by the board and department.—

- (1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):
- (pp) Applicable to a licensee who serves as the designated physician of a pain-management clinic as defined in s. 458.3265 or s. 459.0137:
- 1. Registering a pain-management clinic through misrepresentation or fraud;
- 2. Procuring, or attempting to procure, the registration of a pain-management clinic for any other person by making or causing to be made, any false representation;
- 3. Failing to comply with any requirement of chapter 499, the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Drug Abuse Prevention and Control Act; or chapter 893, the Florida Comprehensive Drug Abuse Prevention and Control Act;
- 4. Being convicted or found guilty of, regardless of adjudication to, a felony or any other crime involving moral turpitude, fraud, dishonesty, or deceit in any jurisdiction of the courts of this state, of any other state, or of the United

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1190 States;

5. Being convicted of, or disciplined by a regulatory agency of the Federal Government or a regulatory agency of another state for, any offense that would constitute a violation of this chapter;

- 6. Being convicted of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction of the courts of this state, of any other state, or of the United States which relates to the practice of, or the ability to practice, a licensed health care profession;
- 7. Being convicted of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction of the courts of this state, of any other state, or of the United States which relates to health care fraud;
- 8. Dispensing any medicinal drug based upon a communication that purports to be a prescription as defined in $\underline{s.\ 465.003}\ \underline{s.}\ 465.003(14)$ or s. 893.02 if the dispensing practitioner knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship; or
- 9. Failing to timely notify the board of the date of his or her termination from a pain-management clinic as required by s. 458.3265(3).

Section 16. Paragraph (rr) of subsection (1) of section 459.015, Florida Statutes, is amended to read:

- 459.015 Grounds for disciplinary action; action by the board and department.—
- (1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):
 - (rr) Applicable to a licensee who serves as the designated

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physician of a pain-management clinic as defined in s. 458.3265 or s. 459.0137:

- 1. Registering a pain-management clinic through misrepresentation or fraud;
- 2. Procuring, or attempting to procure, the registration of a pain-management clinic for any other person by making or causing to be made, any false representation;
- 3. Failing to comply with any requirement of chapter 499, the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Drug Abuse Prevention and Control Act; or chapter 893, the Florida Comprehensive Drug Abuse Prevention and Control Act;
- 4. Being convicted or found guilty of, regardless of adjudication to, a felony or any other crime involving moral turpitude, fraud, dishonesty, or deceit in any jurisdiction of the courts of this state, of any other state, or of the United States;
- 5. Being convicted of, or disciplined by a regulatory agency of the Federal Government or a regulatory agency of another state for, any offense that would constitute a violation of this chapter;
- 6. Being convicted of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction of the courts of this state, of any other state, or of the United States which relates to the practice of, or the ability to practice, a licensed health care profession;
- 7. Being convicted of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction of the courts of this state, of any other state, or

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of the United States which relates to health care fraud;

- 8. Dispensing any medicinal drug based upon a communication that purports to be a prescription as defined in $\underline{s.\ 465.003}\ \underline{s.}$ $\underline{465.003(14)}$ or s. 893.02 if the dispensing practitioner knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship; or
- 9. Failing to timely notify the board of the date of his or her termination from a pain-management clinic as required by s. 459.0137(3).

Section 17. Subsection (1) of section 465.014, Florida Statutes, is amended to read:

465.014 Pharmacy technician.

(1) A person other than a licensed pharmacist or pharmacy intern may not engage in the practice of the profession of pharmacy, except that a licensed pharmacist may delegate to pharmacy technicians who are registered pursuant to this section those duties, tasks, and functions that do not fall within the purview of s. $465.003 ext{ s. } 465.003(13)$. All such delegated acts must be performed under the direct supervision of a licensed pharmacist who is responsible for all such acts performed by persons under his or her supervision. A registered pharmacy technician, under the supervision of a pharmacist, may initiate or receive communications with a practitioner or his or her agent, on behalf of a patient, regarding refill authorization requests. A licensed pharmacist may not supervise more than one registered pharmacy technician unless otherwise permitted by the quidelines adopted by the board. The board shall establish guidelines to be followed by licensees or permittees in determining the circumstances under which a licensed pharmacist

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may supervise more than one pharmacy technician.

Section 18. Paragraph (c) of subsection (2) of section 465.015, Florida Statutes, is amended to read:

465.015 Violations and penalties.-

- (2) It is unlawful for any person:
- (c) To sell or dispense drugs as defined in $\underline{s. 465.003} \ \underline{s.} 465.003(8)$ without first being furnished with a prescription.

Section 19. Subsection (9) of section 465.0156, Florida Statutes, is amended to read:

465.0156 Registration of nonresident pharmacies.-

(9) Notwithstanding <u>s. 465.003</u> s. 465.003(10), for purposes of this section, the registered pharmacy and the pharmacist designated by the registered pharmacy as the prescription department manager or the equivalent must be licensed in the state of location in order to dispense into this state.

Section 20. Paragraph (s) of subsection (1) of section 465.016, Florida Statutes, is amended to read:

465.016 Disciplinary actions.-

- (1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):
- (s) Dispensing any medicinal drug based upon a communication that purports to be a prescription as defined \underline{in} $\underline{s.\ 465.003}$ by $\underline{s.\ 465.003(14)}$ or $\underline{s.\ 893.02}$ when the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship.

Section 21. Subsection (4) of section 465.0197, Florida Statutes, is amended to read:

465.0197 Internet pharmacy permits.

(4) Notwithstanding s. 465.003 s. 465.003(10), for purposes

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of this section, the Internet pharmacy and the pharmacist designated by the Internet pharmacy as the prescription department manager or the equivalent must be licensed in the state of location in order to dispense into this state.

Section 22. Paragraph (j) of subsection (5) of section 465.022, Florida Statutes, is amended to read:

465.022 Pharmacies; general requirements; fees.-

- (5) The department or board shall deny an application for a pharmacy permit if the applicant or an affiliated person, partner, officer, director, or prescription department manager or consultant pharmacist of record of the applicant:
- (j) Has dispensed any medicinal drug based upon a communication that purports to be a prescription as defined <u>in s. 465.003</u> by s. 465.003(14) or s. 893.02 when the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship that includes a documented patient evaluation, including history and a physical examination adequate to establish the diagnosis for which any drug is prescribed and any other requirement established by board rule under chapter 458, chapter 459, chapter 461, chapter 463, chapter 464, or chapter 466.

For felonies in which the defendant entered a plea of guilty or nolo contendere in an agreement with the court to enter a pretrial intervention or drug diversion program, the department shall deny the application if upon final resolution of the case the licensee has failed to successfully complete the program.

Section 23. Paragraph (h) of subsection (1) of section 465.023, Florida Statutes, is amended to read:

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465.023 Pharmacy permittee; disciplinary action.-

- (1) The department or the board may revoke or suspend the permit of any pharmacy permittee, and may fine, place on probation, or otherwise discipline any pharmacy permittee if the permittee, or any affiliated person, partner, officer, director, or agent of the permittee, including a person fingerprinted under s. 465.022(3), has:
- (h) Dispensed any medicinal drug based upon a communication that purports to be a prescription as defined in s. 465.003 by s. 465.003(14) or s. 893.02 when the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship that includes a documented patient evaluation, including history and a physical examination adequate to establish the diagnosis for which any drug is prescribed and any other requirement established by board rule under chapter 458, chapter 459, chapter 461, chapter 463, chapter 464, or chapter 466.

Section 24. Section 465.1901, Florida Statutes, is amended to read:

465.1901 Practice of orthotics and pedorthics.—The provisions of chapter 468 relating to orthotics or pedorthics do not apply to any licensed pharmacist or to any person acting under the supervision of a licensed pharmacist. The practice of orthotics or pedorthics by a pharmacist or any of the pharmacist's employees acting under the supervision of a pharmacist shall be construed to be within the meaning of the term "practice of the profession of pharmacy" as $\frac{\text{defined}}{\text{set}}$ $\frac{\text{set}}{\text{forth}}$ in $\frac{\text{s. 465.003}}{\text{s. 465.003}}$, and shall be subject to regulation in the same manner as any other pharmacy practice.

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The Board of Pharmacy shall develop rules regarding the practice of orthotics and pedorthics by a pharmacist. Any pharmacist or person under the supervision of a pharmacist engaged in the practice of orthotics or pedorthics is not precluded from continuing that practice pending adoption of these rules.

Section 25. Subsection (40) of section 499.003, Florida Statutes, is amended to read:

499.003 Definitions of terms used in this part.—As used in this part, the term:

(40) "Prescription drug" means a prescription, medicinal, or legend drug, including, but not limited to, finished dosage forms or active pharmaceutical ingredients subject to, defined by, or described by s. 503(b) of the federal act or s. 465.003 s. 465.003(8), s. 499.007(13), subsection (31), or subsection (47), except that an active pharmaceutical ingredient is a prescription drug only if substantially all finished dosage forms in which it may be lawfully dispensed or administered in this state are also prescription drugs.

Section 26. Paragraph (c) of subsection (24) of section 893.02, Florida Statutes, is amended to read:

893.02 Definitions.—The following words and phrases as used in this chapter shall have the following meanings, unless the context otherwise requires:

(24) "Prescription" includes any order for drugs or medicinal supplies which is written or transmitted by any means of communication by a licensed practitioner authorized by the laws of this state to prescribe such drugs or medicinal supplies, is issued in good faith and in the course of professional practice, is intended to be dispensed by a person

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authorized by the laws of this state to do so, and meets the requirements of s. 893.04.

(c) A prescription for a controlled substance may not be issued on the same prescription blank with another prescription for a controlled substance that is named or described in a different schedule or with another prescription for a medicinal drug, as defined in $\underline{s.\ 465.003}\ \underline{s.\ 465.003(8)}$, that is not a controlled substance.

Section 27. This act shall take effect July 1, 2020.