An act relating to the sale and distribution of prescription drugs; amending s. 499.003, F.S.; redefining the term "pedigree paper"; amending s. 499.012, F.S.; providing an exemption from wholesale distribution for the transfer of prescription drugs due to a change in the ownership of a pharmacy; amending s. 499.0121, F.S.; abrogating the expiration of recordkeeping provisions for pedigree papers which relate to chain drug entities that are part of an affiliated group; prohibiting the Agency for Health Care Administration from reviewing or using certain violations relating to recordkeeping for prescription drugs to deny or withhold Medicaid payments to pharmacies or to audit the records of such pharmacies; providing an effective date.

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

Section 1. Subsection (31) of section 499.003, Florida Statutes, is amended to read:

499.003 Definitions of terms used in ss. 499.001-499.081.--As used in ss. 499.001-499.081, the term:

(31) "Pedigree paper" means:

(a) A document required pursuant to s. 499.0121(6)(d) or (e); or

(b) Effective July 1, 2006, a document or electronic ~~in a~~ form approved by the Department of Health and containing information that records each distribution of any given legend

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drug, from sale by a pharmaceutical manufacturer, through acquisition and sale by any wholesaler or repackager, until final sale to a pharmacy or other person administering or dispensing the drug. The information required to be included on a legend drug's pedigree paper must at least detail the amount of the legend drug~~;~~ its dosage form and strength~~;~~ its lot numbers~~;~~ the name and address of each owner of the legend drug and his or her signature~~;~~ its shipping information, including the name and address of each person certifying delivery or receipt of the legend drug; an invoice number, a shipping document number, or another number uniquely identifying the transaction~~;~~ and a certification that the recipient wholesaler has authenticated the pedigree papers. If the manufacturer or repackager has uniquely serialized the individual legend drug unit, that identifier must also be included on the pedigree. It must also include the name, address, telephone number and, if available, e-mail contact information of each wholesaler involved in the chain of the legend drug's custody. The department shall adopt rules and a form relating to the requirements of this paragraph no later than 90 days after the effective date of this act.

Section 2. Paragraph (a) of subsection (1) of section 499.012, Florida Statutes, is amended to read:

499.012 Wholesale distribution; definitions; permits; applications; general requirements.--

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

(a) "Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

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1. Any of the following activities, which is not a violation of s. 499.005(21) if such activity is conducted in accordance with s. 499.014:

a. The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a prescription drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of that organization.

b. The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug by a charitable organization described in s. 501(c)(3) of the Internal Revenue Code of 1986, as amended and revised, to a nonprofit affiliate of the organization to the extent otherwise permitted by law.

c. The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug among hospitals or other health care entities that are under common control. For purposes of this section, "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, by voting rights, by contract, or otherwise.

d. The sale, purchase, trade, or other transfer of a prescription drug from or for any federal, state, or local government agency or any entity eligible to purchase prescription drugs at public health services prices pursuant to Pub. L. No. 102-585, s. 602 to a contract provider or its subcontractor for eligible patients of the agency or entity under the following conditions:

(I) The agency or entity must obtain written authorization for the sale, purchase, trade, or other transfer

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of a prescription drug under this sub-subparagraph from the Secretary of Health or his or her designee.

(II) The contract provider or subcontractor must be authorized by law to administer or dispense prescription drugs.

(III) In the case of a subcontractor, the agency or entity must be a party to and execute the subcontract.

(IV) A contract provider or subcontractor must maintain separate and apart from other prescription drug inventory any prescription drugs of the agency or entity in its possession.

(V) The contract provider and subcontractor must maintain and produce immediately for inspection all records of movement or transfer of all the prescription drugs belonging to the agency or entity, including, but not limited to, the records of receipt and disposition of prescription drugs. Each contractor and subcontractor dispensing or administering these drugs must maintain and produce records documenting the dispensing or administration. Records that are required to be maintained include, but are not limited to, a perpetual inventory itemizing drugs received and drugs dispensed by prescription number or administered by patient identifier, which must be submitted to the agency or entity quarterly.

(VI) The contract provider or subcontractor may administer or dispense the prescription drugs only to the eligible patients of the agency or entity or must return the prescription drugs for or to the agency or entity. The contract provider or subcontractor must require proof from each person seeking to fill a prescription or obtain treatment that the person is an eligible patient of the agency or entity and must, at a minimum, maintain a copy of this proof as part

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of the records of the contractor or subcontractor required under sub-sub-subparagraph (V).

(VII) In addition to the departmental inspection authority set forth in s. 499.051, the establishment of the contract provider and subcontractor and all records pertaining to prescription drugs subject to this sub-subparagraph shall be subject to inspection by the agency or entity. All records relating to prescription drugs of a manufacturer under this sub-subparagraph shall be subject to audit by the manufacturer of those drugs, without identifying individual patient information.

2. 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:

a. The sale, purchase, or trade 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.

b. The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug for emergency medical reasons. For purposes of this sub-subparagraph, the term "emergency medical reasons" includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage.

c. The transfer 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.

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d. The revocation of a sale or the return of a prescription drug to the person's prescription drug wholesale supplier.

e. 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.

f. The transfer 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.

g. The transfer of a prescription drug by a hospital or other health care entity to a person licensed under this chapter 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(6), the hospital or health care entity that transfers prescription drugs pursuant to this sub-subparagraph must reconcile all drugs transferred and returned and resolve any discrepancies in a timely manner.

3. The distribution of prescription drug samples by manufacturers' representatives or distributors' representatives conducted in accordance with s. 499.028.

4. The sale, purchase, or trade of blood and blood components intended for transfusion. As used in this

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subparagraph, the term "blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing, and the term "blood components" means that part of the blood separated by physical or mechanical means.

5. The lawful dispensing of a prescription drug in accordance with chapter 465.

6. The sale, purchase, or trade of a prescription drug between pharmacies as a result of a sale, transfer, merger, or consolidation of all or part of the business of the pharmacies from or with another pharmacy, whether accomplished as a purchase and sale of stock or of business assets.

Section 3. Paragraph (h) of subsection (6) of section 499.0121, Florida Statutes, is amended to read:

499.0121 Storage and handling of prescription drugs; recordkeeping.--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.

(6) RECORDKEEPING.--The department shall adopt rules that require keeping such records of prescription drugs as are necessary for the protection of the public health.

(h)1. This paragraph applies only to an affiliated group, as defined by s. 1504 of the Internal Revenue Code of 1986, as amended, which is composed of chain drug entities, including at least 50 retail pharmacies, warehouses, or repackagers, which are members of the same affiliated group, if the affiliated group:

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a. Discloses to the department the names of all its members; and

b. Agrees in writing to provide records on prescription drug purchases by members of the affiliated group not later than 48 hours after the department requests such records, regardless of the location where the records are stored.

2. Each warehouse within the affiliated group must comply with all applicable federal and state drug wholesale permit requirements and must purchase, receive, hold, and distribute prescription drugs only to a retail pharmacy or warehouse within the affiliated group. Such a warehouse is exempt from providing a pedigree paper in accordance with paragraphs (d)<u>, (e),</u> and<u>(f)</u>~~(e)~~ to its affiliated group member warehouse <u>or retail pharmacy</u>, provided that:

a. Any affiliated group member that purchases or receives a prescription drug from outside the affiliated group must receive a pedigree paper if the prescription drug is distributed in or into this state and a pedigree paper is required under this section and must authenticate the documentation as required in subsection (4), regardless of whether the affiliated group member is directly subject to regulation under this chapter; and

b. The affiliated group makes available to the department on request all records related to the purchase or acquisition of prescription drugs by members of the affiliated group, regardless of the location where the records are stored, if the prescription drugs were distributed in or into this state.

3. If a repackager repackages prescription drugs solely for distribution to its affiliated group members for

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the exclusive distribution to and among retail pharmacies that are members of the affiliated group to which the repackager is a member:

a. The repackager must:

(I) In lieu of the written statement required by paragraph (d), ~~or~~ paragraph (e), or paragraph (f), for all repackaged prescription drugs distributed in or into this state, state in writing under oath with each distribution of a repackaged prescription drug to an affiliated group member warehouse or repackager: "All repackaged prescription drugs are purchased by the affiliated group directly from the manufacturer or from a prescription drug wholesaler that purchased the prescription drugs directly from the manufacturer.";

(II) Purchase all prescription drugs it repackages:

(A) Directly from the manufacturer; or

(B) From a prescription drug wholesaler that purchased the prescription drugs directly from the manufacturer; and

(III) Maintain records in accordance with this section to document that it purchased the prescription drugs directly from the manufacturer or that its prescription drug wholesale supplier purchased the prescription drugs directly from the manufacturer.

b. All members of the affiliated group must provide to agents of the department on request records of purchases by all members of the affiliated group of prescription drugs that have been repackaged, regardless of the location where the records are stored or where the repackager is located.

~~4. This paragraph expires July 1, 2006.~~

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Section 4. Notwithstanding any other provisions of law to the contrary, the Agency for Health Care Administration may not:

(1) Review or use any violation or alleged violation of section 499.0121(6), Florida Statutes, 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, Florida Statutes; or

(2) Review or use compliance with section 499.0121(6), Florida Statutes, 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, Florida Statutes.

Section 5. This act shall take effect upon becoming a law.

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