

Prescription Drugs, Health Professions, Wholesale Drug Distribution Note

According to an Indiana legislative staff report:

In 1988, the US Congress passed the Prescription Drug Monitoring Act. This law did several things. The Indiana Legislature and the Indiana Board of Pharmacy were most interested in the following provisions:

- It required drug pedigrees to be passed along with the drug for certain wholesale drug distributions. This is due to counterfeit drugs being detected within the system.

- It gave the states the authority to regulate the wholesale drug industry.

The wholesale drug distribution (WDD) industry and pharmaceutical manufacturing industry fought the pedigree requirement by insisting that the requirement was too onerous to enact. Thus the FDA has stayed that part of the law for 18 years and it has yet to be enacted. The states did license wholesale drug distributors but, the requirements were very loose and not consistent across states. Some states required inspections and security systems while other states just required a form and a fee.

In 2003 the Food and Drug Administration (FDA) formed an anti-counterfeiting task force in response to the increasing reports of counterfeit drugs infiltrating the US drug distribution system. This task force released an interim report in September of 2003, which was followed by the issuance of a final report issued by the FDA in February 2004. The final report adopted the task force's recommendations. That report made the following recommendations. It asked National Association of Boards of Pharmacy (NABP) to examine and update its current state model regulations for wholesalers in an effort to tighten up the licensure of wholesalers. It requested that states increase the penalties for parties that are caught counterfeiting drugs. The FDA strongly encouraged the voluntary adoption of RFID technology to attach electronic pedigrees to drugs and suggested implementation by 2007. NABP convened a task force in October 2003 to meet this mandate. NABP worked quickly and thoroughly to produce a new model for regulation of the wholesale drug industry. In February 2004, NABP released the Model Rules for the Licensure of Wholesale Distributors, which was based upon Florida's laws for wholesalers, and the input from industry stakeholders. NABP also addressed the FDA's request by creating an accreditation program for wholesale drug distributors—the Verified-Accredited Wholesale Distributors (VAWD) Program. Applicants for VAWD accreditation undergo a criteria compliance review, licensure verification, an inspection, background checks, and screening through NABP's Disciplinary Clearinghouse. State utilization of the VAWD program can help mitigate the adverse fiscal and operational impact of the increased regulation on state government. The model language also set stiffer penalties for the counterfeiting of medications.

Indiana's amendment of its WDD laws began with State Senator Marvin Riegsecker, an Indiana pharmacist. The Senator contacted the Indiana Board of Pharmacy for guidance and was given a copy of NABP's Model Rules for the Licensure of Wholesale Distributors. The language initially introduced by Senator Riegsecker as a Senate bill worked its way through the legislative process. HEA 1098, the final home for the WDD language, was signed by Governor Mitch Daniels in May of 2005.

In general, Indiana's new law brought about three tiers of change to their previous statute:

- Established criminal penalties for counterfeiting;
- Increased licensing requirements and required NABP's VAWD accreditation for each wholesaler; and
- Requires pedigrees for products that leave the normal distribution chain of custody and authorized the Board to eventually establish an electronic pedigree system for all prescription

drugs. HEA 1098 is being recognized as a national model and has received commendations in state legislatures throughout the country, as well as the United States Congress and the Food and Drug Administration.

In addition, HEA 1098:

- Establishes a program for the licensing and regulation of personal services agencies;
 - Provides that home health agencies and personal services agencies are approved to provide home health or personal services under certain federal waivers;
 - Provides that home health services include services that are required to be ordered or performed by certain health care professionals;
 - Increases the home health agency license fee;
 - Requires a personal services agency to comply with employee criminal history check requirements;
 - Provides that a home health agency that operates a personal services agency is not required to obtain a license to operate the personal services agency;
 - Makes operating or advertising an unlicensed personal services agency a Class A misdemeanor;
 - Requires a placement agency to provide the consumer and worker with certain information when a home care services worker is placed in the consumer's home;
 - Allows the state department of health to impose a civil penalty against a placement agency for failing to provide the notice;
 - Relocates the definition of "attendant care services;"
 - Requires the board of pharmacy to establish procedures to ensure that pharmacies may return expired prescription drugs to drug wholesalers and manufacturers;
 - Specifies information that the board must consider in establishing the procedures;
 - Expands the requirements that must be met by a wholesale drug distributor for eligibility for licensure;
 - Allows certain state licensure exams to apply to the psychology reciprocity requirements;
 - Amends several definitions concerning speech-language pathology and audiology;
 - Requires licensure of speech-language pathology aides, associates, and assistants;
 - Amends licensure requirements of speech-language pathologists and audiologists;
 - Requires an audiologist to possess a doctorate degree after January 1, 2007, for an initial license;
 - Allows the professional standards board to issue credentials to certain speech language professionals;
 - Allows certified speech-language pathologists and audiologists who meet certain requirements to be considered to have a National Board of Professional Teaching Standards certification;
 - Requires a referral to administer a test of vestibular function;
 - Amends reciprocity licensure requirements for speech language pathologists and audiologists;
 - Requires licenses to be displayed;
 - Specifies criminal acts related to wholesale drug distribution and legend drugs; and
 - Allows the board of pharmacy to establish an electronic pedigree pilot program.
- Makes conforming changes.

The passage of this bill was the first of its kind in the nation. The process of negotiation to achieve consensus was enormous. Since the entire drug distribution chain is affected by the

language of the bill, many parties were involved in the discussions and ultimately the agreement on this legislation. Parties involved were manufacturers, primary and secondary wholesalers and their associations, National Association of Chain Drug Stores, third party logistics providers, Indiana Pharmacists Alliance and the Indiana Board of Pharmacy.

In 2006, SEA 202 was enacted to make technical corrections to the WDD law. Again, the stakeholders were involved in building a consensus to improve the WDD licensure process.

SEA 202:

- Allows a mechanical device that dispenses drugs to be used at certain remote locations and health care facilities.
- Removes authority for pharmacist extern programs. Adds persons who are allowed to be pharmacist interns.
- Changes references from the Foreign Pharmacy Graduate Equivalency Examination to the Foreign Pharmacy Graduate Examination Committee Certificate.
- Removes the practical examination requirement for certain pharmacists who are licensed in another jurisdiction.
- Provides that a person who has not renewed a pharmacist license within seven years must apply for a new license.
- Allows certain hospitals to operate Type II pharmacies in approved locations near the licensed area.
- Prohibits licensing a pharmacy in a residence.
- Authorizes the board of pharmacy (board) to temporarily suspend certain statutes or administrative rules that would prevent, hinder, or delay the appropriate delivery of pharmaceutical care during a state of emergency declared by the governor or the President of the United States.
- Provides that companies that only manufacture or distribute medical gases are not wholesale drug distributors or manufacturers.
- Adds and amends definitions concerning wholesale drug distributors.
- Allows the board to appoint a designee to inspect wholesale distribution operations. Requires a person seeking a wholesale drug distributor license to provide the board with a criminal history and financial background checks.
- Requires a record keeping pedigree for certain legend drugs that leave the normal chain of custody. Removes the requirement that drug distributors have: (1) a continuous quality improvement system; and (2) policies concerning certain drugs that may be returned.
- Requires that certain wholesale drug accreditation bodies that have an agreement with the board review accreditation denials; and
- Allows the board to grant reciprocity to out of state home medical equipment service providers.

Submitted as:

Indiana HEA 1098 and SEA 202

Status:

HEA 1098 - Enacted into law in 2005.

SEA 202 – Enacted into law in 2006.