



Model Rules for the Licensure of Wholesale Distributors

February 20, 2004

Issued by:

National Association of Boards of Pharmacy
700 Busse Highway
Park Ridge, IL 60068

Carmen A. Catizone, MS, RPh, DPh
Executive Director/Secretary

Model Rules for the Licensure of Wholesale Distributors

Definitions:

Terms not herein defined shall have the definitions set forth in the Model Pharmacy Practice Act¹.

“Adulterated”: A Drug or Device shall be deemed to be Adulterated:

(1) IF:

(A) It consists in whole or in part of any filthy, putrid, or decomposed substance;
or

(B) (i) It has been produced, prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or

(ii) If the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that the Drug or Device meets the requirements of this part as to safety and has the identity and strength, and meets the quality and purity characteristics which it purports or is represented to possess; or

(C) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

(D) If: (i) It bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of the Federal Act; or

(ii) It is a color additive, the intended use of which is for purposes of coloring only, and is unsafe within the meaning of the Federal Act;

(2) If it purports to be or is represented as a Drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in the compendium. Such a determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in the compendium, or in the absence of or inadequacy of these tests or methods of assay, those prescribed under authority of the Federal Act. No Drug defined in an official compendium shall be deemed to be Adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefore set forth in the compendium, if its difference in strength, quality, or purity from that standard is plainly stated on its label.

¹ The NABP Model Act is constructed as a guide to assist state boards of pharmacy in developing and implementing legislation and regulations. Definitions which are used in the Act and Rules are stated and defined in Section 105 of the Act. The definitions are also included in the Rules to provide a quick reference to the definitions introduced or used extensively in the Model Rules. All definitions and provisions of the Model Rules shall be construed so that they are consistent with all definitions of the Model Act

Whenever a Drug is recognized in both the United States Pharmacopoeia and the Homeopathic Pharmacopoeia of the United States it shall be subject to the requirements of the United States Pharmacopoeia unless it is labeled and offered for sale as a homeopathic Drug, in which case it shall be subject to the Homeopathic Pharmacopoeia of the United States and not those of the United States Pharmacopoeia;

(3) If it is not subject to paragraph (2) and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess;

(4) If it is a Drug and any substance has been (A) mixed or packed therewith so as to reduce its quality or strength; or (B) substituted wholly or in part therefore.

(5) If it is a Device, all considerations as noted in the Federal Food, Drug and Cosmetic Act.

“Authenticate” means to affirmatively verify before any Distribution of a Drug occurs that each transaction listed on the Pedigree (if required) and other accompanying documentation has occurred.

“Authorized Distributor” or “Authorized Distributor of Record” means a Wholesale Distributor with whom a Manufacturer has established an ongoing relationship to Distribute the Manufacturer's products. An ongoing relationship is deemed to exist between a Wholesale Distributor and a Manufacturer when a Wholesale Distributor complies with any one of the following:

- (1) The Wholesale Distributor has a written agreement currently in effect with the Manufacturer evidencing an ongoing relationship; or
- (2) The Wholesale Distributor is listed on the Manufacturer's current list of Authorized Distributors of Record, which is updated by the Manufacturer on no less than a monthly basis.

“Centralized Prescription Processing” means the processing by a Pharmacy of a request from another Pharmacy to fill or refill a Prescription Drug Order or to perform processing functions such as Dispensing, DUR, claims adjudication, refill authorizations, and therapeutic interventions.

“Closed Pharmacy” means a Pharmacy that purchases Drugs or Devices for a limited patient population and is not open for dispensing to the general patient population and cannot operate or be licensed as a Wholesale Distributor.

“Contraband Device” means a Device which is Counterfeit, stolen, Misbranded, obtained by fraud, purchased by a non-profit institution for its own use and placed in commerce in violation of the own use agreement for that Device, or for which the documentation in existence has been forged, Counterfeited, falsely created, or contains any altered, false, or misrepresented information.

“Contraband Drug” means a Drug which is Counterfeit, stolen, Misbranded, obtained by fraud, purchased by a non-profit institution for its own use and placed in commerce in violation of the own use agreement for that Drug, or for which a Pedigree (if required) does not exist, or for which the Pedigree in existence has been forged, Counterfeited, falsely created, or contains any altered, false, or misrepresented information.

“Counterfeit Device” means a Device which, or the container, shipping container, seal, or Labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or any likeness thereof, of a Manufacturer, processor, packer, or Distributor other than the Person or Persons who in fact Manufactured, processed, packed, or Distributed such Device and which thereby falsely purports or is represented to be the product of, or to have been packed or Distributed by, such other Manufacturer, processor, packer, or Distributor.

“Counterfeit Drug” means a Drug which, or the container, shipping container, seal, or Labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or Device, or any likeness thereof, of a Manufacturer, processor, packer, or Distributor other than the Person or Persons who in fact Manufactured, processed, packed, or Distributed such Drug and which thereby falsely purports or is represented to be the product of, or to have been packed or Distributed by, such other Manufacturer, processor, packer, or Distributor.

“Designated Representative” means an individual designated by the Wholesale Distributor who will serve as the responsible individual of the Wholesale Distributor with the Board who is actively involved in and aware of the actual daily operation of the Wholesale Distributor.

“Distribute” or “Distribution” means to sell, offer to sell, deliver, offer to deliver, broker, give away, or transfer a Drug, whether by passage of title, physical movement, or both. The term does not include:

- (i) To Dispense or Administer
- (ii) Delivering or offering to deliver a Drug by a common carrier in the usual course of business as a common carrier
- (iii) Providing a Drug sample to a patient by a Practitioner licensed to prescribe such Drug; a health care professional acting at the direction and under the supervision of a Practitioner; or the Pharmacy of a hospital or of another health care entity that is acting at the direction of such a Practitioner and that received such sample in accordance with the act and regulations to administer or dispense.

“Emergency Medical Reasons” include, but are not limited to, transfers of a prescription Drug between a Wholesale Distributor or Pharmacy to alleviate a temporary shortage of a prescription Drug arising from delays in or interruption of regular distribution schedules; sales to nearby emergency medical services, i.e., ambulance companies and fire fighting organizations in the same state or same marketing or service area, or nearby

licensed Practitioners, of Drugs for use in the treatment of acutely ill or injured Persons; provision of minimal emergency supplies of Drugs to nearby nursing homes for use in emergencies or during hours of the day when necessary Drugs cannot be obtained; and transfers of prescription Drugs by a retail Pharmacy to another retail Pharmacy to alleviate a temporary shortage.

“FDA” means the Food and Drug Administration, a federal agency within the United States Department of Health and Human Services, established to set safety and quality standards for Drugs, food, cosmetics, and other consumer products.

“Federal Act” means the Federal Food, Drug and Cosmetic Act.

“Health Care Entity” means any Person that provides diagnostic, medical, surgical, dental treatment, or rehabilitative care but does not include any retail Pharmacy or Wholesale Distributor.

“Immediate Container” means a container and does not include package liners.

“Intracompany Transaction” means any transaction between a division, subsidiary, parent and/or affiliated or related company under the common ownership and control of a corporate entity.

“Label” means a display of written, printed, or graphic matter upon the immediate container of any Drug or Device.

“Labeling” means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

“Manufacturer” means a Person engaged in the Manufacture of Drugs or Devices.

“Misbranded”: A Drug or Device shall be deemed to be misbranded if the label is false or misleading in any particular; or the label does not bear the name and address of the Manufacturer, packer, or Distributor and does not have an accurate statement of the quantities of the active ingredients in case of a Drug; or do not show an accurate monograph for Legend Drugs; or other considerations as noted in the Federal Food, Drug and Cosmetic Act.

“Pedigree” means a document in a form, written or electronic, approved by the Board that records each Distribution of any given Drug, from the sale by a Manufacturer through acquisition and sale by any Wholesaler Distributor or Repackager and includes the following information for each transaction:

- (1) The source of the Drug(s), including the name and principal address of the seller;

- (2) The amount of the Drug, its dosage form and strength, the date of the purchase, the sales invoice number, container size, number of containers, and lot number(s) of the Drug;
- (3) The business name and address of each owner of the Drug, its shipping information, including the name and address of the facility of each Person certifying delivery or receipt of the Drug;
- (4) Information that states the Wholesale Distributor has conducted Due Diligence of the Wholesale Distributor(s) from which the Wholesale Distributor purchased, or may have purchased the Drug; and
- (5) A certification from the Designated Representative of the Wholesale Distributor that the information contained therein is true and accurate under penalty of perjury.

“Repackage” means changing the container, wrapper, quantity, or Labeling of a Drug or Device to further the Distribution of the Drug or Device.

‘Repackager’ means a Person who Repackages.

“Specified List of Susceptible Products” means a specific list of Drugs or Devices to be designated by the State, or a third party approved by the State, determined to be susceptible to adulteration, Counterfeiting, or diversion and posing the potential for a greater public health risk.

“USP Standards” means current USP Standards.

“Wholesale Distribution” means the Distribution of Drugs or Devices by Wholesale Distributors to Persons other than consumers or patients, and includes the transfer of Drugs by a Pharmacy to another Pharmacy if the value of the goods transferred exceeds five percent (5%) of total Drug sales revenue of either the transferor or transferee Pharmacy during any consecutive twelve (12) month period. Wholesale Distribution does not include:

- (1) The sale, purchase, or trade of a Drug or Device, an offer to sell, purchase, or trade a Drug or Device, or the Dispensing of a Drug or Device pursuant to a Prescription;
- (2) The sale, purchase, or trade of a Drug or Device or an offer to sell, purchase, or trade a Drug or Device for Emergency Medical Reasons;
- (3) Intracompany Transactions, unless in violation of own use provisions;
- (4) The sale, purchase, or trade of a Drug or Device or an offer to sell, purchase or trade a Drug or Device among hospitals or other health care entities that are under common control;
- (5) The sale, purchase, or trade of a Drug or Device or the offer to sell, purchase, or trade a Drug or Device by a charitable organization described in 503(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

- (6) The purchase or other acquisition by a hospital or other similar health care entity that is a member of a group purchasing organization of a Drug or Device for its own use from the group purchasing organization or from other hospitals or similar health care entities that are members of these organizations;
- (7) The transfer of Drugs or Devices between Pharmacies pursuant to a Centralized Prescription Processing agreement.
- (8) The Distribution of Drug samples by Manufacturers' representatives or Wholesale Distributors' representatives;
- (9) The sale, purchase, or trade of blood and blood components intended for transfusion.

“Wholesale Distributor” means any Person engaged in Wholesale Distribution of Drugs 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, chain Drug warehouses, and wholesale Drug warehouses, independent wholesale Drug traders, and retail Pharmacies that conduct Wholesale Distributions.

Section 1. Requirements for Licensure.

Wholesale Distributors that provide services within this State, whether the Wholesale Distributor is located within this State or outside this State, shall be licensed by the Board and shall annually renew their license with the Board using an application provided by the Board. Wholesale Distributors cannot operate from a place of residence. Where Wholesale Distribution operations are conducted at more than one location, each such location shall be licensed by the Board of Pharmacy.

(A). Every Wholesale Distributor who engages in the Wholesale Distribution of Drugs or Devices shall license annually with the Board by application and provide information required by the Board on an application approved by the Board, including, but not limited to:

- (1) All trade or business names used by the licensee, which cannot be identical to the name used by another Wholesale Distributor licensed to purchase Drugs or Devices in the State;
- (2) Name(s) of the owner and operator of the licensee (if not the same Person), including:
 - a) if a Person: the name, address, social security number and date of birth;
 - b) if a partnership: the name, address, and social security number and date of birth of each partner, and the name of the partnership and federal employer identification number;
 - c) if a corporation: the name, address, social security number and date of birth, and title of each corporate officer and director, the corporate names, the name of the state of incorporation, federal employer identification number, and the name of the parent company, if any; the name, address, and social security number of each shareholder owning ten percent (10%) or more of the voting stock of the corporation, including over-the-counter stock, unless the stock is traded on a major stock exchange and not over-the-counter;
 - d) if a sole proprietorship: the full name, address, social security number and date of birth of the sole proprietor and the name and federal employer identification number of the business entity;
 - e) if a limited liability company, the name of each member, the name of each manager, the name of the limited liability company and federal employer identification number, and the name of the state in which the limited liability company was organized; and
 - f) any other relevant information that the Board requires.
- (3) Name(s), address(es), telephone number(s) of a Person(s) to serve as the Designated Representative(s) for each facility of the Wholesale Distributor which engages in the Distribution of Drugs or Devices and additional information as required in Section 10.

(B). A “surety” bond of not less than \$100,000, or other equivalent means of security acceptable to the Board, or the Board’s agent, to secure payment of any

administrative penalties imposed by the Board and any fees and costs incurred by the Board regarding that license which are authorized under state law and which the Wholesale Distributor fails to pay 30 days after the fine or costs become final. The Board may make a claim against such bond or security until one year after the Wholesale Distributor's license ceases to be valid or until 60 days after any administrative or legal proceeding before or on behalf of the Board which involves the Wholesale Distributor is concluded, including any appeal, whichever occurs later.

- (C). Every Manufacturer must establish and maintain with monthly updates the list of "Authorized Distributors" or "Authorized Distributors of Record" approved by that Manufacturer and make the list readily available upon request or via a web site posting.
- (D). Every Manufacturer shall file a written list of all of the Manufacturer's "Authorized Distributors" or "Authorized Distributors of Record" with the Board. A Manufacturer shall notify the Board not later than 10 days after any change to the list. The Board shall publish a list of all "Authorized Distributors" or "Authorized Distributors of Record" on its website.
- (E). A reasonable fee to be determined by the Board.
- (F). Each facility which engages in Wholesale Distribution must undergo an inspection by the Board or the Board's agent for the purpose of inspecting the Wholesale Distribution operations prior to initial licensure and periodically thereafter in accordance with a schedule to be determined by the Board but not less than once every three (3) years.
- (G). All Wholesale Distributors must publicly display or have readily available all licenses and the most recent inspection report administered by the Board.
- (H). Changes in any information in this section shall be submitted to the Board within 30 days of such change (unless otherwise noted).

Section 2. Minimum Qualifications.

- (A). The Board will use the following factors in determining the eligibility for, and renewal of, licensure of Persons who engage in the Wholesale Distribution of Drugs or Devices:
- (1) Any findings by the Board that the applicant has violated or been disciplined by a regulatory agency in any state for violating any federal, state, or local laws relating to Drug or Device Distribution;
 - (2) Any criminal convictions of the applicant under federal, state, or local laws;
 - (3) The applicant's past experience in the Manufacture or Distribution of Drugs or Devices;
 - (4) The furnishing by the applicant of false or fraudulent material in any application made in connection with Drug or Device Manufacturing or Distribution;
 - (5) Suspension, sanction, or Revocation by federal, state, or local government against any license currently or previously held by the applicant or any of its owners for violations of state or federal laws regarding Drugs or Devices;
 - (6) Compliance with previously granted licenses of any kind;
 - (7) Compliance with the requirements to maintain and/or make available to the Board licensing authority or to federal, state, or local law enforcement officials those records required to be maintained by Wholesale Drug Distributors; and
 - (8) Any other factors or qualifications the Board considers relevant to and consistent with the public health and safety.
- (B). The Board shall consider the results of a criminal background check of the applicant, all personnel involved in the operations of the Wholesale Distributor, including the most senior Person responsible for facility operations, purchasing, inventory control and the Person or Persons they report to; and all company officers, key management, principals and owners with 10% or greater interest in the company (applying to non-publicly held companies only) to determine if an applicant or others associated with the ownership, management, or operations of the Wholesale Distributor has committed criminal acts that would constitute grounds for denial of licensure. The background check will be conducted in compliance with any applicable state laws, at the applicant's expense, and will be sufficient to include all states of residence since the Person has been an adult.
- (C). The applicant shall provide, and attest to, a statement providing a complete disclosure of any past criminal convictions and violations of the state and federal laws regarding Drugs or Devices or an affirmation and attestation that the applicant has not been involved in, or convicted of, any criminal or prohibited acts.

Section 3. Personnel.

Each Person that is issued an initial or renewal license as a Wholesale Distributor, whether in or out-of-state, must designate in writing on a form required by the Board a Person for each facility to serve as the Designated Representative of the Wholesale Distributor.

(A). To be certified as a Designated Representative, a Person must:

- (1) Submit an application on a form furnished by the Board and provide information that includes, but is not limited to:
 - a) A set of fingerprints for the Person, under procedures specified by the Board, together with the payment of the amount equal to the costs incurred by the Board for the criminal background check of the Person;
 - b) Date and place of birth;
 - c) Occupations, positions of employment, and offices held during the past 7 years;
 - d) Principal business and address of any business corporation, or other organization in which each such office of the Person was held or in which each such occupation or position of employment was carried on;
 - e) Whether the Person, during the past 7 years, 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 Drugs or Devices, together with details of such events;
 - f) Description of any involvement by the Person with any business, including any investments, other than the ownership of stock in a publicly traded company or mutual fund, during the past 7 years, which Manufactured, Administered, Prescribed, Distributed, or stored Drugs and Devices in which such businesses were named as a party in a lawsuit;
 - g) Description of any criminal offense (not including minor traffic violations) of which the Person, as an adult, was found guilty, regardless of whether adjudication of guilt was withheld or whether the Person pled guilty or nolo contendere. If the Person indicates that a criminal conviction is under appeal and submits a copy of the notice of appeal of the criminal offense, the applicant must, within 15 days after the disposition of the appeal, submit to the Board a copy of the final written order of disposition;

- h) Photograph of the Person taken within the previous 30 days under procedures as specified by the Board;
 - i) Name, address, occupation, and date and place of birth for each member of the Person's immediate family. As used in this subparagraph, the term "member of the immediate family" includes the Person's spouse(s), children, parents, siblings, the spouses of the Person's children, and the spouses of the Person's siblings; and
 - j) Any other information the Board deems relevant.
 - (2) Have a minimum of two years of verifiable full-time managerial or supervisory experience in a Pharmacy or Wholesale Distributor licensed in this State or another state, where the Person's responsibilities included but were not limited to recordkeeping, storage, and shipment for Drugs or Devices;
 - (3) May serve as the Designated Representative for only one Wholesale Distributor at any one time;
 - (4) Must be actively involved and aware of the actual daily operations of the Wholesale Distributor:
 - a) Employed full time in a managerial position by the Wholesale Distributor;
 - b) Physically present at the Wholesale Distributor during normal business hours, except for time periods when absent due to illness, family illness or death, scheduled vacation, or other authorized absence; and
 - c) Aware of, and knowledgeable about, all policies and procedures pertaining to the operations of the Wholesale Distributor.
- (B). Each licensed Wholesale Distributor located outside of this State that Distributes Drugs in this State shall designate a registered agent in this State for service of process. Any licensed Wholesale Distributor that does not so designate a registered agent shall be deemed to have designated the Secretary of State of this State to be its true and lawful attorney, upon who may be served all legal process in any action or proceeding against such licensed Wholesale Distributor growing out of or arising from such Distribution. A copy of any such service of process shall be mailed to such Wholesale Distributor by the Board by certified mail, return receipt requested, postage prepaid, at the address such licensed Wholesale Distributor has designated on its application for licensure in this State. If any such Wholesale Distributor is not licensed in this State, service on the Secretary of State only shall be sufficient service.
- (C). Additional personnel engaged in the operation and handling of Drugs or Devices shall be employed by the Wholesale Distributor following the appropriate criminal background check as indicated in Section 2 (Minimum Qualifications), and with

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

- (D). A Designated Representative must complete continuing education programs specified by the Board regarding federal and state laws in regard to the Distribution, handling, and storage of Drugs or Devices.

Section 4. Minimum Requirements for the Storage, Handling, Transport, and Shipment of Drugs and Maintenance of Drug Records.

The following are required for the storage, handling, transport and shipment of Drugs or Devices, and for the establishment and maintenance of Wholesale Distribution records by Wholesale Distributors and their officers, agents, representatives, and employees:

- (A). All facilities at which Drugs and Devices are received, stored, warehoused, handled, held, offered, marketed, displayed, or transported from shall:
 - (1) be of suitable construction to ensure that all Drugs and Devices in the facilities are maintained in accordance with Labeling of such Drugs and Devices, or in compliance with official compendium standards such as USP/NF;
 - (2) be of suitable size and construction to facilitate cleaning, maintenance, and proper Wholesale Distribution operations;
 - (3) have adequate storage areas to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;
 - (4) 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;
 - (5) be maintained in a clean and orderly condition; and
 - (6) be free from infestation of any kind.
- (B). Shall provide a Pedigree for the Wholesale Distribution of Drugs before the transaction to another Wholesale Distributor in accordance with Section 10 (Recordkeeping).
- (C). Shall be a commercial location and not a personal dwelling or residence.
- (D). Shall provide for the secure and confidential storage of information with restricted access and policies and procedures to protect the integrity and confidentiality of the information.
- (E). Shall provide and maintain appropriate inventory controls in order to detect and document any theft, Counterfeiting, or diversion of Drugs or Devices.
- (F). Wholesale Distributors involved in the Distribution of controlled substances shall be duly registered with the Drug Enforcement Administration (DEA) and appropriate state controlled substance agency and in compliance with all applicable laws and rules for the storage, handling, transport, shipment and Distribution of controlled substances.

Section 5. Security and Anti-Counterfeiting.

- (A). All facilities used for Wholesale Drug Distribution shall be secure from unauthorized entry:
 - (1) Access from outside the premises shall be kept to a minimum and be well-controlled;
 - (2) The outside perimeter of the premises shall be well-lighted;
 - (3) Entry into areas where Drugs or Devices are held shall be limited to authorized personnel;
- (B). All facilities shall be equipped with an alarm system to detect entry after hours.
- (C). 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.
- (D). All facilities shall be equipped with inventory management and control systems that protect against, detect, and document any instances of theft, diversion, or Counterfeiting.
- (E). Wholesale Distributors should possess and maintain in good working order technology and equipment that allows the Wholesale Distributor to Authenticate, track and trace Drugs and Devices. The technology and equipment shall satisfy standards set by the Board for such technology and equipment. The technology and equipment shall be used, as required by the Board, to conduct For Cause and Random tracking, tracing, and Authentication of Drugs and Devices. Wholesale Distributors shall employ, train, and document the training of personnel in the proper use of such technology and equipment.
- (F). All facilities shall be equipped with security systems to protect the integrity and confidentiality of data and documents and make such data and documents readily available to the Board and other state and federal law enforcement officials.
- (G). For Cause Authentications:
 - (1) If a Wholesale Distributor that purchases Drugs or Devices from another Wholesale Distributor has reason to believe, based on the totality of the facts and circumstance, that any Drug or Device purchased from the Wholesale Distributor is Counterfeit, suspected of being Counterfeit, Misbranded, or Adulterated, the purchasing Wholesale Distributor must Authenticate every Distribution of the Drug or Device back to the Manufacturer;
 - (2) Each Wholesale Distributor that has engaged in the Distribution of a Drug or Device, for which a purchasing Wholesale Distributor is conducting a For Cause Authentication shall provide, upon request, detailed information regarding the Distribution of the Drug or Device, including:
 - (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, the Distribution of which is being Authenticated.
 - (3) If the Wholesale Distributor that is attempting to Authenticate the Distribution of the Drug or Device back to a Manufacturer is unable to Authenticate each Distribution of the Drug or Device, the Wholesale Distributor shall quarantine the Drug or Device and report this to the Board and FDA within ten (3) business days after completing the attempted Authentication; and
 - (4) If the Wholesale Distributor that is attempting to Authenticate the Distribution of the Drug or Device back to a Manufacturer satisfactorily completes the Authentication, the Wholesale Distributor shall maintain records of the Authentication for three (3) years, and shall produce them to the Board and FDA upon request.
- (H). Random Authentications:
- (1) Wholesale Distributors that purchase Drugs or Devices from other Wholesale Distributors, shall, at least annually, conduct Random Authentications of Pedigrees on at least ten percent (10%) of sales units of Wholesale Distributions of Drugs or Devices that were purchased from other Wholesale Distributors;
 - (2) If a Wholesale Distributor has purchased a Drug or Device that is on the Board's Specified List of Susceptible Products or the List of Susceptible Products recognized by the Board, from other Wholesale Distributors, the Wholesale Distributor shall, at least quarterly, conduct Random Authentications of Pedigrees on at least ninety percent (90%) of sales units of Distributions of Drugs or Devices that are on the Board's Specified List of Susceptible Products or the List of Susceptible Products recognized by the Board that were purchased from other Wholesale Distributors; and
 - (3) Wholesale Distributors from whom other Wholesale Distributors have purchased Drugs or Devices shall cooperate with the Random Authentications of the Pedigrees and provide the requested information in a timely manner.

Section 6. Storage.

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 with requirements in the current edition of an official compendium such as the USP/NF.

- (A). 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.
- (B). Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, and/or logs shall be utilized to document proper storage of Drugs and Devices.
- (C). Packaging of the Drugs and Devices should be in accordance with an official compendium such as USP/NF and identify any compromise in the integrity of the Drugs or Devices due to tampering or adverse storage conditions.
- (D). Controlled substance Drugs should be isolated from non-controlled substance Drugs and stored in a secure area in accordance with DEA security requirements and standards.
- (E). The record-keeping requirements in Section 10 shall be followed for the Wholesale Distribution of all Drugs and Devices.

Section 7. Examination of Materials.

- (A). 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, suspected of being Counterfeit, or other damage to the contents.
- (B). The Drugs or Devices found to be unacceptable under paragraph (A) should be quarantined from the rest of stock until the examination and determination that the Drugs and Devices are not outdated, damaged, deteriorated, Misbranded, Counterfeited, or Adulterated and determined to be fit for human use.
- (C). 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.
- (D). Upon receipt, a Wholesale Distributor must review records for the acquisition of Drugs or Devices for accuracy and completeness, considering the total facts and circumstances surrounding the transactions and the Wholesale Distributors involved.
- (E). The record-keeping requirements in Section 10 (Recordkeeping) shall be followed for all incoming and outgoing Drugs and Devices.

Section 8. Returned, Damaged, and Outdated Drugs.

- (A). Any Drug or Device that was ordered in error or in excess of need by the Wholesale Distributor, identified as such within three (3) business days, and the integrity has been maintained shall be returned to the Manufacturer or Wholesale Distributor from which it was acquired, provided the appropriate documentation is completed and any necessary notations made to the Pedigree.
- (B). Any Drug or Device that is outdated, damaged, deteriorated, Misbranded, Counterfeited, suspected of being Counterfeited, Adulterated, or otherwise deemed unfit for human consumption shall be quarantined and physically separated from other Drugs and Devices until they are returned to either the Manufacturer or Wholesale Distributor from which it was acquired. When Drugs and Devices are Adulterated, Misbranded, Counterfeited, or suspect of being Counterfeit, notice of the Adulteration, Misbranding, Counterfeiting, or suspected Counterfeiting shall be provided to the Board, FDA and Manufacturer or Wholesale Distributor from which it was acquired within three (3) business days. Any Drug or Device returned to a Manufacturer or Wholesale Distributor shall be kept under proper conditions for storage, handling, transport, shipment, and documentation showing that proper conditions were maintained is provided to the Manufacturer or Wholesale Distributor to which the Drugs are returned.
- (C). Any Drug or Device whose immediate or sealed outer or secondary containers or Labeling are Adulterated, Misbranded, Counterfeited, or suspect of being Counterfeit shall be quarantined and physically separated from other Drugs or Devices until they are 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 suspect of being Counterfeit, notice of the Adulteration, Misbranding, Counterfeiting, or suspected Counterfeiting shall be provided to the Board, FDA and Manufacturer or Wholesale Distributor from which it was acquired within three (3) business days.
- (D). Any Drug or Device that has been opened or used, but is not Adulterated, Misbranded, Counterfeited, or suspect of being Counterfeit, shall be identified as such, and shall be quarantined and physically separated from other Drugs or Devices until they are returned to the Manufacturer or Wholesale Distributor from which acquired or destroyed.
- (E). 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.

- (F). Contraband, Counterfeit, or suspected to be Counterfeit Drugs and Devices, other evidence of criminal activity, and accompanying documentation shall be retained and not destroyed until its disposition is authorized by the Board and FDA.
- (G). The shipping, immediate or sealed outer or secondary container or Labeling, and accompanying documentation, suspected of or determined to be Counterfeit or fraudulent shall not be destroyed until its disposition is authorized by the Board and FDA.
- (H). The record-keeping requirements in Section 10 (Recordkeeping) of this rule shall be followed for all outdated, damaged, deteriorated, Counterfeit, Misbranded, or Adulterated Drugs.

Section 9. Due Diligence.

If a Wholesale Distributor is licensed in accordance with these Model Rules, then the following Due Diligence requirements may be waived by the Board:

- (A). Prior to the initial purchase of Drugs or Devices from another Wholesale Distributor, a Wholesale Distributor shall obtain the following information from the selling Wholesale Distributor:
- (1) A list of states the Wholesale Distributor is licensed in, and into which it ships Drugs;
 - (2) Copies of all state and federal regulatory licenses and registrations;
 - (3) The Wholesale Distributor's most recent facility inspection reports;
 - (4) Information regarding general and product liability insurance, including copies of relevant policies;
 - (5) A list of other names under which the Wholesale Distributor is doing business, or was formerly known as;
 - (6) A list of corporate officers and managerial employees;
 - (7) A list of all owners of the Wholesale Distributor that own more than ten percent (10%) of the Wholesale Distributor, unless the Wholesale Distributor is publicly traded;
 - (8) A list of all disciplinary actions by state and federal agencies;
 - (9) A description, including the address, dimensions, and other relevant information, of each facility or warehouse used for Drug storage and Distribution;
 - (10) A description of Drug import and export activities of the Wholesale Distributor;
 - (11) A description of the Wholesale Distributor's process to comply with this Act; and
 - (12) A statement as to whether and for whom the Wholesale Distributor is an Authorized Distributor of Record.
- (B). Prior to the first purchase of Drugs from another Wholesale Distributor, the purchasing Wholesale Distributor shall:
- (1) conduct a criminal background check of all of the Wholesale Distributor's Personnel, shareholders, and owners involved in operations and management as specified in Section 2 (Minimum Qualifications);
 - (2) verify the Wholesale Distributor's status as an Authorized Distributor of Record, if applicable.
- (C). If the selling Wholesale Distributor's facility has not been inspected by the Board or the Board's agent within three (3) years of the contemplated purchase, the purchasing Wholesale Distributor shall conduct an inspection of the Wholesale

Distributor's facility prior to the first purchase of Drugs or Devices from another Wholesale Distributor, to ensure compliance with applicable laws and regulations relating to the storage and handling of Drugs or Devices. A third party may be engaged to conduct the site inspection on behalf of the purchasing Wholesale Distributor.

- (D). At least annually, a Wholesale Distributor that purchases Drugs from another Wholesale Distributor shall update the information set forth in Section 10 (Recordkeeping).
- (E). At least once every three (3) years, a Wholesale Distributor that purchases Drugs or Devices from another Wholesale Distributor shall inspect, or engage a third party to inspect, the premises of the facility or facilities of the Wholesale Distributor from whom it is purchasing Drugs, as set forth in Section 10. If the selling Wholesale Distributor's facility has been inspected by the Board, or the Board's agent, within the three (3) year time period, the inspection report of the Board is sufficient to meet the requirements of this subsection.
- (F). For Cause Authentications:
 - (1) If a 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, the purchasing Wholesale Distributor must Authenticate every Distribution of the Drug or Device back to the Manufacturer;
 - (2) Each Wholesale Distributor that has engaged in the Distribution of a Drug or Device, for which a purchasing Wholesale Distributor is conducting a For Cause Authentication shall provide, upon request, detailed information regarding the Distribution of the Drug or Device, including:
 - (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, the Distribution of which is being Authenticated.
 - (3) If the Wholesale Distributor that is attempting to Authenticate the Distribution of the Drug or Device back to a Manufacturer is unable to Authenticate each Distribution of the Drug or Device, the Wholesale Distributor shall quarantine the Drug or Device and report this to the Board and FDA within three (3) business days after completing the attempted Authentication; and
 - (4) If the Wholesale Distributor that is attempting to Authenticate the Distribution of the Drug or Device back to the Manufacturer satisfactorily completes the Authentication, the Wholesale Distributor shall maintain

records of the Authentication for three (3) years, and shall produce them to the Board upon request.

(G). Random Authentications:

- (1) Wholesale Distributors that purchase Drugs or Devices from other Wholesale Distributors, shall, at least annually, conduct Random Authentications of Pedigrees on at least ten percent (10%) of sales units of Distributions of Drugs or Devices that were purchased from other Wholesale Distributors;
- (2) If a Wholesale Distributor has purchased a Drug or Device that is on the State's Specified List of Susceptible Products or List of Susceptible Products recognized by the State, the Wholesale Distributor shall, at least quarterly, conduct Random Authentications of Pedigrees on at least ninety percent (90%) of sales units of Distributions of Drugs or Devices that are on the Board's Specified List of Susceptible Products or the List of Susceptible Products recognized by the Board that were purchased from other Wholesale Distributors; and
- (3) Wholesale Distributors from whom other Wholesale Distributors have purchased Drugs or Devices shall cooperate with the Random Authentications of the Pedigrees and provide the requested information in a timely manner.

Section 10. Recordkeeping.

- (A). Wholesale Distributors shall establish and maintain inventories and records of all transactions regarding the receipt and Distribution or other disposition of Drugs and Devices. These records shall include:
- (1) If an Authorized Distributor, Pedigrees for Drugs distributed that are included on the Specified List of Susceptible Products;
 - (2) If not an Authorized Distributor, Pedigrees for all Drugs that are distributed; and
 - (3) Effective January 1, 2007², all Wholesale Distributors, whether located in or out-of-State, whether an Authorized Distributor or not, must provide and maintain an electronic Pedigree developed in accordance with standards and requirements of the Board, for all Drugs received and distributed.
- (B). Wholesale Distributors shall establish and maintain inventories and records of all transactions regarding the receipt and Distribution, or other disposition of all Drugs and Devices. Such records shall include the dates of receipt and Distribution or other disposition of the Drugs and Devices. Inventories and records shall be made available for inspection and photocopying by any authorized official of any state, federal, or local governmental agency for a period of 3 (three) years following their creation date.
- (C). Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by an authorized official of any state and federal governmental agency charged with enforcement of these rules.
- (D). Should maintain an ongoing list of Persons with whom they do business.
- (E). All facilities shall establish and maintain procedures for reporting Counterfeit or suspected Counterfeit Drugs or Devices or Counterfeiting or suspected Counterfeiting activities to the Board and FDA.
- (F). Shall maintain a system for the mandatory reporting of significant shortages or losses of Drugs and Devices where it is known or suspected that diversion is occurring to the Board and FDA.

² NABP recognizes that technology must be available in order for a Wholesale Distributor to comply with these requirements. Information from the Wholesale Distribution industry indicates that the January 1, 2007 implementation date is a realistic goal for enacting the requirements of this section. However, states should monitor the availability of technology in developing statutes and rules and allow for variances if the technology needed to comply with the requirements of the Pedigree provisions is not available.

Section 11. Prohibited Acts.

It is unlawful for a Person to perform or cause the performance of or aid and abet any of the following acts in this State:

- (A). The Manufacture, Repackaging, sale, delivery, or holding or offering for sale of any Drug or Device that is Adulterated, Misbranded, Counterfeit, suspected of being Counterfeit, or has otherwise been rendered unfit for Distribution;
- (B). The adulteration, misbranding, or Counterfeiting of any Drug or Device;
- (C). The receipt of any Drug or Device that is Adulterated, Misbranded, stolen, obtained by fraud or deceit, Counterfeit, or suspected of being Counterfeit, and the delivery or proffered delivery of such Drug or Device for pay or otherwise;
- (D). The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the Labeling of a Drug or Device or the commission of any other act with respect to a Drug or Device that results in the Drug or Device being Misbranded;
- (E). Forging, Counterfeiting, simulating, falsely representing any Drug or Device without the authority of the Manufacturer, using any mark, stamp, tag, label, or other identification Device without the authorization of the Manufacturer;
- (F). The purchase or receipt of a Drug or Device from a Person that is not licensed to distribute Drugs or Devices to that purchaser or recipient;
- (G). The sale or transfer of Drug or Device to a Person that is not authorized under the law of the jurisdiction in which the Person receives the Drug or Device to purchase or possess Drugs or Devices from the Person selling or transferring the Drug or Device;
- (H). Failure to maintain or provide records as required by this Act and Rules;
- (I). Providing the Board or any of its representatives or any state or federal official with false or fraudulent records or making false or fraudulent statements regarding any matter within the provisions of this Act and Rules;
- (J). The Wholesale Distribution of any Drug or Device that was:
 - (1) Purchased by a public or private hospital or other health care entity;
 - (2) Donated or supplied at a reduced price to a charitable organization; or
 - (3) Stolen or obtained by fraud or deceit.
- (K). Failure to obtain a license or operating without a valid license when a license is required;
- (L). Obtaining or attempting to obtain a Drug or Device by fraud, deceit, misrepresentation or engaging in misrepresentation or fraud in the Distribution of a Drug or Device;
- (M). Distributing a Drug or Device to the patient without a Prescription or Prescription Order from a Practitioner licensed by law to use or prescribe the Drug or Device;

- (N). Failure to obtain, Authenticate when required under Section 10 of these Rules, or pass on a Pedigree;
- (O). The receipt of a Drug or Device pursuant to a Wholesale Distribution without first receiving a Pedigree, when required, that was attested to as accurate and complete by the Wholesale Distributor; or
- (P). Distributing a Drug or Device that was previously dispensed by a Pharmacy or distributed by a Practitioner.
- (Q). Failure to report any Prohibited Act and Rules.
- (R). Failure to exercise Due Diligence as provided in Section 9 of these regulations.

Section 12: Criminal Acts.

- (A). A Person who engages in the Wholesale Distribution of Drugs or Devices who, with intent to defraud or deceive, fails to deliver to another Person complete and accurate Pedigree, when required, concerning a Drug or Device prior to transferring the Drug or Device to another Person commits a felony of the third degree;
- (B). A Person who engages in the Wholesale Distribution of Drugs or Devices who, with intent to defraud or deceive, fails to acquire complete and accurate Pedigree, when required, concerning a Drug or Device prior to obtaining the Drug or Device from another Person commits a felony of the third degree;
- (C). A Person who engages in the Wholesale Distribution of Drugs and Devices and knowingly destroys, alters, conceals, or fails to maintain complete and accurate Pedigree concerning any Drug or Device in his possession commits a felony of the third degree;
- (D). A Person who engages in the Wholesale Distribution of Drugs or Devices who is in possession of drug pedigree documents required by the board and who knowingly fails to Authenticate the matters contained in the documents as required, and who nevertheless distributes or attempts to further distribute Drugs or Devices commits a felony of the third degree;
- (E). A Person who engages in the Wholesale Distribution of Drugs or Devices who, with intent to defraud or deceive, falsely swears or certifies that he has Authenticated any documents related to the Wholesale Distribution of Drugs or Devices, commits a felony of the third degree;
- (F). A Person who engages in the Wholesale Distribution of Drugs or Devices and knowingly forges, Counterfeits, or falsely creates any Pedigree, who falsely represents any factual matter contained on any Pedigree, or who knowingly omits to record material information required to be recorded in a Pedigree commits a felony of the third degree;
- (G). A Person who engages in the Wholesale Distribution of Drugs or Devices and knowingly purchases or receives Drugs or Devices from a Person, not authorized to distribute Drugs or Devices, in Wholesale Distribution commits a felony of the third degree;
- (H). A Person who engages in the Wholesale Distribution of Drugs or Devices and knowingly sells, barter, brokers, or transfers Drugs or Devices to a Person not authorized to purchase Drugs or Devices, under the jurisdiction in which the Person receives the Drug(s) or Device(s) in a Wholesale Distribution commits a felony of the third degree;
- (I). A Person who knowingly possesses, actually or constructively, any amount of a Contraband Drug(s) or Device(s), who knowingly sells or delivers, or who possesses with intent to sell or deliver any amount of a Contraband Drug(s) or Device(s) commits a felony of the third degree;

- (J). A Person who knowingly forges, Counterfeits, or falsely creates any Label for a Drug(s) or Device(s) or who falsely represents any factual matter contained in any Label of a Drug(s) or Device(s) commits a felony of the third degree;
- (K). A Person who knowingly Manufactures, purchases, sells, delivers or brings into the State, or who is knowingly in actual or constructive possession of any amount of Contraband Drug(s) or Device(s) commits a felony of the third degree; and
- (L). A Person who knowingly Manufactures, purchases, sells, delivers, or brings into the State, or who is knowingly in actual or constructive possession of any amount of Contraband Drug(s) or Device(s), and whose acts result in the death of a Person, commits a felony in the first degree.
- (M). A Person found guilty of any offense under this section, under the authority of the Court convicting and sentencing the Person, shall order that the Person forfeit to the State any real or Personal property:
 - (1) Used or intended to be used to commit, to facilitate or to promote the commission of such offense;
 - (2) Constituting, derived from, or traceable to the gross proceeds that the defendant obtained directly or indirectly as a result of the offense. Any property or assets subject to forfeiture under this section may be seized pursuant to a warrant obtained in the same manner as a search warrant or as otherwise permitted by law, and held until the case against a defendant is adjudicated. Monies ordered forfeited, or proceeds from the sale of other assets ordered forfeited shall be equitably divided between the Board and other agencies involved in the investigation and prosecution which led to the conviction. Other property ordered forfeited after conviction of a defendant may, at the discretion of the investigating agencies, be placed into official use by the Board or the agencies involved in the investigation and prosecution which led to the conviction.

Section 13: Policies and Procedures.

Wholesale Distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for 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 implementing and maintaining a continuous quality improvement system. Wholesale Distributors shall include in their written policies and procedures the following:

- (A). A procedure to be followed for handling recalls and withdrawals of Drugs and Devices. Such procedure shall be adequate to deal with recalls and withdrawals due to:
 - (1) any action initiated at the request of the FDA or any other federal, state, or local law enforcement or other government agency, including the Board of Pharmacy;
 - (2) any volunteer action by the Manufacturer to remove defective or potentially defective Drugs or Devices from the market; or
 - (3) any action undertaken to promote public health and safety by the replacing of existing merchandise with an improved product or new package design.
- (B). A procedure to ensure that Wholesale Distributors prepare for, protect against, and handle any crisis that affects 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.
- (C). A procedure 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 two years after disposition of the outdated Drugs.
- (D). A procedure for the destruction in accordance with federal and state laws, including all necessary documentation, maintained for a minimum of two years, and the appropriate witnessing of the destruction of outdated or expired Drugs in accordance with all applicable federal and state requirements.
- (E). A procedure for 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 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.
- (F). A procedure for investigating discrepancies involving Counterfeit, suspect of being Counterfeit, Contraband, or suspect of being Contraband, in the inventory and

reporting such discrepancies within three (3) business days to the Board and/or appropriate federal or state agency.

- (G). A procedure for reporting criminal or suspected criminal activities involving the inventory of Drug(s) and Device(s) to the Board within the three (3) business days.
- (H). A procedure for conducting the For Cause and Random Pedigree Authentication requirements under Section 9 (Due Diligence).

Comments:

DEFINITIONS

“Authenticate”: Although pedigrees record each transaction of a drug and are therefore primarily used in authenticating, “other accompanying documents” such as purchase orders and invoices should also be utilized to assist in authenticating. For example, when such “accompanying documents” seem false or misleading, every attempt should be made to authenticate the drug before it is further distributed.

The designation of “Authorized Distributor” or “Authorized Distributor of Record” is applicable to all affiliated groups and subsidiaries of a corporation and therefore a separate designation for each affiliated group or subsidiary is not required. Additionally, the “Authorized Distributor” status would apply across all product lines of the manufacturer and would not be segregated by individual products.

In addition to written agreements between wholesale distributors and manufacturers, and manufacturers’ listings of “Authorized Distributor of Record”, states may want to consider a transaction based definition for an “Authorized Distributor of Record”. This transaction based definition could be based on the percentage of purchases made directly from the manufacturer and the amount of annual prescription drug sales of the wholesale distributor combined with the ability of the wholesale distributor to prove that it has an active and verifiable account number issued by the manufacturer authorizing the wholesale distributor to purchase products directly from the manufacturer.

“Designated Representative” should serve as a liaison to the Board who is extremely knowledgeable about and involved in the daily operations of the wholesale distributor. If a wholesale distributor is licensed by multiple states, it is not necessary for the wholesale distributor to have multiple designated representatives. One designated representative per wholesale distributor facility is sufficient.

“Manufacturer” is also defined as a wholesale distributor in the Model Act and Rules. Therefore, all of the conditions, requirements, and prohibited and criminal acts would apply to manufacturers in states where applicable definitions and sections of the Model Act or these Model Rules were adopted. An integral component of the licensing of manufacturers as wholesale distributors in the design to prevent or detect counterfeit or contraband drugs or devices is the requirement for the development, maintenance, and release of the list of authorized distributors or authorized distributors of record accepted by the manufacturer. Failure to do so would preclude licensure and if the manufacturer is licensed, could be grounds for suspension or revocation of the license.

The “Pedigree” should contain the names and addresses of each person certifying delivery or receipt of the drug. “Certifying” is to attest and confirm the actual delivery and receipt of the drug via a signature or other acceptable means as approved by the Board on the pedigree. Current rules mandate that the pedigree record each distribution of a drug from the manufacturer through each wholesale distributor involved in the

distribution of that drug. However, states may consider adopting language which allows the pedigree to be documented back to the last authorized distributor of record if the situation develops that authorized distributors of record are not providing pedigrees therefore precluding non designated wholesale distributors from further distributing the drug.

Feedback from the wholesale distributor industry suggests that the sales invoice may not accompany the products when delivered. Customarily, a packaging slip or other similar documentation is provided with the delivery of the product and therefore states may consider allowing such documentation to accompany the pedigree.

Although the “Specified List of Susceptible Products” will be primarily designated by the State, it is highly suggested that states adopt the National Specified List of Susceptible Products that will be developed in conjunction with FDA, NABP, and other industry stakeholders.

“Wholesale Distribution” does include the term “Devices” in its definition although currently federal law and some state laws don’t define “Wholesale Distribution” as such. Wherever appropriate under the Model Rules, the term is included and recognized that wholesale distribution also includes devices. A disparity could be caused if those persons which only distribute devices are not currently licensed by the state and therefore not subject to regulation by the Board. Different requirements and standards would exist for these persons than would apply for persons who distribute both drugs and devices. It is NABP’s position that persons which manufacture and/or distribute devices should be licensed with the Board and adhere to the same requirements as those in place for persons which manufacture and/or distribute drugs. In developing laws and rules, states may need to review their current regulations and standing on the question of required licensure for persons which manufacture and/or distribute devices in order to determine the applicability of these Model Rules to persons which manufacture and/or distribute devices.

SECTION 1: REQUIREMENTS FOR LICENSURE

The application and screening process for licensing wholesale distributors represents a critical point in efforts to prevent the introduction of counterfeit drugs into the medication distribution system. An application that requires detailed information about the applicant and every individual involved in the operations of the wholesale distributor are critical. A sample application that has proved successful in the State of Nevada is appended to these Model Rules.

Subsection (B)

Although wholesale distributors may be licensed in multiple states, it is not intended for wholesale distributors to procure a separate “surety” bond (or other equivalent means) for each state of licensure. States should consider waiving this requirement if the wholesale distributor has procured a “surety” bond (or other equivalent means) through a central clearinghouse. States should also consider not requiring separate bonds for different

facilities of the same corporation if the corporation is bonded with a central clearinghouse.

Subsection (F)

The Board may designate a third party to conduct inspections and ensure that all requirements for licensure established by the legislature and Board are fulfilled. The National Association of Boards of Pharmacy (NABP) wholesale distributor Accreditation and Clearinghouse Service is available to the Board.

SECTION 3. PERSONNEL

Subsection: (A) (1) (a)

Fingerprints represent one of the current means of authenticating the identity of the Person as well as providing a reliable means to conduct criminal background checks. As technology changes and other means become available to the Board such as retina scanning or DNA sampling, the Board must stay current with such technologies and amend rules as necessary and appropriate.

Subsection (D)

The Board will need to ensure that continuing education programs for the desired content areas are available when considering the implementation of this requirement.

SECTION 5: SECURITY AND ANTI-COUNTERFEITING

Subsection (E)

Standards regarding track and trace technologies should be developed using a coalition of experts and regulators. In order to implement an effective track and trace system that is consistent throughout the entire distribution system, it is suggested that national standards for such technology and equipment be developed.

Subsection (G)(1)

Authentications conducted back to the manufacturer removes a “loophole” identified in Florida that was exploited by wholesale distributors who were able to launder illegitimate Drugs by funneling them through an authorized distributor of record.

Subsection (H)

The Board may want to consider specifying that random authentications should not include only one product, but involve a spectrum of products and sources.

A sales unit is the unit of measure the manufacturer uses to invoice its customer for the particular product.

SECTION 9: DUE DILIGENCE

Subsection (G)

A sales unit is the unit of measure the manufacturer uses to invoice its customer for the particular product.

SECTION 10: RECORDKEEPING

Subsection (A) (3)

NABP recognizes that technology must be available in order for a wholesale distributor to comply with these requirements. Information from the wholesale distribution industry indicates that the January 1, 2007 implementation date is a realistic goal for enacting the requirements of this section. However, states should monitor the availability of technology in developing statutes and rules and allow for variances if the technology needed to comply with the requirements of the pedigree provisions is not available.

SECTION 11: PROHIBITED ACTS

When the Model Rules for the licensure of wholesale distributors are incorporated into the Model Act, this section will be assimilated into Section 402 of the Act, Grounds, Penalties, and Reinstatement. Additionally, Section 213 (Powers and Responsibilities of the Board) will be updated to allow the Board to take lawful action within its authority against any person or party found to have violated a prohibited act.

SECTION 13: POLICIES AND PROCEDURES

In developing policies and procedures for the management and quality improvement of the wholesale distribution activities of a wholesale distributor, the Board may want to refer to the Healthcare Distribution Management Association (HDMA).