By Senator Burgess

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A bill to be entitled

An act relating to storage and disposal of prescription drugs and sharps; requiring the Department of Health and the Department of Environmental Protection to conduct a study of the safe collection and proper disposal of sharps; requiring the departments to make a specified assessment of the use of sharps in the home; establishing the collection methods to be considered in conducting the study; authorizing the departments to work or contract with counties, municipalities, and private entities; requiring the departments to submit a specified report to the Governor and the Legislature by a certain date; providing for an appropriation; amending s. 499.0121, F.S.; providing applicability; providing requirements for establishments that store, warehouse, or hold certain prescription drugs solely for the purpose of destruction; amending ss. 465.022, 499.003, 499.0051, 499.01, 499.012, 499.01201, 499.05, and 499.067, F.S.; conforming cross-references; providing an effective date.

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

Section 1. (1) The Department of Health, in partnership with the Department of Environmental Protection, shall conduct a study of the safe collection and proper disposal of sharps, as defined in s. 381.0098(2)(d), Florida Statutes, used by individuals to self-administer prescription drugs in the home.

(a) The departments shall assess the risk of injury to patients, health care professionals, caregivers, family members, and waste industry workers from the use of sharps in the home.

(b) In conducting the study, the departments shall consider at least the following two methods of safe collection in both rural and urban environments:

1. Sharps disposal by mail.

2. Sharps disposal at drop-off locations such as pharmacies or other health-care-related sites.

(2) The departments may work or contract with counties and municipalities and private entities that wish to participate in the study.

(3) By July 1, 2026, the departments shall submit a report of their findings and recommendations to the Governor, the President of the Senate, and the Speaker of the House of Representatives. The report must contain, at a minimum, all of the following:

(a) An evaluation of the sharps collection methods, including consideration of cost, convenience, safety, consumer preference, and effectiveness.

(b) Information regarding the current local government sharps collection methods practiced in this state, recommendations for improving existing sharps collection programs, and whether such programs have been updated or adopted based on the findings of the study.

(c) Recommendations for safely collecting sharps used by individuals to self-administer prescription drugs in the home, including the estimated costs associated with statewide adoption of one or more sharps collection methods.

(d) Information regarding current sharps collection methods practiced by health care and home health agency professionals performing services in a patient's home, and any recommendations for improving current practices.

(4) For the 2025-2026 fiscal year, the nonrecurring sum of $200,000 from the Solid Waste Management Trust Fund is appropriated to the Department of Health and the Department of Environmental Protection to implement this section.

Section 2. Section 499.0121, Florida Statutes, is amended to read:

499.0121 Storage and handling of prescription drugs; recordkeeping.—

(1) AUTHORITY TO PRESCRIBE RULES.—

(a) The department shall adopt rules to implement this section as necessary to protect the public health, safety, and welfare. Such rules shall include, but not be limited to, requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records.

(b) This section does not apply to Schedule IV, Schedule V, and nonscheduled prescription drugs pursuant to s. 893.03, or prescription drugs collected under a program authorized by 21 C.F.R. s. 1317, subpart B, which are stored, warehoused, or held solely for the purpose of destruction, except as provided in subsection (7).

(2)~~(1)~~ ESTABLISHMENTS.—An establishment at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed must:

(a) Be of suitable size and construction to facilitate

cleaning, maintenance, and proper operations;

(b) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(c) Have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;

(d) Be maintained in a clean and orderly condition; and

(e) Be free from infestation by insects, rodents, birds, or vermin of any kind.

(3) ~~(2)~~ SECURITY.—

(a) An establishment that is used for wholesale drug distribution must be secure from unauthorized entry.

1. Access from outside the premises must be kept to a minimum and be well controlled.

2. The outside perimeter of the premises must be well lighted.

3. Entry into areas where prescription drugs are held must be limited to authorized personnel.

(b) An establishment that is used for wholesale drug distribution must be equipped with:

1. An alarm system to detect entry after hours; however, the department may exempt by rule establishments that only hold a permit as prescription drug wholesale distributor-brokers; and

2. A security system that will provide suitable protection against theft and diversion. When appropriate, the security system must provide protection against theft or diversion that is facilitated or hidden by tampering with computers or

electronic records.

(c) Any vehicle that contains prescription drugs must be secure from unauthorized access to the prescription drugs in the vehicle.

(4)~~(3)~~ STORAGE.—All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the official compendium.

(a) If no storage requirements are established for a prescription drug, the drug may be held at "controlled" room temperature, as defined in the official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(b) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, or logs must be used to document proper storage of prescription drugs.

(c) The recordkeeping requirements in subsection (8) ~~(6)~~ must be followed for all stored prescription drugs.

(5)~~(4)~~ EXAMINATION OF MATERIALS AND RECORDS.—

(a) Upon receipt, each outside shipping container must be visually examined for identity and to prevent the acceptance of contaminated prescription drugs that are otherwise unfit for distribution. This examination must be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(b) Each outgoing shipment must be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have expired or been damaged in storage or held under improper conditions.

(c) The recordkeeping requirements in subsection (8) ~~(6)~~ must be followed for all incoming and outgoing prescription drugs.

(d) Upon receipt, a wholesale distributor must review records required under this section for the acquisition of prescription drugs for accuracy and completeness, considering the total facts and circumstances surrounding the transactions and the wholesale distributors involved.

(6)~~(5)~~ RETURNED, DAMAGED, OR OUTDATED PRESCRIPTION DRUGS.—

(a)1. Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated must be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier. A quarantine section must be separate and apart from other sections where prescription drugs are stored so that prescription drugs in this section are not confused with usable prescription drugs.

2. Prescription drugs must be examined at least every 12 months, and drugs for which the expiration date has passed must be removed and quarantined.

(b) Any prescription drugs of which the immediate or sealed outer containers or sealed secondary containers have been opened or used must be identified as such and must be quarantined and physically separated from other prescription drugs until they are destroyed or returned to the supplier.

(c) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the drug must be destroyed or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards

of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale distributor must consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the conditions of the drug and its container, carton, or labeling, as a result of storage or shipping.

(d) The recordkeeping requirements in subsection (8) ~~(6)~~ must be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs.

(7) DESTRUCTION OF SCHEDULE IV, SCHEDULE V, AND NONSCHEDULED PRESCRIPTION DRUGS OR PRESCRIPTION DRUGS COLLECTED UNDER A PROGRAM AUTHORIZED BY 21 C.F.R. S. 1317, SUBPART B.—An establishment that stores, warehouses, or holds Schedule IV, Schedule V, and nonscheduled prescription drugs pursuant to s. 893.03, or prescription drugs collected under a program authorized by 21 C.F.R. s. 1317, subpart B, solely for the purpose of arranging for their destruction, shall only be required to:

(a) Secure the establishment that is used for activities related to destruction against unauthorized entry or unauthorized access to the prescription drugs when establishment personnel are not present.

(b) Maintain records of the address of the location from which the prescription drugs were collected and a formulary or description of that location's prescription drugs, or documentation that the prescription drugs were collected under a program authorized by 21 C.F.R. s. 1317, subpart B, and the

address at which the prescription drugs were destroyed.

(c) Operate in compliance with applicable federal laws and regulations.

(8) ~~(6)~~ RECORDKEEPING.—The department shall adopt rules that require keeping such records of prescription drugs, including active pharmaceutical ingredients, as are necessary for the protection of the public health.

(a) The following persons must maintain business records that include the information specified in paragraph (b):

1. Persons permitted or required to be permitted under this chapter to engage in the manufacture, repackaging, or distribution of active pharmaceutical ingredients or prescription drugs.

2. Persons other than those set forth in subparagraph 1. that engage in the receipt of active pharmaceutical ingredients or prescription drugs.

(b) Business records for persons specified in paragraph (a) must include:

1. The name and address of the seller, and the Florida permit number of the seller if such seller is not exempt from Florida permitting requirements, of the active pharmaceutical ingredient or prescription drug.

2. The address of the location the active pharmaceutical ingredient or prescription drug was shipped from.

3. The distribution date of the active pharmaceutical ingredient or prescription drug.

4. The name, strength, and quantity, and the National Drug Code if such code has been assigned, of the distributed active pharmaceutical ingredient or prescription drug.

5. The name and Florida permit number of the person that purchased the active pharmaceutical ingredient or prescription drug.

6. The financial data, including the unit type and unit price, for the distributions involving active pharmaceutical ingredients or prescription drugs.

7. The date and method of disposition of the active pharmaceutical ingredient or prescription drug.

(c) Each manufacturer or repackager of medical devices, over-the-counter drugs, or cosmetics must maintain business records that include:

1. The name and address of the seller or transferor of the product.

2. The address of the location the product was shipped from.

3. The date of the sale or distribution of the product.

4. The name and quantity of the product involved.

5. The name and address of the person who purchased the product.

(d) Persons permitted, or required to be permitted, under this chapter to engage in the manufacture, repackaging, or distribution of active pharmaceutical ingredients or prescription drugs; or the manufacture or repackaging of medical devices, over-the-counter drugs, and cosmetics; must establish, maintain, or have the capability to create a current inventory of the active pharmaceutical ingredients, prescription drugs, over-the-counter drugs, cosmetics, and devices at an establishment where activities specified in this paragraph are undertaken and must be able to produce such inventory for

inspection by the department within 2 business days.

(e) Business records required to be kept pursuant to this section, and that are kept at the inspection site or can be immediately retrieved by computer or other electronic means, must be readily available for authorized inspection during the retention period. Records kept at a central location outside of this state which are not electronically retrievable must be made available for inspection within 2 working days after a request by an authorized official of a federal, state, or local law enforcement agency. Records maintained at a central location within this state must be maintained at an establishment that is permitted pursuant to this part, and such records must be readily available for inspection.

(f) Records required to be kept pursuant to this subsection must be maintained as specified for a period of not less than 6 years from the date of disposition of the active pharmaceutical ingredients, prescription drugs, over-the-counter drugs, medical devices, or cosmetics.

(g) To the extent that prescription drugs are also products as defined in the federal act, as amended, and the information required by the business records requirements of this section are also included in the tracking and tracing requirements of the federal act, as amended, and departmental rules, the manufacturer, wholesale distributor, repackager, or dispenser must follow both the requirements of the federal act, as amended, and departmental rules.

(9)~~(7)~~ PRESCRIPTION DRUG PURCHASE LIST.—Each wholesale distributor, except for a manufacturer, shall annually provide the department with a written list of all wholesale distributors

and manufacturers from whom the wholesale distributor purchases prescription drugs. A wholesale distributor, except a manufacturer, shall notify the department not later than 10 days after any change to either list.

(10)~~(8)~~ WRITTEN POLICIES AND PROCEDURES.—Wholesale distributors must establish, maintain, and adhere to written policies and procedures, which must be followed for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesale distributors must include in their written policies and procedures:

(a) A procedure whereby the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement, if the deviation is temporary and appropriate.

(b) A procedure to be followed for handling recalls and withdrawals of prescription drugs. Such procedure must be adequate to deal with recalls and withdrawals due to:

1. Any action initiated at the request of the Food and Drug Administration or any other federal, state, or local law enforcement or other government agency, including the department.

2. Any voluntary action by the manufacturer or repackager to remove defective or potentially defective drugs from the market; or

3. Any action undertaken to promote public health and safety by replacing existing merchandise with an improved

product or new package design.

(c) A procedure to ensure that wholesale distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility if a strike, fire, flood, or other natural disaster, or a local, state, or national emergency, occurs.

(d) A procedure to ensure that any outdated prescription drugs are segregated from other drugs and returned to the manufacturer or repackager or destroyed. This procedure must provide for written documentation of the disposition of outdated prescription drugs. This documentation must be maintained for 2 years after disposition of the outdated drugs.

(11)~~(9)~~ RESPONSIBLE PERSONS.—Wholesale distributors must establish and maintain lists of officers, directors, managers, designated representatives, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

(12)~~(10)~~ COMPLIANCE WITH FEDERAL, STATE, AND LOCAL LAW.—A wholesale distributor must operate in compliance with applicable federal, state, and local laws and regulations.

(a) A wholesale distributor must allow the department and authorized federal, state, and local officials to enter and inspect its premises and delivery vehicles, and to audit its records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.

(b) A wholesale distributor that deals in controlled substances must register with the Drug Enforcement Administration and must comply with all applicable state, local,

and federal laws. A wholesale distributor that distributes any substance controlled under chapter 893 must notify the department when registering with the Drug Enforcement Administration pursuant to that chapter and must provide the department with its DEA number.

(13) ~~(11)~~ SALVAGING AND REPROCESSING.—A wholesale distributor is subject to any applicable federal, state, or local laws or regulations that relate to prescription drug product salvaging or reprocessing.

(14) ~~(12)~~ SHIPPING AND TRANSPORTATION.—The person responsible for shipment and transportation of a prescription drug in a wholesale distribution may use a common carrier; its own vehicle or employee acting within the scope of employment if authorized under s. 499.03 for the possession of prescription drugs in this state; or, in the case of a prescription drug intended for domestic distribution, an independent contractor who must be the agent of the authorized seller or recipient responsible for shipping and transportation as set forth in a written contract between the parties. A person selling a prescription drug for export must obtain documentation, such as a validated airway bill, bill of lading, or other appropriate documentation that the prescription drug was exported. A person responsible for shipping or transporting prescription drugs is not required to maintain documentation from a common carrier that the designated recipient received the prescription drugs; however, the person must obtain such documentation from the common carrier and make it available to the department upon request of the department.

(15) ~~(13)~~ DUE DILIGENCE OF SUPPLIERS.—Prior to purchasing

any prescription drugs from another wholesale distributor, a prescription drug wholesale distributor, an out-of-state prescription drug wholesale distributor, or a prescription drug repackager must:

(a) Enter an agreement with the selling wholesale distributor by which the selling wholesale distributor will indemnify the purchasing wholesale distributor for any loss caused to the purchasing wholesale distributor related to the purchase of drugs from the selling wholesale distributor which are determined to be counterfeit or to have been distributed in violation of any federal or state law governing the distribution of drugs.

(b) Determine that the selling wholesale distributor has insurance coverage of not less than the greater of 1 percent of the amount of total dollar volume of the prescription drug sales reported to the department under s. 499.012(8)(g) or $500,000; however the coverage need not exceed $2 million.

(c) Obtain information from the selling wholesale distributor, including the length of time the selling wholesale distributor has been licensed in this state, a copy of the selling wholesale distributor’s licenses or permits, and background information concerning the ownership of the selling wholesale distributor, including the experience of the wholesale distributor in the wholesale distribution of prescription drugs.

(d) Verify that the selling wholesale distributor’s Florida permit is valid.

(e) Inspect the selling wholesale distributor’s licensed establishment to document that it has a policies and procedures manual relating to the distribution of drugs, the appropriate

temperature controlled environment for drugs requiring temperature control, an alarm system, appropriate access restrictions, and procedures to ensure that records related to the wholesale distribution of prescription drugs are maintained as required by law:

1. Before purchasing any drug from the wholesale distributor, and at least once each subsequent year; or

2. Before purchasing any drug from the wholesale distributor, and each subsequent year obtain a complete copy of the most recent inspection report for the establishment which was prepared by the department or the regulatory authority responsible for wholesale distributors in the state in which the establishment is located.

(16)~~(14)~~ DISTRIBUTION REPORTING.—Each prescription drug wholesale distributor, out-of-state prescription drug wholesale distributor, retail pharmacy drug wholesale distributor, manufacturer, or repackager that engages in the wholesale distribution of controlled substances as defined in s. 893.02 shall submit a report to the department of its receipts and distributions of controlled substances listed in Schedule II, Schedule III, Schedule IV, or Schedule V as provided in s. 893.03. Wholesale distributor facilities located within this state shall report all transactions involving controlled substances, and wholesale distributor facilities located outside this state shall report all distributions to entities located in this state. If the prescription drug wholesale distributor, out-of-state prescription drug wholesale distributor, retail pharmacy drug wholesale distributor, manufacturer, or repackager does not have any controlled substance distributions for the

month, a report shall be sent indicating that no distributions occurred in the period. The report shall be submitted monthly by the 20th of the next month, in the electronic format used for controlled substance reporting to the Automation of Reports and Consolidated Orders System division of the federal Drug Enforcement Administration. Submission of electronic data must be made in a secured Internet environment that allows for manual or automated transmission. Upon successful transmission, an acknowledgment page must be displayed to confirm receipt. The report must contain the following information:

(a) The federal Drug Enforcement Administration registration number of the wholesale distributing location.

(b) The federal Drug Enforcement Administration registration number of the entity to which the drugs are distributed or from which the drugs are received.

(c) The transaction code that indicates the type of transaction.

(d) The National Drug Code identifier of the product and the quantity distributed or received.

(e) The Drug Enforcement Administration Form 222 number or Controlled Substance Ordering System Identifier on all Schedule II transactions.

(f) The date of the transaction.

The department must share the reported data with the Department of Law Enforcement and local law enforcement agencies upon request and must monitor purchasing to identify purchasing levels that are inconsistent with the purchasing entity's clinical needs. The Department of Law Enforcement shall

investigate purchases at levels that are inconsistent with the purchasing entity's clinical needs to determine whether violations of chapter 893 have occurred.

(17)~~(15)~~ DUE DILIGENCE OF PURCHASERS.—

(a) Each prescription drug wholesale distributor, out-of-state prescription drug wholesale distributor, and retail pharmacy drug wholesale distributor must establish and maintain policies and procedures to credential physicians licensed under chapter 458, chapter 459, chapter 461, or chapter 466 and pharmacies that purchase or otherwise receive from the wholesale distributor controlled substances listed in Schedule II or Schedule III as provided in s. 893.03. The prescription drug wholesale distributor, out-of-state prescription drug wholesale distributor, or retail pharmacy drug wholesale distributor shall maintain records of such credentialing and make the records available to the department upon request. Such credentialing must, at a minimum, include:

1. A determination of the clinical nature of the receiving entity, including any specialty practice area.

2. A review of the receiving entity's history of Schedule II and Schedule III controlled substance purchasing from the wholesale distributor.

3. A determination that the receiving entity's Schedule II and Schedule III controlled substance purchasing history, if any, is consistent with and reasonable for that entity's clinical business needs.

(b) A wholesale distributor must take reasonable measures to identify its customers, understand the normal and expected transactions conducted by those customers, and identify those

transactions that are suspicious in nature. A wholesale distributor must establish internal policies and procedures for identifying suspicious orders and preventing suspicious transactions. A wholesale distributor must assess orders for more than 7,500 unit doses of any one controlled substance in any one month to determine whether the purchase is reasonable. In making such assessments, a wholesale distributor may consider the purchasing entity's clinical business needs, location, and population served, in addition to other factors established in the distributor's policies and procedures. A wholesale distributor must report to the department any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of the law. The wholesale distributor shall maintain records that document the report submitted to the department in compliance with this paragraph.

(c) A wholesale distributor may not distribute controlled substances to an entity if any criminal history record check for any person associated with that entity shows that the person has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction related to controlled substances, the practice of pharmacy, or the dispensing of medicinal drugs.

Section 3. Paragraph (b) of subsection (3) of section 465.022, Florida Statutes, is amended to read:

465.022 Pharmacies; general requirements; fees.—

(3) Any person or business entity, before engaging in the

operation of a pharmacy, shall file with the board a sworn application on forms provided by the department. For purposes of this section, any person required to provide fingerprints under this subsection is an affiliated person within the meaning of s. 465.023(1).

(b) The department shall annually submit the fingerprints provided by the applicant to the Department of Law Enforcement for a state criminal history records check. The Department of Law Enforcement shall annually forward the fingerprints to the Federal Bureau of Investigation for a national criminal history records check. The department shall report the results of annual criminal history records checks to wholesale distributors permitted under chapter 499 for the purposes of s. 499.0121(17) ~~s. 499.0121(15)~~.

Section 4. Paragraph (b) of subsection (48) 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:

(48) "Wholesale distribution" means the distribution of a prescription drug to a person other than a consumer or patient, or the receipt of a prescription drug by a person other than the consumer or patient, but does not include:

(b) Any of the following activities, which is not a violation of s. 499.005(21) if such activity is conducted in accordance with rules established by the department:

1. The distribution of a prescription drug among federal, state, or local government health care entities that are under common control and are authorized to purchase such prescription drug.

2. The distribution of a prescription drug or offer to distribute a prescription drug for emergency medical reasons, which may include transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage. For purposes of this subparagraph, a drug shortage not caused by a public health emergency does not constitute an emergency medical reason.

3. The distribution of a prescription drug acquired by a medical director on behalf of a licensed emergency medical services provider to that emergency medical services provider and its transport vehicles for use in accordance with the provider's license under chapter 401.

4. The donation of a prescription drug by a health care entity to a charitable organization that has been granted an exemption under s. 501(c)(3) of the Internal Revenue Code of 1986, as amended, and that is authorized to possess prescription drugs.

5. The distribution of a prescription drug by a person authorized to purchase or receive prescription drugs to a person licensed or permitted to handle reverse distributions or destruction under the laws of the jurisdiction in which the person handling the reverse distribution or destruction receives the drug.

6. The distribution of a prescription drug by a hospital or other health care entity to a person licensed under this part to repackage prescription drugs for the purpose of repackaging the prescription drug for use by that hospital, or other health care entity and other health care entities that are under common control, if ownership of the prescription drugs remains with the

hospital or other health care entity at all times. In addition to the recordkeeping requirements of s. 499.0121(8) ~~s. 499.0121(6)~~, the hospital or health care entity that distributes prescription drugs pursuant to this subparagraph must reconcile all drugs distributed and returned and resolve any discrepancies in a timely manner.

Section 5. Subsections (15) and (16) of section 499.0051, Florida Statutes, are amended to read:

499.0051 Criminal acts.—

(15) FALSE REPORT.—Any person who submits a report required by s. 499.0121(16) ~~s. 499.0121(14)~~ knowing that such report contains a false statement commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(16) CONTROLLED SUBSTANCE DISTRIBUTION.—Any person who engages in the wholesale distribution of prescription drugs and who knowingly distributes controlled substances in violation of s. 499.0121(16) ~~s. 499.0121(14)~~ commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. In addition to any other fine that may be imposed, a person convicted of such a violation may be sentenced to pay a fine that does not exceed three times the gross monetary value gained from such violation, plus court costs and the reasonable costs of investigation and prosecution.

Section 6. Paragraph (m) of subsection (2), subsection (3), and paragraphs (a), (b), and (c) of subsection (4) of section 499.01, Florida Statutes, are amended to read:

499.01 Permits.—

(2) The following permits are established:

(m) *Limited prescription drug veterinary wholesale*

distributor permit.—Unless engaging in the activities of and permitted as a prescription drug manufacturer, nonresident prescription drug manufacturer, prescription drug wholesale distributor, or out-of-state prescription drug wholesale distributor, a limited prescription drug veterinary wholesale distributor permit is required for any person that engages in the distribution in or into this state of veterinary prescription drugs and prescription drugs subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act under the following conditions:

1. The person is engaged in the business of wholesaling prescription and veterinary prescription drugs to persons:

a. Licensed as veterinarians practicing on a full-time basis;

b. Regularly and lawfully engaged in instruction in veterinary medicine;

c. Regularly and lawfully engaged in law enforcement activities;

d. For use in research not involving clinical use; or

e. For use in chemical analysis or physical testing or for purposes of instruction in law enforcement activities, research, or testing.

2. No more than 30 percent of total annual prescription drug sales may be prescription drugs approved for human use which are subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act.

3. The person does not distribute in any jurisdiction prescription drugs subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act to any person

who is authorized to sell, distribute, purchase, trade, or use these drugs on or for humans.

4. A limited prescription drug veterinary wholesale distributor that applies to the department for a new permit or the renewal of a permit must submit a bond of $20,000, or other equivalent means of security acceptable to the department, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to the Professional Regulation Trust Fund. The purpose of the bond is to secure payment of any administrative penalties imposed by the department and any fees and costs incurred by the department regarding that permit which are authorized under state law and which the permittee fails to pay 30 days after the fine or costs become final. The department may make a claim against such bond or security until 1 year after the permittee's license ceases to be valid or until 60 days after any administrative or legal proceeding authorized in this part which involves the permittee is concluded, including any appeal, whichever occurs later.

5. A limited prescription drug veterinary wholesale distributor must maintain at all times a license or permit to engage in the wholesale distribution of prescription drugs in compliance with laws of the state in which it is a resident.

6. A limited prescription drug veterinary wholesale distributor must comply with the requirements for wholesale distributors under s. 499.0121.

7. A limited prescription drug veterinary wholesale distributor may not return to inventory for subsequent wholesale distribution any prescription drug subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic

Act which has been returned by a veterinarian.

8. A limited prescription drug veterinary wholesale distributor permit is not required for an intracompany sale or transfer of a prescription drug from an out-of-state establishment that is duly licensed to engage in the wholesale distribution of prescription drugs in its state of residence to a licensed limited prescription drug veterinary wholesale distributor in this state if both wholesale distributors conduct wholesale distributions of prescription drugs under the same business name. The recordkeeping requirements of s. 499.0121(8) ~~s. 499.0121(6)~~ must be followed for this transaction.

(3) A nonresident prescription drug manufacturer permit is not required for a manufacturer to distribute a prescription drug active pharmaceutical ingredient that it manufactures to a prescription drug manufacturer permitted in this state intended for research and development and not for resale or human use other than lawful clinical trials and biostudies authorized and regulated by federal law. A manufacturer claiming to be exempt from the permit requirements of this subsection and the prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient shall comply with the recordkeeping requirements of s. 499.0121(8) ~~s. 499.0121(6)~~. The prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient shall maintain on file a record of the FDA registration number; if available, the out-of-state license, permit, or registration number; and, if available, a copy of the most current FDA inspection report, for all manufacturers from whom they purchase active pharmaceutical ingredients under this section. The failure to comply with the

requirements of this subsection, or rules adopted by the department to administer this subsection, for the purchase of prescription drug active pharmaceutical ingredients is a violation of s. 499.005(14), and a knowing failure is a violation of s. 499.0051(3).

(a) The immediate package or container of a prescription drug active pharmaceutical ingredient distributed into the state that is intended for research and development under this subsection shall bear a label prominently displaying the statement: "Caution: Research and Development Only—Not for Manufacturing, Compounding, or Resale."

(b) A prescription drug manufacturer that obtains a prescription drug active pharmaceutical ingredient under this subsection for use in clinical trials and or biostudies authorized and regulated by federal law must create and maintain records detailing the specific clinical trials or biostudies for which the prescription drug active pharmaceutical ingredient was obtained.

(4)(a) A permit issued under this part is not required to distribute a prescription drug active pharmaceutical ingredient from an establishment located in the United States to an establishment located in this state permitted as a prescription drug manufacturer under this part for use by the recipient in preparing, deriving, processing, producing, or fabricating a prescription drug finished dosage form at the establishment in this state where the product is received under an approved and otherwise valid New Drug Approval Application, Abbreviated New Drug Application, New Animal Drug Application, or Therapeutic Biologic Application, provided that the application, active

pharmaceutical ingredient, or finished dosage form has not been withdrawn or removed from the market in this country for public health reasons.

1. Any distributor claiming exemption from permitting requirements pursuant to this paragraph shall maintain a license, permit, or registration to engage in the wholesale distribution of prescription drugs under the laws of the state from which the product is distributed. If the state from which the prescription drugs are distributed does not require a license to engage in the wholesale distribution of prescription drugs, the distributor must be licensed as a wholesale distributor as required by the federal act.

2. Any distributor claiming exemption from permitting requirements pursuant to this paragraph and the prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient shall comply with the recordkeeping requirements of s. 499.0121(8) ~~s. 499.0121(6)~~.

(b) A permit issued under this part is not required to distribute a prescription drug that has not been repackaged from an establishment located in the United States to an establishment located in this state permitted as a prescription drug manufacturer under this part for research and development or to a holder of a letter of exemption issued by the department under s. 499.03(4) for research, teaching, or testing.

1. Any distributor claiming exemption from permitting requirements pursuant to this paragraph shall maintain a license, permit, or registration to engage in the wholesale distribution of prescription drugs under the laws of the state from which the product is distributed. If the state from which

the prescription drugs are distributed does not require a license to engage in the wholesale distribution of prescription drugs, the distributor must be licensed as a wholesale distributor as required by the federal act.

2. All purchasers and recipients of any prescription drugs distributed pursuant to this paragraph shall ensure that the products are not resold or used, directly or indirectly, on humans except in lawful clinical trials and biostudies authorized and regulated by federal law.

3. Any distributor claiming exemption from permitting requirements pursuant to this paragraph, and the purchaser and recipient of the prescription drug, shall comply with the recordkeeping requirements of s. 499.0121(8) ~~s. 499.0121(6)~~.

4. The immediate package or container of any active pharmaceutical ingredient distributed into the state that is intended for teaching, testing, research, and development shall bear a label prominently displaying the statement: "Caution: Research, Teaching, or Testing Only – Not for Manufacturing, Compounding, or Resale."

(c) An out-of-state prescription drug wholesale distributor permit is not required for an intracompany sale or transfer of a prescription drug from an out-of-state establishment that is duly licensed as a prescription drug wholesale distributor in its state of residence to a licensed prescription drug wholesale distributor in this state, if both wholesale distributors conduct wholesale distributions of prescription drugs under the same business name. The recordkeeping requirements of s. 499.0121(8) ~~s. 499.0121(6)~~ must be followed for such transactions.

Section 7. Paragraph (p) of subsection (8) of section 499.012, Florida Statutes, is amended to read:

499.012 Permit application requirements.—

(8) An application for a permit or to renew a permit for a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor submitted to the department must include:

(p) Documentation of the credentialing policies and procedures required by s. 499.0121(17) ~~s. 499.0121(15)~~.

Section 8. Section 499.01201, Florida Statutes, is amended to read:

499.01201 Agency for Health Care Administration review and use of statute and rule violation or compliance data.—Notwithstanding any other provision of law, the Agency for Health Care Administration may not:

(1) Review or use any violation or alleged violation of s. 499.0121(8) ~~s. 499.0121(6)~~, or any rules adopted under that section, as a ground for denying or withholding any payment of a Medicaid reimbursement to a pharmacy licensed under chapter 465; or

(2) Review or use compliance with s. 499.0121(8) ~~s. 499.0121(6)~~, or any rules adopted under that section, as the subject of any audit of Medicaid-related records held by a pharmacy licensed under chapter 465.

Section 9. Paragraphs (m) and (n) of subsection (1) of section 499.05, Florida Statutes, are amended to read:

499.05 Rules.—

(1) The department shall adopt rules to implement and enforce this chapter with respect to:

(m) Wholesale distributor reporting requirements of s. 499.0121(16) ~~s. 499.0121(14)~~.

(n) Wholesale distributor credentialing and distribution requirements of s. 499.0121(17) ~~s. 499.0121(15)~~.

Section 10. Subsections (8) and (9) of section 499.067, Florida Statutes, are amended to read:

499.067 Denial, suspension, or revocation of permit, certification, or registration.—

(8) The department may deny, suspend, or revoke a permit under this part if it finds the permittee has not complied with the credentialing requirements of s. 499.0121(17) ~~s. 499.0121(15)~~.

(9) The department may deny, suspend, or revoke a permit under this part if it finds the permittee has not complied with the reporting requirements of, or knowingly made a false statement in a report required by, s. 499.0121(16) ~~s. 499.0121(14)~~.

Section 11. This act shall take effect July 1, 2025.