

State Wholesale Distributor Licensing Legislation (2003 - 2005) Prepared by HDMA Attachment 2

State/Bill No.	Legislative Effective Dates	Pedigree Requirements	Pedigree Data Elements	RFID/Electronic Pedigree	Third party Accreditation	Returns
Arizona HB 2193	Effective 8/12/2005	Pedigree for all Rx drugs that leave "Normal distribution channel" - "Normal distribution channel" defined as the chain of custody for a Rx drug that begins with the delivery of the drug by a manufacturer to a wholesale distributor who then delivers the drug to a pharmacy or a practitioner for final receipt by a patient. "Normal distribution channel" includes the receipt of a Rx drug by a common carrier or other delivery service that delivers the drug at the direction of a manufacturer, full service wholesale permittee or pharmacy and that does not purchase, sell, trade or take title to any Rx drug.	1. Name of Rx drug; 2. Dosage form & strength of Rx drug; 3. Size of container; 4. Number of containers; 5. Lot # of Rx drug; 6. Name of mfr. 7. All nec. identifying info. about each sale in chain of dist. of product from mfr. through acquisition & sale by any full serv. wholesaler & until final sale to a pharmacy or other person dispensing or administering the drug. This info. must include: (a) name, address, telephone # &, the e-mail address of each owner of the Rx drug & each wholesaler that does not take title to the Rx drug, (b) name & address of each location from which product was shipped, if diff. from owner's, (c) transaction dates, (d) certification that each recipient has authenticated pedigree; 8. any other info. required by board.	Yes, allows for electronic pedigree option.	Not addressed in legislation.	A wholesaler may accept returns from pharmacy or chain pharmacy warehouse pursuant to an agreement between the parties. Wholesaler shall not accept: adulterated or counterfeited Rx drugs; an amt. or quantity of a Rx drug that exceeds the amt. or quantity that the full serv. wholesaler or another full serv. wholesaler under common ownership sold to the pharmacy or chain pharmacy warehouse.

<p>California SB 1307 (2004)</p>	<p>1/1/07 Electronic Ped. Req. (1/1/09 legislature extension possible; 1/108 board extension possible)</p>	<p>A pedigree means a record, in electronic form, containing information regarding each transaction resulting in a change of ownership of a given dangerous drug, from sale by a manufacturer, through acquisition and sale by a wholesaler, until final sale to a pharmacy or other person furnishing, administering, or dispensing the dangerous drug and must accompany each distribution of a dangerous drug. A wholesaler or pharmacy is prohibited from selling, trading, or transferring a dangerous drug without a pedigree, and prohibited from acquiring a dangerous drug without receiving a pedigree.</p>	<p>A pedigree shall include: (1) Source of the drug, including name, state license #, Cal. license # if available, and principal address of source. (2) Quantity, dosage form and strength, date of the transaction, sales invoice number, container size, # of containers, expiration dates, and lot #s. (3) The business name, address, and if appropriate, the state license #, a Cal. license #, of each owner of the dangerous drug, and the dangerous drug shipping information, including the name and address of each person certifying delivery or receipt of the dangerous drug.</p>	<p>Yes, electronic pedigree only (no paper).</p>	<p>Not addressed in legislation.</p>	<p>Not addressed in legislation.</p>
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Florida SB 1312 (2003)	7/1/06: Full Pedigree on all Rx transactions	Effective July 1, 2006, each person who is engaged in the wholesale distribution of a Rx drug and who is not the manufacturer of that drug must, before each wholesale distribution of such drug, provide to the person who receives the drug, a pedigree paper containing information that records each distribution, 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.	Required on a legend drug's pedigree, at least detail; the amount of the legend drug, dosage form, 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, a certification that the recipient has authenticated the pedigree papers, and the name, address, telephone number and, e-mail contact information of each wholesaler involved in the chain of the legend drug's custody.	Yes, upon Dept. of Health approval.	Not addressed in legislation.	** Not in legislation. Current returns allows returns within 7 days for mistake or error in shipment or ordering. DOH will be revising returns rules in 2005.
Iowa HF 882	Effective 7/01/05	The Board is required to establish rules that establish provisions or exceptions for pharmacies, chain pharmacy distribution centers, logistics providers, and other types of wholesalers relating to pedigree requirements, drug or device returns, and other related matters, so as not to prevent or interfere with usual, customary, and necessary business activities.	See Pedigree Requirement (Board to establish rules).	"Pedigree" means a recording of each distribution of any given drug or device, from the sale by the manufacturer through acquisition and sale by any wholesaler, pursuant to rules adopted by the board. (open as to RFID/electronic pedigree).	Not addressed in legislation.	See Pedigree Requirement (Board to establish rules).

<p>Indiana HB 1098</p>	<p>7/1/05 Board must establish proc. before 1/1/06 to establish returns policy (see Returns) After 12/31/05 accreditation required by NABP (see 3rd party) Pedigree requirements 1/1/06; 1/1/07 Electronic Pedigree</p>	<p>"Normal distribution chain of custody" means the route that a legend drug travels: (1) manufacturer-wholesaler-pharmacy-to a patient or a patient's agent; (2) manufacturer-wholesaler-chain drug warehouse-pharmacy affiliated with the chain drug warehouse-to a patient or a patient's agent; (3) manufacturer-chain drug warehouse-pharmacy affiliated with the chain drug warehouse-to a patient or a patient's agent; (4) manufacturer-third party logistics provider-wholesaler-pharmacy-a patient or a patient's agent; (5) manufacturer-third party logistics provider-wholesaler-chain drug warehouse-pharmacy affiliated with the chain drug warehouse-a patient or a patient's agent; (6) manufacturer-third party logistics provider-chain drug warehouse-pharmacy affiliated with the chain drug warehouse-patient or a patient's agent; or, (7) as prescribed by the board.</p>	<p>After 6/30/06, a wholesale drug distributor may not accept or deliver a legend drug without a current, accompanying pedigree. For legend drugs manufactured by a manufacturer for which the wholesale drug distributor is an authorized distributor, a pedigree for each distributed legend drug that leaves the normal distribution chain of custody, as determined by rules adopted by the board. For legend drugs manufactured by a manufacturer for which the wholesale drug distributor is not an authorized distributor, a pedigree for each distributed legend drug.</p>	<p>After 1/1/07, and after consulting with the FDA, at the board's discretion, for each legend drug received and distributed by the distributor, an electronic ped. must be developed in accordance with standards and requirements of the board to authenticate, track, and trace legend drugs. The standards and requirements of the board may indicate the information required to be part of the electronic pedigree.</p>	<p>A person may not engage in wholesale distributions of legend drugs without, after 12/31/05, obtaining & maintaining accreditation or certification from the NABP's VAWD or a board approved body under subsection.</p>	<p>Board shall establish standards and procedures (s&p) to ensure that a pharmacist: A. has entered into a contract that accepts the return of expired drugs with; or B. is subject to a policy that accepts the return of expired drugs; back to a wholesaler, mfr., or agent of a wholesaler of expired legend drugs or controlled drugs.</p>
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<p>New Jersey S. 1753</p>	<p>Effective 180 days after enactment. Signed by governor August 24, 2005</p>	<p>The selling distributor must provide (1) for specified list drugs, pedigree on all sales to other distributors unless the original distributor is an ADR and the prescription drug was purchased directly from the manufacturer, and (2) for all other prescription drug transactions, a pedigree is required unless the seller is the manufacturer or an ADR. A "specified list of susceptible products" will be developed in rulemaking by the Department of Health and Senior Services.</p>	<p>A pedigree shall include the following information: the proprietary and established name of the prescription drug; the dosage; container size; number of containers; the date, business name and address of all parties to each prior transaction involving the prescription drug starting with the last authorized distributor or the manufacturer if the prescription drug has not been purchased previously by an authorized distributor or is a prescription drug on the specified list of susceptible products.</p>	<p>Requires the commissioner of Health and Senior Services to report annually to the legislature on the availability of an effective electronic tracking system.</p>	<p>Not addressed in legislation.</p>	<p>Requires pharmacy to physically return the prescription drug within 30 business days of notification to the wholesale distributor or as consistent with the wholesale distributor's return policy. If the prescription drug cannot be returned to the wholesale distributor, it shall be returned to the manufacturer. A manufacturer or wholesale distributor who receives returned prescription drugs shall notify the department of the return. A wholesale distributor shall quarantine a prescription drug, container or labeling that is received outdated, damaged, deteriorated, misbranded, counterfeited, suspected of being counterfeited, adulterated, or otherwise deemed unfit for human consumption until it is returned.</p>
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<p>New Mexico SB 413</p>	<p>Effective 6/17/05</p>	<p>The board shall promulgate the requirements for a pedigree. "Pedigree" is defined as "the recorded history of a drug". All regulations promulgated by the board shall be in accordance with the Uniform Licensing Act. All records required to be kept under the provisions of the New Mexico Drug, Device and Cosmetic Act shall be preserved for a period of three years, provided that records requirements do not apply to the administration of a drug to a patient upon whom the practitioner personally attends, and provided that records of controlled substances shall be kept in accordance with the provisions of the Controlled Substances Act.</p>	<p>The board shall promulgate the requirements for a pedigree. Specific elements not addressed in legislation.</p>	<p>Not addressed in legislation.</p>	<p>Not addressed in legislation.</p>	<p>Not addressed in legislation.</p>
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<p>Nevada SB 37</p>	<p>Most provisions effective 10/01/05</p>	<p>Each wholesaler shall provide a statement identifying each sale of a Rx drug before the drug is sold to another wholesaler or to a pharmacy when supplying drugs which are to be sold to other than retail consumers if the wholesaler: (a) Has not established an ongoing relationship with the manufacturer from whom the drug was purchased; or (b) Purchased the drug from another wholesaler. **If a statement of prior sales indicates that more than 3 prior sales of a Rxdrug have occurred, including, without limitation, a sale involving an ADR, a person who is licensed to engage in wholesale distribution pursuant to this chapter shall not sell that Rxdrug to another wholesaler.</p>	<p>The statement must include all necessary identifying info. concerning each sale in the chain of distribution of the product from the mfr. or wholesaler; accompany all prescription drugs purchased from a wholesaler, even if they are resold to another distributor; Include: the bus. name & address of the person from whom the drug was purchased; the sale date; (1) the drug name; (2) drug strength; (3) container size; (4) # of containers; (5) Lot # of the drug; & (6) Name of the mfr. of the finished dosage form.</p>	<p>Statement or "pedigree" must be in (1) In written or electronic form, if the transaction occurs before January 1, 2007; and (2) In electronic form, if the transaction occurs on or after January 1, 2007. (Board has option to extend date with adequate notice to relevant parties).</p>	<p>Not addressed in legislation.</p>	<p>If a wholesaler receives a Rxdrug pursuant to this subsection(covers returns) and the wholesaler subsequently sells the Rxdrug to another wholesaler, the Rxdrug must be accompanied by a statement of prior sales as defined in section 5 of this act.</p>
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<p>Oklahoma SB 640</p>	<p>Effective 11/01/05</p>	<p>The Board shall promulgate rules regarding the issuance and renewal of licenses and permits pursuant to the Oklahoma Pharmacy Act which shall include, but need not be limited to: provisions for the establishment of a pedigree or electronic file to be used by wholesale distributors, chain pharmacy warehouses and repackagers for the purpose of ensuring the integrity of drugs owned, purchased, distributed, returned, transferred and sold when the products leave the "normal distribution channel". Does not define "normal distribution channel".</p>	<p>See Pedigree Requirements.</p>	<p>See Pedigree Requirements.</p>	<p>The Board shall be authorized to use an outside agency, such as "the NABP or the VAWD," to accredit wholesale distributors and repackagers. The Board may exempt by rule wholesalers accredited by VAWD from the provisions of subparagraphs a and b of paragraph 1 of this subsection. In promulgating such rules, the Board shall seek input from manufacturers, wholesale distributors, chain pharmacy warehouses and repackagers.</p>	<p>See Pedigree Requirements.</p>
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<p>Texas HB 164</p>	<p>Effective 8/01/05. See electronic ped: Not before 12/31/07 (expires 1/1/09)</p>	<p>Distributors shall provide a pedigree for each Rx drug that is not distributed through the "normal distribution chain" and is sold, traded, or transferred to any other person. "Normal distribution chain" means a chain of custody for a drug from: (A) a manufacturer to an authorized distributor of record or to a wholesale distributor licensed under this subchapter to a pharmacy or practitioner to a patient; (B) a manufacturer to an authorized distributor of record to one other authorized distributor of record to a pharmacy or practitioner to a patient; or (C) a manufacturer to an authorized distributor of record to a chain pharmacy warehouse to a pharmacy or practitioner to a patient.</p>	<p>Chain of distribution info. must include: (1)name, address, phone #, &, if available, the e-mail address of each person who owns or possesses the prescription drug, except common carriers & logistics providers; (2)signature of each owner of the prescription drug; (3)name & address of each location from which product was shipped, if different from owner's; (4)transaction dates; & (5)certification that each recipient authenticated the pedigree. (b)Pedigree must include, at a min.: (1)name of prescription drug; (2)dosage form & strength of prescription drug; (3)size of container; (4)# of containers;(5)lot # of prescription drug; & (6)name of the mfr. of the finished dosage form. (c)Each pedigree statement must be: (1)maintained by purchaser and the wholesale dist. for at least 3 years; & (2)available for inspection & photocopying on request by the dept. or peace officer in this state.</p>	<p>"Pedigree" means a document or elec. file containing info. that records each wholesale distribution of a Rxdrug, from sale by a mfr. through final sale to a pharmacy or other person dispensing/administering the Rxdrug. The dept.shall: (1) conduct a study on the implementation of elec.pedigrees; (2) in conducting the study consult with mfrs., distributors, & pharmacies responsible for the sale and distribution of Rxdrugs in this state; & (3) based on the results of the study, establish an implementation date, which may not be earlier than 12/31/07.</p>	<p>Not addressed in legislation.</p>	<p>A wholesale distributor shall receive Rxdrug returns or exchanges from a pharmacy or chain pharmacy warehouse in accordance with terms and conditions of their agreement. The returns or exchanges received by the wholesale dist. as provided by this subsection are not subject to the pedigree requirement. In connection with the returned goods process, a wholesale dist. should establish appropriate business practices and exercise due diligence designed to prevent entry of adulterated or counterfeit drugs into distribution channel.</p>
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Virginia SB 1326	Effective 7/1/05	The Board's regulations shall include, but shall not be limited to, the establishment and implementation of a pedigree system. The pedigree system shall be limited to certain schedules or certain drugs, upon finding that such drugs are more subject to counterfeiting; "Pedigree" means a paper document or electronic file recording each distribution of a controlled substance from sale by a pharmaceutical manufacturer through acquisition and sale by any wholesale distributor, until final sale to a pharmacy or other person dispensing or administering the controlled substance.	Not addressed in legislation.	See Pedigree Requirements.	Not addressed in legislation.	Returns from a pharmacy to the originating wholesale distributor or pharmaceutical manufacturer shall not be subject to the pedigree requirements of this section.
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9/7/2005