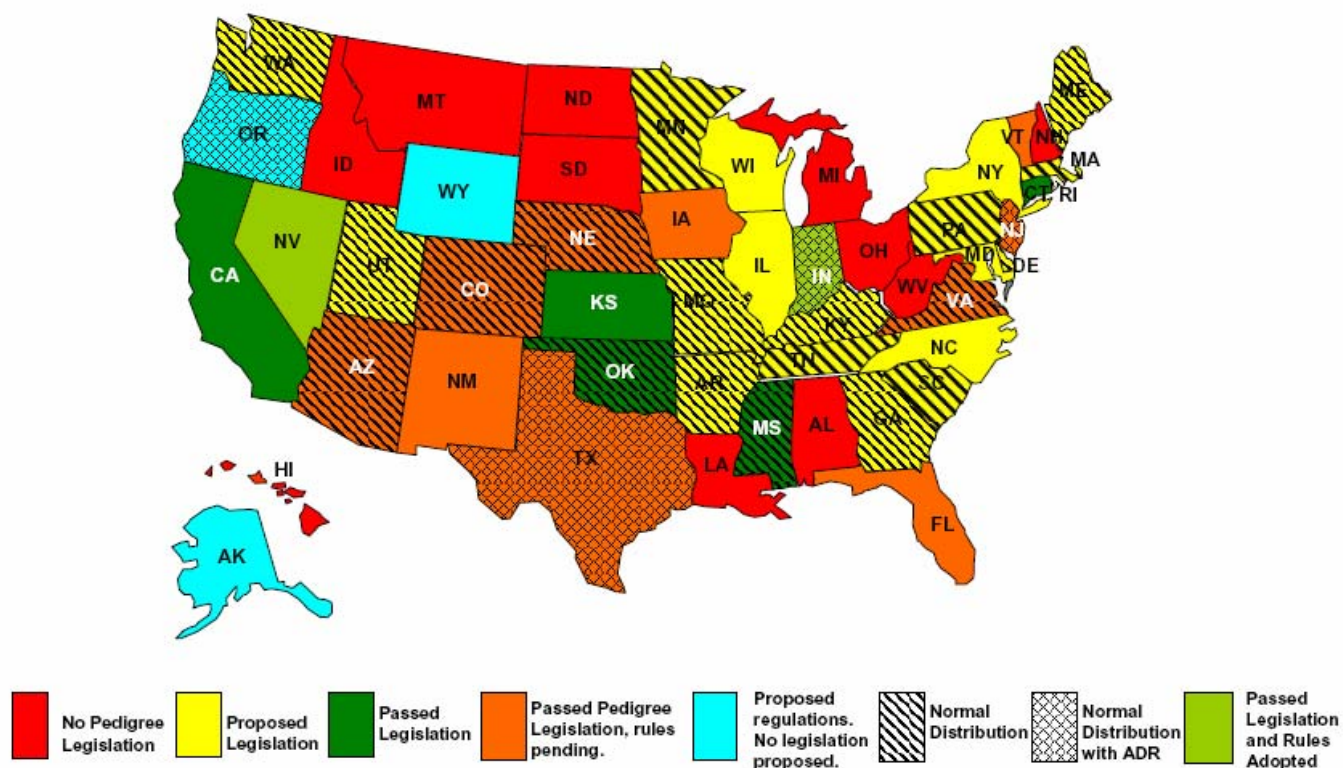


2005-2006 State Pedigree Legislation/Regulations



Here is a spot check "status" on several states in the [news:](#)*

Oklahoma — Allow the State Board to waive requirements for distributors with Verified-Accredited Wholesale Distributors (VAWD) certification; considering exempting VAWD approved distributors from licensure requirements; unlikely to exempt distributors from pedigree requirements; background check required; bond requirement; Federal Bureau of Prisons (BoP) to promulgate rules for drugs leave the normal distribution channel; *issues yet to be resolved include treatment of 3PLs and returns.*

North and South Dakota — considering requiring distributors to adhere to new licensing requirements and require pedigree for prescription drugs which travel outside of the normal distribution channel; distributors located in the state would be required to obtain certification from National Association of Boards of Pharmacy (NABP's) Verified-Accredited Wholesale Distributors (VAWD) or another Board-approved accreditation program. Out-of-state distributors would have the option of accreditation or presenting a license from a state with comparable requirements.

California — postpones pedigree rules to 2009; pedigree law is notable in that it requires the input of manufacturers (unlike most other states' rules), and it specifies electronic (as opposed to paper) tracking. Both were thought to be major incentives for adopting RFID technology for labeling drug packages; wholesaler: (1) Must have designated representative (DR); (2) \$100K Bond requirement; (3) Electronic pedigrees required for all distributions from manufacturer to pharmacy or other dispenser, effective January 1, 2009 (unless otherwise amended)

Arizona — Wholesaler ("full service wholesale permittee"): (1) Does not include chain pharmacy warehouse, (2) Must have designated representative (DR), (3) Boards of Pharmacy (BoP) may conduct background check of DR, (4) \$100K Bond requirement (may be waived if similar bond held in another state); Pedigrees required outside normal distribution channel

Colorado — Wholesaler: (1) Inspection required; (2) Must have a designated representative; (3) Background check required; Pedigrees required outside the normal distribution channel

Florida — Wholesaler: (1) Must have designated representative, (2) \$100K Bond requirement, (3) Inspection Requirements; Pedigree: (1) Complex requirements from wholesaler to pharmacy, (2) Recent legislation reduced burden, (3) Authentication requirements

Indiana — Wholesaler: (1) Chain pharmacy warehouses included, (2) \$100K bond required, (3) Background check required, (4) Must have a designated representative, (5) VAWD mandatory; Pedigrees required for prescription drugs that leave the normal distribution channel

Iowa — Wholesaler: (1) BoP may conduct background checks, (2) Inspection requirements; Pedigree: Requirements to be promulgated by BoP

Mississippi — Wholesaler: (1) BoP may inspect, (2) Bond requirement, (3) BoP to conduct background checks, (4) includes chain pharmacy warehouses, (5) BoP may use VAWD; Pedigree: Requirements to be promulgated by BoP for drugs that leave the normal distribution channel

Nebraska — Wholesaler: (1) Must have a designated representative, (2) Background check required, (3) \$100K bond required, (4) Inspection required; Pedigree required for prescription drugs that leave the normal distribution channel

Nevada — Wholesaler: (1) Bond requirement, (2) BoP to conduct background checks, (3) Inspection requirements, (4) Must certify claims of ADR status, (5) May engage only in "bona fide transactions"; Pedigree: Statement of prior sales may include only three sales to wholesale distributors

New Jersey — Wholesaler: (1) Does not include chain pharmacy warehouses, (2) Bond requirement, (3) Inspection requirement, (4) Background check requirement, (5) Must have a designated representative; Pedigree: (1) Required for non-ADRs (as defined by NJ), (2) ADRs: For susceptible products not purchased from manufacturer, (3) Discretionary authentication requirement

New Mexico — Wholesaler: Inspection required; Pedigree: BoP to promulgate pedigree requirements

Texas — Wholesaler: (1) Bond requirement, (2) Background check may be conducted; Pedigrees are required outside the normal distribution channel

Virginia — Wholesaler: (1) Does not include chain pharmacy warehouses, (2) BoP may inspect; BoP will promulgate a pedigree system for drugs that leave the normal distribution channel

*Federal Prescription Drug Marketing Act

Sources: HDMA, Government Affairs Weekly Activity Report, February 20, 2007; HDMA, Government Affairs Weekly Activity Report, January 29, 2007; Pharmaceutical Commerce, [Date: 2006-10-15](#); Healthcare; RFID Healthcare Industry Adoption Summit, Cardinal Health Presentation, Julie Kuhn and Renard Jackson, November 14, 2006; HDMA Returns Task Force Report, Washington, DC, March 1, 2007 – CLS MedTurn attendees: Sharon Joyner-Payne and Robert Reid)