



**MARYLAND  
BOARD OF PHARMACY  
WHOLESALE DISTRIBUTOR  
PERMITTING AND PRESCRIPTION DRUG  
INTEGRITY ACT**

**SECOND ANNUAL REPORT TO THE  
GOVERNOR  
AND  
THE GENERAL ASSEMBLY**

**January 1, 2009**

**MARYLAND BOARD OF PHARMACY WHOLESALE DISTRIBUTOR  
PERMITTING AND PRESCRIPTION DRUG INTEGRITY ACT**

**SECOND ANNUAL REPORT**

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## EXECUTIVE SUMMARY

This is the second annual report on the implementation of the Wholesale Distributor Permitting and Prescription Drug Integrity Act (the “Act”) as required by Health Occupations Article, Subtitle 6C, Annotated Code of Maryland. The Act, Senate Bill 759, Chapter 352, was passed in the 2007 Legislative Session. The Act imposed additional requirements for persons applying to be licensed to distribute prescription drugs or devices into Maryland. The Act further required a pedigree, or history of the distribution chain, for prescription drugs that are distributed in Maryland.

As required, the Board of Pharmacy (the “Board”) adopted regulations to implement the Act. The regulations, COMAR 10.34.22.01 - .08 became effective on April 7, 2008. (See Appendix I.) All new wholesale distributor applicants and existing wholesale distributors licensed to operate in Maryland are required to comply with the new Act and the revised regulations after December 31, 2008 or upon expiration of their 2008 current permits, respectively. Operational procedures implemented by the Board have included: creating systems required by the Act, development of the application and application review process, and development of procedures for inspections and otherwise insuring compliance. One issue of concern for smaller wholesale distributors has been difficulty meeting the \$100,000 surety bond requirement. The Board was bound by the statutory language (HO §12-6C-05(f)) that required evidence of bonding regardless of the size of the distributor or the fact that several other states also required independent surety bonds.

The Act also required the Board to convene a Workgroup (Wholesale Distributor SB 759 Workgroup) to (1) survey the availability of electronic track and trace pedigree technology across the entire prescription pharmaceutical supply chain; (2) determine when electronic track and trace pedigree technology will be universally available across the entire prescription pharmaceutical supply chain; and (3) based on its determination of the universal availability of electronic track and trace pedigree technology, make recommendations to the Board for a target date, no sooner than July 1, 2010, for implementation of electronic track and trace pedigree technology across the entire prescription pharmaceutical supply chain.

The Board and the Workgroup worked diligently over the past year to complete the tasks assigned by the Legislature. After promulgated the revised regulations, throughout the remainder of 2008 the Board revised application forms and processes, mailed the application and instructions during November and regularly posted supplemental information on the Board’s website. The convened Workgroup met throughout 2008, conducted a survey on the availability of electronic track and trace pedigree technology across the entire prescription pharmaceutical supply chain, and made its recommendations to the Board as required by Section 2, chs. 352, 353, Acts 2007.

Based on recommendations from the Workgroup, the target dates established by the Board for implementation of electronic track and trace pedigree technology are as follows:

- January 1, 2016: Manufacturers (generic and brand) must pedigree:
  - 50 percent of their products by 2016; and
  - 50 percent by 2017;
- July 1, 2017: Wholesalers and repackagers must accept and pass pedigrees.
- July 1, 2018: Pharmacies and pharmacy warehouses must accept pedigrees.

## IMPLEMENTATION OF NEW REGULATORY REQUIREMENTS

### **Creating systems required by the Act.**

The Board utilized the statute and the revised regulations to develop new applications and permit processes. Beginning in October 2008, applications were mailed to existing wholesale distributor permit holders whose permits expired December 31, 2008. In general, in order to distribute wholesale prescription drugs or devices in Maryland:

1. **All Wholesale Prescription Drug or Device Distributors** that apply to operate in Maryland in 2009 are required to demonstrate that they can meet the provisions of the new Distribution Permitting and Prescription Drug Integrity Act and revised COMAR 10.34.22 Licensing of Wholesale Prescription Drug or Device Distributors regulations. Both the law and regulations are available to the public on the Board's website at [www.mdbop.org](http://www.mdbop.org).
2. **All current and new licensed wholesale distributor permit holders** are required to demonstrate that the new legal provisions will be met and adhered to in the revised application for operating in Maryland in 2009 and after. An application must be filed before the permit expires on December 31 each year. See Appendix II. An application fee of \$1,000 is required for a Distributor permit which is valid for up to two (2) years. A late fee shall be paid to the Board if the renewal application is post-marked or otherwise delivered to the Board after December 31<sup>st</sup>.
3. **Manufacturers that are engaged in wholesale distribution of only their own prescription drugs or devices** approved by the FDA, are not exempted and must hold a permit issued by the Board, if they are distributing directly into Maryland. Manufacturers that meet this criterion will not be required to meet all of the criteria set forth for other types of distributors and will need only to demonstrate to the Board that they have met federal requirements by submitting to the Board a condensed application form, and the application fee. See Appendix III for the condensed application forms.

### **Development of the Application and Application Review Process**

The newly developed applications will require wholesale distributors to provide more in-depth information about their operations and personnel. In addition to traditional contact information, names, and manner of ownership, the applicant will also have to provide, if applicable, the:

- Date of birth of individual or partner owners;
- Names and contact information of shareholders of more than 10 percent of the corporation;
- Names and contact information of corporate officers and director, if applicable;
- Names and contact information of each partner;
- Name of parent company or companies;
- Name and address of resident agent, if a corporation;
- Addresses, telephone numbers, and the names of contact persons for the facility used by the applicant for the storage, handling, and distribution of prescription drugs;
- All trade or business names used by the permit holder which may not be identical to the name used by another unrelated applicant in the State;

- A list of federal and state licenses, registrations, or permits, including the license, registration, or permit numbers issued to the wholesale distributor by federal authority or another state that authorizes the wholesale distributor to purchase, possess and distribute prescription drugs or devices;
- Written evidence that the wholesale distributor has obtained general and product liability insurance; and
- A description of the wholesale distributor's import and export activities.

Substantial information will now be required on the application concerning the designated representatives and the immediate supervisor of designated representatives. This information includes:

- Names;
- Places of residence for the past 7 years;
- Dates and places of birth;
- The name and address of each business where the individual was employed during the past 7 years, and the individual's job title or office held at each business;
- A statement of whether, during the past 7 years, the individual has been the subject of any proceeding for the revocation of any professional or business license or any criminal violation and, if so, the nature and disposition of the proceeding;
- A statement of whether, during the past 7 years, the individual has been enjoined, either temporarily or permanently, by a court of competent jurisdiction from violating any federal or state law regulating the possession, control, or distribution of prescription drugs, together with details concerning the event;
- A description of any involvement, including any investments other than the ownership of stock in a publicly traded company or mutual fund, by the individual during the past 7 years, with any business that manufactures, administers, prescribes, distributes, or stores prescription drugs, and any lawsuits in which the business was named as a party;
- A description of any misdemeanor or felony offense of which the individual, as an adult, was found guilty, regardless of whether adjudication of the guilt was withheld or whether the individual pled guilty or nolo contendere;
- If the individual indicates that a criminal conviction is under appeal and submits a copy of the notice of appeal, within 15 days after the disposition of the appeal, a copy of the final written order of disposition;
- A photograph of the individual taken in the previous 180 days;
- Two complete sets of legible fingerprints taken on forms approved by the Director of the Central Repository and the Director of the Federal Bureau of Investigation;
- The fee authorized under the Criminal Procedure Article, §10-221(b)(7), Annotated Code of Maryland, for access to State criminal history records; and
- The processing fee required by the Federal Bureau of Investigation for a national criminal history records check.

The new regulations require that the applicant provide detailed information, beyond a floor plan diagram, for the applicant's wholesale distribution facility and/or warehouse. Required details include the facility's square footage, security and alarm system descriptions, terms of lease or ownership, address, and a description of temperature and humidity controls. The new law also does not allow a wholesale distribution facility in a residence. Health Occupations Article, 12-6C-09(e),

Annotated Code of Maryland. In addition, the applicant for a wholesale distributor permit is required to submit a surety bond of at least \$100,000, or an irrevocable letter of credit acceptable to the State. The Board provides sample bond forms and sample irrevocable letters of credit with the Application and Instructions.

One substantive change included in the new licensure process is a requirement for wholesale distributors' facilities to be inspected. The Board developed procedures and obtained personnel resources to insure that required inspections can be performed at facilities located in Maryland. For out of state wholesale distributors, the regulations allow the Board to accept reports of inspections performed through the National Association of Boards of Pharmacy Verified-Accredited Wholesale Distributors (VAWD) Certification process or by states that have strengthened laws similar to Maryland's. The Board also recognizes some U.S. Food and Drug Administration (FDA) or Drug Enforcement Administration (DEA) inspections reports if a particular report is determined similar to Maryland's inspection report. If a distributor located outside of Maryland has not been inspected or does not have an acceptable inspection report done by another entity, the Board will attempt to establish memorandums of understanding for an inspection to be performed by a qualified third party or Board staff may be required to travel to another state to perform an inspection as a last resort.

The Board staff made itself available to wholesale distributor permit holders by fielding dozens of daily phone calls and responding to numerous emails concerning the new process during November and December 2008. "Frequently Asked Questions" were added to the Board's website, to assist permit holders as they completed the more extensive application form. See Appendix IV for the FAQs.

With the implementation of any new law, there are issues that arise that may not have been contemplated by the drafters and negotiators of the legislation during the 2007 Legislative Session. One issue of concern for smaller wholesale distributors is the requirement of a surety bond of \$100,000. Some states have allowed for smaller bonds based on the wholesale distributor's size and assets. Other states have accepted surety bonds prepared for sister states, instead of requiring a new bond specific to that state. The Board, however; at this time is bound by the language of Health Occupations Article, 12-6C-05(f), Annotated Code of Maryland, and requires a surety bond of \$100,000 regardless of the size of the distributor or how many other states where the distributor may also hold surety bonds.

## **WHOLESALE DISTRIBUTOR SB 759 WORKGROUP RECOMMENDATIONS TO THE BOARD OF PHARMACY**

During 2008, the Wholesale Distributor SB 759 Workgroup (the "Workgroup") completed the work necessary for it to make a recommendation to the Board for a target date for implementation of electronic track and trace pedigree technology. The Workgroup continued to collect information regarding electronic track and trace technology during the fall of 2007 and conducted a survey of the availability of electronic track and trace pedigree technology across the entire prescription pharmaceutical supply chain during July and August 2008. The survey was completed and analyzed in September and October of 2008. Based on the survey, but unable to reach consensus, the Workgroup submitted recommendations to the Board on November 12, 2008, regarding target dates for the implementation of electronic track and trace technology across the entire pharmaceutical supply chain.

The Workgroup's recommendation had two conflicting target dates. Some members of the Workgroup recommended that a target date should not be set at this time due to the significant technological and financial challenges in upgrading the current supply chain system. Because a uniform electronic track and trace system should be implemented on a national scale, the U.S. Food and Drug Administration (FDA) should be recognized as the appropriate authority on this issue. NACDS and Cardinal Health recommended that the target dates in Maryland should be one year later than the target dates set forth in the California Senate Bill 1307. Specifically, the first target implementation date for manufacturers should be January 1, 2016; subsequent Federal pedigree laws or regulations should preempt these recommendations; and no further legislation should be introduced or further regulations should be promulgated establishing earlier target dates than the Workgroup's recommendation. See Appendix V for the complete Workgroup Recommendation with all attachments.

### **BOARD OF PHARMACY-ESTABLISHED TARGET DATE FOR IMPLEMENTATION OF ELECTRONIC TRACK AND TRACE PEDIGREE TECHNOLOGY IN MARYLAND**

At the November 19, 2008 Public Board Meeting, the Board considered the Workgroup's recommendations. The Board also considered the requirement of the Act that the Board must establish a target date for implementation for electronic track and trace pedigree technology on or before July 1, 2009. Faced with a Workgroup that did not reach consensus on an actual date, but did reach consensus on the complexities of establishing electronic track and trace technology, the Board made the decision not to delay setting a target date for implementation of electronic track and trace pedigree technology until next summer. The passage of 6 months would not alter the issues or see significant advances in technology to warrant waiting until the May or June 2009 Board Meetings. With the Workgroup's recommendation before it, the Board set the target date for implementation for electronic track and trace pedigree technology to be the same dates as set by the State of California's legislature, plus one year. A copy of the California law is included in the Workgroup's attached recommendation. Those dates are summarized as follows:

- January 1, 2016: Manufacturers (generic and brand) must pedigree:
  - 50 percent of their products by 2016;
  - The remaining 50 percent by 2017;
- July 1, 2017: Wholesalers and repackagers must accept and pass pedigrees.
- July 1, 2018: Pharmacies and pharmacy warehouses must accept pedigrees.

Keep in mind that under the Maryland Act, pedigrees are only required from a person who is engaged in the wholesale distribution of a prescription drug that leaves, or has ever left, the normal distribution channel. Manufacturers licensed as wholesale distributors in Maryland that engage in the wholesale distribution of a prescription drug that would leave the normal distribution channel would be required to provide pedigrees beginning January 1, 2016. Wholesalers and repackagers would follow by July 1, 2017 and pharmacies will begin accepting pedigrees by July 1, 2018. Federal preemption may require pedigrees at an earlier date, if federal legislation or regulations are enacted which address pedigrees.

## CONCLUSION

Although the Board established a target date for implementation of electronic track and trace pedigree technology far beyond the target date of July 2, 2010 that was set forth by the legislature, there have still been great strides in protecting consumers in Maryland from counterfeit drugs. With the new application requirements, the Board is confident that many disreputable wholesale distributors will not renew in Maryland. As the Workgroup discovered, the process of establishing electronic track and trace pedigree technology is a daunting task. The entire industry has to “re-tool” if you will, to insert this type of technology on their packaging and to “read” this type of technology as the prescription drugs and devices pass down the supply chain to the consumer. At the present time there is not one standard for the type of electronic track and trace technology that will be used, or one type of standard “reader” that will have to be installed. The industry is moving forward and has begun using it for some life-style prescription drugs that have been subject to extensive counterfeiting such as Oxycontin, Viagra and Celebrex. But these are isolated instances and the industry is simply not ready to implement electronic track and trace technology across the entire pharmaceutical supply chain which includes hundreds of thousands of prescription drugs.

Industry stakeholders have assured the California legislature that they will move forward with research and pilots so that they are ready for implementation of electronic track and trace technology in 2015 in California. Please go to the California Board of Pharmacy website to review the letter from California Senator Ridley-Thomas to the California Secretary of State that explains the future implementation dates and the stakeholders who have pledged their compliance.

<http://www.pharmacy.ca.gov/publications/ridleythomasletter.pdf>

Beginning in 2016, Maryland will expect all wholesale distributors that distribute prescription drugs into, out of, or within Maryland to be ready to comply with Maryland’s Act.

The Board commends Delegates Morhaim and Montgomery for their leadership and perseverance throughout the past year in monitoring the work of the Workgroup. The Board also commends the stakeholders who met throughout the year as part of the Workgroup. They took their task seriously and provided the Board with extensive insight into this complex task. Since the enactment of the Act and with the implementation of the new application process, prescription drugs and devices in Maryland are safer for the consumers. Only those wholesale distributors that complete the extensive application process and receive a permit from the Board may distribute prescription drugs and devices to Maryland consumers.

## APPENDIX I

### **Title 10 DEPARTMENT OF HEALTH AND MENTAL HYGIENE Subtitle 34 BOARD OF PHARMACY**

#### Chapter 22 Licensing of Wholesale Prescription Drug or Device Distributors

#### **Authority: Health Occupations Article, §§12-205, 12-601, and 12-6C-01—12-6C-13, Annotated Code of Maryland**

10.34.22.01

##### *.01 Scope.*

This chapter applies to any person engaged in the wholesale distribution of prescription drugs or devices in Maryland.

10.34.22.02

##### *.02 Definitions.*

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Authenticate" means to affirmatively verify, before any wholesale distribution of a prescription drug occurs, that each transaction listed on the pedigree for the prescription drug has occurred.

(2) "Authorized distributor of record" means a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drug.

(3) "Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

(4) "Blood component" means that part of blood separated by physical or mechanical means.

(5) "Board" means the State Board of Pharmacy.

(6) "Co-licensed partner" means a person in a relationship in which two or more persons have the right to engage in the manufacturing or marketing of a prescription drug, consistent with the U.S. Food and Drug Administration's implementation of the Federal Prescription Drug Marketing Act.

(7) "DEA" means the U. S. Drug Enforcement Administration.

(8) "Designated representative" means an individual who:

(a) Is designated by the wholesale distributor;

(b) Serves as the primary contact of the wholesale distributor with the Board; and

(c) Is actively involved in, and aware of, the daily operation of the wholesale distributor.

(9) "Drop shipment" means the sale of a prescription drug:

(a) To a wholesale distributor by:

(i) The manufacturer of the prescription drug; or

(ii) The manufacturer's co-licensed partner, third-party logistics provider, or manufacturer's exclusive distributor; and

(b) Through which:

(i) The wholesale distributor or a pharmacy warehouse takes title to, but not physical possession of, the prescription drug;

(ii) The wholesale distributor invoices the pharmacy, pharmacy warehouse, or other person authorized by law to dispense or administer the prescription drug to a patient; and

(iii) The pharmacy, pharmacy warehouse, or other authorized person receives delivery of the prescription drug directly from the manufacturer, the manufacturer's third-party logistics provider, or the manufacturer's exclusive distributor.

(10) "FDA" means the U. S. Food and Drug Administration.

(11) Health Care Entity.

(a) "Health care entity" means a person that provides diagnostic, medical, surgical, or dental treatment, or chronic or rehabilitative care.

(b) "Health care entity" does not include a community pharmacy or a wholesale distributor.

(c) "Health care entity" may not simultaneously be a health care entity and a community pharmacy or wholesale distributor.

(12) "Manufacturer" means a person licensed or approved by the U.S. Food and Drug Administration to engage in the manufacture of prescription drugs or prescription devices, consistent with the definition of "Manufacturer" under the U.S. Food and Drug Administration's regulations and guidelines implementing the Prescription Drug Marketing Act.

(13) "Manufacturer's exclusive distributor" means a person who:

(a) Contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of the manufacturer; and

(b) Takes title to the manufacturer's prescription drug, but does not have general responsibility to direct the sale or disposition of the manufacturer's prescription drug.

(14) "Normal distribution channel" means a chain of custody for a prescription drug that, directly or by drop shipment, goes:

(a) From:

(i) A manufacturer of the prescription drug; or

(ii) The manufacturer's co-licensed partner, third-party logistics provider, or manufacturer's exclusive distributor; and

(b) To:

(i) A pharmacy or other designated person authorized by law to dispense or administer the prescription drug to a patient;

(ii) A wholesale distributor to a pharmacy or other designated person authorized by law to dispense or administer the prescription drug to a patient;

(iii) A wholesale distributor to a pharmacy warehouse to the pharmacy warehouse's intracompany pharmacy or other designated person authorized by law to dispense or administer the prescription drug to a patient;

(iv) A pharmacy warehouse to the pharmacy warehouse's intracompany pharmacy, or other designated person authorized by law to dispense or administer the prescription drug to a patient; or

(v) An authorized distributor of record to another authorized distributor of record solely for distribution to an office-based health care practitioner authorized by law to dispense or administer the prescription drug to a patient.

(15) "Pedigree" means a document or electronic file containing information that records each wholesale distribution of a prescription drug.

(16) "Prescription device" means any device required by federal law or regulation to be dispensed only by a prescription.

(17) Prescription Drug.

(a) "Prescription drug" means any drug required by federal law or regulation to be dispensed only by a prescription.

(b) "Prescription drug" includes:

(i) A biological product; and

(ii) Finished dosage forms and bulk drug substances subject to §503(b) of the Federal Food, Drug and Cosmetic Act.

(c) "Prescription drug" does not include blood and blood components intended for transfusion or biological products that are also medical devices.

(18) Repackage.

(a) "Repackage" means to repackage or otherwise change the container, wrapper, or labeling of a prescription drug to further the distribution of the prescription drug.

(b) "Repackage" does not include changes to a container, wrapper, or labeling of a prescription drug completed by the pharmacist responsible for dispensing the prescription drug to a patient.

(19) "Repackager" means a person who repackages prescription drugs.

(20) "Third-party logistics provider" means a person who:

(a) Contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of the manufacturer; and

(b) Does not take title to the prescription drug, or have general responsibility to direct the prescription drug's sale or disposition.

(21) Wholesale Distribution.

(a) "Wholesale distribution" means the distribution of prescription drugs or prescription devices to persons other than a consumer or patient.

(b) "Wholesale distribution" does not include:

(i) Intra-company sales;

(ii) The sale, purchase, distribution, trade, or transfer of a prescription drug or an offer to sell, purchase, distribute, trade, or transfer a prescription drug for emergency medical reasons which include transfers of prescription drugs or devices by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage;

(iii) The distribution of samples of a prescription drug by a manufacturer's representative;

(iv) Prescription drug returns conducted by a hospital, health care entity, or charitable institution in accordance with 21 CFR §203.23, as amended;

(v) The sale of minimal quantities of prescription drugs by retail pharmacies to licensed health care practitioners for office use;

(vi) The sale, purchase, or trade of a prescription drug, an offer to sell, purchase, or trade a prescription drug, or the dispensing of a prescription drug in accordance with a prescription;

(vii) The sale, transfer, merger, or consolidation of all or part of the business of a pharmacy to or with another pharmacy, whether accomplished as a purchase and sale of stock or business assets;

(viii) The sale, purchase, distribution, trade, or transfer of a prescription drug from one authorized distributor of record to one additional authorized distributor of record, if the manufacturer has stated in writing to the receiving authorized distributor of record that the manufacturer is unable to supply the prescription drug, and the supplying authorized distributor of record states in writing that the prescription drug being supplied had until that time been exclusively in the normal distribution channel;

(ix) The delivery of, or offer to deliver, a prescription drug by a common carrier solely in the common carrier's usual course of business of transporting prescription drugs, if the common carrier does not store, warehouse, or take legal ownership of the prescription drug; or

(x) The sale or transfer from a retail pharmacy or pharmacy warehouse of expired, damaged, returned, or recalled prescription drugs to the original manufacturer, or to a third-party returns processor.

(22) Wholesale Distributor.

(a) "Wholesale distributor" means a person that is engaged in the wholesale distribution of prescription drugs or prescription devices.

(b) "Wholesale distributor" includes:

(i) A manufacturer;

(ii) A repackager;

(iii) An own-label distributor;

(iv) A private-label distributor;

(v) A jobber;

- (vi) A broker;
- (vii) A warehouse, including a manufacturer's or distributor's warehouse;
- (viii) A manufacturer's exclusive distributor, or an authorized distributor of record;
- (ix) A drug wholesaler or distributor;
- (x) An independent wholesale drug trader;
- (xi) A third-party logistics provider;
- (xii) A retail pharmacy that conducts wholesale distribution, if the wholesale distribution business accounts for more than 5 percent of the retail pharmacy's annual sales; and
- (xiii) A pharmacy warehouse that conducts wholesale distribution.

10.34.22.03

*.03 Minimum Application Requirements for Applicant.*

A. The Board shall require the following minimum information from a wholesale distributor as part of an application for a permit and as part of a renewal of a permit:

- (1) The type of business form under which the applicant operates, such as partnership, corporation, or sole proprietorship;
- (2) The full name or names of the owner and the operator of the wholesale distributor applying for or renewing a permit, including:
  - (a) For an individual, the:
    - (i) Full name of the individual;
    - (ii) Telephone number of the individual;
    - (iii) Business address of the individual; and
    - (iv) Date of birth of the individual;
  - (b) For a partnership, the:
    - (i) Full name of each partner;
    - (ii) Telephone number of the partnership;
    - (iii) Address of each partner;
    - (iv) Date of birth of each partner;
    - (v) Business address of the partnership; and

- (vi) Federal employer identification number of the partnership;
- (c) For a publicly traded corporation, the:
  - (i) Full name and title of each corporate officer and director;
  - (ii) Telephone number of the publicly traded corporation;
  - (iii) Business address of the corporation;
  - (iv) Federal employer identification number of the corporation;
  - (v) Name of parent company or companies if applicable;
  - (vi) Corporate names;
  - (vii) Name of the state of incorporation; and
  - (viii) Name and address of the resident agent of the corporation;
- (d) For a nonpublicly traded corporation, the:
  - (i) Full name and title of each corporate officer and director;
  - (ii) The telephone number of the nonpublicly traded corporation;
  - (iii) Business address of the corporation;
  - (iv) Federal employer identification number of the corporation;
  - (v) Name of parent company or companies if applicable;
  - (vi) Corporate names;
  - (vii) Full name and business address of shareholders of more than 10 percent of the corporation, including over-the-counter stock, unless the stock is traded on a major stock exchange;
  - (viii) Name of the state of incorporation; and
  - (ix) Name and address of the resident agent of the corporation;
- (e) For a sole proprietorship, the:
  - (i) Full name of the sole proprietor;
  - (ii) The telephone number of the sole proprietor;
  - (iii) Full name of the business entity;
  - (iv) Business address; and
  - (v) Date of birth of the sole proprietor;

(f) For a limited liability company, the:

(i) Full name and business address of the limited liability company;

(ii) Telephone number of the limited liability company;

(iii) Full name of each member;

(iv) Full name of each manager;

(v) Federal employer identification number of the limited liability company;

(vi) Name of the state in which the limited liability company was organized; and

(vii) Name and address of the resident agent of the company;

(3) Addresses, telephone numbers, and the names of contact persons for the facility used by the applicant for the storage, handling, and distribution of prescription drugs;

(4) All trade or business names used by the permit holder which may not be identical to the name used by another unrelated applicant in the State;

(5) A list of federal and state licenses, registrations, or permits, including the license, registration, or permit numbers issued to the wholesale distributor by federal authority or another state that authorizes the wholesale distributor to purchase, possess, and distribute prescription drugs or devices;

(6) A list of disciplinary actions by federal or state agencies against the wholesale distributor as well as any such actions against principals, owners, directors, or officers;

(7) For the designated representative and the immediate supervisor of the designated representative at the applicant's place of business the following information:

(a) Names;

(b) Places of residence for the past 7 years;

(c) Dates and places of birth;

(d) The name and address of each business where the individual was employed during the past 7 years, and the individual's job title or office held at each business;

(e) A statement of whether, during the past 7 years, the individual has been the subject of any proceeding for the revocation of any professional or business license or any criminal violation and, if so, the nature and disposition of the proceeding;

(f) A statement of whether, during the past 7 years, the individual has been enjoined, either temporarily or permanently, by a court of competent jurisdiction from violating any federal or state law regulating the possession, control, or distribution of prescription drugs, together with details concerning the event;

(g) A description of any involvement, including any investments other than the ownership of stock in a publicly traded company or mutual fund, by the individual during the past 7 years, with any business that manufactures, administers, prescribes, distributes, or stores prescription drugs, and any lawsuits in which the business was named as a party;

(h) A description of any misdemeanor or felony offense of which the individual, as an adult, was found guilty, regardless of whether adjudication of the guilt was withheld or whether the individual pled guilty or nolo contendere;

(i) If the individual indicates that a criminal conviction is under appeal and submits a copy of the notice of appeal, within 15 days after the disposition of the appeal, a copy of the final written order of disposition; and

(j) A photograph of the individual taken in the previous 180 days;

(8) A full description of the facility and warehouse including:

(a) Square footage;

(b) Security and alarm system descriptions;

(c) Terms of lease or ownership;

(d) Address; and

(e) Description of temperature and humidity controls;

(9) Written evidence that the wholesale distributor has obtained general and product liability insurance;

(10) A description of the wholesale distributor's import and export activities; and

(11) Other relevant information that the Board may require.

B. The Board shall require the following information from the designated representative and the immediate supervisor of the designated representative at the applicant's place of business as part of the initial application for a permit:

(1) Two complete sets of legible fingerprints taken on forms approved by the Director of the Central Repository and the Director of the Federal Bureau of Investigation;

(2) The fee authorized under the Criminal Procedure Article, §10-221(b)(7), Annotated Code of Maryland, for access to State criminal history records; and

(3) The processing fee required by the Federal Bureau of Investigation for a national criminal history records check.

C. The information required under §A of this regulation shall be provided under oath.

D. The Board may not issue an initial or renewal wholesale distributor permit to an applicant unless the Board or its designee:

(1) Conducts a physical inspection of the applicant's place of business, including any facility of the applicant;

(2) Finds that the place of business and facility, if any, meets the Board's requirements;

(3) Determines that the designated representative of the applicant meets the following qualifications:

(a) Is 21 years old or older;

(b) Has been employed full time for at least 3 years in a pharmacy or with a wholesale distributor in a capacity related to the dispensing and distribution of, and record keeping relating to, prescription drugs;

- (c) Is employed by the applicant full time in a managerial level position;
  - (d) Is actively involved in, and aware of, the daily operation of the wholesale distributor;
  - (e) Is physically present, except for an authorized absence such as sick leave or vacation leave, at the facility of the applicant during regular business hours;
  - (f) Is serving as a designated representative for only one applicant at a time, or for two or more wholesale distributors who are located in the same facility and are members of an affiliated group, as defined in §1504 of the Internal Revenue Code;
  - (g) Does not have any convictions for a violation of any federal, State, or local laws relating to wholesale or retail prescription drug distribution or distribution of controlled substances; and
  - (h) Does not have any convictions for a felony under federal, State, or local laws; and
- (4) Determines that the immediate supervisor of the designated representative of the applicant meets the following qualifications:
- (a) Is 21 years old or older;
  - (b) Has been employed full time for at least 3 years in a pharmacy or with a wholesale distributor in a capacity related to the dispensing and distribution of, and record keeping relating to, prescription drugs;
  - (c) Is employed by the applicant full time in a managerial level position;
  - (d) Is actively involved in, and aware of, the daily operation of the wholesale distributor;
  - (e) Does not have any convictions for a violation of any federal, state, or local laws relating to wholesale or retail prescription drug distribution, or distribution of controlled substances; and
  - (f) Does not have any convictions for a felony under federal, state, or local laws.

E. Surety Bond.

- (1) An applicant for a wholesale distributor permit shall submit a surety bond of at least \$100,000, or other equivalent means of security acceptable to the State such as an irrevocable letter of credit, or a deposit in a trust account or financial institution, payable to an account established by the State under Health Occupations Article, §12-6C-05(f)(6), Annotated Code of Maryland.
- (2) A surety bond is not required for a pharmacy warehouse that is not engaged in wholesale distribution.
- (3) A single surety bond shall cover all facilities operated by the applicant in the State.

F. If a wholesale distributor distributes prescription drugs or prescription devices from more than one facility, the wholesale distributor shall obtain a permit for each facility.

G. The Board shall notify the applicant of the Board's acceptance or rejection of the application within 30 days after the date the Board receives a completed application, including the results of all required criminal history records checks.

H. The applicant shall pay to the Board an application fee set forth in COMAR 10.34.09.02.

I. The wholesale distributor shall provide changes in information provided pursuant to Regulation .03 of this chapter to the Board within 30 days of the effective date of the change.

*10.34.22.04*

*.04 Personnel.*

A. The permit holder shall affirm in the initial application and subsequent renewal applications that personnel employed in wholesale distribution have appropriate education and experience to assume responsibilities related to compliance with State licensing requirements.

B. Registered Agent.

(1) Each licensed wholesale distributor located outside of this State that wholesale distributes prescription drugs or devices in this State shall designate a registered agent in this State for service of process.

(2) If any wholesale distributor is not licensed in this State, service on the Director of the State Department of Assessments and Taxation only shall be sufficient service.

C. Requirements and Responsibilities of the Designated Representative.

(1) The designated representative shall be aware of, and knowledgeable about, all policies and procedures pertaining to the operations of the wholesale distributor, including applicable State and federal laws.

(2) The designated representative shall have documented training sufficient to ensure that operations of the wholesale distributor are in compliance with applicable State and federal laws and are provided by qualified in-house specialists, outside counsel, or consulting specialists with capabilities to help ensure compliance with all applicable State and federal laws and regulations.

(3) The designated representative shall maintain current working knowledge of the requirements for wholesale distributor and assure ongoing training for personnel to ensure compliance.

(4) The designated representative shall be responsible for all record keeping requirements and make all records available for inspection.

*10.34.22.05*

*.05 Violations and Penalties.*

A. After a hearing held under Health Occupations Article, §12-601, Annotated Code of Maryland, the Board may deny, suspend, revoke, or place on probation a permit holder, reprimand a permit holder, or impose a fine if the permit holder:

(1) Is convicted of, or pleads guilty or nolo contendere to, violations of federal, State, or local drug or device laws or regulations;

(2) Is convicted of, or pleads guilty or nolo contendere to, a felony or to a crime involving moral turpitude, whether or not any appeal or other proceeding is pending to have the conviction or plea set aside;

(3) Commits any of the following acts:

(a) Obtains or attempts to obtain a permit by:

(i) Providing false information to the Board; or

(ii) Other fraudulent or deceptive means;

(b) Fails to:

(i) Establish or maintain inventories, records, or written policies and procedures as required by Regulation .07 of this chapter;

(ii) Register with the Maryland Division of Drug Control, and with the U.S. Drug Enforcement Agency, as required by Regulation .07D of this chapter; or

(iii) Permit the Board, the Maryland Division of Drug Control, the U.S. Drug Enforcement Agency, or other authorized federal, State, or local law enforcement officials showing proper identification, to enter, inspect, copy records, or audit as required by Regulation .07D of this chapter;

(c) Willfully makes or maintains false inventories or records;

(d) Violates a provision of, or regulation promulgated under, Health Occupations Article, Title 12, Annotated Code of Maryland;

(e) Manufactures, repackages, sells, delivers, or holds or offers for sale any prescription drug or device that is adulterated, misbranded, counterfeit, suspected of being counterfeit, or has otherwise been rendered unfit for distribution or wholesale distribution;

(f) Adulterates, misbrands, or counterfeits prescription drugs or devices;

(g) Receives prescription drugs or devices that are adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit, or suspected of being counterfeit, or delivers or proffers delivery of such prescription drug or device for pay or otherwise;

(h) Alters, mutilates, destroys, obliterates, or removes the whole or any part of the product labeling of a prescription drug or device, or commits any other act with respect to a prescription drug or device that results in the prescription drug or device being misbranded;

(i) Forges, counterfeits, simulates, or falsely represents prescription drugs or devices without the authority of the manufacturer, or uses any mark, stamp, tag, label, or other identification device without the authorization of the manufacturer;

(j) Purchases or receives a prescription drug or device from a person who is not licensed to wholesale distribute prescription drugs or devices to that purchaser or recipient;

(k) Sells or transfers a prescription drug or device to a person who is not legally authorized to receive a prescription drug or device;

(l) Provides the Board, its representatives, or federal or State officials with false or fraudulent records, or makes a false or fraudulent statements regarding any matter within the provisions of these regulations;

(m) Wholesale distributes prescription drugs or devices that were:

(i) Purchased by a public or private hospital, or other health care entity;

(ii) Donated or supplied at a reduced price to a charitable organization;

(iii) Stolen or obtained by fraud or deceit; or

(iv) Donated to a drop-off site or repository under the Prescription Drug Repository Program set forth in Health-General Article, Title 15, Subtitle 6, Annotated Code of Maryland;

(n) Fails to obtain a license, or operates without a valid license when a license is required;

(o) Obtains, or attempts to obtain, a prescription drug or device by fraud, deceit, misrepresentation, or engages in misrepresentation or fraud in the distribution or wholesale distribution of a prescription drug or device;

(p) Distributes a prescription drug or device to the patient without a prescription or prescription order from a practitioner licensed by law to use or prescribe the prescription drug or device;

(q) Fails to obtain, authenticate, or pass on a pedigree when required under these regulations;

(r) Receives a prescription drug pursuant to a wholesale distribution without first receiving a pedigree, when required, that was attested to as accurate and complete by the wholesale distributor;

(s) Distributes or wholesale distributes a prescription drug or device that was previously dispensed by a pharmacy or distributed by a practitioner;

(t) Fails to report prohibited acts as listed in these regulations;

(u) Fails to exercise due diligence as provided in Regulation .08 of this chapter;

(v) Otherwise conducts the wholesale distribution of prescription drugs or devices in a manner not in accordance with the law;

(w) Accepts payment or credit for the sale of prescription drugs in violation of Health Occupations Article, §12-6C-09(d), Annotated Code of Maryland; or

(x) If the requirements of Health Occupations Article, §12-6C-09(a), Annotated Code of Maryland, are applicable and are not met, the purchasing or otherwise receiving a prescription drug from a pharmacy; or

(4) Is disciplined by a licensing or disciplinary authority of any state or country, or disciplined by a court of any state or country, for an act that would constitute a ground for Board action against a wholesale distributor permit holder under §A or B of this regulation.

B. Acts prohibited under this regulation do not include a prescription drug manufacturer, or agent of a prescription drug manufacturer, obtaining or attempting to obtain a prescription drug for the sole purpose of testing the prescription drug for authenticity.

*10.34.22.06*

*.06 Minimum Requirements for the Storage and Handling of Prescription Drugs or Devices.*

A. Facilities. Facilities at which prescription drugs or devices are stored, warehoused, handled, held, offered, marketed, or displayed shall:

(1) Be of suitable size and construction to facilitate:

(a) Cleaning;

(b) Maintenance; and

- (c) Proper operations;
- (2) Have storage areas designed to provide adequate:
  - (a) Equipment;
  - (b) Humidity control;
  - (c) Lighting;
  - (d) Sanitation;
  - (e) Security conditions;
  - (f) Space;
  - (g) Temperature; and
  - (h) Ventilation;
- (3) Have a quarantine area for storage of prescription drugs or devices that are:
  - (a) Adulterated;
  - (b) Damaged;
  - (c) Deteriorated;
  - (d) In immediate or sealed secondary containers that have been opened;
  - (e) Misbranded; or
  - (f) Outdated;
- (4) Be maintained in a clean and orderly condition; and
- (5) Be free from infestation by insects, rodents, birds, or vermin.

**B. Security. A facility:**

- (1) Used for wholesale distribution shall be secure from unauthorized entry as follows:
  - (a) Access from outside the premises shall be:
    - (i) Kept to a minimum; and
    - (ii) Well controlled;
  - (b) The outside perimeter of the premises shall be well lit; and
  - (c) Entry into areas where prescription drugs or devices are held shall be limited to authorized personnel;

(2) Shall be equipped with:

- (a) An alarm system to detect entry after hours;
- (b) A security system that provides protection against theft and diversion;
- (c) Appropriate software to facilitate the identification of evidence of tampering with computers or electronic records;
- (d) An inventory management and control system that protects against, detects, and documents any instances of theft, diversion, or counterfeiting;
- (e) A security system to protect the integrity and confidentiality of data and documents;
- (f) Video monitoring of all entrances and exits, or alternate acceptable security; and
- (g) A means to make the data and documentation required under this section readily available to the Board, an agent of the Board, or federal and other State law enforcement officials.

#### C. Storage.

(1) A wholesale distributor shall store a prescription drug or device at appropriate temperatures and under appropriate conditions in accordance with requirements:

- (a) If any, of the labeling of the drug or device; or
- (b) Set forth in the current edition of an official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF), under 21 CFR §205.50(c), as amended.

(2) If no storage requirements are established for a prescription drug or device, the drug or device shall be held at a controlled room temperature, as defined in an official compendium as set forth in §C(1)(b) of this regulation to help assure that its identity, strength, quality, and purity are not adversely affected.

(3) A wholesale distributor shall use appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and logs to document proper storage of prescription drugs or devices.

(4) A wholesale distributor shall follow the record-keeping requirements in Regulation .07 of this chapter for stored prescription drugs or devices.

#### D. Examination of Materials.

(1) Upon receipt, a wholesale distributor shall visually examine each outside shipping container for identity and to prevent the acceptance of:

- (a) Contaminated prescription drugs or devices; or
- (b) Prescription drugs or devices that are otherwise unfit for distribution.

(2) The examination required under §D(1) of this regulation shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(3) A wholesale distributor shall carefully inspect each outgoing shipment:

- (a) For identity of the prescription drug or device product; and

(b) To ensure that there is no delivery of a prescription drug or device that has been damaged in storage or held under improper conditions.

(4) A wholesale distributor shall follow the record-keeping requirements in Regulation .07 of this chapter for incoming and outgoing prescription drugs or devices.

#### E. Returned, Damaged, and Outdated Prescription Drugs or Devices.

(1) A wholesale distributor shall quarantine and physically separate prescription drugs or devices that are outdated, damaged, deteriorated, misbranded, or adulterated from other prescription drugs or devices until the quarantined and separated drugs or devices are destroyed or returned to their supplier for proper disposal.

(2) The wholesale distributor shall identify, mark, quarantine, and physically separate from other prescription drugs or devices those prescription drugs or devices whose immediate or sealed outer or sealed secondary containers have been opened or used, until the drugs or devices are either destroyed or returned to their supplier for proper disposal.

#### (3) Prescription Drugs.

(a) If the conditions under which a prescription drug has been returned cast doubt on the prescription drug's safety, identity, strength, quality, or purity, then the wholesale distributor shall destroy or return the prescription drug to the supplier, unless examination, testing, or other investigation proves that the prescription drug meets appropriate standards of safety, identity, strength, quality, and purity.

(b) In determining whether the conditions under which a prescription drug has been returned cast doubt on the prescription drug's safety, identity, strength, quality, or purity, the wholesale distributor shall consider, at a minimum, the:

(i) Conditions under which the prescription drug has been held, stored, or shipped before or during its return; and

(ii) Condition of the prescription drug and its container, carton, or labeling, as a result of storage or shipping.

#### (4) Prescription Devices.

(a) If the conditions under which a prescription device has been returned cast doubt on the prescription device's safety, identity, or quality, then the wholesale distributor shall destroy or return the prescription device to the supplier, unless examination, testing, or other investigation proves that the prescription device meets appropriate standards of safety, identity, strength, and quality.

(b) In determining whether the conditions under which a prescription device has been returned cast doubt on the prescription device's safety, identity, or quality, the wholesale distributor shall consider, among other things, the:

(i) Conditions under which the prescription device has been held, stored, or shipped before or during its return; and

(ii) Condition of the prescription device and its container, carton, or labeling, as a result of storage or shipping.

(5) A wholesale distributor shall follow the record-keeping requirements in Regulation .07 of this chapter for outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs or devices.

*10.34.22.07*

### *.07 Minimum Requirements for Maintenance of Prescription Drug or Device Distribution Records.*

#### A. Record Keeping.

(1) A wholesale distributor shall establish and maintain inventories and records of transactions regarding the receipt and distribution or other disposition of prescription drugs or devices.

(2) The records required under §A(1) of this regulation shall include the following information:

(a) The source of the prescription drugs or devices, including the:

(i) Name and principal address of the seller or transferor; and

(ii) Address of the location from which the prescription drugs or devices were shipped;

(b) The identity and quantity of the prescription drugs or devices received and distributed or disposed of;

(c) The dates of receipt and distribution or other disposition of the prescription drugs or devices; and

(d) The pedigrees, if required by Health Occupations Article, §12-6C-10, Annotated Code of Maryland, for prescription drugs that are wholesale distributed outside the normal distribution channel.

(3) The wholesale distributor shall make available inventories and records for inspection and copying by authorized federal, State, or local law enforcement agency officials for a period of 3 years after their date of creation.

(4) The wholesale distributor shall keep the records described in this regulation readily available for inspection by authorized federal, State, or local law enforcement agency officials during the retention period, either:

(a) At the inspection site; or

(b) So as to be immediately retrievable by computer or other electronic means.

(5) Within 5 working days of a request by an authorized official of a federal, State, or local law enforcement agency, the wholesale distributor shall make available for inspection records kept at a central location apart from the inspection site and not electronically retrievable.

(6) Facilities shall establish and maintain procedures for reporting counterfeit and contraband or suspected counterfeit and contraband drugs or devices or counterfeiting and contraband or suspected counterfeiting and contraband activities to the Board and the FDA.

(7) Wholesale distributors shall maintain a system for the mandatory reporting of significant inventory losses of prescription drugs and devices where it is known or suspected that diversion is occurring to the Board, the FDA, and, where applicable, to the DEA.

(8) Wholesale distributors shall consider the following factors when determining if there has been a significant inventory loss:

(a) The schedule of the missing items;

(b) The abuse or misuse potential of the missing items;

(c) The abuse or misuse potential in the wholesale distributor's area of the missing substance;

(d) The quantity missing in relation to the total quantity purchased (one tablet vs. one bottle or container);

(e) Whether this is the first time a potentially significant inventory loss has occurred;

(f) Whether this loss was reported to local law enforcement authorities; and

(g) Whether there is a significant resale value of the missing items.

#### B. Written Policies and Procedures.

(1) A wholesale distributor shall establish, maintain, and adhere to written policies and procedures which shall be followed for:

(a) The receipt, security, storage, inventory, and distribution of prescription drugs or devices;

(b) Identifying, recording, and reporting losses or thefts; and

(c) Correcting errors and inaccuracies in inventories.

(2) A wholesale distributor shall include in the written policies and procedures the following:

(a) A procedure by which the oldest approved and unexpired stock of a prescription drug or device is distributed first;

(b) Procedures to be followed for adequate handling of a recall and withdrawal of a prescription drug or device due to:

(i) An action initiated at the request of the United States Food and Drug Administration or other federal, State, or local law enforcement or other government agency, including the Maryland Division of Drug Control;

(ii) A voluntary action by the manufacturer to remove a defective or potentially defective drug or device from the market; and

(iii) An 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 the wholesale distributor is prepared for, protected against, and is able to handle a crisis that affects security or operation of a facility if any of the following situations occurs:

(i) Strike;

(ii) Fire;

(iii) Flood;

(iv) Catastrophic health emergency as defined in Public Safety Article, §14-3A-01, Annotated Code of Maryland;

(v) Terrorist activities;

(vi) Other natural disaster; or

(vii) Other situations of local, State, or national emergency;

(d) A procedure to ensure that an outdated prescription drug or device is segregated from other drugs or devices and either returned to the manufacturer or destroyed;

(e) A procedure for the disposing and destruction of containers, labels, and packaging to ensure that the containers, labels, and packaging cannot be used in counterfeiting activities, including all necessary documentation, maintained for

a minimum of 3 years, and the appropriate witnessing of the destruction of any labels, packaging, immediate containers, or containers in accordance with applicable federal and State requirements; and

(f) A procedure for identifying, segregating, investigating, and reporting prescription drug inventory discrepancies involving counterfeit, suspect of being counterfeit, contraband, or suspect of being contraband, in the inventory and reporting of such discrepancies within 5 business days to the Board and appropriate federal or State agency upon discovery of such discrepancies.

(3) If deviation is appropriate, a wholesale distributor may temporarily deviate from the requirement in §B(2)(a) of this regulation that the oldest approved and unexpired stock be distributed first.

(4) The wholesale distributor shall maintain documentation of the disposition of outdated prescription drugs or devices for 2 years after the disposition of the outdated prescription drugs or devices pursuant to procedures under §B(2)(d) of this regulation.

C. Responsible Individuals. A wholesale distributor shall establish and maintain a list of officers, directors, managers, the designated representative, and others in charge of wholesale distribution, storage, and handling, including:

(1) A description of their duties; and

(2) A summary of their qualifications.

D. Compliance with Federal, State, and Local Law. A wholesale distributor shall:

(1) Operate in compliance with applicable federal, State, and local laws and regulations;

(2) Permit at reasonable times and in a reasonable manner, the Board, the State Division of Drug Control, and any other authorized federal, State, and local law enforcement officials showing proper identification to:

(a) Enter and inspect the distributor's premises and delivery vehicles; and

(b) Audit and copy the distributor's records and written operating procedures; and

(3) If dealing in controlled substances:

(a) Register with the:

(i) Maryland Division of Drug Control; and

(ii) United States Drug Enforcement Administration; and

(b) Comply with all applicable federal, State, and local regulations.

E. Salvaging and Reprocessing.

(1) A wholesale distributor is subject to the provisions of applicable federal, State, or local laws or regulations that relate to prescription drug product salvaging or reprocessing, including 21 CFR Parts 207, 210, and 211, as amended.

(2) A wholesale distributor is subject to the provisions of any applicable federal, State, or local laws or regulations that relate to prescription device product salvaging or reprocessing.

10.34.22.08

*.08 Due Diligence.*

Wholesale distributors having transactions with persons not licensed by the Board or not certified by a third party recognized by the Board shall have in place policies and procedures to perform due diligence on transactions that take place that include:

- A. Verification of alternate licensure;
- B. Verification of identity; and
- C. Verification of recent inspections by a state or third party entity recognized by the Board.

### Administrative History

Effective date: August 31, 1992 (19:17 Md. R. 1607)

Regulation .03B amended effective November 7, 1994 (21:22 Md. R. 1877)

Regulation .04 amended effective November 7, 1994 (21:22 Md. R. 1877)

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Regulations .01—.10 repealed and new Regulations .01—.09 adopted effective March 28, 2005 (32:6 Md. R. 636)

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Regulations .01—.09 repealed and new Regulations .01—.08 adopted effective April 7, 2008 (35:7 Md. R. 748)

## APPENDIX II



STATE OF MARYLAND

# HMH

Department of Health and Mental Hygiene

*Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – John M. Colmers, Secretary*

MARYLAND BOARD OF PHARMACY

4201 Patterson Avenue • Baltimore, Maryland 21215-2299

Donald Taylor, Board President - LaVerne G. Naesea, Executive Director

November 3, 2008

Dear Wholesale Prescription Drug or Device Distributor:

Enclosed please find a revised application and instructions for requesting a Maryland 2009 permit under the recently enacted Wholesale Distribution Permitting and Prescription Drug Integrity Act and related regulations (*COMAR 10.34.22*). All new and existing wholesale distributor applicants must demonstrate through application that they can meet the new state requirements before receiving a 2009 permit to operate in Maryland. In addition to information included in the enclosures, please be advised of the following important information:

**3. A \$1000.00 application fee must be submitted with the completed application.**

The application fee has been increased from \$500.00 to \$1000.00 because applicants are allowed under the new Act to operate under an issued permit for two years rather than the one year allowed under previous Maryland laws.

4. **DO NOT submit the \$37.25 check, payable to CJIS – Central Repository, until information is received from the Board regarding how to meet federal and state criminal background checks requirements.**
5. **The Maryland Board of Pharmacy will provide information regarding how to meet federal and state criminal background check requirements, subsequent to this correspondence.**
6. **Applications should be submitted to the Maryland Board of Pharmacy no later than December 16, 2008 with or without criminal background check documentation and fingerprints.**

Applications received on or before December 16, 2008 will be processed as soon as possible. If the Board has not notified applicants by December 31, 2008 of a determination regarding approval or disapproval of applications received by December 16, 2008, current Maryland permit holders will be permitted to operate under their existing 2008 wholesale distributor permit until the Board's determination is received.

However, regarding applications received after December 16, 2008, if the Board has not notified applicants by December 31, 2008 of a determination regarding approval or disapproval, Board approval to operate under the existing 2008 Maryland Board of Pharmacy permit will expire December 31, 2008.

Thank you for your cooperation as the Maryland Board of Pharmacy continues to implement procedures under the Wholesale Distribution Permitting and Prescription Drug Integrity Act. Please monitor the Board's website at [www.mdbop.org](http://www.mdbop.org) for up-to-date information.

Sincerely,

LaVerne G. Naesea  
Executive Director

# MARYLAND BOARD OF PHARMACY

4201 PATTERSON AVE, BALTIMORE, MD 21215

410-764-4755 800-542-4964 FAX 410-358-6207

Email: [mdbop@dhmh.state.md.us](mailto:mdbop@dhmh.state.md.us)

Web site: [www.mdbop.org](http://www.mdbop.org)

## INSTRUCTIONS FOR MARYLAND WHOLESALE PRESCRIPTION DRUG OR DEVICE DISTRIBUTOR APPLICATION

A Wholesale Distributor is any person, partnership, corporation, or business firm engaging in the wholesale distribution of prescription drugs or prescription devices to persons other than a consumer or patient.

### **GENERAL INFORMATION:**

The Wholesale Distribution Permitting and Prescription Drug Integrity Act was enacted on July 1, 2007. The Act requires greater oversight of the practice of wholesale distribution in Maryland. Regulations to interpret the Act, COMAR 10.34.22 Licensing of Wholesale Prescription Drug or Device Distributors, were effective on April 7, 2008

All Wholesale Prescription Drug or Device Distributors that apply to operate in Maryland in 2009 will be required to demonstrate that they can meet the provisions of the new Distribution Permitting and Prescription Drug Integrity Act and revised COMAR 10.34.22 Licensing of Wholesale Prescription Drug or Device Distributors regulations. Maryland Law information and specific text is available on the Board of Pharmacy web site [www.mdbop.org](http://www.mdbop.org) under Legislations & Regulation.

All current and new licensed wholesale distributor permit holders are required to demonstrate that the new legal provisions will be met and adhered to in the revised application for operating in Maryland in 2009. An application for renewal must be filed before the permit expires on December 31 each year. An application fee of \$1,000 is required for a Distributor permit. Effective January 1, 2009, a permit is valid for two (2) years. An additional late fee of \$150.00 shall be paid to the Board if the renewal application is post-marked or otherwise delivered to the Board after December 31.

A physical inspection of the applicant's place of business, including any facility of the applicant is required unless the applicant is accredited by a Board-approved accreditation organization.. All applications must include a diagram of the business and inventory areas. Upon the Board's receipt of submitted applications, the Board's Compliance Unit will contact the applicants to arrange for an inspection, if necessary. All permits expire December 31 on or before two years after issuance of a permit.

All distributors doing business in Maryland will be required to pay any outstanding Maryland Use and Sales taxes and any outstanding Unemployment insurance fees before the Board may issue a permit. To settle a State business tax or insurance liability, call 410-649-0633 in Central Maryland or toll-free at 1-888-614-6337.

## **APPLICATION INSTRUCTIONS:**

It is important that the applicants' name, date and page number is recorded at the top of all pages of the application, including attachments.

**Applications received on or before December 16, 2008 will be processed as soon as possible. If the Board has not notified applicants by December 31, 2008 of a determination regarding approval or disapproval of applications that are received by December 16, 2008, current Maryland permit holders will be permitted to operate under their existing 2008 wholesale distributor permit until the Board's determination is received. Permit holders who submit applications after December 16, 2008, will not be able to continue operating after their permits expire if a determination of approval by the Board has not been rendered.**

- I. TYPE OF BUSINESS** – Indicate the type of ownership (*Individual, Partnership, etc.*) check all that apply and circle application type (*new, renewal, relocation, etc.*).

## **II. APPLICANT INFORMATION:**

**A. Name of Applicant** - Provide the trade name in which the company is doing business. If the applicant wants to retain a permit number previously issued, and the trade name has changed since the last permit was issued, you must submit legal documentation of the name change with this application.

**B.–C. Contact Info** – Indicate the telephone phone and fax numbers listed for contacting the establishment directly. List the business website address, email address and federal tax id number.

**D. Legal Name** - Provide the cooperate name if different from the trade name, include the State where incorporated and date of incorporation.

**E. Parent Company** - List all parent companies that have direct or indirect control over the applicant.

**F. Resident Agent** - Establishments located outside of Maryland shall designate a registered agent in this State for service of process. A Resident Agent may be an attorney or other party legally responsible for representing the company.

- III. APPLICATION FEE:** Applications submitted without the \$1,000.00 application fee will not be processed.

## **IV. FACILITY INFORMATION:**

**A. Facility Address** – Provide the address and other information for the physical location of the establishment. This address will appear on the permit and must be reflected on all sales invoices and shipping documents.

**B. Date of last Inspection** – Provide date of inspection and the state in which the inspection was performed. Indicate if the facility is VAWD certified by placing a check mark in the space provided and attach a copy of the VAWD certificate. List the company DEA and MD CDS #'s and enclose a copy of both permits with the application.

**C. State(s) and permit # where licensed** - List all states and permit numbers in which the facility is permitted to distribute prescription drugs and/or devices.

**D. Facility Ownership Description** – Indicate whether the facility is owned or leased. And answer all related questions. Failure to complete this information may cause a delay in processing your application.

**E. Physical Description** – Provide a physical description of the facility as requested and provide a diagram drawing of the facility. Failure to provide a diagram of the facility may cause a delay in processing your application

**V. OPERATIONS:**

**A. Days Open & Hours of Operation** - Provide hours of operations for each day of the week that the facility operates.

**B. Type of Drug/Devices Distributed & Type Distributor** – Check all that apply under each listed heading.

**C. Personnel** – An owner must initial to legally affirm that the **statement** is true.

**D. Import and export** – If yes is indicated for either question, FDA documentation must be attached with the application.

**Note: For sections VI Through VIII, DO NOT LEAVE ANY INITIAL LINE BLANK.** Indicate “n/a” if documentation or information is not applicable. Initialing will verify an awareness of the applicable documentation required. Blank lines may delay the processing of the application.

**VI. OWNERSHIP INFORMATION:** The owner/applicant for the company must provide initials.

**A. Required Attachments** - Initial to indicate that all applicable documentation is attached with the application.

**B. Surety Bond** - Applicants shall submit with the application, evidence of a surety bond of at least \$100,000, payable to the *Maryland Board of Pharmacy*, **OR** an irrevocable letter of credit. A single surety bond or irrevocable letter of credit shall cover all facilities operated by the applicant in the State of Maryland. Sample letters, with minimally required language, are included with the application.

**C. Liability Insurance** – Check yes that the applicant has submitted the required written evidence that the wholesale distributor has obtained general and product liability insurance. Attach appropriate documentation with the application.

**VII. DESIGNATED REPRESENTATIVE:**

**A. Attestation** – Initial each statement to indicate applicant agreement with each testament.

**B1. Required Attachments** – Please initial and attached requested information if applicable or indicate ‘n/a’

**B2. Additional Information** – For each item, please initial and attach requested information, if applicable or indicate ‘n/a.’

**B3. Criminal Background** - *Submit two complete sets of legible fingerprints taken on forms approved by the Director of Central Repository and the Director of the Federal Bureau of Investigation.* (Note: The Maryland Board of Pharmacy will provide information regarding how to meet federal and state criminal background check requirements as soon as development of procedures is completed. If information is not received from the Board in

order to make a timely submission, please submit the completed application without fingerprints )

*Designated Representative – All information must be provided and signed as indicated by the designated representative.*

**VIII. IMMEDIATE SUPERVISOR OF DESIGNATED REPRESENTATIVE:**

**A. Attestation** – Initial each statement to indicate that you understand and agree to abide by the requirements of an immediate supervisor of a designated representative for a wholesale distributor.

**B1. Required Attachments** – For each item, please initial and attach requested information, if applicable or indicate ‘n/a.’

**B2. Additional Information** – For each item, please initial and attach requested information, if applicable or indicate ‘n/a.’

**B3. Criminal Background - Submit two complete sets of legible fingerprints taken on forms approved by the Director of Central Repository and the Director of the Federal Bureau of Investigation.** (Note: The Maryland Board of Pharmacy will provide information regarding how to meet federal and state criminal background check requirements as soon as development of procedures is completed. If information is not received from the Board in order to make a timely submission, please submit the completed application without fingerprints )

*Immediate Supervisor of the Designated Representative – All information must be provided and signed as indicated by the immediate supervisor of the designated representative.*

**IX. SIGNATURE OF APPLICANT:** *After confirming that all required information is included and attachments provided, the applications must be signed by the legal applicant (owner or designated representative).*

NOTE: Please submit completed, signed application and include a diagram of the facility and all other applicable attachments. Also include the \$1,000 bi-annual fee made payable to: *Maryland Board of Pharmacy.*

Applicants located outside of Maryland must enclose a copy of the most recent inspection report from their home state with the application.

Before returning the completed application to the Board of Pharmacy, it is recommended that a copy of the application and attachments is retained for the applicant’s records.

## **NON RESIDENT APPLICATIONS LIST OF AGENTS IN MARYLAND**

**Baltimore Office:**  
**The Corp Trust Inc.**  
32 South Street  
Bel Air, MD 21014  
410-539-2837

**Corp Assist of Baltimore**  
11 E. Chase Street, Suite 9-E  
Baltimore, MD 21202  
410-539-5370  
Contact: Jim Brincefield

**Harbor City Research, Inc**  
201 N Charles St. suite 900  
410-539-0400  
Contact: Tim Jordan

**Federal Research Corp.**  
400-7<sup>th</sup> Street N.W., Suite 101  
Washington, DC 20004  
Contact: Michele Baldwin or Jim Mott

**Baltimore Office:**  
928 N. Charles Street, Suite 2-B  
Baltimore, MD 21201  
410-659-1455  
Contact: Sandy Keyes

**The Prentice-Hall Corp Sys. Maryland**  
11 E. Chase Street, Suite 7-C  
Baltimore, MD 21202  
410-332-1540  
Contact: Freddie Collins

**HIQ Corporate Services Inc**  
715 St. Paul Street  
Baltimore, MD 21202  
Contact: James Strott

**WHOLESALE DISTRIBUTOR SURETY BOND [SAMPLE]**

Bond No. \_\_\_\_\_

Application/Permit No. \_\_\_\_\_

This Surety Bond is given by \_\_\_\_\_, as Principal, as  
*name of applicant/permit holder*

applicant for a Maryland wholesale distributor permit/permit holder for renewal of a

Maryland wholesale distributor permit, located at \_\_\_\_\_

\_\_\_\_\_  
*address*

and authorized to do business in the State of Maryland, and \_\_\_\_\_,

*name of surety company*

as Surety, located at \_\_\_\_\_

\_\_\_\_\_  
*address*

, a Surety Company incorporated under the laws of the State of \_\_\_\_\_,

*State of incorporation*

and authorized to do business in the State of Maryland, and are held and firmly bound

to the Maryland Board of Pharmacy, for the sum of One Hundred Thousand Dollars

(\$100,000), for which payment binds the applicant/permit holder, their heirs, executors,

administrators, successors and assigns jointly and severally. This bond term shall become

effective on \_\_\_\_\_.

WHEREAS, Health Occupations Article, 12-6C-05(f), Annotated Code of Maryland, requires that the Applicant/Permit Holder file or have on file with the Maryland Board of Pharmacy a bond in the sum of \$100,000 payable to the Pharmacy Board, and this bond is executed and tendered in accordance therewith. The purpose of the bond is to secure payment of any fines or penalties imposed by the Board and any fees and costs incurred by the State of Maryland relating to the permit that are authorized under State law; and are not paid by the permit holder within 30 days after the fines, penalties, fees or costs become final.

NOW THEREFORE, the conditions of the foregoing obligation are that if the Applicant/Permit Holder shall comply with and be subject to the provisions of Health Occupations Article, Subtitle 6C, Annotated Code of Maryland, then this obligation shall be null and void; otherwise it shall remain in full force and effect.

PROVIDED HOWEVER, this bond is subject to the following express conditions:

1. This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Permit Holder may be licensed, until two (2) years after the permit holder's permit ceases to be valid, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
2. This bond is executed by the Applicant/Permit Holder and the Surety to comply with Health Occupations Article, 12-6C-05, Annotated Code of Maryland and shall be subject to all of the terms and provisions thereof.
3. The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
4. The limitations of the liability of the Surety and the conditions of the bond are set forth in Health Occupations Article, 12-6C-05, Annotated Code of Maryland. The Board may make a claim against the bond for any administrative fine imposed on Applicant/Permit Holder by the Board pursuant to Health Occupations Article, Title 12, Annotated Code of Maryland, or for any cost recovery ordered payable by Applicant/Permit Holder pursuant to Health Occupations Article, Title 12, Annotated Code of Maryland, if Applicant/Permit Holder fails to pay to the Board the fine or cost recovery within thirty (30) days of the order imposing the fine or cost recover. Any such claim may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Pharmacy Board.
5. The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the sum of this bond in any event.
6. It is mutually agreed and understood between all parties hereto, that if the Surety shall so elect, this bond may be cancelled and discontinued by giving 60 days notice in writing to the Principal and the Maryland Board of Pharmacy, 4201 Patterson Avenue, Baltimore, MD 21215 by U.S. Registered Mail and this bond shall be deemed cancelled at the expiration of said 60 days from the service of said notice. The Surety remaining liable for all or any part of obligation covered by this bond which may have accrued by default of the Principal prior to the effective date of cancellation.

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I certify under penalty of perjury, under the laws of the State of Maryland, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this \_\_\_\_\_  
Day of \_\_\_\_\_, 20\_\_\_\_.

**PRESCRIPTION DRUG OR  
DEVICE WHOLESALE DISTRIBUTOR**

\_\_\_\_\_  
*Principal's Authorized Representative*

SIGNED and SEALED in the presence of:

\_\_\_\_\_  
*Witness*

\_\_\_\_\_  
*Witness*

**SURETY COMPANY**

\_\_\_\_\_  
*Surety Company's Representative*

\_\_\_\_\_, Attorney-in-Fact  
*Print name*

SIGNED and SEALED in the presence of:

\_\_\_\_\_  
*Witness*

\_\_\_\_\_  
*Witness*

Countersigned by:

\_\_\_\_\_  
*Maryland Resident Agent*

**MARYLAND BOARD OF PHARMACY**  
**4201 Patterson Avenue**  
**Baltimore, Maryland 21215**

**IRREVOCABLE LETTER OF CREDIT**

Name of Financial Institution: \_\_\_\_\_

Address: \_\_\_\_\_

City, State, Zip: \_\_\_\_\_

Name of Applicant/Permit Holder: \_\_\_\_\_

Address: \_\_\_\_\_

City, State, Zip: \_\_\_\_\_

**Irrevocable Letter of Credit No.** \_\_\_\_\_ **Dated:** \_\_\_\_\_

To Beneficiary:

Maryland Board of Pharmacy  
4201 Patterson Avenue  
Baltimore, Maryland 21215  
Attention: Executive Director

1. At the request and on the instructions of \_\_\_\_\_ (Applicant/Permit Holder), we \_\_\_\_\_ (Financial Institution) hereby establish in favor of the Beneficiary, the Maryland Board of Pharmacy (Board), this Irrevocable Letter of Credit (Credit) in the principal sum of \$100,000.
2. This Credit is and has been established for the sole benefit of the Board pursuant to the terms of Health Occupations Article, 12-6C-05(f), Annotated Code of Maryland, pertaining to the initial or renewal application filed by the Applicant/Permit Holder.
3. This Credit is intended by the parties to serve as security device for the performance by the Applicant/Permit Holder of its obligations under Health Occupations Article, Title 12, Annotated Code of Maryland.
4. Upon the occurrence of any fines or penalties imposed by the Board and any fees and costs incurred by the State relating to the wholesale distributor's permit that are authorized under State law; and are not paid by the permit holder within 30 days after the fines, penalties fees, or costs become final, the Board shall be entitled to draw upon this credit.
5. Funds may be drawn in one or more drawings not to exceed the principal sum.

6. All drawings under this Credit shall be paid with our funds. Each drawing honored by us hereunder shall reduce, pro tanto, the principal sum. By paying to the Board an amount demanded in accordance herewith, we make no representations as to the correctness of the amount demanded.

7. This Credit will be cancelled in whole or in part upon receipt by us of a written request, and shall be completed and signed by any person purporting to be an Authorized Representative, as defined in the next paragraph.

8. An "Authorized Representative" shall mean the following person: Executive Director of the Maryland Board of Pharmacy.

9. Communications with respect to this Credit shall be in writing and addressed to us at \_\_\_\_\_ (Address of Financial Institution) specifically referring upon such writing to this Credit by number.

10. This Credit may not be transferred or assigned, either in whole or in part.

11. This Credit shall be deemed a contract made under the laws of the State of Maryland.

12. This Credit shall, if not cancelled as provided herein, expire no later than two (2) years after the permit holder's permit ceases to be valid.

THEREFORE, \_\_\_\_\_ (Financial Institution or Bonding Company) has executed and delivered this IRREVOCABLE LETTER OF CREDIT to the Board as of the \_\_\_\_\_ day of \_\_\_\_\_, 20\_\_.

**STATE OF MARYLAND**  
**DEPARTMENT OF HEALTH & MENTAL HYGIENE**  
**MARYLAND BOARD OF PHARMACY**

4201 PATTERSON AVENUE,  
BALTIMORE, MARYLAND 21215

APPLICATION FOR MARYLAND WHOLESALE PRESCRIPTION DRUG OR  
DEVICE DISTRIBUTOR PERMIT (COMAR 10.34.22)

Tele: 410-764-4756 800-542-4964

Fax: 410-358-6207

Web site: [www.mdbop.org](http://www.mdbop.org)

email: [mdbop@dnhm.state.md.us](mailto:mdbop@dnhm.state.md.us)

# MARYLAND BOARD OF PHARMACY

4201 PATTERSON AVENUE, BALTIMORE, MARYLAND 21215

410-764-4756 800-542-4964 FAX 410-358-6207

Web site: [www.mdbop.org](http://www.mdbop.org) email: [mdbop@dhhm.state.md.us](mailto:mdbop@dhhm.state.md.us)

## APPLICATION FOR MARYLAND WHOLESALE PRESCRIPTION DRUG OR DEVICE DISTRIBUTOR PERMIT (COMAR 10.34.22)

BOARD USE ONLY

Date Received: \_\_\_\_\_ Inspection Date: \_\_\_\_\_ Approval Date: \_\_\_\_\_

Permit Number: \_\_\_\_\_ Inspector Initials: \_\_\_\_\_ Approved By: \_\_\_\_\_

Approval may be delayed if appropriate responses to all questions are not entered. Type or print application in ink.

### I. TYPE OF BUSINESS (check all that apply and provide appropriate documentation):

\_\_\_\_\_ Individual \_\_\_\_\_ Corporation  
\_\_\_\_\_ Sole Proprietorship \_\_\_\_\_ Publicly traded  
\_\_\_\_\_ Partnership \_\_\_\_\_ Limited Liability  
\_\_\_\_\_ Other (describe) \_\_\_\_\_

Application Type (Circle):    New    Renewal    Ownership Assumption    Late Renewal  
Relocation

### II. APPLICANT INFORMATION: COMAR 10.34.22.03

#### A.

\_\_\_\_\_  
Name of Applicant (name in which company is doing business):

Mailing Address (renewal application and other Board correspondence will be sent to this address):

\_\_\_\_\_  
No.                      Street    Suite No.

\_\_\_\_\_  
City    State    Zip Code

#### B.

\_\_\_\_\_  
Area Code & Telephone Number                      Area Code & Fax Number

#### C.

\_\_\_\_\_  
Web Site Address                      Email Address                      Federal Tax Identification No.

D. Legal Name: \_\_\_\_\_ State of Incorp/Date: \_\_\_\_\_ /

\_\_\_\_\_  
(If different from Applicant Name)

E. Parent Company (to include any and all parent companies that have direct or indirect control over the applicant)

F. Resident Agent: (if distributor is located outside of Maryland)

---

**Name** \_\_\_\_\_ **Title** \_\_\_\_\_  
**Mailing Address:**  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
**No.** \_\_\_\_\_ **Street** \_\_\_\_\_ **Suite No.** \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
**City** \_\_\_\_\_ **State** \_\_\_\_\_ **Zip Code** \_\_\_\_\_  
 \_\_\_\_\_  
**Telephone** \_\_\_\_\_ **Fax** \_\_\_\_\_

**III. APPLICATION FEE:** Enclose a check, in the amount of **\$1,000.00**, payable to the "Maryland Board of Pharmacy."

**IV. FACILITY INFORMATION:**

**A. Facility Address** (physical location of establishment which should be reflected on all sales invoices and shipping documents):

---

\_\_\_\_\_  
**No.** \_\_\_\_\_ **Street** \_\_\_\_\_ **Suite No.** \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
**City** \_\_\_\_\_ **State** \_\_\_\_\_ **Zip Code** \_\_\_\_\_  
 \_\_\_\_\_  
**Area Code & Telephone Number** \_\_\_\_\_ **Area Code & Fax Number** \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
**Web Site Address** \_\_\_\_\_ **Email Address** \_\_\_\_\_ **Federal Tax Id No.** \_\_\_\_\_

**B. Date of Last Inspection:** \_\_\_\_\_ **State** \_\_\_\_\_ **VAWD** \_\_\_\_\_ **Cert. Attached** \_\_\_\_\_  
 (Initial)  
**DEA #** \_\_\_\_\_ **Maryland CDS #** \_\_\_\_\_

**C. State(s) and permit # where licensed:**

\_\_\_\_\_ (attach additional pages as required)  
**Maryland Permit #:** \_\_\_\_\_

**D. Facility Ownership Description:**

1. Own? No \_\_\_\_\_ Yes \_\_\_\_\_ Number of years? \_\_\_\_\_
2. Lease? No \_\_\_\_\_ Yes \_\_\_\_\_ Name of Leaser: \_\_\_\_\_ Terms of Lease \_\_\_\_\_



1. Do you import? \_\_\_\_\_

2. Do you export? \_\_\_\_\_

(If yes, attach documentation of FDA approval.)

**VI. OWNERSHIP INFORMATION/REQUIREMENTS**

**A. Required Attachments**

*(initial each that applies and attach with application):*

- \_\_\_\_\_ 1. Full Name(s) and Title of Sole Proprietor, Each Partner or Each Corp. Director and Officer
- \_\_\_\_\_ 2. Full Name of each manager of a limited liability company
- \_\_\_\_\_ 3. Full Name(s) and business address(es) for more than 10% of shareholders for non-publicly traded corporation
- \_\_\_\_\_ 4. Corporate name(s) for non-publicly traded corporation
- \_\_\_\_\_ 5. Date(s) of birth for each listed Individual referenced in this section
- \_\_\_\_\_ 6. Business address(es) for each listed individual referenced in this section
- \_\_\_\_\_ 7. Addresses, telephone numbers and contact persons for the facility used by the applicant for the storage, handling, and distribution of prescription drugs
- \_\_\_\_\_ 8. All trade or business names used by the applicant, which may not be identical to the name used by another unrelated permit holder in Maryland
- \_\_\_\_\_ 9. List of federal and state licenses, registrations or permits (including those issued by a federal authority or other state(s)) that authorizes the wholesale distributor to purchase, possess, and distribute prescription drugs or devices
- \_\_\_\_\_ 10. List of all disciplinary actions by federal or state agencies against the wholesale distributor, as well as any such actions against principals, owners, directors or officers

**B. Surety Bond Attached? Yes\_\_\_\_\_ No\_\_\_\_\_**

*An applicant for a wholesale distributor permit shall submit a surety bond, payable to the Maryland Board of Pharmacy, of at least \$100,000, or other equivalent means of security acceptable to the Board.. (NOTE: A surety bond is not required for a pharmacy warehouse that is not engaged in wholesale distribution. A single surety bond shall cover all facilities operated by the applicant in the State)*

**C. General and Product Liability Insurance Documentation Attached? Yes\_\_\_\_\_ No\_\_\_\_\_**

**VII. DESIGNATED REPRESENTATIVE**

***(TO BE COMPLETED BY DESIGNATED REPRESENTATIVE)***

**A. Attestations by Designated Representative**

**Attestation:** *(initial each statement to indicate your understanding and agreement to abide by the requirements of \_\_\_\_\_ a designated representative for a wholesale distributor):*

- \_\_\_\_\_ Employed full time for at least 3 years in a pharmacy or with a wholesale distributor in a capacity related to the dispensing and distribution of, and record keeping \_\_\_\_\_ related to prescription drugs.
- \_\_\_\_\_ Employed by the applicant full time in a managerial level position.
- \_\_\_\_\_ Actively involved in, and aware of, the daily operation of the wholesale distributor.
- \_\_\_\_\_ Physically present, except for an authorized absence such as sick or vacation leave, at the facility of the applicant during regular business hours.
- \_\_\_\_\_ Serving as a designated representative for only one applicant at a time, or for two or more members of an affiliated group as defined in §1504 of the Internal Revenue Code.
- \_\_\_\_\_ Do not have any convictions for a violation of any federal, state or local laws relating to wholesale or retail prescription drug distribution or distribution of controlled substances.
- \_\_\_\_\_ Do not have any convictions for a felony under federal, State, or local laws.

**B. Required Attachments**

**B1. For the last seven (7) years - initial each line and attach information with application:**

- \_\_\_\_\_ 1. Places of residence;
- \_\_\_\_\_ 2. Names, addresses of each business where employed;
- \_\_\_\_\_ 3. Job titles or offices held at each business;
- \_\_\_\_\_ 4. Description of any involvements or investments with any business(es) that manufactures, administers, prescribes, distributes or stores prescription drugs (other than the ownership of \_\_\_\_\_ stock in a publicly traded company or mutual fund) and any lawsuits in which the business was named a party;
- \_\_\_\_\_ 5. Statement of whether the individuals have been the subjects of any proceeding for the revocation of any professional or business license or any criminal violation and if so, the nature and disposition of the proceeding; and
- \_\_\_\_\_ 6. Statement of whether the individuals have been enjoined, either temporarily or permanently, by a court of competent jurisdiction from violating any federal or state law regulating the possession, control, or distribution of prescription drugs, together with details concerning the event.

**B2. Additional information – initial each line and attach information with application:**

- \_\_\_\_\_ 1. Description of any misdemeanor or felony offense of which the individual, as an adult, was found guilty, regardless of whether adjudication of the guilt was withheld

or whether the individual pled guilty or *nolo contendere* and whether any criminal conviction is under appeal;

\_\_\_\_\_ 2. If a criminal conviction is under appeal at the time of application, a copy of the notice of appeal (a final written order of disposition must be submitted within 15 days after the disposition of the appeal).

**B3. Criminal Background Check – initial each line and attach information with application**

- \_\_\_\_\_ 1. Photographs taken within 180 days previous to submission of application;
- \_\_\_\_\_ 2. Two complete sets of legible fingerprints taken on forms approved by the Director of the Central Repository and the Director of the Federal Bureau of Investigations;
- \_\_\_\_\_ 3. Check, payable to “CJIS – Central Repository”, in the amount of \$37.25 (authorized under the Criminal Procedure Article, §10-221(b)(7), Annotated Code of Maryland, for access to State criminal history records; and the processing fee required by the Federal Bureau of Investigations for a national criminal history records check).

**SIGNATURE: Designated Representative**

By signing this application, I solemnly affirm under the penalties of perjury that the contents of this section (Section VII) of the application are true to the best of my knowledge, information, and belief. I further certify that I am aware of and will meet the requirements of a Designated Representative under the Maryland Pharmacy Act and Maryland Board of Pharmacy regulations pertaining to Wholesale Distribution Permitting. I understand that in the Maryland wholesale distributor permit issued pursuant to this application may be revoked if any assertion made in this application is found to be false.

<i>Name - Typed</i> <i>older)</i>	<i>Date of birth and place of birth (Must be 21 y/o or</i>
<i>Telephone</i>	<i>Fax</i>
<i>Signature</i>	<i>Date</i>

**VIII. IMMEDIATE SUPERVISOR OF DESIGNATED REPRESENTATIVE  
(TO BE COMPLETED BY IMMEDIATE SUPERVISOR OF DESIGNATED REPRESENTATIVE)**

**A. Attestations by Immediate Supervisor of Designated Representative**

**Attestation:** *(initial each statement to indicate your understanding and agreement to abide by the requirements of an immediate supervisor of the designated representative for a wholesale distributor):*

\_\_\_\_\_ Employed full time for at least 3 years in a pharmacy or with a wholesale

- \_\_\_\_\_ distributor in a capacity related to the dispensing and distribution of, and record keeping related to prescription drugs.
- \_\_\_\_\_ Employed by the applicant full time in a managerial level position.
- \_\_\_\_\_ Actively involved in, and aware of, the daily operation of the wholesale distributor.
- \_\_\_\_\_ Do not have any convictions for a violation of any federal, state or local laws relating to wholesale or retail prescription drug distribution or distribution of controlled substances.
- \_\_\_\_\_ Do not have any convictions for a felony under federal, State, or local laws.

**B. Required Attachments**

**B1. For the last seven (7) years - initial each line and attach information with application:**

- \_\_\_\_\_ 1. Places of residence;
- \_\_\_\_\_ 2. Names, addresses of each business where employed;
- \_\_\_\_\_ 3. Job titles or offices held at each business;
- \_\_\_\_\_ 4. Description of any involvements or investments with any business(es) that manufactures, administers, prescribes, distributes or stores prescription drugs (other than the ownership of stock in a publicly traded company or mutual fund) and any lawsuits in which the business was named a party;
- \_\_\_\_\_ 5. Statement of whether the individuals have been the subjects of any proceeding for the revocation of any professional or business license or any criminal violation and if so, the nature and disposition of the proceeding; and
- \_\_\_\_\_ 6. Statement of whether the individuals have been enjoined, either temporarily or permanently, by a court of competent jurisdiction from violating any federal or state law regulating the possession, control, or distribution of prescription drugs, together with details concerning the event.

**B2. Additional information – initial each line and attach information with application:**

- \_\_\_\_\_ 1. Description of any misdemeanor or felony offense of which the individual, as an adult, was found guilty, regardless of whether adjudication of the guilt was withheld or whether the individual pled guilty or nolo contendere and whether any criminal conviction is under appeal;
- \_\_\_\_\_ 2. If a criminal conviction is under appeal at the time of application, a copy of the notice of appeal (a final written order of disposition must be submitted within 15 days after the disposition of the appeal).

**B3. Criminal Background Check – initial each line and attach information with application**

- \_\_\_\_\_ 1. Photographs taken within 180 days previous to submission of application;
- \_\_\_\_\_ 2. Two complete sets of legible fingerprints taken on forms approved by the Director of the Central Repository and the Director of the Federal Bureau of Investigations;
- \_\_\_\_\_ 3. Check, payable to “CJIS – Central Repository”, in the amount of \$37.25

(authorized under the Criminal Procedure Article, §10-221(b) (7), Annotated Code of Maryland, for access to State criminal history records; and the processing fee required by the Federal Bureau of Investigations for a national criminal history records check).

**Signature: Immediate Supervisor of the Designated Representative**

By signing this application, I solemnly affirm under the penalties of perjury that the contents of this section (Section VIII) of the application are true to the best of my knowledge, information, and belief. I further certify that I am aware of and will meet the requirements for an Immediate Supervisor of a Designated Representative under the Maryland Pharmacy Act and Maryland Board of Pharmacy regulations pertaining to Wholesale Distribution Permitting. I understand that in the Maryland wholesale distributor permit issued pursuant to this application may be revoked if any assertion made in this application is found to be false.

<i>Name- Typed</i>	<i>Date of birth and place of birth (Must be 21 y/o or older)</i>
<i>Phone</i>	<i>Fax</i>
<i>Signature</i>	<i>Date</i>

**IX. SIGNATURE OF APPLICANT:** By signing this application, I solemnly affirm under the penalties of perjury that the contents of this application are true to the best of my knowledge, information, and belief. I further certify that I am aware of and will meet the requirements of the Maryland Pharmacy Act and Maryland Board of Pharmacy regulations pertaining to Wholesale Distribution Permitting. I understand that in a Maryland wholesale distributor permit may be revoked if any assertion made in this application is found to be false.

_____ Signature of Applicant	_____ Business Telephone Number	_____ Business Fax Number
_____ Typed Name and Title		

APPENDIX III

**STATE OF MARYLAND**  
**DEPARTMENT OF HEALTH & MENTAL HYGIENE**  
**MARYLAND BOARD OF PHARMACY**  
4201 PATTERSON AVENUE,  
BALTIMORE, MARYLAND 21215

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APPLICATION FOR MARYLAND WHOLESALE PRESCRIPTION DRUG OR  
DEVICE DISTRIBUTOR PERMIT (Health Occupations Article, §12-  
6C-03 -Annotated Code of Maryland )

**FOR MANUFACTURERS THAT DISTRIBUTE OWN PRODUCTS**  
**ONLY**

# MARYLAND BOARD OF PHARMACY

4201 PATTERSON AVENUE, BALTIMORE, MARYLAND 21215

410-764-4755 800-542-4964 FAX 410-358-6207

Web site: [www.mdbop.org](http://www.mdbop.org) email: [mdbop@dhhm.state.md.us](mailto:mdbop@dhhm.state.md.us)

## APPLICATION FOR MARYLAND WHOLESALE PRESCRIPTION DRUG OR DEVICE DISTRIBUTOR PERMIT (§ 12-6C-03)

### FOR MANUFACTURERS DISTRIBUTING THEIR OWN PRODUCTS DIRECTLY INTO MARYLAND

NOTE: Approval may be delayed if complete responses to all questions are not entered. Type or print application in ink.

#### I. TYPE OF BUSINESS/OWNERSHIP (check all that apply and provide appropriate documentation):

\_\_\_\_\_ Distributor of own prescription products \_\_\_\_\_ Repacker \_\_\_\_\_ Relabeler

\_\_\_\_\_ Sole Proprietorship \_\_\_\_\_ Partnership \_\_\_\_\_ Coop. Assn. \_\_\_\_\_ Corporation

\_\_\_\_\_ Other (describe) \_\_\_\_\_

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|                            |     |         |                      |              |
|----------------------------|-----|---------|----------------------|--------------|
| Application Type (Circle): | New | Renewal | Ownership Assumption | Late Renewal |
| Relocation                 |     |         |                      |              |

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#### II. APPLICANT INFORMATION: Health Occupations – Article, §12-6C-03 Annotated Code of MD

A. \_\_\_\_\_

\_\_\_\_\_  
*Name of Manufacturer (name in which firm is doing business):*      *State of Incorporation*

Site Address:

\_\_\_\_\_

\_\_\_\_\_  
*No.*      *Street*      *Suite No.*

\_\_\_\_\_  
*City*      *State*      *Zip Code*

B. (\_\_\_\_\_) \_\_\_\_\_

(\_\_\_\_\_) \_\_\_\_\_

*Site Telephone Number*

*Site Fax Number*

C. \_\_\_\_\_

\_\_\_\_\_  
*Site Internet Address*

*Email Address*

*Federal Tax Identification*

*No.*

D. Legal Name: \_\_\_\_\_

*(If different from Name of Manufacturer)*

E. \_\_\_\_\_

*Parent Company Name (to include any and all parent companies that have direct or indirect control over the applicant)*

F. Name of person submitting data and telephone

---

*Name*

*Title*

**G. Site Mailing Address** (if different from site address Board correspondence will be sent to this address :

---

*No.*

*Street*

---

*Suite No.*

---

*City*

---

*State*

---

*Zip Code*

---

*Telephone*

---

*Fax*

**III. SIGNATURE OF AUTHORIZING OFFICIAL:** By signing this application, I solemnly affirm under the penalties of perjury that the manufacturer manufactures and distributes its own products only. I further certify that the contents of this application are true to the best of my knowledge, information, and belief and that I am aware of and will meet the requirements of the Maryland Pharmacy Act and Maryland Board of Pharmacy regulations pertaining to Wholesale Distribution Permitting. I understand that in a Maryland wholesale distributor permit may be revoked if any assertion made in this application is found to be false.

---

*Signature of Authorizing Official*

*Date*

---

*Typed Name and Title*

**Required Attachments (please initial each):**

1. \_\_\_\_\_ A completed application form provided by the Maryland Board of Pharmacy;
2. \_\_\_\_\_ Documentation of FDA registration as an establishment approved to distribute the list of prescription drugs or an approved FDA Site Registration Form(s) 2656;
3. \_\_\_\_\_ The Name(s) Title(s) and Position(s) all of Owners, Partners and Officers;  
and
4. \_\_\_\_\_ An application fee in the amount of \$1,000.00 (payable to the Maryland Board of Pharmacy).

*BOARD USE ONLY*

---

**Date Received:** \_\_\_\_\_ **Inspection Date:** \_\_\_\_\_ **Approval Date:** \_\_\_\_\_

**Permit Number:** \_\_\_\_\_ **Inspector Initials:** \_\_\_\_\_ **Approved By:** \_\_\_\_\_

## APPENDIX IV

### Wholesale Distributor Permitting and Prescription Drug Integrity Act Frequently Asked Questions

#### **GENERAL INFORMATION**

**Q. Can I apply for a wholesale distributor permit electronically (on-line) as I have done in the past?**

A. No. All renewing and new wholesale distributors will need to submit Hardcopy applications this year.

**Q. What is the fee to apply for a Maryland Wholesale Distributor Permit?**

A. \$1,000.00. The new law changed the renewal period from annually to biennial. Thus, the application is increased from \$500.00 annually to \$1,000.00 biennially.

**Q. When does the current Maryland Wholesale Distributor Permit expire?**

A. December 31, 2008. Currently licensed distributors will not be able to operate in Maryland after December 31, 2008 without a new permit issued for the 2009/2010 period. However, the Board may allow an applicant to continue operating under their 2008 permit, if a complete application for a new 2009/2010 permit has been submitted to the Board post marked no later than December 16, 2009 and the Board has not rendered a determination by December 31, 2008.

**Q. Will the Board of Pharmacy send out a receipt after an application is received?**

A. No, the canceled bank check will serve as the receipt for the application and payment.

#### **WHO NEEDS A PERMIT**

**Q. Who is required to apply for a permit as a Maryland wholesale distributor?**

A. Any person, including any business entity that meets the definition for a Wholesale Distributor as defined in HO, 12-6C-O1(v), Annotated Code of Maryland, that does business in Maryland is required to apply for a permit to operate as a wholesale Distributor in Maryland, using an application provided by the Maryland Board of Pharmacy.

**Q. Does a manufacturer need to apply for a permit under these rules?**

A. Yes. A manufacturers that distributes products in addition to its own products needs to apply for a Maryland distributor permit under HO, 12-6C-O3, Annotated Code of Maryland using an application form provided by the Maryland Board of Pharmacy.

**Q. Is a FDA-approved manufacturer who distributes its own drugs and devices required to maintain a wholesale distributor license to distribute its product in the State of Maryland?**

A. Yes. Manufacturers that are engaged in wholesale distribution of their own prescription drugs approved by the U.S. Food and Drug Administration are not exempted and must hold a permit issued by the Board if they are distributing directly into Maryland. However, manufacturers that meet this criterion will not be required to meet all of the criteria set forth for other types of distributors and will need only to demonstrate to the Board that they have met federal requirements by submitting to the Board:

1)A completed condensed application form provided by the Maryland Board of Pharmacy;

- 2) Documentation of FDA registration as an establishment approved to distribute the list of prescription drugs or a FDA Site Registration Form(s) 2656;
- 3) The Name(s) Title(s) and Position(s) all of Owners, Partners and Officers; and
- 4) An application fee in the amount of \$1,000.00 (*payable to the Maryland Board of Pharmacy*).

### **WHO NEEDS A PERMIT**

**Q. Does an out-of-state manufacturer who distributes to an out-of-state third party logistics provider need to obtain a Maryland distributor permit?**

A. No. An out of state manufacturer who distributes to an out of state third party logistics provider does not need to be licensed in Maryland.

**Q. Are Oxygen suppliers to surgery centers, hospitals and physician's offices required to obtain a distributor permit?**

A. Yes.

**Q. Will an entity that “directs or controls” the distribution of prescription medications in Maryland be required to hold a Maryland Distributor permit?**

A. Yes. An entity must be licensed as a wholesale distributor in Maryland if it "directs or controls" the distribution of prescription medications in Maryland, even if it does not take actual physical possession of the prescription medications. (See Health Occupations Article, 12-6C-01(g) and (v), Annotated Code of Maryland, which lists entities required to be licensed in Maryland.)

**Q. My out of state wholesale distributor company has a Call Center located in Maryland to which we ship. In the past the Call Center was licensed as a Maryland Distributor, but my out-of-state company was not. Will both of our facilities be required to obtain individual distributor permits under the new law?**

A. Submit an application for each facility. If the out of state company arranges the sales or drop shipments to the Call Center which serves as its distributor, then both facilities will require a permit. If the information contained in the Call Center’s application indicates that it is not a distributor, but a customer service center instead, then the Board would likely determine that the Call Center located in Maryland does not require a permit.

**Q. Are distributors and manufacturers of non-prescription medical devices and/or of over-the-counter drugs and cosmetics used by health care professionals for institutional purposes, required to obtain a distributor permit?**

A. No. A wholesale distributor is defined as a person that is engaged in the wholesale distribution of prescription drugs or prescription devices. See Health Occupations Article, 12-6C-01 and 12-6C-03, Annotated Code of Maryland.

## **SURETY BONDS**

### **Q. Why is a surety bond or an irrevocable letter of credit required from distributors?**

A. The purpose of the surety bond is to secure payment of any fines or penalties imposed by the Board and any fees and costs incurred by the State relating to the permit that:

- (i) Are authorized under State law; and
- (ii) Are not paid by the permit holder within 30 days after the fines, penalties, fees, or costs become final. (HO §12-6C-05(f), Annotated Code of Maryland). The State may make a claim against the surety bond or other security until 2 years after the permit holder's permit ceases to be valid.

### **Q. What amount does Maryland require a surety bond or irrevocable letter of credit to be?**

A. Wholesalers must provide evidence that they have obtained a bond or irrevocable letter of credit for at least \$100,000.00. The applicant may NOT submit a surety bond issued for another state.

### **Q. When should the bond requirement be made effective?**

A. The bond should be made effective January 1, 2009 through December 31, 2010 (or the period that the permit is effective).

### **Q. How should I obtain a surety bond?**

A. For information about what is required to obtain a surety bond or other equivalent, please contact your insurance carrier or financial institution. The Board's Distributor application contains sample language for use with a surety bond or irrevocable letter of credit.

## **SURETY BONDS**

### **Q. Is a distributor required to acquire more than one surety bond if it has several facilities?**

A. Only one surety bond is required for multiple facilities if they are located in Maryland. However, individual surety bonds must also be acquired for each facility that is located outside of Maryland.

### **Q. If a distributor has more than one facility in Maryland, which permit number should be placed on the surety bond?**

A. All of the permit numbers for all of facilities located in Maryland should be placed on one surety bond. Then, a copy of that surety bond must be attached to each distributor application.

## **INSPECTIONS & ACCREDITATION PROGRAMS**

### **Q. What accreditation programs will be accepted by the Maryland Board of Pharmacy?**

A. NABP's Verified Accredited Wholesale Distributor (VAWD) inspection process is currently the only approved accreditation program that the Board accepts. The Board may recognize other accredited programs and inspection services; however, documentation must be submitted for full Board consideration and possible approval.

**Q. Will the Board accept my resident state Board of Pharmacy’s inspection process in lieu of VAWD or an additional accreditation program?**

A. The Board is currently reviewing the registration and inspection procedures of other states and will post a list of accepted state inspections on its website. If a distributor has been inspected within the past two years by a state that is posted on the list or accredited by VAWD within the last three years, an inspection is not required as part of the application process. If the applicant feels that a recent inspection performed on the facility may meet Maryland’s inspection standards (even if the entity that performed the inspection is not on the Board of Pharmacy website posted list), please submit a copy of the approved inspection with the application for Board consideration.

**PEDIGREES, DESIGNATED REPRESENTATIVES, ETC.**

**Q. Can an individual be a Designated Representative for more than one facility?**

A. Yes. If two or more wholesale distributors are located in the same facility, and are members of an affiliated group, as defined in §1504 of the Internal Revenue Code – COMAR 10.34.22.03D(3), they may name the same individual as their Designated Representative.

**Q. My company has one supervisor of three designated representatives that work at three separate facilities. Can the supervisor submit one card with the set of fingerprints?**

A. Yes. For each application submitted, indicate that the designated representatives are under the same supervisor and after the supervisor receives the results of the criminal background report, a copy must be submitted to the Board along with a cover letter that indicates the names of the each designated representative supervised and the permit number for each facility where each designated representative works.

**Q. Are applicants required to provide a copy of their lease agreements?**

A. No. An explanation of the basic terms of the lease, including the lessor name, start dates and expiration dates should be provided.

**Q. Can a designated representative or supervisor of a designated representative submit a resume that includes all of the required information?**

A. Yes.

**Q. Who is responsible for initiating a pedigree?**

A. The wholesaler who first distributes a drug outside of the “Normal Chain of Distribution” is responsible for initiating the pedigree. Wholesalers also need to follow FDA rules concerning pedigrees. (See [http://www.fda.gov/cder/regulatory/PDMA/pdma\\_addendum.pdf](http://www.fda.gov/cder/regulatory/PDMA/pdma_addendum.pdf))

**Wholesale Distributor SB 759  
Workgroup**

**Recommendations to the Maryland  
Board of Pharmacy  
For Implementation of Electronic  
Track and Trace Pedigree Technology  
across the Entire Prescription  
Pharmaceutical Supply Chain**

**November 12, 2008**

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## **Attending Members of the Wholesale Distributor SB 759 Workgroup<sup>1</sup>**

### **Board of Pharmacy Chairs**

David Chason, Co-Chair  
Donald W. Taylor, Co-Chair

### **Workgroup Participants**

#### **Abbott**

Jennifer H. Palmer

#### **Alexander & Cleaver**

Ashlie Bagwell  
Lorenzo M. Bellamy

#### **Amgen**

Deron Johnson

#### **Apotex Corp**

Colin Chiles

#### **Barr Pharmaceuticals**

Vivion Maisenbacker

#### **Cardinal Health**

Nate Filler  
Martha Russell

#### **CVS Caremark**

Tracy L. Baroni Allmon  
Ramesh Murthy

#### **GPhA**

#### **(Generic Pharmaceutical Association)**

Shawn Brown

#### **GlaxoSmithKline**

Jan L. Burrus  
Tim Kvanvig

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<sup>1</sup> Additional members obtained information from the web-based Wholesale Distributor SB 759 Workgroup Google Group.

**HDMA**  
**(Healthcare Distribution Management Association)**

Dan Bellingham  
John Howells  
Heather Morris

**Johnson & Johnson**

Jim Cannon  
Michael Rose  
Thomas J. Warren

**MPhA**  
**(Maryland Pharmacists Association)**

Howard Schiff, P.D.

**McKesson Pharmaceutical**

Pamela J. Burch

**MedImmune**

Nancy A. Bukar

**Medstar**

Matt McBride

**NACDS**  
**(National Association of Chain Drug Stores)**

Stanton Ades  
Diane Darvey  
Gil Genn

**PhRMA**  
**(Pharmaceutical Research and Manufacturers of America)**

Andrew Corsig  
Clem Cypra  
Julia Pitcher  
J. William Pitcher  
Tara Ryan

**Pfizer**

Michael Wolf

**Rite-Aid**

Hannah Powers

**Schering-Plough Corporation**

Gary L. Riddle

**TAP Pharmaceuticals, Inc.**

Nicole L. Palya

Stacey Poole

**University of Maryland**

Steve Hoag

**Venable, LLP**

Angel Lavin

**Board of Pharmacy Staff**

LaVerne G. Naesea, Executive Director

Anna D. Jeffers, Legislation and Regulations Manager

Dorcas Ann Taylor, Compliance Officer

## Executive Summary

SB 759, Wholesale Distribution Permitting and Prescription Drug Integrity Act required the Maryland Board of Pharmacy (the “Board”) to convene a Workgroup to:

- (1) Survey the availability of electronic track and trace pedigree technology across the entire prescription pharmaceutical supply chain;
- (2) Determine when electronic track and trace pedigree technology will be universally available across the entire prescription pharmaceutical supply chain; and
- (3) Based on its determination of the universal availability of electronic track and trace pedigree technology, make recommendations to the Board for a target date, no sooner than July 1, 2010, for implementation of electronic track and trace pedigree technology across the entire prescription pharmaceutical supply chain.

To address the requirements of SB 759, the Workgroup received briefings from industry experts about electronic track and trace technology and the status of implementation within the industry. Some members of the Workgroup and Board and staff members also attended an RFID/Track & Trace Health Care Industry Adoption Summit. The Workgroup then developed survey questions concerning the availability of electronic track and trace pedigree technology across the entire prescription pharmaceutical supply chain. The Workgroup staff then distributed the survey in the summer of 2008 through the website *Survey Monkey*. The Workgroup analyzed the results of the survey and formulated recommendations to the Board.

Noting several benchmarks that should occur before realistic implementation of electronic track and trace technology in Maryland, the Workgroup determined that electronic track and trace pedigree technology will not be universally available across the entire prescription pharmaceutical supply chain until after it is required by federal pedigree laws or regulations. Based on that information, but unable to reach consensus, the Workgroup submitted the following recommendations to the Board regarding a target date for the implementation of electronic track and trace technology across the entire pharmaceutical supply chain:

The target dates should not be set at this time due to the significant technological and financial challenges in upgrading the current supply chain system. Because a uniform electronic track and trace system should be implemented on a national scale, the U.S. Food and Drug Administration (FDA) should be recognized as the appropriate authority on this issue. A joint statement with this recommendation by HDMA, PhRMA, NCPA, BIO and HIDA is attached as Appendix I.

NACDS and Cardinal Health recommend that the target dates in Maryland should be one year later than the target dates set forth in the California Senate Bill 1307. Specifically, the first target implementation date for manufacturers should be January 1, 2016; subsequent Federal pedigree laws or regulations should preempt

these recommendations; and no further legislation should be introduced or further regulations should be promulgated establishing earlier target dates than the Workgroup's recommendation.

### **Information Gathering**

Beginning at the September 10, 2007 Workgroup meeting, the Workgroup discussed how to approach the survey. Recognizing the need to educate the Workgroup participants concerning electronic track and trace technology, the Workgroup invited experts in the field to make presentations at the September, November and December 2007 meetings. The purpose of the presentations was to enable the Workgroup to formulate valid survey questions.

**John Howells**, Director, Industry Relations at the Healthcare Distribution Management Association (HDMA), described electronic product code (EPC) and radio frequency identification (RFID) at the September 10, 2007 Workgroup meeting. RFID uses radio waves to identify items. An EPC system contains unique identifiers that allow identification of numerous items at the same time. In summary, there are some major aspects that remain to be completed before there can be industry wide adoption of electronic track and trace technology that include: 1) developing uniform standards; 2) uniform implementation of track and trace technology across states; 3) data sharing, ownership; 4) frequency, as in radio frequency; 5) incorporating new technology; 6) developing tag numbering schemes; 7) insuring privacy; and 8) agreed upon industry roll out plan. It will be a challenge to only track products outside the normal distribution channel because different states require different tracking. Eventually the industry will need to track all products. HDMA is currently in the process of implementing standards which may be finalized by the end of 2009. However, industry adoption of those standards by others in the industry will be a longer process. The presentation was detailed in the Board's Wholesale Distributor Permitting and Distribution Integrity Act 2008 Annual Report to the Governor and General Assembly.

**Michael P. Rose**, Vice President, RFID/EPC Global Value Chain, Johnson & Johnson, presented a Power Point Presentation entitled, "Securing the Pharmaceutical Supply Chain SB 759 Workgroup." Mr. Rose indicated that his company maintains that RFID can improve supply chain efficiency, visibility and enhance brand protection, but that important considerations for industry adoption of RFID include consumer notice; conformance to consumer privacy and security concerns; clearly developed industry standards to ensure interoperability across trading partners; and interoperability of product identified across bar codes and RFID. Considerable learning and piloting must take place before RFID can be widely adopted. Bar codes (2D data matrix and linear) are practical solutions that can be adopted now.

Johnson & Johnson supports the use of pedigrees as a means of protecting the drug supply and believes that pedigrees do help secure the supply chain, however; manufacturer shipping records should be considered ample documentation to relieve the

manufacturer from further pedigree obligations. Securing the supply chain requires industry wide coordination among manufacturers, wholesalers, institutions and pharmacies. It is estimated it could take 40 to 46 weeks from the fall of 2007 to complete standards development and implementation. Other steps after standards development and implementation, however; must occur before industry adoption such as:

- Software & manufacturers must build standards into their solutions
- Solutions must be certified
- Each company has to develop their own project plans and appropriate necessary funding and resources.
- Each company has to execute their own project plans to implement e-Pedigree and Serialized susceptible products
- Connectivity and interoperability must be established between trading parties

The presentation was concluded with Johnson & Johnson's recommendations for securing the pharmaceutical supply chain. Those recommendations are to:

- Endorse the intention to protect patients from counterfeit products
- Support a single federal standard to regulate pharmaceutical supply chain security
- Support risk-based serialization in conjunction with mandatory pedigree and track and trace by all downstream parties for products susceptible for counterfeiting
- Develop criteria for a national list of susceptible prescription drugs
- Support the use of anti-counterfeiting covert and overt features on the packaging of susceptible prescription drugs
- Establish interim milestones for serialization, pedigree, and track and trace of susceptible prescription drugs
- Allow companies to select the data carrier most appropriate for the product, e.g., 2D data matrix for biologics.

During the question and answer session that followed it was asked if one system could track both track & trace and pedigrees. Mr. Rose indicated that it is possible that track & trace can include pedigree information, but it may not be possible in the immediate future and it would be difficult to predict when both of those standards would be ready. Most companies will be left with a mix of data carriers because one data carrier will not work for all products. There will be a mix of bar coding, 2D data matrix and RFID. Many companies are recommending 2D data matrix. The biggest challenge is RFID because at this time different frequencies are being used – HF and UHF. The Power Point presentation will be included as Appendix II.

**Ramesh Murthy**, Vice President, Inventory Replenishment, CVS Caremark, presented a Power Point presentation entitled, “Maryland Board of Pharmacy SB 759 Workgroup Update” at the December 10, 2007 meeting. The presentation described CVS Caremark's (CVS) industry readiness, standards, and approach to electronic pedigrees. The presentation included definitions, actions to date, CVS experience, challenges, and CVS commitment to securing the supply chain. For educational purposes the definitions from his presentation, which are basically agreed upon in the industry, are below:

*Drug Pedigree* - A record of each distribution of a prescription drug from the sale by a Manufacturer through acquisition and sale by any Wholesale Distributor, until final sale to a Pharmacy or other authorized person administering or dispensing the Prescription Drug. It can be paper or electronic.

*Trace* – The capability to identify the historical locations, the records of ownership, and the packaging hierarchy for a particular traceable item. “Trace” answers questions such as, where has the item been, who has previously owned the item, and in what packaging hierarchy did the product exist at various locations.

*Track* – Track increases technology significantly and provides the capability to identify the current (and at time of shipment the intended future) location, ownership, and packaging hierarchy of a traceable item through the supply chain as it moves between parties. Track also addresses both forward- and reverse-logistics operations and answers questions such as where is the item currently, who is the next intended recipient, and what is the current packaging hierarchy of this item.

Mr. Murthy described the actions that CVS had taken to-date in order to secure the pharmaceutical supply chain. CVS only buys directly from the manufacturer or their authorized wholesaler. They do not trade or deal in other markets. Their focus is on detecting counterfeit product so that counterfeit products do not get into their supply chain. They have also worked with state and federal regulatory agencies to address this issue. CVS’s experience with technology and serialization is not fully developed. 2-D barcode has space for a huge numbering scheme, but requires line of sight and adds significant labor costs. RFID is strongly suited to the goal of serialization at the item level, however; it is a non-line-of-sight technology and has the highest start up costs. It is not suitable for biologics and the FDA will not support RFID in biologics at this time. Some companies are choosing different paths by using both 2-D and RFID. CVS plans to prepare to use both. Serialization standards are still in progress and may not be determined until 2008 or 2009. Passing the information is the main problem and creates major infrastructure needs. There will be potentially different approaches by trading partners.

CVS has noted that industry pilots continue to raise more questions. There is technology available in the gambling industry where an RFID chip is inserted within individual gambling chips and can be read even when the chips are stacked. The different approaches, different tagging methods, and various solutions may be difficult to implement in the complex pharmaceutical industry on a large scale. Consideration has to be given to the scope of trading partners and the number of sites that have to deploy the solution. They cannot be proscriptive. Some manufacturers are going with barcode and others are going with RFID.

The major consideration going forward is patient safety. CVS then has to consider how the solutions can maximize the initial investment. Not all products are susceptible to counterfeiting, yet they still have to make the investment for all products, regardless of

risk. In California every item needs to be checked for pedigree. CVS does not want cases opened to scan barcodes on items because it would be difficult to determine whether anyone had tampered with or taken the items. In theory RFID technology would eliminate the need to open the cases because it could scan the items within the case with radio frequencies. Again, RFID is not appropriate for biologics. CVS supports cross industry efforts. They would like to see consistency from state to state with standards set through federal regulations. The Murthy presentation is included as Appendix III.

### **Survey Development**

Beginning at the November 2007 meeting through the April 2008 meeting the Workgroup discussed and developed the questions to be included in the survey. The Board staff researched the existing studies and reports completed by other states. Indiana's response to a required study consisted of the Indiana Board of Pharmacy issuing a letter to their legislature stating that the Board and stakeholders "felt that RFID (radio frequency identification tags) or track and trace technology was still in its infancy and could not meet the demands of a mandatory implementation across the entire supply chain." Research in the states of Oregon, Vermont and Kansas also indicated that no actual studies or surveys were completed.

At the December 2007 meeting the Workgroup discussed the mechanics of the survey. The focus of the discussion was to keep the approach of the survey positive and to concentrate on what permit holders have in place currently and the possible challenges to utilizing electronic track and trace pedigree technology. In January 2008, the Workgroup began drafting survey questions based on discussions and submissions by Dan Bellingham, HDMA, Nancy Bukar, MedImmune and Diane Darvey, NACDS. By the April 2008 meeting the Workgroup began reviewing the draft survey. The Workgroup included a cover letter with the survey that explained the purpose of the survey, provided definitions, and noted that pedigrees under Maryland law are only required for prescription drugs that fall outside of the "normal distribution channel." The cover letter also requested that the survey be completed by all pharmacy and wholesale distributor Maryland permit holder locations, even if part of a chain drug store. A copy of the cover letter is attached as Appendix IV.

The survey was divided into three categories: Current Operations, Current Track and Trace Technology Users, and Planning for Track and Trace Technology. The Workgroup discussed and revised the questions in great detail arriving at 21 key questions for the final survey. The survey is attached to this report as Appendix V.

### **Survey Administration**

Prior to administering the survey, the Board sent a mailing to all Maryland and out-of-state licensed Wholesale Distributor and Pharmacy permit holders in June 2008 to request new or updated email addresses. This mailing went to 1610 pharmacies and 937 wholesale distributors. Email addresses were collected and added to the Board's database during June and July. The survey was conducted through the *Survey Monkey* website

which utilized a Board provided email address database to distribute surveys. This website was chosen because of its efficiency in conducting surveys electronically and because of the low economic impact to the Board.

The survey was distributed through *Survey Monkey* on July 15, 2008 and again on July 25, 2008. It was distributed on two separate dates because a number of emails were returned to the Board after the first distribution. Board staff contacted those permit holders by phone and verified their emails to obtain as many valid email addresses as possible. The survey distribution on July 25, 2008 was sent to the corrected email addresses. In total the survey was distributed to 550 permit holders, of which 13 were chain drug stores (representing 742 stores).

The total number of surveys returned to *Survey Monkey* was 127. Four additional surveys were returned directly to the Board by FAX or email. Those surveys were completed by Cardinal Health, Purdue Pharma, Amylin and Merck. The survey results are attached as Appendix VI.

### **Survey Analysis**

The September 2008 Workgroup meeting was devoted to a discussion of the results of the survey. The results reflected obstacles to implementing uniquely identified unit-level products because of cost, time, technology, lack of uniform standards, lack of computer technology, and availability of hardware/software throughout the supply chain. Most survey respondents were unsure what technology they were using, or planning to use, for data interchange with their trading partners.

The survey reflected the following key findings:

- Relatively few respondents currently track any prescription pharmaceutical products (8 out of 112 who answered the question) through electronic means.
- Relatively few respondents indicated that they were equipped, or planning to supply down stream partners, with equipment and/or software for electronic track and trace technology. Seventy five out of 112 who responded, are not so equipped.
- 25 out of 108 respondents indicated that they use linear barcodes to identify product at the unit level.
- 35 of the responses indicated they use no unique identifier system at the unit level and the numbers were similar for identifying product at the case level.
- Very few individual products are currently being identified.
- A majority of respondents indicated that few permit holders have the capability to make pedigree information available to customers on the internet.
- Respondents who current use some type of track and trace technology seemed evenly divided concerning which approach they support in implementing track and trace technology: phase in by product or only products outside the normal distribution channel. A larger group simply was not sure.

- Nineteen out of 54 permit holders indicated that 2012 was their timeline for completing investment in a system and infrastructure to implement an electronic track and trace system. (73 permit holders did not answer the timeline question.)
- Potential pilots appear to be planned in 2009 with the remainder planned for 2010 – 2012. (Not all permit holders answered this question, 83 out of 127.)

In addition, very few respondents answered a question about the frequency used, if they use RFID. Many respondents had no idea of which entities that they do business with, are currently using RFID. Many respondents were not sure how they would make electronic track and trace data available.

The Workgroup assessed, based on the survey, when electronic track and trace pedigree technology will be universally available across the entire prescription pharmaceutical supply chain in Maryland. It was noted that the enacted California Legislation, Senate Bill 1307, delays the implementation of electronic track and trace technology in California until 2015, with a phase-in through 2017. A copy of Senate Bill 1307 is attached as Appendix VII. The bill includes specific language on preemption by subsequently enacted federal pedigree laws or regulations. Kentucky and Wyoming were also states noted to have included federal preemption language in their statutes, without setting a definite date for the requirement of electronic track and trace pedigree technology.

Keeping in mind the results of the survey, the recently passed California legislation, and the fact that existing Maryland law already requires many restrictions for safety in the new applications and renewals that begin December 1, 2008, the Workgroup was reluctant to recommend a date for Maryland’s implementation of electronic track and trace pedigree technology. The survey was also analyzed using only those responses from wholesale distributors and including their “comments” from the comment sections provided in the survey. A copy of those results is attached as Appendix VIII. Certain Workgroup members subsequently met informally with Delegate Karen S. Montgomery, a member of the House Health and Government Operations Committee, to discuss survey findings, which suggested the need to extend the date included in the initial legislation beyond July 1, 2010. Delegate Montgomery requested that the Workgroup consider 2013, which is an earlier date than the 2015 date required in California.

### **Workgroup Recommendation**

The October 20, 2008 meeting was attended by most of the major industry stakeholders. Workgroup reluctance to set a specific date for implementation of electronic track and trace technology in Maryland was based on the numerous benchmarks that must occur before a realistic implementation of electronic track and trace technology may occur. Below is a list of the key necessary benchmarks identified by the Workgroup:

- Uniform standards must be developed for whatever technology is eventually utilized: linear barcode, 2D barcode, matrix or RFID;

- Budgeting, hardware and software must be developed;
- Data management, data sharing and security must be addressed;
- Implementation guidelines must be established;
  - Piloting of standards and guidelines;
  - Testing of equipment;
  - Training of employees;
  - Start up of 2 to 6 months to get one site up and running, multiplied by approximately 1,000 sites;
- Infrastructure guidelines;
  - Upgraded labeling;
  - Upgraded packaging;
- Establish interoperability between the manufacturer, wholesale distributor and the pharmacy

Stakeholders in attendance at the October meeting requested an opportunity to submit statements outlining their specific concerns with implementation of electronic track and trace technology and their specific recommendations for an implementation date. Below are very brief summaries of the stakeholders' submissions:

- HDMA, PhRMA, NCPA, BIO and HIDA submitted a joint recommendation to not set a target date for implementation of electronic track and trace pedigree technology. Their collective extensive experience in pilots and through industry work groups has taught them that in order for electronic track and trace technologies to become a reality in Maryland and across the country the benchmarks set forth above must occur. Their complete recommendation is attached as Appendix I.
- PhRMA further recommended not setting a target date due to the significant technological and financial challenges in upgrading the current supply chain system. PhRMA's complete recommendation is attached as Appendix IX.
- BIO recommended that the Board exercise its authority to delay the establishment of a target date for implementation of electronic track and trace pedigree technology. BIO's complete recommendation is attached as Appendix X.
- GPhA recommended that given the lack of Federal standards regarding aspects of pedigree and serialization, and the evolving nature of much of the technology required to handle an interoperable system of serialized electronic pedigree within

a global supply chain, a hard deadline is nearly impossible to identify. GPhA urges a consideration of a flexible time frame, in order to allow technology to mature, industry to take a more measured approach and competition to reduce the price of identification technology. GPhA's complete recommendation is attached as Appendix XI.

- NACDS recommended that if the Board must move forward with setting a specific date, the date set by California law, plus a year, should be considered. Also, benchmarks should be incorporated to ensure acknowledgement of the various complex steps and also allowing for Federal pre-emption. NACDS's complete recommendation is attached as Appendix XII.

Noting several benchmarks that should occur before realistic implementation of electronic track and trace technology in Maryland, the Workgroup determined that electronic track and trace pedigree technology will not be universally available across the entire prescription pharmaceutical supply chain until after it is required by federal pedigree laws or regulations. Based on that information, but unable to reach consensus, the Workgroup submitted the following recommendations to the Board regarding a target date for the implementation of electronic track and trace technology across the entire pharmaceutical supply chain:

The target dates should not be set at this time due to the significant technological and financial challenges in upgrading the current supply chain system. Because a uniform electronic track and trace system should be implemented on a national scale, FDA should be recognized as the appropriate authority on this issue. (HDMA, PhRMA, NCPA, BIO and HIDA) The joint statement by HDMA, PhRMA, NCPA, BIO and HIDA is attached as Appendix VIII.

NACDS and Cardinal Health recommend that the target dates in Maryland should be one year later than the target dates set forth in the California Senate Bill 1307. Specifically, the first target implementation date for manufacturers should be January 1, 2016; subsequent Federal pedigree laws or regulations should preempt these recommendations; and no further legislation should be introduced or further regulations should be promulgated establishing earlier target dates than the Workgroup's recommendation.

## APPENDIX I

### **Recommendation of Stakeholders to Board of Pharmacy on Target Date for Implementation of Electronic Track and Trace Pedigree Technology for Maryland**

We the undersigned members of the Wholesale Distribution Senate Bill 759 Workgroup (the “Workgroup”), representing pharmaceutical manufacturers, distributors, and pharmacies that sell and distribute prescription drugs in the State, make the following recommendation to the Maryland Board of Pharmacy regarding a target date for implementation of electronic track and trace pedigree technology for Maryland. In accordance with § 2-1246 of the State Government Article, the Workgroup was given the responsibility to determine when electronic track and trace pedigree technology will be universally available across the entire prescription pharmaceutical supply chain and subsequently make a recommendation to the Board for a target date for implementation of such technology.

Due to the current lack of universal availability and readiness of the appropriate technology across the entire supply chain the Workgroup is unable to make a target date recommendation at this time. This is supported by the highly varied results from the Maryland Board of Pharmacy’s recent survey showing that 100+ respondents from across the supply chain could neither agree on a timeframe nor a universal approach to electronic track and trace pedigree technology. Because a uniform electronic track and trace system should be implemented on a national scale, FDA should be recognized as the appropriate authority on this issue.

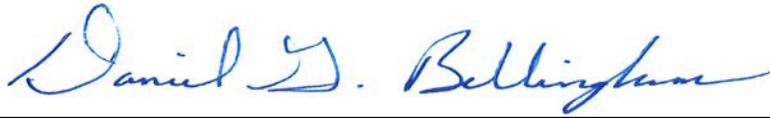
Predicting timelines for the availability of new technologies is tenuous. Thus far, our extensive experience in pilots and through industry work groups has taught us that in order for electronic track and trace technologies to become a reality in Maryland and across the country, the following must occur:

- Uniform standards must be developed;
- Industry must continue to test technologies that collect, store and transmit pedigree data to trading partners;
- The technology infrastructure must be built and tested under real-world scenarios; and
- Challenges associated with data management and data sharing between industry partners must be resolved.

**For the reasons listed above, we recommend that the Board not establish a target date at this time for implementation of electronic track and trace pedigree technology.**

The Workgroup members applaud the efforts of the Board of Pharmacy to further enhance the safety and security of Maryland’s prescription medicine supply and we look forward to continuing to work with you in this effort.

Respectfully submitted,



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Daniel G. Bellingham  
Healthcare Distribution Management Association (HDMA)



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Marjorie Powell  
Pharmaceutical Research and Manufacturers of America (PhRMA)



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Charles B. Sewell  
National Community Pharmacists Association (NCPA)



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Patrick M. Kelly  
Biotechnology Industry Organization (BIO)



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Matthew J. Rowan  
Health Industry Distributors Association (HIDA)

## APPENDIX II

# Securing the Pharmaceutical Supply Chain

## SB 759 Workgroup

Mike Rose – Vice President, RFID/EPC

Jim Cannon – Director, State Government Affairs

Tom Warren – Director, Government Affairs - Policy

Securing Pharmaceutical Supply

- Johnson & Johnson's experience
- Securing the Supply Chain
- Status of Standards
- Commentary on SB 759
- Recommendations

### A Secure Supply Chain: Our Collective Obligation

- The integrity of worldwide pharmaceutical supply has been challenged
- Joint responsibility to address this mounting public health concern
- Existing industry practices must change
- Supply chain security is the responsibility of all parties involved in the movement of goods
- Need industry adoption and standards for serial number format, data exchange between supply chain partners, verification of serial numbers, pedigree, etc.

### Johnson & Johnson's Experience

- Of the 64 pharmaceuticals marketed in the US, we have experienced serious counterfeit and diversion incidents on 3 major brands
- To address and prevent counterfeiting incidents, we've adopted changes in policies, practices, and technologies
- Played leadership role within the industry on securing the Pharmaceutical Supply Chain

### Johnson & Johnson's Industry Involvement & Leadership

- Standards
  - *Member of GSI Healthcare and EPCglobal Board of Governors – Bar code, RFID, Pedigree standards*
  - *Tri-Chair of EPCglobal Healthcare & Lifesciences Industry Action Group*
  - *GSI Healthcare*
- Industry associations
  - *Co-chair of HDMA Industry Relations Council*
  - *Member of PhRMA, BIO Secure Supply Chain Workgroups*
  - *Member of EFPIA Coding and Identification Steering Committee*
- Cross association efforts
  - *Member of RxSafeTrack Steering Committee*
  - *Participant in California Pedigree Coalition*

### **Johnson & Johnson's Partnership with Regulators and Legislators**

- **We are committed to providing access to Johnson & Johnson expertise**
  - *Auto Identification – RFID, bar codes, etc.*
  - *Information Technology & Security – digital signature, system integrity, system architecture*
  - *Operations – Pharmaceutical packaging*
  - *Distribution – supply chain logistics*
  - *Brand Protection – supply chain security*
  - *Trade Relations – trade agreements, data exchange*
- **We have shared our expertise with state and federal staff**
  - *Some examples*
    - Florida – digital signature, auto identification, and pedigree
    - California – packaging, auto identification, brand protection and pedigree
    - Federal – distribution, brand protection, auto identification, and pedigree
- **If Maryland has interest in speaking with other Johnson & Johnson experts, please coordinate your request through Johnson & Johnson State Government Affairs**

### **Johnson & Johnson's Experience with Auto Identification Bar Codes and RFID**

- **Responded to FDA Bar Code Rule – bar code applied to unit of use**
- **Consumer products - RFID tagging limited quantity of cases for specific retailer led RFID initiatives**
- **Participated in Accenture JumpStart program**
- **RFID tagged two pharmaceutical products in response to retailer request**
- **Partnered with packaging provider to integrate RFID tag into injection molded packaging component**
- **Responding to specific requests from countries to serialize products using bar codes**
- **Piloting RFID with selected medical devices for purposes of inventory management and supply chain visibility applications**

### **Johnson & Johnson's RFID Policy Position**

- **Based upon our experience, RFID has the potential to help improve supply chain efficiency, improve supply chain visibility and enhance brand protection**
- **Important considerations for industry adoption of RFID include**
  - *Consumer notice must be given*
  - *Conformance to consumer privacy and security concerns*
  - *Develop industry standards to ensure interoperability across trading partners*
    - GS1 and EPCglobal standards
  - *Interoperability of product identifiers across bar codes and RFID*
- **Considerable learning and piloting must take place before RFID can be widely adopted**
- **Bar codes (2D data matrix and linear) are practical solutions that can be adopted now for uniquely identifying products**

### **Johnson & Johnson's Pedigree Policy Position**

- **Supports the use of pedigrees as a means of protecting the drug supply from products that are adulterated, misbranded or counterfeited**
- **Believes that pedigrees should be employed to ensure that patients and healthcare professionals receive genuine Johnson & Johnson products**
- **Manufacturer shipping records should be considered ample documentation to relieve the manufacturer from further pedigree obligations for products requiring a distribution history**

**Securing the Supply Chain  
Requires Industry Wide Coordination  
Standards Update**

Standards are only a small portion needed for industry to adopt Serialization and e-Pedigree

**Estimate standards will be available late 2008 or early 2009**

**However, the following steps must occur**

- **Software and manufacturers must build standards into their solutions**
- **Solutions must be certified**
- **Each company must develop their own project plans and appropriate necessary funding and resources**
- **Each company must execute their project plans to implement e-Pedigree and Serialized susceptible products**
- **Connectivity and interoperability must be established between trading parties**

**Commentary on Serialization and Pedigree**

- **Pedigree**
  - *Standards exist for pedigree document model*
    - **Three certified vendors**
  - *Track & Trace guidelines and standards are under development*
  - *Standards or guidelines are required to ensure interoperability between the document model and the track & trace model*
- **Data carriers**
  - *2D Data Matrix or RFID can used to apply the serial number*
  - *2D Data Matrix has been selected by EFPIA and other countries*
  - *The FDA has NOT approved RFID for use with biologics or solutions*
- **Supply chain integrity**
  - *Processes will need to be developed to manage serial numbers*
- **FDA responsibility**
  - *FDAAA – requires FDA to establish standards for RFID, pedigree, track & trace, etc. within 30 months after enactment (March/April 2010)*

**Impact of Serialization to Manufacturers**

- **Manufacturers must comply with FDA regulations for Good Manufacturing Practices (GMP's) and Good Distribution Practices (GDP's)**
- **Manufacturers' facilities are subject to FDA inspection and the FDA's assessment of the manufacturer's compliance to GMP's**
- **FDA has yet to issue serialization regulations**
- **Some questions...**
  - *Is a serial number considered part of the product's label?*
  - *If one product out of case of 48 does not have the correct serial number, but the other 47 have to correct numbers, can the one product still be distributed?*

**Commentary on SB 759**

- **We support tightening the security of the pharmaceutical supply chain**
- **To ensure regulation objectives are met, significant prerequisites must be built across the industry**
  - *Technology standardization*
  - *Data standards*
- **Any regulation must include requirements for all downstream parties to authenticate and pass pedigree information**
- **Serialization will require substantial changes to all manufacturing facilities**
- **Lot based pedigree could be an interim milestone**
- **Cases or a subset of products could be serialized as early milestones**
- **Progress can be made with interim milestones, however, serializing all products in such a short term is overly optimistic**
- **Earliest realistic timeframe for the industry to be in full compliance is 2013**

### Recommendations

- We fully endorse the intention to protect patients from counterfeit product
- We support a single Federal Standard to regulate pharmaceutical supply chain security
- We support risk-based serialization in conjunction with mandatory pedigree and track and trace by all downstream parties for products susceptible for counterfeiting
- Criteria should be developed for a national list of susceptible Rx drugs
- We support the use of anti-counterfeiting covert and overt features on the packaging of susceptible Rx drugs
- Interim milestones should be established for serialization, pedigree, and track and trace of susceptible Rx drugs
- Companies should be allowed to select the data carrier most appropriate for the product, e.g., 2D data matrix for biologics

## APPENDIX III

### Maryland Board Of Pharmacy SB 759 Work Group Update December 10, 2007 Discussion Points

- Introduction
- Definitions
- Actions to Date
- Our Experience
- Challenges
- Our Commitment

#### Introduction to CVS Caremark

- CVS Caremark is the nation's premier integrated pharmacy services provider, combining:
  - CVS/pharmacy
  - Caremark Pharmacy Services
  - MinuteClinic
- CVS Caremark has an significant presence in Maryland
  - 168 pharmacy locations
- CVS Caremark recognizes the paramount importance of a secure pharmaceutical supply chain.
- CVS Caremark has taken a leadership position in implementing practical measures that have an immediate impact upon the security and integrity of the supply chain.

#### Definitions

- Drug Pedigree
  - A record of each distribution of a prescription drug from the sale by a Manufacturer through acquisition and sale by any Wholesale Distributor until final sale to a Pharmacy or other authorized person administering or dispensing the Prescription Drug
  - Can be paper or electronic
- Trace
  - The capability to identify the historical locations, the records of ownership, and the packaging hierarchy for a particular traceable item. "Trace" answers questions such as "where has the item been", "who has previously owned the item", and "in what packaging hierarchy did the product exist at various locations"
- Track
  - The capability to identify the current (and at time of shipment the intended future) location, ownership, and packaging hierarchy of a traceable item through the supply chain as it moves between parties
  - "Track" addresses both forward- and reverse-logistics operations. "Track" answers questions such as "where is the item currently", "who is the next intended recipient", and "what is the current packaging hierarchy of this item"

#### Actions to Date

- Wholesaler Certification
  - May 2005 - announced CVS/pharmacy would only purchase directly from the manufacturer or from wholesalers that would certify that they only purchase products directly from the manufacturer.
  - Each of the 3 largest wholesaler's – Cardinal, McKesson and AmerisourceBergen - have since made public announcements stating this exact policy.
- Regulatory
  - Actively engaged in state level initiatives to address this issue.
  - Advocate for stricter licensing requirements for wholesale distributors.
    - i.e. criminal and financial background checks, inspections, surety bonds and penalties.
  - Support pedigree requirements for transactions outside a defined "normal or primary distribution" channel.
  - Support national accreditation – e.g., . NABP's VAWD program
    - 8 of 9 CVS/pharmacy DC's have received VAWD accreditation with the final DC pending as it was recently inspected.

#### Actions to Date

- CVS Caremark has participated in a number of industry groups working on standards and pilots:
  - EPCGlobal
    - CVS Caremark is a one of the Health/Life Sciences Tri-Chairs with McKesson and Johnson & Johnson
    - Participate in industry standards development
    - Industry Adoption Roadmap
  - Jump Start Program

- One of the first industry efforts regarding RFID and emerging technology
- *On Track II program*
  - Industry pilots for RFID and 2D barcode serialization
- *NACDS Supply Chain Workgroup*
- *RxSafeTrack*

- **Cross-industry group working on adoption**

#### Actions to Date

- **Florida pedigree requirement**
  - *Our Caremark Specialty Pharmacies and Mail Order facilities have implemented the capability to receive and pass pedigrees as required by the Florida laws*
  - *Not serialized*

#### Our Experience with Technology & Serialization

- **2-D Barcode**
  - *Capable of supporting serialization at the item level*
  - *Requires line-of-sight and will add significant labour costs to the supply chain*
  - *Relatively low costs to the manufacturing community, but adds complexity and labor to the downstream partners*
- **RFID**
  - *Strongly suited to the goal of serialization at the item level*
  - *Non-line-of-sight technology which can allow for supply chain efficiencies*
  - *Highest start up costs (and potential on-going costs)*
  - *Not suitable for “special situation” products, e.g., biologics*
  - *Potential reliability issues resulting in operational inefficiencies and product disposition concerns*
- **Combination**
  - *Creates the biggest challenge as wholesalers and pharmacies will have to invest in multiple technologies and processes to receive and track pedigrees*

#### Our Experience with Technology & Serialization

- **Serialization**
  - *Standards are still “in process”*
  - *Data management is not the largest issue – data standards, data carrier and the data transfer process remain the biggest hurdles.*
  - *“Special situation” supply chain products present new challenges, i.e. biologics, cold chain, contract manufacturing, etc.*
  - *Potential different approaches by trading partners*

#### Our Learning from Industry Pilots

- **A number of members of the supply chain have embarked on pilots to address serialization and pedigree.**
- **Each of these pilots have employed different technologies and approaches which makes it difficult for pharmacy providers to select a standard approach.**
  - *Manufacturers have tagged product with UHF & HF RFID tags as well as 2-D Barcodes*
    - **There have also been different types of data carriers depending on whether the product is “tagged” at the pallet, case, or item level**
  - *Two key wholesalers have piloted and focused on UHF RFID based pilots and solutions*
  - *A third key wholesaler has been testing UHF at the case level and HF at the item level (in the same shipment) and has also incorporated 2-D barcodes*
    - **While this “mixed” mode approach may work at the “pilot” level with a single location and only a small number of products, there is significant concern about the scalability of such an approach**

#### Key Challenges with Pedigrees and Track and Trace

- **Serialization**
  - *To achieve the ultimate goals of track and trace, serialization of product at the item level is required*
    - **Currently no standards defined (or accepted)**
    - **Lack of agreement on how to manage the data flow**

- *Some elements of the supply chain want a “look-up” model which can place undue (and unnecessary) burden on downstream partners such as retail pharmacy*
- **Data Carrier**
  - *There are a number of solutions to maintaining the serial number on the product*
    - **RFID**
    - **Barcode (linear, 2D)**
    - **Since chain pharmacy is downstream in the supply chain, we could end up with dealing with many disparate solutions**

#### **Key Challenges with Pedigrees and Track and Trace**

- **Data Management and Information Transfer**
  - *We believe in a feed-forward model in which each trading partner sends relevant information to downstream partners to support pedigree management*
    - **Most-straightforward and simple/practical approach**
    - **Does not require complex “database in the sky” or look-up model**
      - *We need our pharmacies to be able to run autonomously in the event networking fails*
- **Track and Trace**
  - *We believe that this can be an eventual element of supply chain integrity*
  - *No standards exist for track and trace (underway)*
  - *Need to first work through an effective approach to serialized pedigree management process as track and trace has significant technology and infrastructure requirements*

#### **For Chain Pharmacy, We Need to Consider the Scope of Trading Partners... ...and the Number of Sites We Have to Deploy the Solution Some Considerations Going Forward**

- **Look at solutions that maximize the initial investment**
  - *Not simply susceptible or priority drugs, but consider the complete transaction (where, where from, etc.)*
    - **E.g., “Normal” or “Primary” distribution**
  - *Phased product approaches will still require the same investment from wholesalers and chain pharmacies (whether 10 products, 100 products, or all products are serialized)*
  - *Some proposed interim steps (such as Lot Number serialization) may not actually advance the process*
  - *Adoption is more likely if we balance the impact across the supply chain*
- **Standards are a necessary prerequisite, but there are other elements that need to occur before these solutions can be deployed**
  - *These standards need to be incorporated into the technology solutions*
  - *Implementation is not guaranteed (e.g., today’s status of EDI)*

#### **Some Considerations Going Forward**

- **Make sure we consider any “unintended” consequences**
  - *For example, current/proposed validation requirements in some states could actually compromise current safety/security practices by requiring that sealed cases be opened to check-in individual items*
- **Develop an effective cost/benefit model for the various feasibility studies**
  - *Articulate the benefits of the pedigree and track and trace solutions*
  - *Support/commission pilots to help gather “real-world” data*
  - *Assist with prioritization of the effort and implementation process*
- **Support cross-industry efforts and consider federal and other states’ approaches**

#### **Our Commitment**

- **We believe in a safe, secure supply chain and will continue to explore both near term and long term opportunities**
- **We will continue to participate in standards development, cross-industry efforts, and pilot activity.**
  - *We will still have a dependency on the “choices” that upstream partners make.*
- **We will maintain an open dialogue with the Maryland Board of Pharmacy as it works through the study and will try and serve as a resource where appropriate.**

## **APPENDIX IV**

TO: Pharmacy and Wholesale Distributor Permit Holders  
FROM: Maryland Board of Pharmacy and the SB 759 Wholesale Distributors  
Workgroup

THE WHOLESALE DISTRIBUTOR SURVEY IS HERE:

(place link)

### **PLEASE READ THE EXPLANATION BELOW BEFORE BEGINNING THE SURVEY.**

The Maryland Board of Pharmacy has been charged with implementing Senate Bill 759, Wholesale Distribution Permitting and Prescription Drug Integrity Act (2007 Legislative Session). The Wholesale Distributor Workgroup was convened to provide guidance for this initiative. As directed by part of this legislation, a survey must be conducted to determine the state of readiness for use of electronic track and trace technology. As a result, your participation in a SHORT SURVEY about the availability of electronic track and trace pedigree technology across the entire prescription pharmaceutical supply chain is requested. Even if you do not currently utilize electronic track and trace pedigree technology, such as bar coding or Radio Frequency Identification (RFID), please take the time to view and to complete the survey. Should you have questions or concerns, please feel free to contact Anna D. Jeffers, Legislation and Regulations Manager at [ADJeffers@dhmh.state.md.us](mailto:ADJeffers@dhmh.state.md.us) . Thank you for your participation.

Below please find background information from the Wholesale Distribution Permitting and Prescription Drug Integrity Act and the Workgroup.

#### **Purpose**

The purpose of the survey is to solicit information from Maryland pharmaceutical establishments including wholesalers and pharmacies, to the SB 759 Wholesale Distributors Workgroup. The Workgroup will collect and analyze the information you provide. From that analysis, the Workgroup will make recommendations to the Board for a target date, no sooner than July 1, 2010, for implementation of electronic track and trace pedigree technology across the prescription pharmaceutical supply chain.

#### **Electronic track and trace technology**

Electronic track and trace technology is software/network technology that indicates where a product was made and what route it has taken until sold to the consumer. This type of technology allows a company to trace upstream history of products and track products downstream in the supply chain. Typical types of technology include bar-code scanning and RFID in addition to paper documents.

#### **Pedigrees**

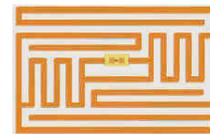
A pedigree is a full electronic or paper description containing information that records each wholesale distribution of a prescription drug to allow participants in the chain of custody to determine the legitimacy of all parties to the transaction. In the new law, electronic pedigrees will only be required for prescription drugs that leave, or have ever left, the normal distribution channel. Please refer to Health Occupations Article, 12-6C-01 through 12-6C-13, Annotated Code of Maryland, for additional definitions and the full text of the law. You may access the Annotated Code of Maryland through our website at [www.mdbop.org](http://www.mdbop.org). Click on *Laws and Regulation* near the top of the homepage. Scroll down and click on *Pharmacy Statute Text*, then click on [*Another Article*] at the top. Enter the article and section in the drop down boxes provided.

**Completion of Survey by all locations**

Keep in mind that it is important that ALL permit holders, including pharmacies, complete the survey. Even if your store is part of an umbrella chain drug store, please take the time to complete the survey. Your participation is vital for the Workgroup's analysis.

**APPENDIX V**

**MARYLAND BOARD OF PHARMACY  
TRACK & TRACE SURVEY QUESTIONS**



**SECTION I** This section pertains to a distributor's or pharmacy's current capabilities.

**1. Please check below if you are:**

Column Choices Are: No , Yes

Independent pharmacy  
Chain pharmacy  
Chain pharmacy  
distribution center  
Hospital pharmacy  
Wholesale Distributor  
Manufacturer  
Third Party Logistics  
Provider  
Returns Processor  
Health Care Facility

**2. At what packaging unit level does your company currently electronically track prescription pharmaceutical products? (choose all that apply)**

Column Choices Are: No , Yes

Unit of Use  
Cases  
Pallets  
Lots  
None  
Other (please specify)

**3. Is your company equipped or planning to supply down stream partners with equipment and/or software for electronic track and trace technology?**

No  
Yes  
Not sure  
Other (please specify)

**4. What unique identifier system (data carrier) does your company use to identify product at the unit level? (choose all that apply)**

Column Choices Are: No , Yes

2-D Barcode  
Linear Barcode  
Data Matrix  
Data Bar Barcode  
Radio Frequency Identifier (RFID)  
None

**5. What unique identifier system (data carrier) does your company use to identify product at the case level? (choose all that apply)**

Column Choices Are: No , Yes

2-D Barcode  
Linear Barcode  
Data Matrix  
Data Bar Barcode  
Radio Frequency Identifier (RFID)  
None  
None Some ( < 50%) Most ( > 50%) All (100%)

**6. Does your company currently use a unique identifier number (serialization) to identify individual products? (choose all that apply)**

Column Choices Are: None, Some ( < 50%), Most ( > 50%), All (100%)

Over-The-Counter (OTC)  
Prescription medications that are Non-Controlled Dangerous Substances (Non-CDS)  
Prescription medications that are Controlled Dangerous Substances (CDS)  
Other identifier System (please specify)

**7. In the future, all companies may need to transition to track and trace technology. What technology is your company using, or planning to use, for data interchange with your partners?**

Electronic Product Code Information System (EPCIS)  
Drug Pedigree Messaging Standard (DPMS)  
Combination of EPCIS & DPMS  
Not sure  
Other (please specify)

**8. Does your company currently have the capability to make pedigree information available to customers on the Internet?**

No  
Yes

**9. Do you currently maintain any repository of drug information at the unit level?**

No  
Yes

**10. What data standards are you using or planning to use for serialization?**

Global Trade Item Number (GTIN-96)  
Serialized Shipping Container Code (SSCC)  
Not sure  
Other (please specify)

**11. Do you include National Drug Code (NDC) in the Global Trade Item Number (GTIN)?**

No  
Yes

**12. What does your company view as obstacles in implementing uniquely identified unit-level products? (choose all that apply)**

Column Choices Are: No, Yes, Not Sure

Cost  
Time  
Technology  
Lack of uniform standards  
Lack of computer technology  
Availability of Hardware/Software throughout the supply chain  
Please comment on responses

**13. Which approach does your company support in implementing track and trace technology?**

Phase in by product  
All products at one time

Products outside normal distribution channel only  
Not Sure  
Other (please specify)

Section II asks questions about companies that are currently using track and trace technology. If your company does not currently use track and trace technology as part of its usual operations, please go to Section III.

**14. If your company uses Radio Frequency Identifiers (RFID), what frequency is used? (choose all that apply)**

Column Choices Are: Pallet, Case, Item

UHF  
HF  
Low frequency

**15. Of the following entities that you do business with, which ones are currently using electronic track and trace technology? (choose all that apply)**

Manufacturer  
Pharmacy  
Wholesale Distributor  
Trade Partners  
Track and Trace Technology Vendor(s)  
Not Sure  
None  
Other (please specify)

**16. If your company is using electronic track and trace technology, how does your company plan to make electronic track and trace data available? (choose all that apply)**

Column Choices are: Company level access, Store level access, Not Sure

Internet  
Intranet  
Third Party Network  
Electronic Delivery  
Other(s) in supply chain (please specify)

**17. What data is captured in your company's RFID or Bar Codes at the unit, case and pallet levels? (choose all that apply)**

Column Choices Are: Unit Level, Case Level, Pallet Level  
Lot Number  
Expiration Date  
Unique Serial Number  
National Drug Code (NDC)  
Not Sure  
Other (please specify)

**18. Does your company currently uniquely serialize products? If so, what percentage of your total product line?**

Column Choices Are: 0 - 5% , 5 - 33% , 33 - 75% , 75 - 100%

- Yes
- No
- Will, in the future
- Other (please specify)

**Section III Surveys distributors and pharmacies that are testing, piloting, exploring and/or experimenting with track and trace technologies.**

**19. What is your company's time line for completing investment in a system and infrastructure necessary to implement an electronic track and trace system?**

- 2009
- 2010
- 2011
- 2012
- Other (please specify)

**20. What type(s) of track and trace technology is your company piloting or considering phasing into its operations and when? (choose all that apply)**

Column Choices Are: 2009, 2010, 2011, 2012

- None (skip to next question)
- 2-D Barcode
- Linear Barcode
- Matrix
- Radio Frequency Identifier (RFID)
- Electronic Product Code (EPC)
- Not sure
- None
- Other (please specify)

**20. What partners are working with you in exploring, testing, piloting or phasing in electronic track and trace technology? (choose all that apply)**

- Manufacturer
- Pharmacy
- Wholesale Distributor
- Trade Partners
- Track and Trace Technology Vendor(s)
- Not Sure
- None
- Other (please specify)

**21. What type(s) of track and trace technology is your company piloting or considering phasing into its operations and when? (choose all that apply)**

Column Choices Are: 2009, 2010, 2011, 2012

- None (skip to next question)
- 2-D Barcode
- Linear Barcode
- Matrix
- Radio Frequency Identifier (RFID)
- Electronic Product Code (EPC)
- Not sure
- None
- Other (please specify)

## APPENDIX VI

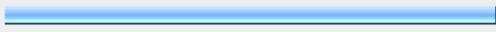
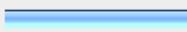
### Electronic Track and Trace Survey

| 1. Please check below if you are:  |            |                          |                |
|------------------------------------|------------|--------------------------|----------------|
|                                    | No         | Yes                      | Response Count |
| Independent pharmacy               | 51.6% (47) | 48.4% (44)               | 91             |
| Chain pharmacy                     | 87.0% (60) | 13.0% (9)                | 69             |
| Chain pharmacy distribution center | 96.8% (61) | 3.2% (2)                 | 63             |
| Hospital pharmacy                  | 95.4% (62) | 4.6% (3)                 | 65             |
| Wholesale Distributor              | 40.3% (31) | 59.7% (46)               | 77             |
| Manufacturer                       | 74.6% (53) | 25.4% (18)               | 71             |
| Third Party Logistics Provider     | 89.7% (61) | 10.3% (7)                | 68             |
| Returns Processor                  | 91.9% (57) | 8.1% (5)                 | 62             |
| Health Care Facility               | 93.8% (60) | 6.3% (4)                 | 64             |
|                                    |            | <i>answered question</i> | 118            |
|                                    |            | <i>skipped question</i>  | 9              |

2. At what packaging unit level does your company currently electronically track any prescription pharmaceutical products? (choose all that apply)

|             | No         | Yes                    | Response Count           |     |
|-------------|------------|------------------------|--------------------------|-----|
| Unit of Use | 18.2% (4)  | 81.8% (18)             | 22                       |     |
| Cases       | 0.0% (0)   | 100.0% (6)             | 6                        |     |
| Pallets     | 100.0% (2) | 0.0% (0)               | 2                        |     |
| Lots        | 13.3% (2)  | 86.7% (13)             | 15                       |     |
| None        | 70.5% (55) | 29.5% (23)             | 78                       |     |
|             |            | Other (please specify) | 16                       |     |
|             |            |                        | <i>answered question</i> | 112 |
|             |            |                        | <i>skipped question</i>  | 15  |

3. Is your company equipped or planning to supply down stream partners with equipment and/or software for electronic track and trace technology?

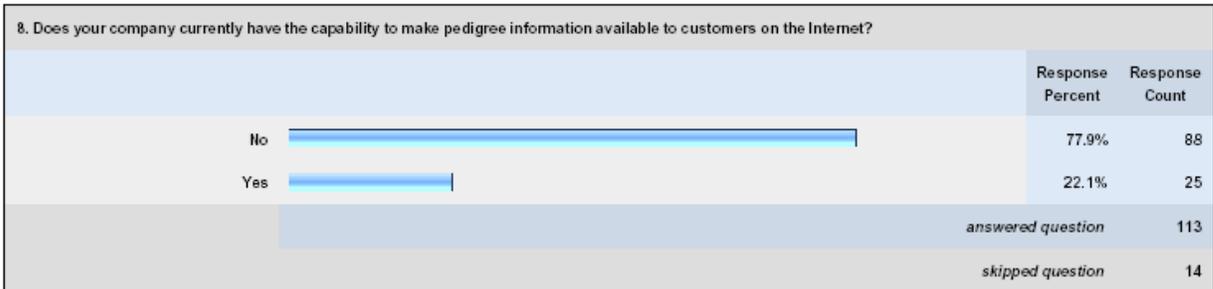
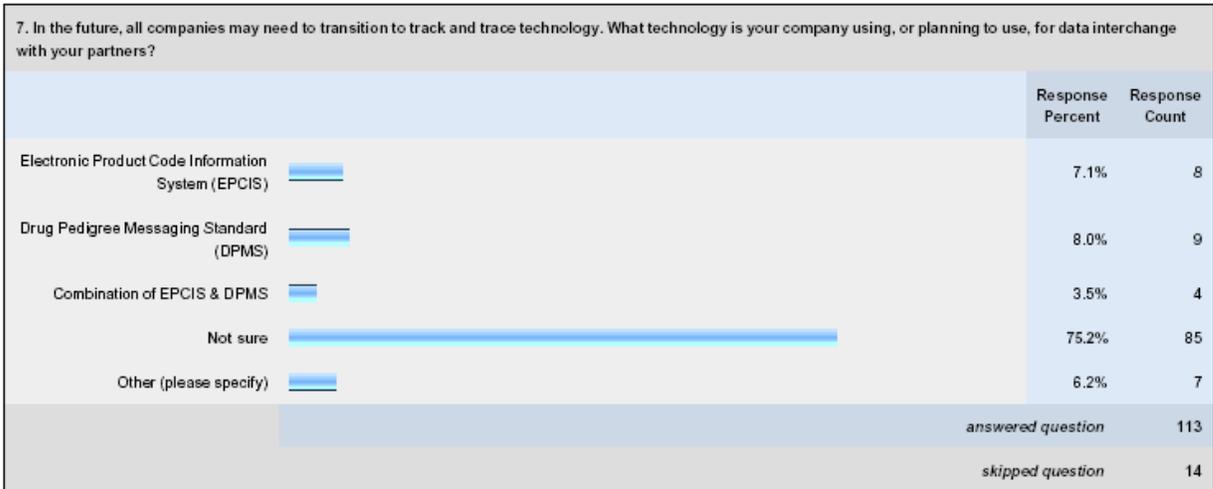
|                                                                                            | Response Percent       | Response Count           |     |
|--------------------------------------------------------------------------------------------|------------------------|--------------------------|-----|
| No       | 67.0%                  | 75                       |     |
| Yes       | 8.9%                   | 10                       |     |
| Not sure  | 25.0%                  | 28                       |     |
|                                                                                            | Other (please specify) | 6                        |     |
|                                                                                            |                        | <i>answered question</i> | 112 |
|                                                                                            |                        | <i>skipped question</i>  | 15  |

4. What unique identifier system (data carrier) does your company use to identify product at the unit level? (choose all that apply)

|                                   | No         | Yes                                      | Response Count           |     |
|-----------------------------------|------------|------------------------------------------|--------------------------|-----|
| 2-D Barcode                       | 78.0% (32) | 22.0% (9)                                | 41                       |     |
| Linear Barcode                    | 48.9% (23) | 53.2% (25)                               | 47                       |     |
| Data Matrix                       | 91.9% (34) | 8.1% (3)                                 | 37                       |     |
| Data Bar Barcode                  | 89.7% (35) | 10.3% (4)                                | 39                       |     |
| Radio Frequency Identifier (RFID) | 92.3% (36) | 7.7% (3)                                 | 39                       |     |
| None                              | 56.3% (45) | 43.8% (35)                               | 80                       |     |
|                                   |            | Other identifier System (please specify) | 12                       |     |
|                                   |            |                                          | <i>answered question</i> | 108 |
|                                   |            |                                          | <i>skipped question</i>  | 19  |

| 5. What unique identifier system (data carrier) does your company use to identify product at the case level? (choose all that apply) |            |                                          |  |                |
|--------------------------------------------------------------------------------------------------------------------------------------|------------|------------------------------------------|--|----------------|
|                                                                                                                                      | No         | Yes                                      |  | Response Count |
| 2-D Barcode                                                                                                                          | 75.0% (27) | 25.0% (9)                                |  | 36             |
| Linear Barcode                                                                                                                       | 47.5% (19) | 52.5% (21)                               |  | 40             |
| Data Matrix                                                                                                                          | 93.8% (30) | 6.3% (2)                                 |  | 32             |
| Data Bar Barcode                                                                                                                     | 91.4% (32) | 8.6% (3)                                 |  | 35             |
| Radio Frequency Identifier (RFID)                                                                                                    | 88.2% (30) | 11.8% (4)                                |  | 34             |
| None                                                                                                                                 | 56.0% (47) | 44.0% (37)                               |  | 84             |
|                                                                                                                                      |            | Other Identifier System (please specify) |  | 7              |
|                                                                                                                                      |            | <i>answered question</i>                 |  | 108            |
|                                                                                                                                      |            | <i>skipped question</i>                  |  | 19             |

| 6. Does your company currently use a unique identifier number (serialization) to identify individual products? (choose all that apply) |            |              |              |                          |                |
|----------------------------------------------------------------------------------------------------------------------------------------|------------|--------------|--------------|--------------------------|----------------|
|                                                                                                                                        | None       | Some (< 50%) | Most (> 50%) | All (100%)               | Response Count |
| Over-The-Counter (OTC)                                                                                                                 | 85.4% (88) | 1.0% (1)     | 1.0% (1)     | 12.6% (13)               | 103            |
| Prescription medications that are Non-Controlled Dangerous Substances (Non-CDS)                                                        | 80.0% (84) | 2.9% (3)     | 2.9% (3)     | 16.2% (17)               | 105            |
| Prescription medications that are Controlled Dangerous Substances (CDS)                                                                | 83.5% (86) | 1.0% (1)     | 2.9% (3)     | 12.6% (13)               | 103            |
|                                                                                                                                        |            |              |              | Other (please specify)   | 12             |
|                                                                                                                                        |            |              |              | <i>answered question</i> | 109            |
|                                                                                                                                        |            |              |              | <i>skipped question</i>  | 18             |



| 9. Do you currently maintain any repository of drug information at the unit level? |                                                                                    |  | Response Percent | Response Count |
|------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|--|------------------|----------------|
| No                                                                                 |  |  | 67.9%            | 76             |
| Yes                                                                                |   |  | 32.1%            | 36             |
| <i>answered question</i>                                                           |                                                                                    |  |                  | 112            |
| <i>skipped question</i>                                                            |                                                                                    |  |                  | 15             |

| 10. What data standards are you using or planning to use for serialization? |                                                                                    |  | Response Percent | Response Count |
|-----------------------------------------------------------------------------|------------------------------------------------------------------------------------|--|------------------|----------------|
| Global Trade Item Number (GTIN-96)                                          |   |  | 12.0%            | 13             |
| Serialized Shipping Container Code (SSCC)                                   |   |  | 6.5%             | 7              |
| Not sure                                                                    |  |  | 85.2%            | 92             |
| Other (please specify)                                                      |                                                                                    |  |                  | 6              |
| <i>answered question</i>                                                    |                                                                                    |  |                  | 108            |
| <i>skipped question</i>                                                     |                                                                                    |  |                  | 19             |

| 11. Do you include National Drug Code (NDC) in the Global Trade Item Number (GTIN)? |                                                                                      |  | Response Percent | Response Count |
|-------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|--|------------------|----------------|
| No                                                                                  |  |  | 68.6%            | 72             |
| Yes                                                                                 |   |  | 31.4%            | 33             |
| <i>answered question</i>                                                            |                                                                                      |  |                  | 105            |
| <i>skipped question</i>                                                             |                                                                                      |  |                  | 22             |

| 12. What does your company view as obstacles in implementing uniquely identified unit-level products? (choose all that apply) |            |            |  | Response Count |
|-------------------------------------------------------------------------------------------------------------------------------|------------|------------|--|----------------|
|                                                                                                                               | Yes        | Not sure   |  |                |
| Cost                                                                                                                          | 89.9% (89) | 10.1% (10) |  | 99             |
| Time                                                                                                                          | 86.8% (79) | 13.2% (12) |  | 91             |
| Technology                                                                                                                    | 86.0% (74) | 14.0% (12) |  | 86             |
| Lack of uniform standards                                                                                                     | 85.6% (77) | 14.4% (13) |  | 90             |
| Lack of computer technology                                                                                                   | 69.4% (50) | 30.6% (22) |  | 72             |
| Availability of Hardware/Software throughout the supply chain                                                                 | 80.5% (66) | 19.5% (16) |  | 82             |
| Please comment on responses                                                                                                   |            |            |  | 12             |
| <i>answered question</i>                                                                                                      |            |            |  | 107            |
| <i>skipped question</i>                                                                                                       |            |            |  | 20             |

| 13. Which approach does your company support in implementing track and trace technology? |  |                        | Response Percent | Response Count |
|------------------------------------------------------------------------------------------|--|------------------------|------------------|----------------|
| Phase in by product                                                                      |  |                        | 25.9%            | 28             |
| All products at one time                                                                 |  |                        | 6.5%             | 7              |
| Products outside normal distribution channel only                                        |  |                        | 24.1%            | 26             |
| Not Sure                                                                                 |  |                        | 46.3%            | 50             |
|                                                                                          |  | Other (please specify) |                  | 7              |
| <i>answered question</i>                                                                 |  |                        |                  | 108            |
| <i>skipped question</i>                                                                  |  |                        |                  | 19             |

| 14. If your company uses Radio Frequency Identifiers (RFID), what frequency is used? (choose all that apply) |           |            |                            |                |
|--------------------------------------------------------------------------------------------------------------|-----------|------------|----------------------------|----------------|
|                                                                                                              | Pallet    | Case       | Item                       | Response Count |
| UHF                                                                                                          | 33.3% (1) | 66.7% (2)  | 100.0% (3)                 | 3              |
| HF                                                                                                           | 0.0% (0)  | 100.0% (1) | 0.0% (0)                   | 1              |
| Low frequency                                                                                                | 80.0% (4) | 80.0% (4)  | 100.0% (5)                 | 5              |
|                                                                                                              |           |            | Not Sure? (please comment) | 18             |
| <i>answered question</i>                                                                                     |           |            |                            | 7              |
| <i>skipped question</i>                                                                                      |           |            |                            | 120            |

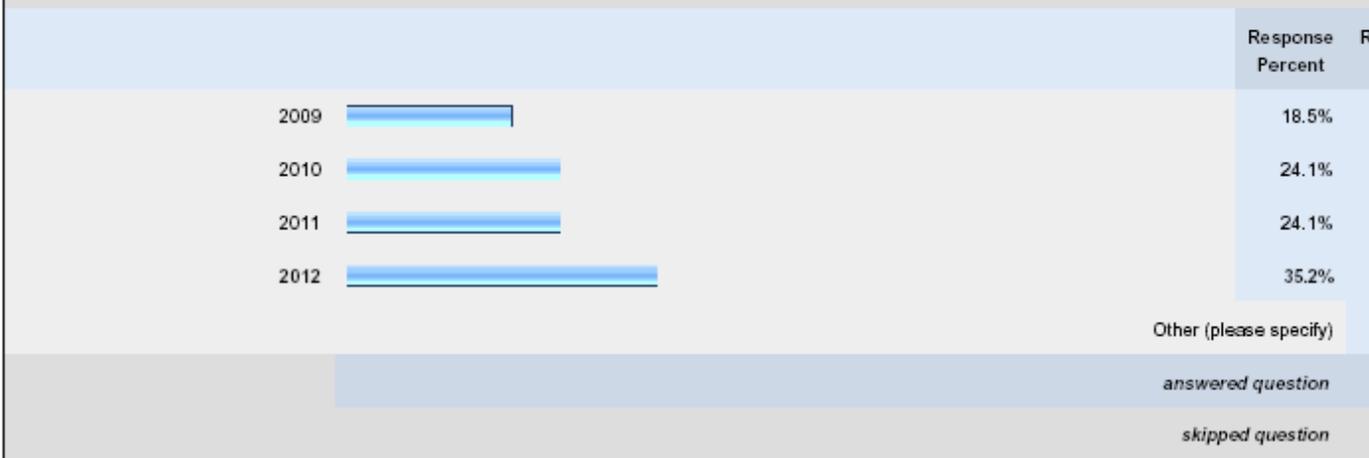
| 15. Of the following entities that you do business with, which ones are currently using electronic track and trace technology? (choose all that apply) |  |  | Response Percent | Response Count |
|--------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|------------------|----------------|
| Manufacturer                                                                                                                                           |  |  | 6.7%             | 5              |
| Pharmacy                                                                                                                                               |  |  | 4.0%             | 3              |
| Wholesale Distributor                                                                                                                                  |  |  | 22.7%            | 17             |
| Trade Partners                                                                                                                                         |  |  | 2.7%             | 2              |
| Track and Trace Technology Vendor (s)                                                                                                                  |  |  | 5.3%             | 4              |
| Not Sure                                                                                                                                               |  |  | 40.0%            | 30             |
| None                                                                                                                                                   |  |  | 33.3%            | 25             |
| Other (please specify)                                                                                                                                 |  |  | 8.0%             | 6              |
| <i>answered question</i>                                                                                                                               |  |  |                  | 75             |
| <i>skipped question</i>                                                                                                                                |  |  |                  | 52             |

| 16. If your company is using electronic track and trace technology, how does your company plan to make electronic track and trace data available? (choose all that apply) |                      |                    |                                           |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|-------------------------------------------|----------------|
|                                                                                                                                                                           | Company level access | Store level access | Not Sure                                  | Response Count |
| Internet                                                                                                                                                                  | 48.1% (13)           | 25.9% (7)          | 44.4% (12)                                | 27             |
| Intranet                                                                                                                                                                  | 16.7% (3)            | 5.6% (1)           | 83.3% (15)                                | 18             |
| Third Party Network                                                                                                                                                       | 30.4% (7)            | 13.0% (3)          | 69.6% (16)                                | 23             |
| Electronic Delivery                                                                                                                                                       | 27.3% (6)            | 22.7% (5)          | 63.6% (14)                                | 22             |
|                                                                                                                                                                           |                      |                    | Other(s) in supply chain (please specify) | 8              |
|                                                                                                                                                                           |                      |                    | <i>answered question</i>                  | 31             |
|                                                                                                                                                                           |                      |                    | <i>skipped question</i>                   | 96             |

| 17. What data is captured in your company's RFID or Bar Codes at the unit, case and pallet levels? (choose all that apply) |            |            |                          |                |
|----------------------------------------------------------------------------------------------------------------------------|------------|------------|--------------------------|----------------|
|                                                                                                                            | Unit Level | Case Level | Pallet Level             | Response Count |
| Lot Number                                                                                                                 | 75.0% (12) | 62.5% (10) | 18.8% (3)                | 16             |
| Expiration Date                                                                                                            | 78.6% (11) | 57.1% (8)  | 14.3% (2)                | 14             |
| Unique Serial Number                                                                                                       | 91.7% (11) | 58.3% (7)  | 16.7% (2)                | 12             |
| National Drug Code (NDC)                                                                                                   | 88.9% (16) | 55.6% (10) | 22.2% (4)                | 18             |
| Not Sure                                                                                                                   | 93.8% (15) | 62.5% (10) | 68.8% (11)               | 16             |
|                                                                                                                            |            |            | Other (please specify)   | 10             |
|                                                                                                                            |            |            | <i>answered question</i> | 36             |
|                                                                                                                            |            |            | <i>skipped question</i>  | 91             |

| 18. Does your company currently uniquely serialize products? If so, what percentage of your total product line? |            |            |            |                          |                |
|-----------------------------------------------------------------------------------------------------------------|------------|------------|------------|--------------------------|----------------|
|                                                                                                                 | 0 - 5%     | 5 - 33%    | 33 - 75%   | 75 - 100%                | Response Count |
| Yes                                                                                                             | 22.2% (4)  | 11.1% (2)  | 5.6% (1)   | 61.1% (11)               | 18             |
| No                                                                                                              | 74.4% (29) | 28.2% (11) | 28.2% (11) | 53.8% (21)               | 39             |
| Will, in the future                                                                                             | 30.0% (3)  | 20.0% (2)  | 20.0% (2)  | 60.0% (6)                | 10             |
|                                                                                                                 |            |            |            | Other (please specify)   | 7              |
|                                                                                                                 |            |            |            | <i>answered question</i> | 61             |
|                                                                                                                 |            |            |            | <i>skipped question</i>  | 66             |

19. What is your company's time line for completing investment in a system and infrastructure necessary to implement an electronic track and trace system?

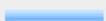
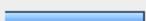


20. What type(s) of track and trace technology is your company piloting or considering phasing into its operations and when? (choose all that apply)

|                                   | 2009        | 2010       | 2011       | 2012       |
|-----------------------------------|-------------|------------|------------|------------|
| None (skip to next question)      | 100.0% (21) | 47.6% (10) | 42.9% (9)  | 38.1% (8)  |
| 2-D Barrode                       | 52.6% (10)  | 31.6% (6)  | 21.1% (4)  | 0.0% (0)   |
| Linear Barrode                    | 88.9% (8)   | 22.2% (2)  | 0.0% (0)   | 0.0% (0)   |
| Matrix                            | 50.0% (1)   | 0.0% (0)   | 50.0% (1)  | 0.0% (0)   |
| Radio Frequency Identifier (RFID) | 43.8% (7)   | 12.5% (2)  | 18.8% (3)  | 31.3% (5)  |
| Electronic Product Code (EPC)     | 80.0% (4)   | 40.0% (2)  | 0.0% (0)   | 0.0% (0)   |
| Not sure                          | 67.9% (19)  | 60.7% (17) | 71.4% (20) | 71.4% (20) |
| None                              | 100.0% (10) | 80.0% (8)  | 70.0% (7)  | 70.0% (7)  |

|                          |    |
|--------------------------|----|
| Other (please specify)   | 7  |
| <i>answered question</i> | 83 |
| <i>skipped question</i>  | 44 |

21. What partners are working with you in exploring, testing, piloting or phasing in electronic track and trace technology? (choose all that apply)

|                                                                                                                         | Response Percent | Response Count |
|-------------------------------------------------------------------------------------------------------------------------|------------------|----------------|
| Manufacturer                           | 12.1%            | 11             |
| Pharmacy                               | 4.4%             | 4              |
| Wholesale Distributor                  | 20.9%            | 19             |
| Trade Partners                         | 13.2%            | 12             |
| Track and Trace Technology Vendor (s)  | 18.7%            | 17             |
| Not Sure                               | 24.2%            | 22             |
| None                                   | 34.1%            | 31             |
| Other (please specify)                 | 2.2%             | 2              |
| <i>answered question</i>                                                                                                |                  | 91             |
| <i>skipped question</i>                                                                                                 |                  | 36             |

## APPENDIX VII

BILL NUMBER: SB 1307 ENROLLED  
BILL TEXT

PASSED THE SENATE AUGUST 21, 2008  
PASSED THE ASSEMBLY AUGUST 18, 2008  
AMENDED IN ASSEMBLY AUGUST 14, 2008  
AMENDED IN ASSEMBLY JUNE 17, 2008  
AMENDED IN SENATE MAY 23, 2008  
AMENDED IN SENATE APRIL 29, 2008  
AMENDED IN SENATE MARCH 25, 2008

INTRODUCED BY Senator Ridley-Thomas

FEBRUARY 20, 2008

An act to amend Sections 4033, 4034, 4162, 4162.5, and 4163 of, to add Sections 4034.1, 4044, 4045, 4163.1, 4163.2, 4163.3, and 4163.4 to, and to repeal and add Section 4163.5 of, the Business and Professions Code, relating to pharmacy.

### LEGISLATIVE COUNSEL'S DIGEST

SB 1307, Ridley-Thomas. Pharmacy: pedigree.

Existing law, the Pharmacy Law, provides for the licensure and regulation of the practice of pharmacy and the sale of dangerous drugs or dangerous devices by the California State Board of Pharmacy, in the Department of Consumer Affairs. Under existing law, on and after January 1, 2009, pedigree means an electronic record 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 one or more wholesalers, manufacturers, or pharmacies, until final sale to a pharmacy or other person furnishing, administering, or dispensing the dangerous drug. On and after January 1, 2009, existing law prohibits a wholesaler or pharmacy from selling, trading, or transferring a dangerous drug without a pedigree or from acquiring a dangerous drug without receiving a pedigree. Existing law, on and after January 1, 2009, requires that a pedigree include certain information, including, but not limited to, the source of the dangerous drug and the trade or generic name of the drug. Existing law exempts specified transactions from the pedigree requirement, and authorizes the board to extend the January 1, 2009, compliance date to January 1, 2011, in specified circumstances. Existing law makes it a crime to knowingly violate the Pharmacy Law.

This bill would instead, on and after January 1, 2015, define a pedigree, as specified, and would revise the information required to be contained in a pedigree to, among other things, include a specified unique identification number.

The bill would prohibit a wholesaler or repackager, as defined, on and after July 1, 2016, or a pharmacy, on and after July 1, 2017, from selling, trading, or transferring a dangerous drug without a pedigree or from acquiring a dangerous drug without receiving a

pedigree, except as specified. The bill would prohibit a pharmacy warehouse, as defined, on and after July 1, 2017, from acquiring a dangerous drug without receiving a pedigree. The bill would delete the board's authority to extend these compliance dates. The bill would also prohibit a repackager or pharmacy from furnishing a dangerous drug or dangerous device to an unauthorized person. The bill would require a manufacturer of a dangerous drug distributed in California to designate certain percentages of the drugs that it manufactures to comply with the pedigree requirement by specified dates, and to notify the board of the drugs so designated and of the technology to be used to meet that requirement. The bill would also revise certain exemptions from the pedigree requirement and would exempt specified additional transactions from the pedigree requirement.

The bill would authorize a manufacturer, wholesaler, or pharmacy in possession of dangerous drugs manufactured or distributed prior to the operative date of the pedigree requirements to designate those drugs as not subject to the requirements by preparing a specified written declaration under penalty of perjury, which would be considered trade secrets and kept confidential by the board. The bill would authorize dangerous drugs designated on such a declaration to be purchased, sold, acquired, returned, or otherwise transferred, without meeting the pedigree requirements if the transfer complies with specified requirements. Because a knowing violation of the bill's provisions would be a crime under the Pharmacy Law and because the bill would expand the crime of perjury, the bill would impose a state-mandated local program.

The bill would require the board to promulgate regulations defining the circumstances under which participants in the distribution chain may infer the contents of a case, pallet, or other aggregate of individual units, packages, or containers of dangerous drugs, from a unique identifier associated with the case, pallet, or other aggregate, if certain standard operating procedures are complied with and made available for the board to review. The bill would require board regulations to specify liability associated with accuracy of product information and pedigree using inference. The bill would declare the intent of the Legislature in this regard.

The bill would make the pedigree requirements inoperative upon the effective date of federal law addressing pedigree or serialization measures for dangerous drugs, or as otherwise specified in the event of a conflict with federal law.

Existing law requires an applicant for issuance or renewal of a wholesaler or nonresident wholesaler license to submit a surety bond of \$100,000 or an equivalent means of security to secure payment of any administrative fines and costs imposed by the board. Existing law makes this requirement inoperative and repeals it on January 1, 2015.

This bill would delete the date upon which these provisions become inoperative and are repealed.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 4033 of the Business and Professions Code is amended to read:

4033. (a) (1) "Manufacturer" means and includes every person who prepares, derives, produces, compounds, or repackages any drug or device except a pharmacy that manufactures on the immediate premises where the drug or device is sold to the ultimate consumer.

(2) Notwithstanding paragraph (1), "manufacturer" shall not mean a pharmacy compounding a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy for the purpose of delivering or administering the drug to the patient or patients named in the prescription, provided that neither the components for the drug nor the drug are compounded, fabricated, packaged, or otherwise prepared prior to receipt of the prescription.

(3) Notwithstanding paragraph (1), "manufacturer" shall not mean a pharmacy that, at a patient's request, repackages a drug previously dispensed to the patient, or to the patient's agent, pursuant to a prescription.

(b) Notwithstanding subdivision (a), as used in Sections 4034, 4163, 4163.1, 4163.2, 4163.3, 4163.4, and 4163.5, "manufacturer" means a person who prepares, derives, manufactures, produces, or repackages a dangerous drug, as defined in Section 4022, device, or cosmetic. Manufacturer also means the holder or holders of a New Drug Application (NDA), an Abbreviated New Drug Application (ANDA), or a Biologics License Application (BLA), provided that such application has been approved; a manufacturer's third party logistics provider; a private label distributor (including colicensed partners) for whom the private label distributor's prescription drugs are originally manufactured and labeled for the distributor and have not been repackaged; or the distributor agent for the manufacturer, contract manufacturer, or private label distributor, whether the establishment is a member of the manufacturer's affiliated group (regardless of whether the member takes title to the drug) or is a contract distributor site.

SEC. 2. Section 4034 of the Business and Professions Code is amended to read:

4034. (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 one or more wholesalers, manufacturers, repackagers, or pharmacies, until final sale to a pharmacy or other person furnishing, administering, or dispensing the dangerous drug. The pedigree shall be created and maintained in an interoperable electronic system, ensuring compatibility throughout all stages of distribution.

(b) A pedigree shall include all of the following information:

(1) The source of the dangerous drug, including the name, the federal manufacturer's registration number or a state license number as determined by the board, and principal address of the source.

(2) The trade or generic name of the dangerous drug, the quantity of the dangerous drug, its dosage form and strength, the date of the transaction, the sales invoice number or, if not immediately available, a customer-specific shipping reference number linked to the sales invoice number, the container size, the number of containers, the expiration dates, and the lot numbers.

(3) The business name, address, and the federal manufacturer's

registration number or a state license number as determined by the board, 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.

(4) A certification under penalty of perjury from a responsible party of the source of the dangerous drug that the information contained in the pedigree is true and accurate.

(5) The unique identification number described in subdivision (i).

(c) A single pedigree shall include every change of ownership of a given dangerous drug from its initial manufacture through to its final transaction to a pharmacy or other person for furnishing, administering, or dispensing the drug, regardless of repackaging or assignment of another National Drug Code (NDC) Directory number. Dangerous drugs that are repackaged shall be serialized by the repackager and a pedigree shall be provided that references the pedigree of the original package or packages provided by the manufacturer.

(d) A pedigree shall track each dangerous drug at the smallest package or immediate container distributed by the manufacturer, received and distributed by the wholesaler or repackager, and received by the pharmacy or another person furnishing, administering, or dispensing the dangerous drug. For purposes of this section, the "smallest package or immediate container" of a dangerous drug shall include any dangerous drug package or container made available to a repackager, wholesaler, pharmacy, or other entity for repackaging or redistribution, as well as the smallest unit made by the manufacturer for sale to the pharmacy or other person furnishing, administering, or dispensing the drug.

(e) Any return of a dangerous drug to a wholesaler or manufacturer shall be documented on the same pedigree as the transaction that resulted in the receipt of the drug by the party returning it.

(f) If a licensed health care service plan, hospital organization, and one or more physician organizations have exclusive contractual relationships to provide health care services, drugs distributed between these persons shall be deemed not to have changed ownership.

(g) The following transactions are exempt from the pedigree requirement created by this section:

(1) An intracompany sale or transfer of a dangerous drug. For purposes of this section, "intracompany sale or transfer" means any transaction for any valid business purpose between a division, subsidiary, parent, or affiliated or related company under the common ownership and control of the same corporate or legal entity.

(2) Dangerous drugs received by the state or a local government entity from a department or agency of the federal government or an agent of the federal government specifically authorized to deliver dangerous drugs to the state or local government entity.

(3) The provision of samples of dangerous drugs by a manufacturer's employee to an authorized prescriber, provided the samples are dispensed to a patient of the prescriber without charge.

(4) (A) A sale, trade, or transfer of a radioactive drug, as defined in Section 1708.3 of Title 16 of the California Code of Regulations, between any two entities licensed by the Radiologic Health Branch of the State Department of Public Health, the federal Nuclear Regulatory Commission, or an Agreement state.

(B) The exemption in this paragraph shall remain in effect unless the board, no earlier than the date that is two years after the

compliance date for manufacturers set forth in subdivision (k) of Section 4034 or Section 4163.5, determines after consultation with the Radiologic Health Branch of the State Department of Public Health that the risk of counterfeiting or diversion of a radioactive drug is sufficient to require a pedigree. Two years following the date of any such determination, this paragraph shall become inoperative.

(5) The sale, trade, or transfer of a dangerous drug that is labeled by the manufacturer as "for veterinary use only."

(6) The sale, trade, or transfer of compressed medical gas. For purposes of this section, "compressed medical gas" means any substance in its gaseous or cryogenic liquid form that meets medical purity standards and has application in a medical or homecare environment, including, but not limited to, oxygen and nitrous oxide.

(7) The sale, trade, or transfer of solutions. For purposes of this section, "solutions" means any of the following:

(A) Those intravenous products that, by their formulation, are intended for the replenishment of fluids and electrolytes, such as sodium, chloride, and potassium, calories, such as dextrose and amino acids, or both.

(B) Those intravenous products used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions.

(C) Products that are intended for irrigation or reconstitution, as well as sterile water, whether intended for those purposes or for injection.

(8) Dangerous drugs that are placed in a sealed package with a medical device or medical supplies at the point of first shipment into commerce by the manufacturer and the package remains sealed until the drug and device are used, provided that the package is only used for surgical purposes.

(9) A product that meets either of the following criteria:

(A) A product comprised of two or more regulated components, such as a drug/device, biologic/device, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity.

(B) Two or more separate products packaged together in a single package or as a unit and comprised of drug and device products or device and biological products.

(h) If a manufacturer, wholesaler, or pharmacy has reasonable cause to believe that a dangerous drug in, or having been in, its possession is counterfeit or the subject of a fraudulent transaction, the manufacturer, wholesaler, or pharmacy shall notify the board within 72 hours of obtaining that knowledge. This subdivision shall apply to any dangerous drug that has been sold or distributed in or through this state.

(i) "Interoperable electronic system" as used in this chapter means an electronic track and trace system for dangerous drugs that uses a unique identification number, established at the point of manufacture and supplemented by a linked unique identification number in the event that drug is repackaged, contained within a standardized nonproprietary data format and architecture, that is uniformly used by manufacturers, wholesalers, repackagers, and pharmacies for the pedigree of a dangerous drug. No particular data carrier or other technology is mandated to accomplish the attachment of the unique identification number described in this subdivision.

(j) The application of the pedigree requirement shall be subject to review during the board's evaluation pursuant to Section 473.4.

(k) This section shall become operative on January 1, 2015.

SEC. 3. Section 4034.1 is added to the Business and Professions Code, to read:

4034.1. (a) (1) Upon the effective date of federal legislation or adoption of a federal regulation addressing pedigree or serialization measures for dangerous drugs, Sections 4034, 4163, 4163.1, 4163.2, 4163.4, and 4163.5 shall become inoperative.

(2) Within 90 days of the enactment of federal legislation or adoption of a regulation addressing pedigree or serialization measures for dangerous drugs, the board shall publish a notice that Sections 4034, 4163, 4163.1, 4163.2, 4163.4, and 4163.5 are inoperative.

(3) Within 90 days of the enactment of federal legislation or adoption of a regulation that is inconsistent with any provision of California law governing the application of any pedigree or serialization requirement or standard, the board shall adopt emergency regulations necessary to reflect the inoperation of state law.

(b) (1) If the Food and Drug Administration (FDA) enacts any rule, standard, or takes any other action that is inconsistent with any provision of California law governing application of a pedigree to a dangerous drug, that provision of California law shall be inoperative.

(2) Within 90 days of the FDA enacting any rule, standard, or taking any other action that is inconsistent with any provision of California law governing application of a pedigree to a dangerous drug, the board shall publish a notice that the provision is inoperative.

(3) Within 90 days of the FDA enacting any rule, standard, or taking any other action that is inconsistent with any provision of California law governing application of a pedigree to a dangerous drug, the board shall adopt emergency regulations necessary to reflect the inoperation of state law.

(c) If the board fails to recognize the inoperation within 90 days pursuant to this section, nothing in this section shall preclude a party from filing an action in state or federal court for declaratory or injunctive relief as an alternative to filing a petition with the board.

SEC. 4. Section 4044 is added to the Business and Professions Code, to read:

4044. "Repackager" means a person or entity that is registered with the federal Food and Drug Administration as a repackager and operates an establishment that packages finished drugs from bulk or that repackages dangerous drugs into different containers, excluding shipping containers.

SEC. 5. Section 4045 is added to the Business and Professions Code, to read:

4045. "Third-party logistics provider" or "reverse third-party logistic provider" means an entity licensed as a wholesaler that contracts with a dangerous drug manufacturer to provide or coordinate warehousing, distribution, or other similar services on behalf of a manufacturer, but for which there is no change of ownership in the dangerous drugs. For purposes of Sections 4034, 4163, 4163.1, 4163.2, 4163.3, 4163.4, and 4163.5, a third-party logistics provider shall not be responsible for generating or updating pedigree documentation, but shall maintain copies of the pedigree. To be exempt from documentation for pedigrees, a reverse third-party logistic provider

may only accept decommissioned drugs from pharmacies or wholesalers.

SEC. 6. Section 4162 of the Business and Professions Code is amended to read:

4162. (a) (1) An applicant, that is not a government owned and operated wholesaler, for the issuance or renewal of a wholesaler license shall submit a surety bond of one hundred thousand dollars (\$100,000) or other equivalent means of security acceptable to the board payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.

(2) For purposes of paragraph (1), the board may accept a surety bond less than one hundred thousand dollars (\$100,000) if the annual gross receipts of the previous tax year for the wholesaler is ten million dollars (\$10,000,000) or less, in which case the surety bond shall be twenty-five thousand dollars (\$25,000).

(3) A person to whom an approved new drug application has been issued by the United States Food and Drug Administration who engages in the wholesale distribution of only the dangerous drug specified in the new drug application, and is licensed or applies for licensure as a wholesaler, shall not be required to post a surety bond as provided in paragraph (1).

(4) For licensees subject to paragraph (2) or (3), the board may require a bond up to one hundred thousand dollars (\$100,000) for any licensee who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to this chapter.

(b) The board may make a claim against the bond if the licensee fails to pay a fine within 30 days after the order imposing the fine, or costs become final.

(c) A single surety bond or other equivalent means of security acceptable to the board shall satisfy the requirement of subdivision (a) for all licensed sites under common control as defined in Section 4126.5.

SEC. 7. Section 4162.5 of the Business and Professions Code is amended to read:

4162.5. (a) (1) An applicant for the issuance or renewal of a nonresident wholesaler license shall submit a surety bond of one hundred thousand dollars (\$100,000), or other equivalent means of security acceptable to the board, such as an irrevocable letter of credit, or a deposit in a trust account or financial institution, payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.

(2) For purposes of paragraph (1), the board may accept a surety bond less than one hundred thousand dollars (\$100,000) if the annual gross receipts of the previous tax year for the nonresident wholesaler is ten million dollars (\$10,000,000) or less in which the surety bond shall be twenty-five thousand dollars (\$25,000).

(3) For applicants who satisfy paragraph (2), the board may require a bond up to one hundred thousand dollars (\$100,000) for any nonresident wholesaler who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to this chapter.

(4) A person to whom an approved new drug application or a biologics license application has been issued by the United States Food and Drug Administration who engages in the wholesale

distribution of only the dangerous drug specified in the new drug application or biologics license application, and is licensed or applies for licensure as a nonresident wholesaler, shall not be required to post a surety bond as provided in this section.

(b) The board may make a claim against the bond if the licensee fails to pay a fine within 30 days of the issuance of the fine or when the costs become final.

(c) A single surety bond or other equivalent means of security acceptable to the board shall satisfy the requirement of subdivision (a) for all licensed sites under common control as defined in Section 4126.5.

SEC. 8. Section 4163 of the Business and Professions Code is amended to read:

4163. (a) A manufacturer, wholesaler, repackager, or pharmacy may not furnish a dangerous drug or dangerous device to an unauthorized person.

(b) Dangerous drugs or dangerous devices shall be acquired from a person authorized by law to possess or furnish dangerous drugs or dangerous devices. When the person acquiring the dangerous drugs or dangerous devices is a wholesaler, the obligation of the wholesaler shall be limited to obtaining confirmation of licensure of those sources from whom it has not previously acquired dangerous drugs or dangerous devices.

(c) Except as otherwise provided in Section 4163.5, commencing on July 1, 2016, a wholesaler or repackager may not sell, trade, or transfer a dangerous drug at wholesale without providing a pedigree.

(d) Except as otherwise provided in Section 4163.5, commencing on July 1, 2016, a wholesaler or repackager may not acquire a dangerous drug without receiving a pedigree.

(e) Except as otherwise provided in Section 4163.5, commencing on July 1, 2017, a pharmacy may not sell, trade, or transfer a dangerous drug at wholesale without providing a pedigree.

(f) Except as otherwise provided in Section 4163.5, commencing on July 1, 2017, a pharmacy may not acquire a dangerous drug without receiving a pedigree.

(g) Except as otherwise provided in Section 4163.5, commencing on July 1, 2017, a pharmacy warehouse may not acquire a dangerous drug without receiving a pedigree. For purposes of this section and Section 4034, a "pharmacy warehouse" means a physical location licensed as a wholesaler for prescription drugs that acts as a central warehouse and performs intracompany sales or transfers of those drugs to a group of pharmacies under common ownership and control.

SEC. 9. Section 4163.1 is added to the Business and Professions Code, to read:

4163.1. (a) For purposes of Sections 4034 and 4163, "drop shipment" means a sale of a dangerous drug by the manufacturer of the dangerous drug whereby all of the following occur:

(1) The pharmacy, or other person authorized by law to dispense or administer the drug, receives delivery of the dangerous drug directly from the manufacturer.

(2) The wholesale distributor takes ownership of, but not physical possession of, the dangerous drug.

(3) The wholesale distributor invoices the pharmacy or other person authorized by law to dispense or administer the drug in place of the manufacturer.

(b) The board may develop regulations to establish an alternative

process to convey the pedigree information required in Section 4034 for dangerous drugs that are sold by drop shipment.

SEC. 10. Section 4163.2 is added to the Business and Professions Code, to read:

4163.2. (a) (1) A manufacturer, wholesaler, or pharmacy lawfully possessing or owning dangerous drugs manufactured or distributed prior to the operative date of the pedigree requirements, specified in Sections 4034 and 4163, may designate these dangerous drugs as not subject to the pedigree requirements by preparing a written declaration made under penalty of perjury that lists those dangerous drugs.

(2) The written declaration shall include the National Drug Code Directory lot number for each dangerous drug designated. The written declaration shall be submitted to and received by the board no later than 30 days after the operative date of the pedigree requirements. The entity or person submitting the written declaration shall also retain for a period of three years and make available for inspection by the board a copy of each written declaration submitted.

(3) The board may, by regulation, further specify the requirements and procedures for the creation and submission of these written declarations. Information contained in these declarations shall be considered trade secrets and kept confidential by the board.

(b) Any dangerous drugs designated on a written declaration timely created and submitted to the board may be purchased, sold, acquired, returned, or otherwise transferred without meeting the pedigree requirements, if the transfer complies with the other requirements of this chapter.

SEC. 11. Section 4163.3 is added to the Business and Professions Code, to read:

4163.3. (a) It is the intent of the Legislature that participants in the distribution chain for dangerous drugs, including manufacturers, wholesalers, or pharmacies furnishing, administering, or dispensing dangerous drugs, distribute and receive electronic pedigrees, and verify and validate the delivery and receipt of dangerous drugs against those pedigrees at the unit level, in a manner that maintains the integrity of the pedigree system without an unacceptable increase in the risk of diversion or counterfeiting.

(b) To meet this goal, and to facilitate efficiency and safety in the distribution chain, the board shall, by regulation, define the circumstances under which participants in the distribution chain may infer the contents of a case, pallet, or other aggregate of individual units, packages, or containers of dangerous drugs, from a unique identifier associated with the case, pallet, or other aggregate, without opening each case, pallet, or other aggregate or otherwise individually validating each unit.

(c) Manufacturers, wholesalers, and pharmacies opting to employ the use of inference as authorized by the board to comply with the pedigree requirements shall document their processes and procedures in their standard operating procedures (SOPs) and shall make those SOPs available for board review.

(d) SOPs regarding inference shall include a process for statistically sampling the accuracy of information sent with inbound product.

(e) Liability associated with accuracy of product information and pedigree using inference shall be specified in the board's regulations.

SEC. 12. Section 4163.4 is added to the Business and Professions

Code, to read:

4163.4. (a) All units of dangerous drug in the possession of a wholesaler or pharmacy, for which the manufacturer does not hold legal title on the effective date of the pedigree requirement set forth in Section 4163.5, shall not be subject to the pedigree requirements set forth in Sections 4034 and 4163. However, if any units of those drugs are subsequently returned to the manufacturer, they shall be subject to the pedigree requirements if the manufacturer distributes those units in California.

(b) All units of dangerous drug manufactured in California but distributed outside the state for dispensing outside the state shall not be subject to the pedigree requirements set forth in Sections 4034 and 4163 at either the time of initial distribution or in the event that any of those units are subsequently returned to the manufacturer.

SEC. 13. Section 4163.5 of the Business and Professions Code is repealed.

SEC. 14. Section 4163.5 is added to the Business and Professions Code, to read:

4163.5. (a) The Legislature hereby finds and declares that:

(1) The electronic pedigree system required by Sections 4034 and 4163 will provide tremendous benefits to the public and to all participants in the distribution chain. Those benefits should be made available as quickly as possible through the full cooperation of prescription drug supply chain participants. To this end, all drug manufacturers and repackagers are strongly encouraged to serialize drug products and initiate electronic pedigrees as soon as possible, and all participants in the supply chain are encouraged to immediately ready themselves to receive and pass electronic pedigrees.

(2) At the same time, it is recognized that the process of implementing serialized electronic pedigree for all prescription drugs in the entire chain of distribution is a complicated technological and logistical undertaking for manufacturers, wholesalers, repackagers, pharmacies, and other supply chain participants. The Legislature seeks to ensure continued availability of prescription drugs in California while participants implement these requirements.

(b) Before January 1, 2015, each manufacturer of a dangerous drug distributed in California shall designate those dangerous drugs representing a minimum of 50 percent of its drugs, generic or single source, distributed in California, for which it is listed as the manufacturer by the federal Food and Drug Administration, which shall be the subject of its initial phase of compliance with the January 1, 2015, deadline of the state's serialized electronic pedigree requirements set forth in Sections 4034 and 4163. Each manufacturer shall notify the Board of Pharmacy of the drugs so designated and the measure or measures used in designating its drugs to be serialized, and shall include in the notification the technology to be used to meet the serialized electronic pedigree requirements. The notification process for these specific actions may be specified by the board.

(c) Before January 1, 2016, each manufacturer of a dangerous drug distributed in California shall designate the final 50 percent of its drugs, generic or single source, distributed in California for which it is listed as the manufacturer by the federal Food and Drug Administration that

are subject to the state's serialized electronic pedigree requirements set forth in Sections 4034 and 4163, which shall comply with the state's serialized electronic pedigree requirement by January 1, 2016. Each manufacturer shall notify the Board of Pharmacy of the drugs so designated and the measure or measures used in designating its drugs to be serialized, and shall include in the notification the technology to be used to meet the serialized electronic pedigree requirements. The notification process for these specific actions may be specified by the board.

(d) For purposes of designating drugs to be serialized as required by subdivisions (b) and (c), manufacturers shall select from any of the following measures:

- (1) Unit volume.
- (2) Product package (SKU) type.
- (3) Drug product family.

(e) Drugs not subject to compliance with the pedigree requirements set forth in Sections 4034 and 4163 under this section shall not be subject to the provisions of subdivisions (c), (d), (e), and (f) of Section 4163.

SEC. 15. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

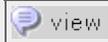
APPENDIX VIII

**MARYLAND BOARD OF PHARMACY  
ELECTRONIC TRACK AND TRACE SURVEY**

**WHOLESALE DISTRIBUTOR RESPONSES**

| <b>1. Please check below if you are:</b> |                    |                    |                       |
|------------------------------------------|--------------------|--------------------|-----------------------|
|                                          | <b>No</b>          | <b>Yes</b>         | <b>Response Count</b> |
| Independent pharmacy                     | <b>91.7% (33)</b>  | 8.3% (3)           | 36                    |
| Chain pharmacy                           | <b>97.1% (33)</b>  | 2.9% (1)           | 34                    |
| Chain pharmacy distribution center       | <b>93.9% (31)</b>  | 6.1% (2)           | 33                    |
| Hospital pharmacy                        | <b>100.0% (34)</b> | 0.0% (0)           | 34                    |
| Wholesale Distributor                    | 0.0% (0)           | <b>100.0% (46)</b> | 46                    |
| Manufacturer                             | <b>73.5% (25)</b>  | 26.5% (9)          | 34                    |
| Third Party Logistics Provider           | <b>91.7% (33)</b>  | 8.3% (3)           | 36                    |
| Returns Processor                        | <b>93.8% (30)</b>  | 6.3% (2)           | 32                    |
| Health Care Facility                     | <b>97.1% (33)</b>  | 2.9% (1)           | 34                    |

| 1. Please check below if you are: |                          |           |
|-----------------------------------|--------------------------|-----------|
|                                   | <i>answered question</i> | <b>46</b> |
|                                   | <i>skipped question</i>  | <b>0</b>  |

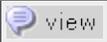
| 2. At what packaging unit level does your company currently electronically track any prescription pharmaceutical products? (choose all that apply) |                                                                                                            |                   |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|-------------------|----------------|
|                                                                                                                                                    | No                                                                                                         | Yes               | Response Count |
| Unit of Use                                                                                                                                        | 33.3% (3)                                                                                                  | <b>66.7% (6)</b>  | 9              |
| Cases                                                                                                                                              | 0.0% (0)                                                                                                   | <b>100.0% (5)</b> | 5              |
| Pallets                                                                                                                                            | <b>100.0% (1)</b>                                                                                          | 0.0% (0)          | 1              |
| Lots                                                                                                                                               | 8.3% (1)                                                                                                   | <b>91.7% (11)</b> | 12             |
| None                                                                                                                                               | <b>75.0% (18)</b>                                                                                          | 25.0% (6)         | 24             |
|                                                                                                                                                    |  Other (please specify) |                   | 7              |
|                                                                                                                                                    | <i>answered question</i>                                                                                   |                   | <b>43</b>      |
|                                                                                                                                                    | <i>skipped question</i>                                                                                    |                   | <b>3</b>       |

| Comment Text                                                                                                                                                             | Response Date        |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
|  1. Currently we use a papertrail for pedigree                                        | Tue, 7/29/08 3:00 PM |
|  2. Invoice - All records are keep on the computer, files or documents stored online. | Wed, 7/16/08 2:10 PM |

-  **3.** Product Description NDC Unite of Sale Quantities Shipped Reference Number Reference Type Date Wed, 7/16/08 11:40 AM
-  **4.** Every pharmaceutical that comes in and goes out of facility is tracked by lot number in our accounting system. It is not "electronically" tracked via any system similar to RFID. Wed, 7/16/08 10:11 AM
-  **5.** Smiths Medical, license #D0219, does not distribute drugs into the state of Maryland. Smiths Medical only distributes prescription medical devices that do NOT contain drugs. Wed, 7/16/08 10:10 AM
-  **6.** We do not electronically track any product Tue, 7/15/08 6:41 PM
-  **7.** What do you want me to write here? Mon, 7/14/08 4:53 PM

| <b>3. Is your company equipped or planning to supply down stream partners with equipment and/or software for electronic track and trace technology?</b> |                                                                                                            |                         |                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|-------------------------|-----------------------|
|                                                                                                                                                         |                                                                                                            | <b>Response Percent</b> | <b>Response Count</b> |
| <b>No</b>                                                                                                                                               |                                                                                                            | <b>61.9%</b>            | 26                    |
| Yes                                                                                                                                                     |                                                                                                            | 16.7%                   | 7                     |
| Not sure                                                                                                                                                |                                                                                                            | 23.8%                   | 10                    |
|                                                                                                                                                         |  Other (please specify) |                         | 2                     |
|                                                                                                                                                         | <b><i>answered question</i></b>                                                                            |                         | <b>42</b>             |
|                                                                                                                                                         | <b><i>skipped question</i></b>                                                                             |                         | <b>4</b>              |

| <b>Comment Text</b>                                                                                                                                                                   | <b>Response Date</b> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
|  <b>1.</b> We operate as a reverse distributor and do not distribute product back to the consumers | Mon, 8/4/08 10:56 AM |
|  <b>2.</b> To the case, yes....To the unit (RFID), no                                              | Tue, 7/15/08 6:18 PM |

| 4. What unique identifier system (data carrier) does your company use to identify product at the unit level? (choose all that apply) |                                                                                                                              |            |                |
|--------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|------------|----------------|
|                                                                                                                                      | No                                                                                                                           | Yes        | Response Count |
| 2-D Barcode                                                                                                                          | 84.2% (16)                                                                                                                   | 15.8% (3)  | 19             |
| Linear Barcode                                                                                                                       | 50.0% (12)                                                                                                                   | 54.2% (13) | 24             |
| Data Matrix                                                                                                                          | 94.4% (17)                                                                                                                   | 5.6% (1)   | 18             |
| Data Bar Barcode                                                                                                                     | 95.0% (19)                                                                                                                   | 5.0% (1)   | 20             |
| Radio Frequency Identifier (RFID)                                                                                                    | 85.7% (18)                                                                                                                   | 14.3% (3)  | 21             |
| None                                                                                                                                 | 48.0% (12)                                                                                                                   | 52.0% (13) | 25             |
|                                                                                                                                      |  Other identifier System (please specify) |            | 4              |
|                                                                                                                                      | <b>answered question</b>                                                                                                     |            | <b>39</b>      |
|                                                                                                                                      | <b>skipped question</b>                                                                                                      |            | <b>7</b>       |

| Comment Text                                                                                                                                     | Response Date         |
|--------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
|  1. NDC number                                                | Wed, 7/23/08 3:23 PM  |
|  2. We use NDC (National Drug Code) to identify all products. | Wed, 7/23/08 3:16 PM  |
|  3. Software                                                  | Wed, 7/16/08 11:40 AM |
|  4. UPC code                                                  | Tue, 7/15/08 6:31 PM  |

| 5. What unique identifier system (data carrier) does your company use to identify product at the case level? (choose all that apply) |                                                                                                                              |            |                |
|--------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|------------|----------------|
|                                                                                                                                      | No                                                                                                                           | Yes        | Response Count |
| 2-D Barcode                                                                                                                          | 70.0% (14)                                                                                                                   | 30.0% (6)  | 20             |
| Linear Barcode                                                                                                                       | 47.6% (10)                                                                                                                   | 52.4% (11) | 21             |
| Data Matrix                                                                                                                          | 88.9% (16)                                                                                                                   | 11.1% (2)  | 18             |
| Data Bar Barcode                                                                                                                     | 95.0% (19)                                                                                                                   | 5.0% (1)   | 20             |
| Radio Frequency Identifier (RFID)                                                                                                    | 85.0% (17)                                                                                                                   | 15.0% (3)  | 20             |
| None                                                                                                                                 | 47.8% (11)                                                                                                                   | 52.2% (12) | 23             |
|                                                                                                                                      |  Other Identifier System (please specify) |            | 4              |
|                                                                                                                                      | <b>answered question</b>                                                                                                     |            | <b>38</b>      |
|                                                                                                                                      | <b>skipped question</b>                                                                                                      |            | <b>8</b>       |

| Comment Text                                                                                                                | Response Date        |
|-----------------------------------------------------------------------------------------------------------------------------|----------------------|
|  1. NDC number                           | Wed, 7/23/08 3:23 PM |
|  2. We use NDC to identify all products. | Wed, 7/23/08 3:16 PM |



3. Software

Wed, 7/16/08 11:40 AM



4. UCC Case Label

Tue, 7/15/08 6:31 PM

| 6. Does your company currently use a unique identifier number (serialization) to identify individual products? (choose all that apply) |            |              |              |            |                |
|----------------------------------------------------------------------------------------------------------------------------------------|------------|--------------|--------------|------------|----------------|
|                                                                                                                                        | None       | Some (< 50%) | Most (> 50%) | All (100%) | Response Count |
| Over-The-Counter (OTC)                                                                                                                 | 76.9% (30) | 2.6% (1)     | 2.6% (1)     | 17.9% (7)  | 39             |
| Prescription medications that are Non-Controlled Dangerous Substances (Non-CDS)                                                        | 67.5% (27) | 5.0% (2)     | 5.0% (2)     | 25.0% (10) | 40             |
| Prescription medications that are Controlled Dangerous Substances (CDS)                                                                | 78.9% (30) | 2.6% (1)     | 5.3% (2)     | 13.2% (5)  | 38             |
|  Other (please specify)                             |            |              |              |            | 3              |
| <b>answered question</b>                                                                                                               |            |              |              |            | <b>41</b>      |
| <b>skipped question</b>                                                                                                                |            |              |              |            | <b>5</b>       |

| Comment Text | Response Date |
|--------------|---------------|
|--------------|---------------|



1. Our own warehouse order number, if applicable.

Tue, 8/5/08 9:18 AM



2. All items are tracked by their lot number. We have adopted a system to enable us to track specific receipts so we can then go

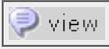
Wed, 7/16/08 10:11 AM

back to the paperwork from our supplier to create pedigrees when needed.



3. Not applicable

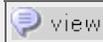
Wed, 7/16/08 10:10 AM

| . In the future, all companies may need to transition to track and trace technology. What technology is your company using, or planning to use, for data interchange with your partners? |  |                          |                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--------------------------|----------------|
|                                                                                                                                                                                          |  | Response Percent         | Response Count |
| Electronic Product Code Information System (EPCIS)                                                                                                                                       |  | 11.6%                    | 5              |
| Drug Pedigree Messaging Standard (DPMS)                                                                                                                                                  |  | 16.3%                    | 7              |
| Combination of EPCIS & DPMS                                                                                                                                                              |  | 7.0%                     | 3              |
| <b>Not sure</b>                                                                                                                                                                          |  | <b>62.8%</b>             | <b>27</b>      |
|  Other (please specify)                                                                               |  | 2.3%                     | 1              |
|                                                                                                                                                                                          |  | <b>answered question</b> | <b>43</b>      |
|                                                                                                                                                                                          |  | <b>skipped question</b>  | <b>3</b>       |

| 8. Does your company currently have the capability to make pedigree information available to customers on the Internet? |  |                          |                |
|-------------------------------------------------------------------------------------------------------------------------|--|--------------------------|----------------|
|                                                                                                                         |  | Response Percent         | Response Count |
| No                                                                                                                      |  | 55.8%                    | 24             |
| Yes                                                                                                                     |  | 44.2%                    | 19             |
|                                                                                                                         |  | <i>answered question</i> | <b>43</b>      |
|                                                                                                                         |  | <i>skipped question</i>  | <b>3</b>       |

| 9. Do you currently maintain any repository of drug information at the unit level? |  |                          |                |
|------------------------------------------------------------------------------------|--|--------------------------|----------------|
|                                                                                    |  | Response Percent         | Response Count |
| No                                                                                 |  | 58.1%                    | 25             |
| Yes                                                                                |  | 41.9%                    | 18             |
|                                                                                    |  | <i>answered question</i> | <b>43</b>      |
|                                                                                    |  | <i>skipped question</i>  | <b>3</b>       |

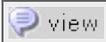
| 10. What data standards are you using or planning to use for serialization? |  |                  |                |
|-----------------------------------------------------------------------------|--|------------------|----------------|
|                                                                             |  | Response Percent | Response Count |
|                                                                             |  |                  |                |

| 10. What data standards are you using or planning to use for serialization? |                                                                                                          |                          |           |
|-----------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|--------------------------|-----------|
| Global Trade Item Number (GTIN-96)                                          |                                                                                                          | 11.9%                    | 5         |
| Serialized Shipping Container Code (SSCC)                                   |                                                                                                          | 9.5%                     | 4         |
| Not sure                                                                    |                                                                                                          | 83.3%                    | 35        |
|                                                                             |  Other (please specify) |                          | 1         |
|                                                                             |                                                                                                          | <b>answered question</b> | <b>42</b> |
|                                                                             |                                                                                                          | <b>skipped question</b>  | <b>4</b>  |

| Comment Text                                                                                                                                                                                                                                                         | Response Date         |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
|  1. Smiths Medical, license #D0219, does not distribute drugs into the state of Maryland. Smiths Medical only distributes prescription medical devices that do NOT contain drugs. | Wed, 7/16/08 10:10 AM |

| 11. Do you include National Drug Code (NDC) in the Global Trade Item Number (GTIN)? |                  |                |
|-------------------------------------------------------------------------------------|------------------|----------------|
|                                                                                     | Response Percent | Response Count |
| No                                                                                  | 68.3%            | 28             |
| Yes                                                                                 | 31.7%            | 13             |

| 11. Do you include National Drug Code (NDC) in the Global Trade Item Number (GTIN)? |                          |    |
|-------------------------------------------------------------------------------------|--------------------------|----|
|                                                                                     | <i>answered question</i> | 41 |
|                                                                                     | <i>skipped question</i>  | 5  |

| 12. What does your company view as obstacles in implementing uniquely identified unit-level products? (choose all that apply) |                                                                                                                 |            |                |
|-------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------|------------|----------------|
|                                                                                                                               | Yes                                                                                                             | Not sure   | Response Count |
| Cost                                                                                                                          | 92.3% (36)                                                                                                      | 7.7% (3)   | 39             |
| Time                                                                                                                          | 86.8% (33)                                                                                                      | 13.2% (5)  | 38             |
| Technology                                                                                                                    | 88.6% (31)                                                                                                      | 11.4% (4)  | 35             |
| Lack of uniform standards                                                                                                     | 91.9% (34)                                                                                                      | 8.1% (3)   | 37             |
| Lack of computer technology                                                                                                   | 59.3% (16)                                                                                                      | 40.7% (11) | 27             |
| Availability of Hardware/Software throughout the supply chain                                                                 | 81.3% (26)                                                                                                      | 18.8% (6)  | 32             |
|                                                                                                                               |  Please comment on responses |            | 3              |
|                                                                                                                               | <i>answered question</i>                                                                                        |            | 42             |
|                                                                                                                               | <i>skipped question</i>                                                                                         |            | 4              |

**12. What does your company view as obstacles in implementing uniquely identified unit-level products? (choose all that apply)**

|                                                                                   | <b>Comment Text</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <b>Response Date</b>  |
|-----------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
|  | 1. Incomplete information from vendors is also a concern.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Tue, 8/5/08 9:18 AM   |
|  | 2. We purchase most items by a case and sell them as an individual unit. Products are mostly purchased direct from manufacturers who are not required or willing to provide any time of electronic information. Otherwise we purchase from a Big 5 wholesaler who does not and will not provide any type of traceability information for the product. So we are stuck with all the investment (time and money) in creating/purchasing a system to assist in this process, but it is futile because we cannot verify items purchased by the major wholesaler, so what good is it for us trace it. Since these laws are being created at the state level, it makes it very difficult for a nation-wide distributor to comply with each state's differing laws. Laws that at times contradict each other and laws that tend to interfere with interstate commerce. | Wed, 7/16/08 10:11 AM |
|  | 3. Not applicable                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Wed, 7/16/08 10:10 AM |

**13. Which approach does your company support in implementing track and trace technology?**

|                                                   | <b>Response Percent</b> | <b>Response Count</b> |
|---------------------------------------------------|-------------------------|-----------------------|
| Phase in by product                               | 31.0%                   | 13                    |
| All products at one time                          | 7.1%                    | 3                     |
| Products outside normal distribution channel only | 33.3%                   | 14                    |
| Not Sure                                          | 33.3%                   | 14                    |



Other (please specify)

4

**13. Which approach does your company support in implementing track and trace technology?**

|  |                          |           |
|--|--------------------------|-----------|
|  | <b>answered question</b> | <b>42</b> |
|  | <b>skipped question</b>  | <b>4</b>  |

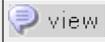
|                                                                                       | Comment Text                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Response Date         |
|---------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
|  1   | We only buy from manuf. or big 3 wholesaler...we do not currently have any ROI info that shows that track and trace is valuable inside the normal dist. channel.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Tue, 8/5/08 9:18 AM   |
|  2   | Some standards have to be agreed upon before distributors can comply with the various states requirements - perhaps a National standard that will apply to all buying and selling pharmaceuticals.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Wed, 7/16/08 2:10 PM  |
|  3   | The most commonly sold item for us is a \$2.00 pre-filled syringe of epinephrine. We deal almost entirely in indictable. There are only a handful of times that cost more than \$25.00 a unit. These are items that are not likely to be counterfeited. I understanding having tracing standards for those items that are likely to be counterfeited and or abused but a \$0.42 vial of furosemide? The cost associated with tracking most of the items we sell would cost more than the product itself. That cost must get paid for somewhere - by our customers. Who are Emergency Medical Service providers (90% publicly funded) who don't have the budget to support the doubling of their pharmaceutical costs for a "guarantee" that their medications are legitimate. | Wed, 7/16/08 10:11 AM |
|  4 | Not applicable                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Wed, 7/16/08 10:10 AM |

Show this Page Only

**Page: Section II. Current Track and Trace Technology Users**

**14. If your company uses Radio Frequency Identifiers (RFID), what frequency is used? (choose all that apply)**

|     | Pallet   | Case              | Item              | Response Count |
|-----|----------|-------------------|-------------------|----------------|
| UHF | 0.0% (0) | <b>100.0% (1)</b> | <b>100.0% (1)</b> | 1              |
| HF  | 0.0% (0) | 0.0% (0)          | 0.0% (0)          | 0              |

| 14. If your company uses Radio Frequency Identifiers (RFID), what frequency is used? (choose all that apply) |           |           |            |           |
|--------------------------------------------------------------------------------------------------------------|-----------|-----------|------------|-----------|
| Low frequency                                                                                                | 50.0% (1) | 50.0% (1) | 100.0% (2) | 2         |
|  Not Sure? (please comment) |           |           |            | 6         |
| <b>answered question</b>                                                                                     |           |           |            | <b>2</b>  |
| <b>skipped question</b>                                                                                      |           |           |            | <b>44</b> |

| Comment Text                                                                                                                                 | Response Date         |
|----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
|  1. papertrail for now                                      | Tue, 7/29/08 3:02 PM  |
|  2. Not applicable.                                         | Wed, 7/23/08 3:25 PM  |
|  3. Don't use                                               | Wed, 7/23/08 3:25 PM  |
|  4. We currently do not employ RFID technology            | Fri, 7/18/08 4:55 PM  |
|  5. Our company doesn't use RFID technogolgy in any form. | Thu, 7/17/08 11:37 AM |
|  6. Currently not using RFID                              | Wed, 7/16/08 10:14 AM |

| 15. Of the following entities that you do business with, which ones are currently using electronic track and trace technology? (choose all that apply) |  |                  |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------|--|------------------|----------------|
|                                                                                                                                                        |  | Response Percent | Response Count |
| Manufacturer                                                                                                                                           |  | 10.7%            | 3              |
| Pharmacy                                                                                                                                               |  | 3.6%             | 1              |
| Wholesale Distributor                                                                                                                                  |  | 21.4%            | 6              |

| 15. Of the following entities that you do business with, which ones are currently using electronic track and trace technology? (choose all that apply) |                          |              |           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------|-----------|
| Trade Partners                                                                                                                                         |                          | 3.6%         | 1         |
| Track and Trace Technology Vendor(s)                                                                                                                   |                          | 3.6%         | 1         |
| Not Sure                                                                                                                                               |                          | 28.6%        | 8         |
| <b>None</b>                                                                                                                                            |                          | <b>39.3%</b> | <b>11</b> |
|  view<br>Other (please specify)                                       |                          | 14.3%        | 4         |
|                                                                                                                                                        | <b>answered question</b> |              | <b>28</b> |
|                                                                                                                                                        | <b>skipped question</b>  |              | <b>18</b> |

| 16. If your company is using electronic track and trace technology, how does your company plan to make electronic track and trace data available? (choose all that apply) |                      |                    |                  |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|------------------|----------------|
|                                                                                                                                                                           | Company level access | Store level access | Not Sure         | Response Count |
| Internet                                                                                                                                                                  | <b>69.2% (9)</b>     | 30.8% (4)          | 23.1% (3)        | 13             |
| Intranet                                                                                                                                                                  | 33.3% (2)            | 0.0% (0)           | <b>66.7% (4)</b> | 6              |
| Third Party                                                                                                                                                               | 44.4% (4)            | 33.3% (3)          | <b>55.6% (5)</b> | 9              |

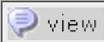
**16. If your company is using electronic track and trace technology, how does your company plan to make electronic track and trace data available? (choose all that apply)**

|                                                                                                                             |           |                      |                  |           |
|-----------------------------------------------------------------------------------------------------------------------------|-----------|----------------------|------------------|-----------|
| Network                                                                                                                     |           |                      |                  |           |
| Electronic Delivery                                                                                                         | 37.5% (3) | 37.5% (3)            | <b>50.0% (4)</b> | 8         |
|  Other(s) in supply chain (please specify) |           |                      |                  | 3         |
| <i>answered question</i>                                                                                                    |           |                      |                  | <b>14</b> |
| <i>skipped question</i>                                                                                                     |           |                      |                  | <b>32</b> |
| <b>Comment Text</b>                                                                                                         |           | <b>Response Date</b> |                  |           |

- |                                                                                     |                                         |                       |
|-------------------------------------------------------------------------------------|-----------------------------------------|-----------------------|
|    | 1. Not applicable.                      | Wed, 7/23/08 3:25 PM  |
|   | 2. Not using electronic track and trace | Wed, 7/23/08 3:25 PM  |
|  | 3. Currently not using                  | Wed, 7/16/08 10:14 AM |

**17. What data is captured in your company's RFID or Bar Codes at the unit, case and pallet levels? (choose all that apply)**

|                      | Unit Level       | Case Level       | Pallet Level | Response Count |
|----------------------|------------------|------------------|--------------|----------------|
| Lot Number           | 60.0% (6)        | <b>80.0% (8)</b> | 20.0% (2)    | 10             |
| Expiration Date      | 62.5% (5)        | <b>87.5% (7)</b> | 25.0% (2)    | 8              |
| Unique Serial Number | <b>83.3% (5)</b> | 66.7% (4)        | 16.7% (1)    | 6              |

| 17. What data is captured in your company's RFID or Bar Codes at the unit, case and pallet levels? (choose all that apply) |           |           |           |           |
|----------------------------------------------------------------------------------------------------------------------------|-----------|-----------|-----------|-----------|
| National Drug Code (NDC)                                                                                                   | 80.0% (8) | 80.0% (8) | 20.0% (2) | 10        |
| Not Sure                                                                                                                   | 66.7% (2) | 33.3% (1) | 66.7% (2) | 3         |
|  Other (please specify)                   |           |           |           | 3         |
| <b>answered question</b>                                                                                                   |           |           |           | <b>14</b> |
| <b>skipped question</b>                                                                                                    |           |           |           | <b>32</b> |

| Comment Text                                                                             | Response Date                                    |
|------------------------------------------------------------------------------------------|--------------------------------------------------|
|  Find  | 1. Not using these systems. Wed, 7/23/08 3:25 PM |
|  Find | 2. Not using the system Wed, 7/23/08 3:25 PM     |
|  Find | 3. N/A Thu, 7/17/08 11:37 AM                     |

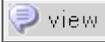
| 18. Does your company currently uniquely serialize products? If so, what percentage of your total product line? |           |           |           |            |                |
|-----------------------------------------------------------------------------------------------------------------|-----------|-----------|-----------|------------|----------------|
|                                                                                                                 | 0 - 5%    | 5 - 33%   | 33 - 75%  | 75 - 100%  | Response Count |
| Yes                                                                                                             | 11.1% (1) | 11.1% (1) | 11.1% (1) | 66.7% (6)  | 9              |
| No                                                                                                              | 60.0% (9) | 26.7% (4) | 26.7% (4) | 66.7% (10) | 15             |
| Will, in the                                                                                                    | 42.9% (3) | 14.3% (1) | 14.3% (1) | 57.1% (4)  | 7              |

**18. Does your company currently uniquely serialize products? If so, what percentage of your total product line?**

|        |  |  |  |                                 |           |
|--------|--|--|--|---------------------------------|-----------|
| future |  |  |  |                                 |           |
|        |  |  |  | Other (please specify)          | 0         |
|        |  |  |  | <b><i>answered question</i></b> | <b>26</b> |
|        |  |  |  | <b><i>skipped question</i></b>  | <b>20</b> |

Page: III. Planning for Track and Trace Technology

19. What is your company's time line for completing investment in a system and infrastructure necessary to implement an electronic track and trace system?

|                                                                                                             | Response Percent | Response Count |
|-------------------------------------------------------------------------------------------------------------|------------------|----------------|
| 2009                                                                                                        | 18.5%            | 5              |
| <b>2010</b>                                                                                                 | <b>37.0%</b>     | 10             |
| 2011                                                                                                        | 22.2%            | 6              |
| 2012                                                                                                        | 25.9%            | 7              |
|  Other (please specify) |                  | 6              |
| <b>answered question</b>                                                                                    |                  | <b>27</b>      |
| <b>skipped question</b>                                                                                     |                  | <b>19</b>      |

| Comment Text                                                                                                                                                                                                                                                                                                                                                                                                                   | Response Date         |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
|  1. We are currently participating in pilot programs to test the technologies; we will invest in a system and infrastructure to implement a track and trace system for all of our facilities when required by federal and state law.                                                                                                        | Fri, 7/25/08 12:02 PM |
|  2. Keeping an eye on California's requirements; however, we are at the mercy of the manufacturer which supplies our 1 RX product (we only distribute 1 RX product which we incorporate into convenience kits). Once the manufacturer determines which system they are moving to, we will be better able to determine our course of action. | Thu, 7/24/08 12:23 PM |
|  3. In future, when we have more information about costs and implementation based on national requirements.                                                                                                                                                                                                                                 | Wed, 7/23/08 3:26 PM  |
|  4. not sure                                                                                                                                                                                                                                                                                                                                | Tue, 7/22/08 1:47 PM  |

**19. What is your company's time line for completing investment in a system and infrastructure necessary to implement an electronic track and trace system?**



5.

Will do so when the cost is less than the benefit. Wed, 7/16/08 10:15 AM



6.

none planned Tue, 7/15/08 6:42 PM

**20. What type(s) of track and trace technology is your company piloting or considering phasing into its operations and when? (choose all that apply)**

|                                   | 2009              | 2010             | 2011              | 2012             | Response Count |
|-----------------------------------|-------------------|------------------|-------------------|------------------|----------------|
| None (skip to next question)      | <b>100.0% (6)</b> | 33.3% (2)        | 16.7% (1)         | 16.7% (1)        | 6              |
| 2-D Barcode                       | <b>38.5% (5)</b>  | <b>38.5% (5)</b> | 23.1% (3)         | 0.0% (0)         | 13             |
| Linear Barcode                    | <b>80.0% (4)</b>  | 40.0% (2)        | 0.0% (0)          | 0.0% (0)         | 5              |
| Matrix                            | 0.0% (0)          | 0.0% (0)         | <b>100.0% (1)</b> | 0.0% (0)         | 1              |
| Radio Frequency Identifier (RFID) | <b>45.5% (5)</b>  | 0.0% (0)         | 18.2% (2)         | 36.4% (4)        | 11             |
| Electronic Product Code (EPC)     | <b>100.0% (1)</b> | 0.0% (0)         | 0.0% (0)          | 0.0% (0)         | 1              |
| Not sure                          | 41.7% (5)         | 50.0% (6)        | <b>66.7% (8)</b>  | <b>66.7% (8)</b> | 12             |
| None                              | <b>100.0% (2)</b> | 50.0% (1)        | 0.0% (0)          | 0.0% (0)         | 2              |

**20. What type(s) of track and trace technology is your company piloting or considering phasing into its operations and when? (choose all that apply)**

|  |                          |           |
|--|--------------------------|-----------|
|  | Other (please specify)   | 0         |
|  | <b>answered question</b> | <b>34</b> |
|  | <b>skipped question</b>  | <b>12</b> |

**21. What partners are working with you in exploring, testing, piloting or phasing in electronic track and trace technology? (choose all that apply)**

|                                                                                                   | Response Percent | Response Count |
|---------------------------------------------------------------------------------------------------|------------------|----------------|
| Manufacturer                                                                                      | 23.5%            | 8              |
| Pharmacy                                                                                          | 11.8%            | 4              |
| Wholesale Distributor                                                                             | 23.5%            | 8              |
| Trade Partners                                                                                    | 20.6%            | 7              |
| Track and Trace Technology Vendor(s)                                                              | 26.5%            | 9              |
| Not Sure                                                                                          | 11.8%            | 4              |
| <b>None</b>                                                                                       | <b>32.4%</b>     | <b>11</b>      |
|  Other (please | 2.9%             | 1              |

**21. What partners are working with you in exploring, testing, piloting or phasing in electronic track and trace technology? (choose all that apply)**

|          |                          |  |           |
|----------|--------------------------|--|-----------|
| specify) |                          |  |           |
|          | <i>answered question</i> |  | <b>34</b> |
|          | <i>skipped question</i>  |  | <b>12</b> |

## APPENDIX IX

Marjorie Powell  
Senior Assistant General Counsel



October 24, 2008

Ms. Anna D. Jeffers, Esq.  
Legislative and Regulations Manager  
Maryland Board of Pharmacy  
4201 Patterson Avenue  
Baltimore, Maryland 21215

Dear Ms. Jeffers:

On behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA), we appreciate the opportunity to participate in the efforts of the Wholesale Distribution Senate Bill 759 Workgroup. PhRMA, representing the country's leading pharmaceutical research and biotechnology companies, strongly supports Maryland's efforts to protect the integrity of the prescription drug supply chain.

PhRMA believes that it is difficult to name a target date for implementation of electronic track and trace pedigree technology due to the absence of FDA approved standards for a national e-pedigree system. We also believe that both the technological feasibility and cost involved with the logistics of implementing an e-track and trace system present real challenges to determining a target date. As you examine the issue, we please urge you to consider the following:

- Recent survey results on the availability of electronic track and trace pedigree technology make it clear that there is no "universal" technology available across the entire prescription pharmaceutical supply chain.
- Maryland faces the same impediments to adoption of electronic track and trace systems that prompted California to push back the date for implementation of its e-pedigree system from January 1, 2009 to January 1, 2015, July 2016 for distributors, and July 2017 for pharmacies and pharmacy distribution centers. Major obstacles to implementation include: lack of developed interoperability standards; absence of certified vendors; vendor inability to service all manufacturers (including generic drug makers), lack of wholesalers and distributors for all products due to limited vendor capacity; and the inability of downstream partners to read and authenticate serialization information across multiple serialization systems.

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*Pharmaceutical Research and Manufacturers of America*

950 F Street, NW Washington, DC 20004 • Tel: 202-835-3517 • FAX: 202-715-7037 • E-Mail: mpowell@phrma.org

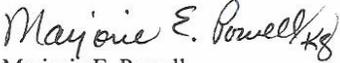
- Two technologies currently under consideration, “2D” bar code, and “RFID” (radiofrequency identification) tags, provide advantages and disadvantages. 2D bar codes can be printed on individual packages and cases, as prescription drugs are shipped by case, pallet, and individual item levels from the manufacturer to the distributor. Alternatively, RFID tags do not require line-of-sight reading for tracking, but insufficient research has been conducted as to the impact of radio frequencies on proteins in biologics, among other types of prescription drugs, and the safety impact on permeable containers for liquids. Further, RFID tags have the potential for being easily damaged during transport, and are giving variable results along a supply chain that is required to deliver high quality prescription products to the patient.
- The typical drug distribution facility receives product from 1154 manufacturers and serves approximately 1700 settings.<sup>ii</sup> The average drug distribution facility processes approximately 1387 orders and delivers over 67,600 products daily.<sup>iii</sup> The diversity and number of dispensing sites presents added concerns and complexities. There are thousands of pharmacies and many other dispensing sites such as hospitals and long term care facilities and physician offices. Given the complexity of the distribution chain and the importance of making sure that Maryland adopts an e-pedigree system that can effectively protect the public’s supply of drugs, it is imperative that the Board recommend to the Legislature that no target date be established for implementation until the foregoing issues can be appropriately resolved
- Any mandate requiring use of currently available, non-universally compatible e-track and trace systems among all entities involved in the supply chain would seriously compromise the overall security of such an e-pedigree system.
- Based on data<sup>iv</sup> developed by the National Association of Chain Drug Stores (NACDS) and the National Community Pharmacists Association (NCPA) and published in June 2008, a small, independent pharmacy up to a large pharmacy would incur, in the first year alone of implementing an e-pedigree system, \$84,000 - \$110,000 in compliance costs for hardware, software, infrastructure, and implementation/labor expenses.<sup>v</sup> The state government would also incur these significant implementation expenses, but on a wider scale through state-owned facilities such as clinics, university hospitals, mental health facilities, etc.

In all, due to the significant technological and financial challenges in upgrading the current supply chain system, we urge the Workgroup to not set a target implementation date at this time.

Ms. Anna D. Jeffers, Esq.  
Maryland Board of Pharmacy  
Page 3 of 3

PhRMA remains committed to working on addressing the security of Maryland's prescription drug supply chain and we look forward to participating with the Workgroup in the future.

Sincerely,

  
Marjorie E. Powell

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<sup>i</sup> Teva Pharmaceuticals. Comment Letter Submitted to California Board of Pharmacy; January, 2008.

<sup>ii</sup> Center for Healthcare Supply Chain Research. 2007-2008 HDMA Fact Book. (2007)

<sup>iii</sup> Id.

<sup>iv</sup> NACDS/NCPA. "Current Status of Safety of the U.S. Prescription Drug Distribution System;" June 2008.

<sup>v</sup> Id.

## Appendix X



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Ms. Anna D. Jeffers, Esq.  
Legislative and Regulations Manager Maryland  
Board of Pharmacy  
4201 Patterson Avenue  
Baltimore, Maryland 21215

### **Re: Wholesale Distribution Senate Bill 759 Workgroup: Target Date for Implementation of Electronic Track and Trace Pedigree Technology for Maryland**

Dear Sir/Madam:

The Biotechnology Industry Organization (BIO) appreciates the opportunity to comment in response to the Board of Pharmacy's (Board's) request for information from stakeholders regarding industry readiness for the implementation date for the electronic track and trace pedigree technology for Maryland. BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations. BIO members are involved in the research and development of health care, agricultural, industrial, and environmental biotechnology products. In particular, many of our members are involved in the research and development of life-saving therapies and play a critical role in delivering treatments that both prolong life and reduce the burden of disease for patients worldwide. Biotech Industry Securing the Safety of Maryland's Drug Supply BIO commends the Board for its commitment to securing Maryland's drug supply against counterfeit drugs and biologics. The biotechnology industry has been proactive in combating counterfeiters, and has taken steps to secure drug and biologic products with holograms, color shifting dyes, and numerous other anti-counterfeiting technologies. In addition to these product-based security features, many companies have put in place integrated programs to protect their medicines. These processes often include:

Full-time, dedicated staff to ensure company-wide vigilance in the fight against counterfeiting.

Contractual requirements for distributors to buy directly and only from the manufacturer, and to report any evidence of product diversion or counterfeiting.

The use of secure distribution practices to prevent a drug shipment from being stolen, tampered with, or otherwise interfered with in transit.

Investigation of all complaints received from patients, health care providers, and others in the chain of distribution and use.

## Current Industry Efforts to Create Electronic Track and Trace Pedigree Technology

In November 2007, BIO conducted a survey of our members to ascertain timelines and milestones toward creation of electronic track and trace pedigree technology<sup>1</sup>. It should

<sup>1</sup> The results of this survey were presented to the California Board of Pharmacy Enforcement Committee on December 5, 2007.

be noted that the creation and implementation of new electronic technologies to track the distribution of drug and biologic products is a tremendous undertaking for large pharmaceutical companies and small biotech companies alike. These changes in business practice will have profound consequences for the highly complex operations of manufacturing facilities, packaging lines, distribution centers, and the operations of third-party partners and logistics providers. Our survey results show that the manufacturers we represent are actively engaged in the process of working toward the development of an interoperable track and trace system that will benefit the industry, the supply chain, and all consumers of drug and biologic products. There is no quick or simple solution to addressing this problem. Companies responding to our survey indicated diverse levels of readiness.

### Barriers to Implementation of Electronic Track and Trace Requirements

As manufacturers work toward electronic track and trace, numerous implementation barriers have come to light. Specifically, companies continue to struggle with technological obstacles, a lack of clear standards, and business process limitations. At the forefront of concern for most manufacturers, and other members of the supply chain, is the fact that to date there is no uniform, agreed upon standard for track-and-trace technology. Additionally, companies are working to overcome the substantial business process system changes, validation issues, interoperability issues, and hardware issues. There are also outstanding challenges related to packaging and labeling. Modifications will be needed for packaging lines and these projects require validation per FDA Good Manufacturing Practice (GMP) requirements. Packaging line modifications pose a significant concern due to the inherent risk that the validation will not prove successful and may result in lost manufacturing capacity that could lead to supply disruption. There are also specific concerns related to biologic products. A particularly difficult issue facing manufacturers of biologic products relates to the extent that biologics will have to be reworked/re-labeled to comply with the electronic track and trace laws. Biologic manufacturers face major cold chain issues and impediments to ensure that track and trace technologies do not affect the biological stability of our products. Most biotechnology drugs are complex, protein-based biologics that are produced by living systems and are particularly vulnerable to changes in their environment. Biologic manufacturers must ensure their products are safe from chemical impurities following the application of the apparatus to be used to track-and-trace the product. With this goal in mind, manufacturers are deliberately and methodically working toward implementing the safest and most appropriate system possible. BIO member companies do not want to make premature decisions or adopt incomplete or inadequate track-and-trace technologies that may be detrimental to the pharmaceutical supply chain and consumers of prescription drugs.

### Target Date for Industry Implementation

The biotechnology industry has developed more than 200 drugs and vaccines that have helped millions of people worldwide. Improving the lives and well-being of patients is **1201 Maryland Ave SW, Suite 900 · Washington, DC 20024-2149 · 202.962.9200 · Fax 202.488.6301 · [www.bio.org](http://www.bio.org)** <sup>3</sup>

our first priority. The adoption of electronic track and trace technology should support patient safety and public health. However, it remains unclear what effect currently available track and trace technologies will have on biologic medicines. In order to ensure that Maryland residents get the safest, most effective medicines available, additional time is needed to study what impact track and trace technologies will have on our industries products. On behalf of the biotechnology industry, including the hundreds of biotechnology companies located in Maryland, we respectfully request that the Board exercise its authority to delay the establishment of a target date for implementation of electronic track and trace pedigree technology. The biotechnology industry will continue to work with all segments of the supply chain, ensuring that the standards, distribution processes and technologies employed will further protect the public. Conclusion We thank the Board for the opportunity to provide our comments and look forward to continuing to work with the Board and all members of the supply chain to fight counterfeit drugs. If we may be of further assistance on any of the topics addressed above, please do not hesitate to contact us.

Sincerely, John R. Gibson Manager,

State Government Relations  
Biotechnology Industry Organization (BIO)

## Appendix XI

October 24, 2008

Ms. LaVerne G. Naesea  
Executive Director  
Maryland Board of Pharmacy  
4201 Patterson Avenue  
Baltimore, MD 21215

Dear Ms. Naesea:

The Generic Pharmaceutical Association (GPhA) welcomes the opportunity to share its views with the Maryland Board of Pharmacy regarding a target date for implementation of electronic track and trace pedigree technology. GPhA represents the manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry. As producers of over 66% of the U.S. prescription drug supply, the generic pharmaceutical industry is highly vested in maintaining the security of the drug supply, and GPhA and its members share the Board of Pharmacy's concern for preventing counterfeit medicines from entering the distribution chain.

Currently, GPhA members are in the process of adapting manufacturing processes to comply with California's pedigree laws that are set to take effect in 2015; a survey of GPhA's members indicates that manufactures are engaged in the following preparations:

- Selecting and implementing solutions for e-pedigrees
- Soliciting proposals for packaging line and other hardware modifications, middleware, and internal or external data centers
- Evaluating multiple identification technologies
- Conducting studies of optimal placement for RFID tags and determining the best RFID tags available for specific applications
- Testing pedigree sharing solutions with major wholesalers and retailers
- Working with consultants to determine best approaches to supplying serialized products
- Implementing systems, such as Warehouse Management System (WMS) and Advanced Ship Notice (ASN), to allow for the serialization of product
- Hiring staff to assist in complying with California requirements
- Conducting pilots with major supply-chain partners, including Wal-Mart

Despite the considerable time and resources dedicated to these efforts, the generic industry has been concerned with establishing a timetable for implementation of new anti-counterfeiting technologies as contemplated by regulatory agencies, various state legislatures, and Congress. Given a lack of Federal standards regarding aspects of

pedigree and serialization, and the evolving nature of much of the technology required to handle an interoperable system of serialized electronic pedigree within a global supply chain, a hard deadline is nearly impossible to identify. GPhA urges consideration of a flexible time frame, in order to allow technology to mature, industry to take a more measured approach and competition to reduce the price of identification technology.

Generic manufacturers have observed that radio frequency technology (RFID tags) and various other identification technologies are not yet ready to be operationalized and interoperable across the entire supply chain. As the State of Maryland considers further adoption of pedigree requirements, every effort should be made to maintain technology neutrality with regard to identification labels. True technology neutrality means that the data carriers used on a product must be the choice of the manufacturer, not mandated by legislation.

GPhA maintains that the most reasonable approach to improving the security of the drug supply chain is to focus on areas of vulnerability, such as the internet and secondary wholesaler market, and on products that are likely to be targeted by counterfeiters. Particularly for an industry that provides enormous savings in health care costs by supplying affordable medicine, the massive investment in time, personnel and financial resources required to implement serialized electronic pedigrees for each unit of medicine is counterintuitive—the inherent affordability of generic medicines makes them the least likely targets for counterfeiters who seek only profit. Raising production costs will significantly impact access to affordable medicine for consumers, state and federal government health care programs, and private payors, with no commensurate benefit to public health.

Finally, GPhA is encouraged that the Board is engaged in the discussion of pedigree and receptive to a single national standard for pedigree and track and trace technology, as compliance with multiple state standards could be unattainable and unworkable.

GPhA appreciates the Board's efforts to combat counterfeit medicines and advance public health. We thank the Board for this opportunity to share the generic industry's comments on this issue.

With best regards,



Kathleen Jaeger  
President & CEO  
Generic Pharmaceutical Association

## **Appendix XII**

Dear Anna,

NACDS understands that the Board Task Force is being asked to provide a target date for implementation of track and trace in the state to the Board of Pharmacy. We are also aware of the joint-response from the drug companies, wholesale distributors and others recommending that the Board not recommend a date at all. We share reservations about choosing a date certain, especially upon consideration of the continued delays being made in California and the lack of readiness and standards for track and trace.

If the Board must move forward with a specific date, we would recommend considering the California law plus a year and incorporating benchmarks to ensure that implementation recognizes the complexity and various steps for such an undertaking, and also federal pre-emption. Finally, members would respectfully ask to review such a proposal before "signing off". As you know, we are but one piece of the picture in the drug distribution supply chain for track and trace implementation.

Please keep me apprised of the Board's efforts to draft a recommendation. Thank you in advance for your continued assistance.

Diane Darvey, Pharm.D., JD

Director Legislative and Regulatory Affairs

NACDS

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