Report of the Task Force on Virtual Manufacturers and Virtual Wholesale Distributors

Members Present:

William Cover (IN), *chair and Executive Committee liaison;* Buford Abeldt (TX); John Dorvee (ME); Mark Hardy (ND); Robert Marshall (NE); Dennis McAllister (AZ); Jerry Moore (AL); Suzanne Neuber (OH); Michael Podgurski (PA); Phil Wickizer (MO).

Others Present:

Virginia Herold, e*x officio member;* Carmen Catizone, Melissa Madigan, Nancy Tay, Gregg Jones, Gertrude Levine, Eileen Lewalski, Emily Shaffer, *NABP staff*.

Introduction:

The Task Force on Virtual Manufacturers and Virtual Wholesale Distributors met December 11-12, 2012, at NABP Headquarters. This task force was established in response to Resolution 108-2-12, Virtual Manufacturers and Wholesale Distributors, which was approved by the NABP membership at the Association's 108th Annual Meeting in May 2012.

Review of the Task Force Charge:

Task force members reviewed their charge and accepted it as follows:

1. Review existing current state laws and regulations addressing virtual manufacturers and virtual wholesale distributors and relevant *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy* (*Model Act)* language.
2. Review the Verified-Accredited Wholesale Distributors (VAWD) criteria.
3. Recommend amendments, if necessary, to the NABP *Model Act* and VAWD criteria addressing these issues.

Recommendation 1: NABP Should Amend the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy* (*Model Act)*

The task force recommends the following changes to the *Model Act*, including changes to the Model Rules for the Licensure of Wholesale Distributors. The revisions recommended by the task force are denoted by underlines.

Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy

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Model Rules for the Licensure of Wholesale Distributors

Definitions.

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(h2) "Reverse Distributor" means any Person who receives, takes inventory, and manages the disposition of outdated, expired, or otherwise non-saleable Drugs from Pharmacies, Wholesale Distributors, or other entities.

…

(m2) "Virtual Wholesale Distributor/Broker" means any Person engaged in Wholesale Distribution of Prescription Drugs or Devices in or into the State which:

(1) may or may not take title but does not take physical possession of the Prescription Drugs or Devices;

(2) must be licensed by the state board of pharmacy or other appropriate state agency as a Wholesale Distributor; and

(3) must be registered as a business entity with the appropriate state or local authority(s) and must operate out of a commercial facility and not out of a residence or personal dwelling. Such location is exempt from the Wholesale Distributor licensure requirements specifically related to possession and storage of Prescription Drugs and Devices.

...

(o2)~~(m2)~~ "Wholesale Distributor" means any Person engaged in Wholesale Distribution of Prescription Drugs or Devices in or into the State, including but not limited to Manufacturers, Repackagers, own-label distributors, private-label distributors, jobbers, brokers, warehouses, including Manufacturers' and Distributors' warehouses, Co-Licensees, Exclusive Distributors, Third-Party Logistics Providers, Chain Pharmacy Warehouses, and Wholesale Drug warehouses, independent Wholesale Drug traders, Reverse Distributors, and retail Pharmacies that conduct Wholesale Distributions.

Background:

Task force members discussed the characteristics of a virtual wholesale distributor in contrast to those found in the current definition of wholesale distributor and whether a specific definition for virtual wholesale distributor should be created. Members agreed that a "broker" is technically engaged in virtual wholesaling but, upon reviewing the current *Model Act* definitions of "distribute," "distribution," and "wholesale distributor," decided that these existing definitions, some of which included the term "broker," failed to fully encompass the activities of a virtual entity and that a new definition for "virtual wholesale distributor/broker" was necessary. It was noted that virtual wholesale distributors almost exclusively transfer the title without having actual possession of the product and that this should be included in the definition. The *ex officio* member described anecdotal cases of individuals establishing wholesale businesses in their homes, which impacted the board's ability to conduct inspections of such businesses. With this in mind, the task force determined that it was important to mandate, as part of the definition, that

the entity be licensed as a wholesale distributor by the board or other appropriate state agency and that it be registered as a business entity with the appropriate state agency.

The task force also agreed that a definition for "reverse distributor" should be created, as the term is used in the VAWD criteria. In addition, the task force agreed that the term should be incorporated in the definition of "Wholesale Distributor." Members concurred that the activities of a "reverse distributor" should be limited to returning drugs to the manufacturer or destroying drugs so as to prevent them from reentering the supply chain.

Recommendation 2: Amend the VAWD Criteria

The task force recommends the following changes to the VAWD Criteria. The revisions recommended by the task force are denoted by underlines and ~~strikethroughs~~.

VAWD® Criteria

Licensure

Qualifying Wholesale Distributor shall provide information to verify that:

1. The Wholesale Distributor is engaged in the "Wholesale Distribution" of prescription drugs which, for the purpose of these criteria, means distribution of prescription drugs to persons other than a consumer or patient and includes the offer to sell, deliver, offer to deliver, give away, or transfer, whether by passage of title, physical movement, or both;

~~1.~~2. The Wholesale Distributor that provides services within a State, whether the Wholesale Distributor is located within the State or outside of the State, is licensed or registered in good standing, or eligible to become licensed or registered, to engage in wholesale drug distribution in all applicable jurisdictions.

~~2.~~3. The Wholesale Distributor complies with all applicable statutes and regulations governing wholesale distribution where licensed or registered, and complies with the more stringent law or regulation as determined by conflicts of law rules.

~~3.~~4. If the Wholesale Distributor is involved in the Distribution of controlled substances, including product that has been identified as a precursor to the manufacture or compounding of methamphetamines, it is duly registered with United States Drug Enforcement Administration (DEA) and the appropriate state controlled substance agency and in compliance with all applicable laws and rules for the storage, handling, reporting, transport, shipment, and Distribution of controlled substances and such precursor products.

~~4.~~5. The Wholesale Distributor maintains sufficient liability insurance coverage and secured monetary funds to ensure payment in the event damages, fines, costs, and the like are assessed against Wholesale Distributor.

~~5.~~6. The Wholesale Distributor has a Person to serve as the Designated Representative for the Wholesale Distributor facility who is actively involved in and aware of the actual daily operation of the Wholesale Distributor that engages in the Distribution of Drugs and Devices and, if required, shall be licensed or registered with the board of pharmacy or appropriate state regulatory agency.

7. The Wholesale Distributor does not engage in the Wholesale Distribution of prescription drugs that are purchased or received from pharmacies or practitioners, or from Wholesale Distributors that obtained them from pharmacies or practitioners. The Wholesale Distributor may receive prescription drugs returned from pharmacies or practitioners that were distributed by the Wholesale Distributor. A Wholesale Distributor that operates solely as a Reverse Distributor may receive drugs from pharmacies and practitioners regardless of where obtained for destruction in accordance with applicable laws and regulations, or return to the manufacturer or agent authorized by the manufacturer to accept returns on the manufacturer's behalf.

Facility

Qualifying Wholesale Distributor shall provide information to verify that:

1. The facility at which Drugs and Devices are received, stored, warehoused, handled, held, offered, marketed, displayed, or transported from shall:

    a. Be of suitable construction to ensure that all Drugs and Devices in the facility are maintained in accordance with Labeling of such Drugs and Devices, or in compliance with official compendium standards such as the United States Pharmacopeia – National Formulary (USP-NF);

    b. Be of suitable size and construction to facilitate cleaning, maintenance, and proper Wholesale Distribution operations;

    c. Have adequate storage areas to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions:

        i. All Drugs and Devices shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the Labeling of such Drugs and Devices, or in accordance with requirements in the current edition of an official compendium such as the USP-NF;

        ii. Documentation of facility assessments, such as temperature mapping, will be maintained by the Wholesale Distributor to demonstrate the ability to properly store prescription drugs in accordance with the Labeling of the drug or the official compendium.

        ~~ii.~~iii. If no storage requirements are established for a Drug, the Drug may be held at "controlled" room temperature, as defined in an official

compendium such as USP-NF, to help ensure that its identity, strength, quality, and purity are not adversely affected; and

~~iii.~~iv. Appropriate ~~manual,~~ electromechanical, or electronic temperature and humidity recording equipment and/or logs shall be utilized to document proper storage of Drugs and Devices. Temperature and humidity monitoring and recording systems will operate continuously.

d. Have a quarantine area for storage of Drugs and Devices that are outdated, damaged, deteriorated, Misbranded, or Adulterated, Counterfeit, or suspected of being Counterfeit, otherwise unfit for Distribution, or that are in immediate or sealed secondary containers that have been opened;

e. Be maintained in a clean and orderly condition;

f. Be free from infestation of any kind; and

g. Not be a personal residence.

2. Appropriate inventory controls are maintained in order to detect and document any theft, Counterfeiting, or diversion of Drugs or Devices.

3. Controlled substance Drugs are isolated from non-controlled substance Drugs and stored in a secure area in accordance with DEA security requirements and standards.

4. Adequate security for the facility has been provided for:

a. All facilities used for Wholesale Drug Distribution shall be secure from unauthorized entry;

b. Access from outside the premises shall be kept to a minimum and be well controlled;

c. The outside perimeter of the premises shall be well lighted;

d. Entry into areas where Drugs or Devices are held shall be limited to authorized personnel;

e. All facilities shall be equipped with an alarm system to detect entry after hours; and

f. All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

g. Verifying that all persons or entities who undertake, whether directly or by any

other arrangement, to transport prescription drugs and devices for compensation, hereafter referred to as "common carriers", used by the Wholesale Distributor ensures security via a verifiable security system.

5. Wholesale Distributor facilities co-located with another business shall maintain processes and systems for separating and securing all aspects of the operation. Co-location with another business authorized to purchase prescription drugs shall comply with state licensing requirements and the records of Wholesale Distribution must provide traceability with a clear audit trail that distinguishes all purchases and distributions of the Wholesale Distributor from any other entity.

Personnel

Qualifying Wholesale Distributor shall provide information to verify that:

1. The Wholesale Distributor's Designated Representative has not been enjoined, disciplined, fined, punished, or the like for violating any federal or state laws regulating prescription Drugs or Devices.

2. The Wholesale Distributor's Designated Representative has not been found guilty, pled guilty, or pled nolo contendere to any criminal offense.

3. The Wholesale Distributor's Designated Representative has a sound financial history.

4. The Wholesale Distributor's Designated Representative:

   a. Has a minimum of two years of verifiable full-time managerial or supervisory experience in a Pharmacy or Wholesale Distributor where the Designated Representative's responsibilities included but were not limited to record keeping, storage, and shipment of Drugs or Devices;

   b. Serves as the Designated Representative for only one ~~Wholesale Distributor~~ Prescription Drug facility at any one time;

   c. Is actively involved in and aware of the actual daily operations of the Wholesale Distributor;

   d. Is employed full-time in a managerial position by the Wholesale Distributor;

   e. Is physically present at the Wholesale Distributor during normal business hours, and there shall be an appropriate individual identified who will be present during~~,~~ ~~except for~~ time periods when the Designated Representative is absent due to illness, family illness or death, scheduled vacation, or other authorized absence; and

   f. Is aware of, and knowledgeable about, all policies and procedures pertaining to the operations of the Wholesale Distributor.

~~5. Additional key personnel engaged in the operation and handling of Drugs or Devices who are employed by the Wholesale Distributor have met the following qualifications:~~

~~a. Appropriate criminal background checks; and~~

~~b. Appropriate education and experience necessary to safely and lawfully engage in the Wholesale Distribution of Drugs.~~

5. All personnel actively engaged in or who supervise the operation and handling of prescription drugs or devices, including owner(s) and/or chief executive officer(s), management, officers, and other key personnel, prior to their association, employment, or contracting and regularly thereafter have met the following qualifications:

   a. Have undergone appropriate local and national credit and criminal background checks; and

   b. Have acquired appropriate education, experience, and training necessary to safely and lawfully engage in the Wholesale Distribution of prescription drugs and devices.

6. All personnel with access to prescription drugs, including owner(s) and/or chief executive officer(s), management, officers, and other key personnel, are subject to toxicology screening prior to their association, employment, or contracting and are subject to toxicology screening for cause and random toxicology screening as warranted.

7. The Wholesale Distributor maintains and enforces policies and procedures requiring documentation of responsible persons and persons in charge, including such persons' titles, duties, and qualifications.

8. The Wholesale Distributor maintains and enforces policies and procedures that ensure the qualifications described in 5 and 6 above are documented and retained. ~~suitable background checks are conducted and documented on the owner(s) and/or chief executive officer and key personnel, management, and officers who actively engage in or supervise the operation and handling of Drugs or Devices, prior to their association, employment, or contracting and regularly thereafter.~~

9. Qualifying Wholesale Distributors shall provide information to verify that, prior to the initial wholesale distribution or acquisition of prescription drugs to or from any Wholesale Distributor, the distributing or acquiring Wholesale Distributor requires all Common Carriers contracted with or utilized by the Wholesale Distributor to require its employees whose responsibilities include the handling of prescription drugs to undergo criminal background checks, initial and random toxicology screening, and security training.

Record Keeping

Qualifying Wholesale Distributor shall provide information to verify that:

1. The Wholesale Distributor is establishing and maintaining inventories and records of all transactions regarding the receipt and Distribution or other disposition of all Drugs and Devices. These records shall include:

   ~~g. Pedigrees for Drugs distributed that are included on the National Specified List of Susceptible Products, if Wholesale Distributor is an Authorized Distributor;~~

   ~~b.~~a. Pedigrees for all Drugs that are distributed, if Wholesale Distributor is not an Authorized Distributor~~;~~, or in accordance with state and Federal Law, if stricter; and

   ~~c.~~b. Appropriate information and data to identify the source of the product and type of product being received or distributed.

   c. All records related to the wholesale distribution of prescription drugs, including but not limited to; invoices of purchase, packing slips, shipping records, and sales invoices will reflect the name of the Wholesale Distributor as it appears on the facility's license issued by the state in which the wholesale distributor is engaged in Wholesale Distribution. Wholesale Distributors to whom a license has been issued in the same name and at the same address as another licensee authorized to purchase prescription drugs must utilize a method to distinguish purchases and distributions that are specific to the Wholesale Distributor.

2. Inventories and records shall be made available for inspection and photocopying by any authorized official of any state, federal, or local government agency for a period of three (3) years following their creation date, or as otherwise required by law.

3. A Pedigree is provided for the Wholesale Distribution of Drugs at the time of the transaction to another Wholesale Distributor, unless otherwise required by law.

4. A Pedigree is received and provided for all prescription drugs received or purchased outside of the Normal Distribution Channel or as required by state or Federal Law, if stricter. As used in these criteria, Normal Distribution Channel means the Wholesale Distributor is engaged in Wholesale Distribution of prescription drugs such that the chain of custody for a Prescription Drug goes from a Manufacturer of the Prescription Drug, the Manufacturer's Co-Licensee, the Manufacturer's Third-Party Logistics Provider, or the Manufacturer's Exclusive Distributor to:

   a. a Wholesale Distributor that is an Authorized Distributor of Record (ADR) including intracompany distribution of any product [between Wholesale Distributor members of an affiliated group (as defined in section 1504(a) of the Internal Revenue Code of 1986) who are ADRs], to a Pharmacy, to a patient, or other designated persons authorized by law to dispense or administer such Prescription Drug to a patient; or

   b. a Wholesale Distributor that is an Authorized Distributor of Record (ADR) including intracompany distribution of any product [between Wholesale Distributor members of an affiliated group (as defined in section 1504(a) of the Internal Revenue

Code of 1986) who are ADRs], to a Chain Pharmacy Warehouse, to that Chain Pharmacy Warehouse's intracompany Pharmacy, to a patient or other designated persons authorized by law to dispense or administer such Prescription Drug to a patient; or

c. a Chain Pharmacy Warehouse, to that Chain Pharmacy Warehouse's intracompany Pharmacy, to a patient or other designated persons authorized by law to dispense or administer such Prescription Drug to a patient.

~~4.~~5. Records described in this section are kept at the inspection site and readily available for inspection during the retention period. Records kept at a central location must be available for inspection within two working days of a request.

~~5.~~6. An ongoing list of Persons with whom the Wholesale Distributor conducts business is maintained.

~~6.~~7. The Wholesale Distributor is establishing and maintaining a system for the mandatory reporting of prescription drug and devices shortages or losses that exceeds a reasonable level established by like persons to the board of pharmacy or appropriate state regulatory agency and Food and Drug Administration (FDA) where it is known or suspected that diversion is occurring.

~~7.~~8. The Wholesale Distributor has adequate processes in place for monitoring purchase activity of customers and identifying suspicious ordering patterns that identify potential diversion or criminal activity related to prescription drugs such as orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

~~8.~~9. Drug and Device records, data, and documents are securely stored and access is restricted, and that policies and procedures have been implemented to protect the integrity of such records, data, and documents.

Authentication and Verification

Qualifying Wholesale Distributor shall maintain and enforce policies and procedures that:

1. Assure the integrity, legitimacy, and authenticity of prescription Drug and Device purchase orders and/or requests.

2. Assure the verification of vendor and customer licenses directly with the appropriate state and federal agencies at least annually.

~~2.~~3. Assure the regular verification of the identity, legitimacy, and proper operation of entities seeking to sell or purchase prescription Drug and Device products.

~~3.~~4. Assure Due Diligence is conducted on prescription drug suppliers not within the Normal Distribution Channel to determine that they are engaged in the lawful distribution of prescription drugs obtained from legitimate sources. This includes an understanding of

the vendor's sources of prescription drugs and a written agreement with vendors that assures the vendor will provide prescription drugs obtained from lawful sources and not in violation of special purchasing contracts for own use or other restricted use.

~~4.~~5. Assure the assessment and authentication of Pedigrees and other accompanying documentation, such as invoices and shipping documents, to verify that each transaction listed on a Pedigree or other documentation has occurred, identify suspicious transactions, and prevent the receipt of prescription drugs that have suspicious sources or transactions. Suspicious sources and transactions include:

a. A Wholesale Distributor located at the same address or having the same name as a pharmacy or practitioner, or other health care entity.

b. Transactions for drugs that are bought and sold by several Wholesale Distributors, including those that occur within short time frames such as the same day.

c. Intracompany transfers from a pharmacy.

d. Sales by pharmacy to a Wholesale Distributor

e. Sources that Wholesale Distribute prescription drugs in violation of contracts for "own use" or other restrictions limited by Group Purchasing Contracts or Federal Purchasing Programs.

~~5.~~6. Assure For Cause Authentications are conducted when the VAWD-accredited Wholesale Distributor that purchases Drugs or Devices from another Wholesale Distributor has reason to believe, based on the totality of the facts and circumstances, that any Drug or Device purchased from the Wholesale Distributor is Counterfeit, suspected of being Counterfeit, Misbranded, or Adulterated. Examining factors shall include but are not limited to:

a. Date of purchase;

b. Lot number;

c. Sales invoice number; and

d. Contact information including name, address, telephone number, and e-mail address (if available) for the Wholesale Distributor that sold the Drug or Device for which Distribution is being Authenticated.

~~6.~~7. Assure that upon receipt, each shipping container shall be visually examined for identity and to determine if it may contain contaminated, Contraband, Counterfeit, suspected of being Counterfeit, or damaged Drugs or Devices, or Drugs or Devices that are otherwise unfit for Distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination, Adulteration, Misbranding, Counterfeiting, suspicion of being Counterfeit, or other damage to the contents.

~~7.~~8. Assure that the Drugs or Devices found to be unacceptable under these criteria are quarantined from the rest of stock until it is determined that the Drugs and Devices are not outdated, damaged, deteriorated, Misbranded, Counterfeited, or Adulterated and they are further determined to be fit for human use.

~~8.~~9. Assure that each outgoing shipment shall be carefully inspected for identity of the Drugs or Devices and to ensure that there is no Delivery of Drugs or Devices that have been damaged in storage or held under improper conditions.

Returned, Damaged, and Outdated Drugs

Qualifying Wholesale Distributor shall maintain and enforce policies and procedures that:

1. Assure that any Drug or Device that is outdated, damaged, deteriorated, Misbranded, Counterfeited, suspected of being Counterfeited, Adulterated, or otherwise deemed unfit for human use shall be quarantined and physically separated from other Drugs and Devices until it is returned to either the Manufacturer or Wholesale Distributor from which it was acquired.

2. Assure that the disposition of prescription drugs sent for destruction is documented and proof of destruction, such as a Certificate of Destruction, is received and maintained by the Wholesale Distributor for inventory accountability.

~~2.~~3. Assure that when Drugs and Devices are Adulterated, Misbranded, Counterfeited, or suspected of being Counterfeit, notice of the Adulteration, Misbranding, Counterfeiting, or suspected Counterfeiting shall be provided to the board of pharmacy or appropriate state regulatory agency, FDA, and the Manufacturer or Wholesale Distributor from which they were acquired within three (3) business days. Any Drug or Device returned to a Manufacturer or Wholesale Distributor shall be kept under proper conditions during storage, handling, transport, and shipment, and documentation showing that proper conditions were maintained shall be provided to the Manufacturer or Wholesale Distributor to which the Drugs are returned.

~~3.~~4. Assure that when any Drug or Device whose immediate or sealed outer or secondary containers or Labeling are Adulterated, Misbranded, Counterfeited, or suspected of being Counterfeit, it shall be quarantined and physically separated from other Drugs or Devices until it is returned to either the Manufacturer or Wholesale Distributor from which it was acquired or destroyed. When the immediate or sealed outer or secondary containers or Labeling of any Drug or Device are Adulterated, Misbranded, Counterfeited, or suspected of being Counterfeit, notice of the Adulteration, Misbranding, Counterfeiting, or suspected Counterfeiting shall be provided to the board of pharmacy or appropriate state regulatory agency, FDA, and the Manufacturer or Wholesale Distributor from which it was acquired within three (3) business days.

~~4.~~5. Assure that when any Drug or Device that has been opened or used, but is not Adulterated, Misbranded, Counterfeited, or suspected of being Counterfeit, it shall be

identified as such, and shall be quarantined and physically separated from other Drugs or Devices until it is returned to the Manufacturer or Wholesale Distributor from which acquired or it is destroyed.

~~5.~~6. Assure that if the conditions under which a Drug or Device has been returned cast doubt on the Drug's or Device's safety, identity, strength, quality, or purity, then the Drug or Device shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the Drug or Device meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a Drug or Device has been returned cast doubt on the Drug's or Device's safety, identity, strength, quality, or purity, the Wholesale Drug Distributor shall consider, among other things, the conditions under which the Drug or Device has been held, stored, or shipped before or during its return and the condition of the Drug and its container, carton, or Labeling as a result of storage or shipping.

Policies and Procedures

Qualifying Wholesale Distributor shall maintain, enforce, and adhere to written policies and procedures, which shall be followed for:

1. The receipt, security, storage, inventory, transport, and shipping and Distribution of Drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, for correcting all errors and inaccuracies in inventories, and for ensuring the oldest approved stock of a prescription Drug product is distributed first.

2. Wholesale Distributors shall include in their written policies and procedures the following:

    a. A procedure to be followed for handling recalls and written withdrawals of Drugs and Devices.

    b. Any volunteer action by the Manufacturer to remove defective or potentially defective Drugs or Devices from the market; or

    c. Any action undertaken to promote public health and safety by the replacement of existing merchandise with an improved product or new package design.

3. To prepare for, protect against, and handle any crisis that affects the security or operation of any facility in the event of a strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

4. To ensure that any outdated Drugs shall be segregated from other Drugs and either returned to the Manufacturer or destroyed in accordance with federal and state laws including all necessary documentation and the appropriate witnessing. This procedure shall provide for written documentation of the disposition of outdated Drugs. This documentation shall be maintained for three (3) years after disposition of the outdated Drugs.

5. A procedure for disposing of and destroying 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 three (3) years, and the appropriate witnessing of the destruction of any Labels, packaging, Immediate Containers, or containers in accordance with all applicable federal and state requirements.

6. A procedure for investigating discrepancies involving Counterfeit, suspected of being Counterfeit, Contraband, or suspected of being Contraband product in the inventory and reporting such discrepancies within three (3) business days to the board of pharmacy or appropriate state regulatory agency and appropriate federal agency.

7. A procedure for reporting criminal or suspected criminal activities involving the inventory of Drug(s) and Device(s) to the board of pharmacy or appropriate state regulatory agency and appropriate federal agency within three (3) business days.

8. A procedure for verifying security provisions of Common Carriers.

9. A procedure for maintaining a quality improvement program that monitors critical operations and tracks trends to improve processes.

History of Criteria Revisions

August 2006: VAWD Criteria updated to reflect amendments to the NABP Model Rules for the Licensure of Wholesale Distributors.

April 2009: VAWD Criteria updated to reflect amendments to the NABP Model Rules for the Licensure of Wholesale Distributors, addressing use of Common Carriers.

February 2013: VAWD Criteria updated pursuant to the recommendations of the Task Force on Virtual Manufacturers and Virtual Wholesale Distributors.

Background:

NABP staff provided the task force with background information regarding proposed revisions to the VAWD criteria. These criteria revisions were proposed so that:

- virtual manufacturers and wholesale distributors could qualify for VAWD accreditation;
- responsible distribution practices to address the influx of applicants with questionable supply chains are mandated; and
- drugs diverted from pharmacies and unlawful sources are prevented from entering into the supply chain.

Task force members agreed that revising the Licensure section to clarify that wholesale distribution includes: 1) the physical movement and possession of the drug; and 2) the passage of title or possession, would allow legitimate virtual entities to become accredited. Members also agreed that the Licensure section should be revised to: 1) prohibit any accredited wholesale distributor from obtaining drugs from pharmacies or from other wholesalers that had obtained

drugs from pharmacies; and 2) allow drugs to be returned for destruction or returned to the manufacturer via reverse distribution.

The task force then discussed revisions proposed for the Facility section. Members agreed that pharmacies and distributors that are co-located should demonstrate that they have: 1) systems in place to separate and secure each entities'drugs; and 2) an audit trail that clearly identifies each entities' purchases and sales. Members also agreed it was important to require accredited wholesale distributors to document that prescription drugs are properly stored in accordance with the labeling or official compendium, such as by temperature mapping. Along those lines, members also revised the temperature and humidity recording provision by requiring that the monitoring and recording systems operate continuously.

The task force also discussed, at length, the Personnel section. Members determined that personnel who were responsible for or who supervise the operation and handling of drugs should undergo credit and criminal background checks, and obtain appropriate education, experience, and training. Members further determined that personnel who have actual access to prescription drugs should be subject to initial toxicology screening, as well as for cause and random toxicology screening. Additionally, the task force agreed to revise the provision regarding the designated representative being present during normal business hours to require the accredited wholesale distributor to name an individual who would serve as back-up during time periods that the designated representative is absent.

The task force then reviewed the Record Keeping section and agreed that a provision should be added that reflected the definition of "Normal Distribution Channel" as used in the *Model Act,* so as to clarify when a pedigree is required to be received and provided. Members also agreed to add a provision that requires accredited wholesale distributors to monitor the purchase activities of customers and identify suspicious ordering patterns, using criteria contained in the Code of Federal Regulations. Members further agreed that an ADR should be required to provide a pedigree for transfers that are made to a non-ADR and to also provide a pedigree when distributing a drug it did not receive from a manufacturer. Additionally, members agreed to add a provision that requires a clear audit trail to prevent interchanging purchases or sales by a wholesale distributor that is located at the same address and with the same name as a pharmacy, physician, or other health care entity. Lastly, the task force agreed that the provision that referred to the National Specified List of Susceptible Products should be removed, as the list was discontinued several years ago.

The Authentication and Verification section was then reviewed by the task force and it was agreed that a fairly extensive revision was necessary to further protect the integrity of the supply chain. Members decided to add a provision that requires secondary wholesale distributors to conduct due diligence on non-ADR to determine that they are engaged in the lawful distribution of drugs obtained from legitimate sources. This provision would bring into question sources such as intercompany transfers from pharmacies, purchases from pharmacies under the 5% rule, and purchases from closed-door pharmacies. Additionally the task force agreed that accredited wholesale distributors should be required to authenticate pedigrees for accuracy as well as make an assessment as to whether a transaction is questionable and added a provision that creates additional responsibility for a wholesale distributor that distributes drugs outside of the normal distribution channel. With that in mind, members also determined that accredited wholesale

distributors should be required to verify vendor and customer licenses directly with the appropriate licensing authority at least annually.

The task force then turned their attention to the Returned, Damaged, and Outdated Drugs section and agreed that a provision should be added that requires accredited wholesale distributors to obtain and maintain documented proof that drugs disposed of for destruction were actually destroyed. Members wanted to assure that drugs sent for destruction could not re-enter the supply chain.

Lastly, the task force reviewed the Policies and Procedures section and determined that an accredited wholesale distributor should have in place a procedure for maintaining a quality improvement program. Members agreed that such a procedure would help identify weaknesses in systems and prevent the theft and diversion of prescription drugs.

Recommendation 3: NABP Should Encourage Stakeholders to Purchase Drugs Only from VAWD-Accredited Wholesale Distributors

The task force recommends that, in light of the issues related to drug shortages and the emergent practice of drugs being brokered on the gray market, NABP encourage stakeholders to purchase drugs only from VAWD-accredited wholesale distributors in order to maintain the integrity of the supply chain.

Background:

The task force was extremely concerned with the recent number of secondary wholesalers that have entered the market. Some of these wholesale distributors contact pharmacies and are able to obtain prescription drugs that are in short supply through questionable legal loopholes and then resell them after exorbitantly marking up prices. Members discussed three primary areas where secondary wholesale distributors may be inappropriately interpreting and taking advantage of laws and/or regulations, including:

- 5% rules that have been interpreted to allow a pharmacy to sell to a wholesale distributor;
- emergency exemptions that have been interpreted to allow the purchasing, selling, and reselling of drugs in shortage while drastically increasing the price with each transaction; and
- intracompany transfer provisions, which have been interpreted to allow a wholesale distributor to open a pharmacy in the same or different location and then transfer drugs between the two entities.

Members linked these types of activities to prescription drugs entering and/or reentering the supply chain from outside the normal distribution channel and emphasized the danger that this may place on the public. Members concluded that to ensure the integrity of the supply chain, prescription drugs should only be purchased through VAWD-accredited wholesale distributors and that NABP should take a role in educating key stakeholders about this.

Recommendation 4: NABP Should Provide State Boards of Pharmacy and Other State Agencies Information Regarding the Advantages of VAWD Accreditation

The task force recommends that NABP provide the state boards of pharmacy and other state agencies with information regarding the advantages of VAWD accreditation and how it protects the public by maintaining the integrity of the supply chain.

Background:

Using the same reasoning provided in Recommendation 3, the task force further concluded that the state boards of pharmacy and other state agencies that oversee the licensure of wholesale distributors should be informed about how some secondary wholesale distributors, particularly those that broker prescription drugs, may be placing the public in danger through noncompliance with state laws and regulations. Members recognized that requiring VAWD accreditation for all wholesale distributors is paramount to maintaining the integrity of the prescription drug supply chain. Members agreed that by informing those responsible for the licensure of wholesale distributors about the advantages of VAWD accreditation, a dialogue can be initiated in which NABP may be called on to assist in this area.