Report of the Committee on Law Enforcement/Legislation

NOTE: The NABP Executive Committee accepted all of the recommendations of this Committee with the following exceptions:

- **Recommendations 4 and 5, which recommended revising the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (*Model Act*), were accepted in part and rejected in part by the Executive Committee. Rejected was wording that disallowed Certified Pharmacy Technicians from both accepting all new prescriptions and transferring prescriptions.**

Members Present:

Kevin Borcher (NE), *chair*; Patrick Adams (HI); Gay Dodson (TX); Patricia Donato (NY); Edie Goodmaster (CT); Larry Mokhiber (NY); Nona Rosas (AZ); Dennis Wiesner (TX).

Others Present:

Cathryn Lew, *Executive Committee Liaison*; Carmen A. Catizone, Melissa Madigan, Eileen Lewalski, Emily Shaffer, Deborah Zak, *NABP staff*.

Introduction:

The Committee on Law Enforcement/Legislation met February 29, 2012, at NABP Headquarters.

Review of the Committee Charge

Committee members reviewed their charge and accepted it as follows:

1. Review and comment on existing legislation and rules for the practice of pharmacy, legal distribution of drugs, and related areas within pharmacy, including impaired pharmacists.

2. Develop model regulations for pharmacy as assigned by the Executive Committee, or from resolutions adopted by the members of the Association, or from reports of the other committees of the Association.

3. Recommend to the Executive Committee areas where model regulations are needed in pharmacy for improving the protection of the public health.

Committee members then reviewed the report of the 2010-2011 Committee on Law Enforcement/Legislation for background information.

LE/L Recommendation 1: The Committee Recommends Approval of the Amendments to the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* suggested by the Task Force on the Control and Accountability of Prescription Medications, with Revisions.

The recommended revisions by the task force are denoted by underlines and ~~strikethroughs~~. The recommended revisions by the committee are denoted by double underlines and ~~double strikethroughs~~.

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

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Article III

Licensing

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Section 302. Qualifications for Licensure by Examination.

(a) To obtain a license to engage in the Practice of Pharmacy, an applicant for licensure by examination shall:

(1) have submitted a written application in the form prescribed by the Board of Pharmacy;
(2) have attained the age of majority;
(3) be of good moral character;
(4) have graduated and received the first professional degree from a college or school of Pharmacy that has been approved by the Board of Pharmacy;
(5) have graduated from a foreign college of Pharmacy, completed a transcript verification program, taken and passed a college of Pharmacy equivalency examination program, and completed a process of communication-ability testing as defined under Board of Pharmacy regulations so that it is ensured that the applicant meets standards necessary to protect public health and safety;
(6) have completed a Pharmacy practice experience program or other program that has been approved by the Board of Pharmacy, or demonstrated to the Board's satisfaction that experience in the Practice of Pharmacy which meets or exceeds the minimum Pharmacy practice experience requirements of the Board;
(7) have successfully passed an examination or examinations given by the Board of Pharmacy;
(8) have undergone a state and federal fingerprint-based criminal background check as specified by Board rule; and
(9) have paid the fees specified by the Board of Pharmacy for the examination and any related materials, and have paid for the issuance of the license.

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Section 305. Renewal of Licenses and Registrations.

(a) Each Pharmacist and Pharmacy Intern shall apply for renewal of his or her license annually [or at such interval determined by the Board], no later than the first day of _____. A Pharmacist, Pharmacy Intern, Certified Pharmacy Technician, or Pharmacy Technician who desires to continue or assist in the Practice of Pharmacy in this State shall file with the Board an application in such form and containing such data as the Board may require for renewal of the license. If the Board finds that the applicant has been licensed, and that such license has not been Revoked or placed under Suspension, that the applicant <u>has attested that he or she has no criminal convictions or arrests,</u> has paid the renewal fee, has continued his or her Pharmacy education, if required, in accordance with the rules of the Board, and is entitled to continue in or assist in the Practice of Pharmacy, the Board shall issue a license to the applicant.

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~~(c) A Pharmacist shall apply for renewal of his or her registration to Practice Telepharmacy Across State Lines annually [or at such interval determined by the Board], no later than the first day of (month). A Pharmacist who desires to continue in the Practice of Telepharmacy Across State Lines shall file with the Board an application in such form and containing such data as the Board may require for renewal of the registration. If the Board finds that the applicant has been licensed to Practice Pharmacy in another State and registered to Practice Telepharmacy Across State Lines in this State, that such license and registration have not been Revoked or placed under Suspension, and that the applicant has attested that he or she has no criminal convictions or arrests, has paid the renewal fee and is entitled to continue to engage in the Practice of Telepharmacy Across State Lines, the Board shall issue a registration to the applicant.~~

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Section 302(a)(8). Comment.

If the applicant does not complete the application process within a period specified by the Board, it is recommended that the state and federal fingerprint-based criminal background check be repeated.

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Section 308. Registration of Certified Pharmacy Technicians.

(a) In order to be registered as a Certified Pharmacy Technician in this State, an applicant shall:
- (1) have submitted a written application in the form prescribed by the Board of Pharmacy;
- (2) have attained the age of _____;
- (3) have good moral character;
- (4) have graduated from high school or obtained a Certificate of General Educational Development (GED) or equivalent;
- (5) have:
  - (i) graduated from a competency-based pharmacy technician education and training program approved by the Board of Pharmacy; or

(ii) been documented by the Pharmacist-in-Charge of the Pharmacy where the applicant is employed as having successfully completed a site-specific, competency-based education and training program approved by the Board of Pharmacy;

(6) have successfully passed an examination developed using nationally recognized and validated psychometric and pharmacy practice standards approved by the Board of Pharmacy;

(7) have undergone a state and federal fingerprint-based criminal background check as specified by Board rule; and

(8) have paid the fees specified by the Board of Pharmacy for the examination and any related materials, and have paid for the issuance of the registration.

(b) No Pharmacist whose license has been denied, Revoked, Suspended, or restricted for disciplinary purposes shall be eligible to be registered as a Certified Pharmacy Technician.

(c) The Board of Pharmacy shall, by rule, establish requirements for registration of Certified Pharmacy Technicians.

Section 309. Registration of Pharmacy Technicians.

(a) In order to be registered as a Pharmacy Technician in this State, an applicant shall:

(1) have submitted a written application in the form prescribed by the Board of Pharmacy;

(2) have attained the age of _____;

(3) have good moral character;

(4) have undergone a state and federal fingerprint-based criminal background check as specified by Board rule;

(5) have paid the fees specified by the Board; and

(6) have been documented by the Pharmacist-in-Charge of the Pharmacy where the applicant is employed as having successfully completed a site-specific training program and having successfully completed an objective assessment mechanism prepared in accordance with any rules established by the Board.

(b) No Pharmacist whose license has been denied, Revoked, Suspended, or restricted for disciplinary purposes shall be eligible to be registered as a Pharmacy Technician.

(c) The Board of Pharmacy shall, by rule, establish requirements for registration of Pharmacy Technicians.

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Section 308(b) and 309(b). Comment.

The Board may specifically authorize a pharmacist whose license has been disciplined to register as a Certified Pharmacy Technician or Pharmacy Technician under terms and conditions deemed appropriate. ~~The state may decide to perform a criminal background check on individuals seeking to register as Certified Pharmacy Technicians or Pharmacy Technicians.~~

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Article V

Licensing of Facilities

Section 501. Licensing.

(a) The following Persons located within this State, and the following Persons located outside this State that provide services to patients within this State, shall be licensed by the Board of Pharmacy and shall annually renew their license with the Board:
(1) persons engaged in the Practice of Pharmacy;
(2) persons engaged in the Manufacture, production, sale, or Distribution or Wholesale Distribution of Drugs or Devices;
(3) pharmacies where Drugs or Devices are Dispensed, or Pharmacist Care is provided; and
(4) pharmacy Benefits Managers.
Where operations are conducted at more than one location, each such location shall be licensed by the Board of Pharmacy.

(b) The Board shall establish by rule, under the powers granted to it under Section 212 and 213 of this Act and as may be required from time to time, under federal law, the Criteria that each Person must meet to qualify for licensure in each classification. The Board shall adopt definitions in addition to those provided in Article I, Section 105, where necessary to carry out the Board's responsibilities. The Board may issue licenses with varying restrictions to such Persons where the Board deems it necessary.

(c) Each Pharmacy shall have a Pharmacist-in-Charge. Whenever an applicable rule requires or prohibits action by a Pharmacy, responsibility shall be that of the owner <u>and/or pharmacy permit holder</u> and the Pharmacist-in-Charge of the Pharmacy, whether the owner <u>and/or pharmacy permit holder</u> is a sole proprietor, partnership, association, corporation, or otherwise.

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(f) The Board of Pharmacy may deny or refuse to renew a license if it determines that the granting or renewing of such license would not be in the public interest.

(g) The Board shall establish the standards that a Person must meet for initial and continued licensure under Article V and shall ~~determine those facilities that~~ require initial inspections and periodic inspections thereafter for purposes of licensure or licensure renewal.

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Section 503. Notifications.

(a) All licensed Persons shall report to the Board of Pharmacy the occurrence of any of the following:
(1) permanent closing;
(2) change of ownership, management, location, or Pharmacist-in-Charge of a Pharmacy;
(3) any theft or loss of Drugs or Devices;
(4) any conviction of any employee of any State or Federal Drug laws;
<u>(5) any criminal conviction or pleas of guilty or nolo contendere of all licensed or registered personnel;</u>
(<u>6</u>) disasters, accidents, or any theft, destruction, or loss of records required to be maintained by State or Federal law;

(7) occurrences of Significant Adverse Drug Reactions as defined by Rules of the Board;
(8) illegal use or disclosure of Protected Health Information; or
(9) any and all other matters and occurrences as the Board may require by rule.

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Model Rules for the Practice of Pharmacy

Section 1. Facility.

(a) To obtain a license for a Pharmacy, an applicant shall:
(1) have submitted a written application in the form prescribed by the Board of Pharmacy;
(2) have attained the age of majority;
(3) be of good moral character; and
(4) have paid the fees specified by the Board of Pharmacy for the issuance of the license.
(b) The facility owner, if an individual, shall have undergone a state and federal fingerprint-based criminal background check as specified by Board rule;
(c) The facility shall have undergone a Pharmacy inspection by the Board; and
(d) Minimum requirements for a Pharmacy:
(1) Each Pharmacy shall be of sufficient size, as determined by the Board, to allow for the safe and proper storage of Prescription Drugs and for the safe and proper Compounding and/or preparation of Prescription Drug Orders.

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(8) Security.
(i) Each Pharmacist, while on duty, shall be responsible for the security of the Pharmacy, including provisions for effective control against theft or diversion of Drugs and/or Devices.
(ii) The Pharmacy shall be secured by either a physical barrier with suitable locks and/or an electronic barrier to detect entry at a time when the Pharmacist is not present. Such barrier shall be approved by the Board of Pharmacy before being put into use. ~~Locks and access codes shall be changed~~ In the event of separation of employment of an employee due to any suspected or confirmed Drug-related reason, including diversion, or other acts involving dishonesty, suitable action shall be taken to ensure the security of the pharmacy.

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Section 2. Personnel.

(a) Duties and Responsibilities of the Pharmacist-in-Charge
(1) No Person shall operate a Pharmacy without a Pharmacist-in-Charge. The Pharmacist-in-Charge of a Pharmacy shall be designated in the application of the Pharmacy for license, and in each renewal thereof. A Pharmacist may not serve as Pharmacist-in-Charge unless he or she is physically present in the Pharmacy a sufficient amount of time to provide supervision and control. A Pharmacist may not serve as Pharmacist-in-Charge for more than one Pharmacy at any one time except upon obtaining written permission from the Board.

(2) The Pharmacist-in-Charge has the following responsibilities:

(i) Developing or adopting, implementing, and maintaining:

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(C) policies and procedures for the procurement, storage, security, and disposition of Drugs and Devices, particularly controlled substances and drugs of concern. Quality assurance programs shall be designed to prevent and detect Drug diversion.

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(iii) Notifying the Board of Pharmacy immediately of any of the following changes:

(A) change of employment or responsibility as the Pharmacist-in-Charge;

(B) the separation of employment of any Pharmacist, Pharmacy Intern, Pharmacy Technician, or Certified Pharmacy Technician for any ~~suspected or~~ confirmed Drug-related reason, including but not limited to, Adulteration, abuse, theft, diversion, and shall include in the notice the reason for the termination: if it is the employment of the Pharmacist-in-Charge that is terminated, the owner and/or pharmacy permit holder ~~or other Person in charge of the Pharmacy~~ shall notify the Board of Pharmacy;

(C) change of ownership of the Pharmacy;

(D) change of address of the Pharmacy; or

(E) permanent closing of the Pharmacy.

(iv) Making or filing any reports required by State or Federal laws and rules.

(v) Reporting any theft, suspected theft, diversion, or other Significant Loss of any Prescription Drug within one business day of discovery to the Board of Pharmacy and as required by Drug Enforcement Administration (DEA) or other State or federal agencies for Prescription Drugs and controlled substances.

(vi) Responding to the Board of Pharmacy regarding any minor violations brought to his or her attention.

(5) The owner and/or pharmacy permit holder and the Pharmacist-in-Charge of a Pharmacy that ships medications by mail or common carrier shall be responsible for the development and implementation of ~~a~~ policies and procedures to:

a. properly transfer prescription information to an alternative Pharmacy of the patient's choice in situations where the medication is not Delivered or Deliverable;

b. ~~require common carrier to conduct~~ verify that common carriers have in place security provisions, such as criminal background checks and random drug screens on its employees who have access to prescription medications;

c. track all shipments; and

d. provisions to ensure that drugs do not become adulterated in transit.

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(c) If any action of the Pharmacy is deemed to contribute to or cause a violation of any provision of this section, the Board may hold the owner and/or Pharmacy permit holder

responsible and/or absolve the Pharmacist-in-Charge from the responsibility of that action.

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Section 2(a)(2)(i)(C). Comment

As part of a quality assurance program designed to prevent and detect drug diversion, the Pharmacist-in-Charge is ~~encouraged~~ expected to ensure policies and procedures are in place that address the following:

- inspection of shipments;
- receipt verification oversight and checking in shipments;
- reconciliation of orders;
- inventory management including:
  - determination of Medications that need to be monitored and controlled beyond existing systems such as controlled substances and drugs of concern; and
  - conducting quarterly reconciliations at a minimum but shall be more frequent up to perpetual, depending on the potential for or incidence of diversion for a particular drug.

The Pharmacist-in-Charge, if the practice setting warrants, may also consider implementing diversion prevention and detection policies and procedures that address the following:

- periodic reviews of employee access to any secure controlled substance storage areas, which may include:
  - alarm codes and lock combinations;
  - passwords;
  - keys and access badges; and
  - video surveillance systems.

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Section 2(a)(~~32~~)(iii). Comment.

If states require the Pharmacist-in-Charge or other Person in charge of the Pharmacy to submit information regarding the separation of employment of licensees, especially in circumstances of suspected or confirmed abuse, theft, or diversion of Drugs, states should also be aware of confidentiality and employment laws that may restrict the release of information and be cautioned that the release of such information may create a liability for the reporting Pharmacy.

In instances where the Pharmacist-in-Charge and the owner and/or pharmacy permit holder are the same person and that person is no longer employed or designated as the Person in charge, then the Board must take action to cease operation of the Pharmacy.

Boards of pharmacy are strongly encouraged to require that pharmacy owners and/or permit holders have policies and procedures in place to conduct initial and random drug screenings of all employees that have access to prescription drugs including controlled substances.

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Model Rules for Pharmacy Interns

Section 1. Licensure.

Every individual shall be licensed by the Board of Pharmacy before beginning Pharmacy practice experiences in this State. A license to practice Pharmacy as a Pharmacy Intern shall be granted only to those individuals who:

(a) are enrolled in a professional degree program of a school or college of pharmacy that has been approved by the Board and satisfactorily progressing toward meeting the requirements for licensure as a Pharmacist; or

(b) are graduates of an approved professional degree program of a school or college of Pharmacy or are graduates who have established educational equivalency by obtaining a Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) Certificate, who are currently licensed by the Board of Pharmacy for the purpose of obtaining practical experience as a requirement for licensure as a Pharmacist; or

(c) are qualified applicants awaiting examination for licensure or meeting Board requirements for re-licensure; or

(d) are participating in a residency or fellowship program; and

(e) have undergone a state and federal fingerprint-based criminal background check as specified by Board rule.

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Background:

The committee discussed and agreed on the vast majority of the task force's recommended revisions. Members did, however, decide to add the phrase "as specified by Board rule" to the criminal background check provisions throughout to provide for flexibility. Additionally, the committee determined that the renewal provision for the practice of telepharmacy across state lines should be removed as no boards require a separate pharmacist license for this activity. Members also suggested several revisions to the facility provisions in the Model Rules for the Practice of Pharmacy to clarify certain requirements and to be less proscriptive in certain instances. Along these lines, the members also agreed to revise the provisions for a pharmacy that ships medications by mail or common carriers to be less proscriptive. The committee did, however, strengthen comments related to quality assurance programs designed to prevent and detect drug diversion.

LE/L Recommendation 2: NABP Should Not Revise the Existing Model Act Language Pertaining to the Reporting of Separation of Employment for Suspected Drug-Related Reasons.

The committee recommends that NABP encourage the boards of pharmacy to incorporate, if they have yet to do so, existing *Model Act* language pertaining to the reporting of separation of employment of any pharmacist, pharmacy intern, pharmacy technician, or certified pharmacy technician for only confirmed drug-related reasons, including but not limited to, adulteration, abuse, theft, or diversion, and shall include in the notice the reason for the termination.

Background:

The committee expressed concern that to require the reporting of the separation of employment of a licensee based on suspected diversion could result in negative legal implications and agreed that only confirmed drug-related reasons should be reported to the boards.

LE/L Recommendation 3: The Committee Recommends Adoption of the Model Rules for the Licensure of Medical Gas and Medical Gas Related Equipment Wholesale Distributors with Revisions.

The recommended revisions by NABP staff are denoted by underlines and ~~strikethroughs~~. The recommended revisions by the committee are denoted by double underlines and ~~double strikethroughs~~.

Model Rules for the Licensure of Medical Gas and Medical Gas Related Equipment Wholesale Distributors

Section 1. Definitions.

(a) "Adulterated Medical Gas or Medical Gas Related Equipment." A Medical Gas or Medical Gas Related Equipment shall be deemed to be Adulterated:

(1) if:

(i) it consists in whole or in part of any impurities or deleterious substances exceeding normal specifications;

(ii) it has been produced, prepared, packed, or held under conditions whereby the medical gas may have been contaminated causing it to be rendered injurious to health; or 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 practices to ensure that the medical gas meets the requirements of this part as to safety and has the identity and strength, and meets the quality and purity characteristics that it purports or is represented to possess; or

(iii) its container interior is contaminated with any poisonous or deleterious substance that may render the contents injurious to health; or

(2) if it purports to be or is represented as a Medical Gas, the name of which is recognized in the United States Pharmacopeia – National Formulary (USP/NF), and its strength differs from, or its quality or purity falls below, the standard set forth in the USP/NF. 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 USP/NF, or validated equivalent, or in the absence of or inadequacy of these tests or methods of assay, those prescribed under authority of the Federal Act. No medical gas defined in

USP/NF 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; or

(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.

(b) "Authorized Distributor of Record of Medical Gases or Medical Gas Related Equipment" means a distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's products. An ongoing relationship is deemed to exist between such wholesale distributor and a manufacturer when the wholesale distributor, including any affiliated group of the wholesale distributor, as defined in Section 1504 of the Internal Revenue Code, complies with the following:

(1) the wholesale distributor has a written agreement currently in effect with the manufacturer evidencing such ongoing relationship; and

(2) the wholesale distributor is listed on the manufacturer's current list of authorized distributors of record, which must be updated by the manufacturer when changes are made.

(c) "Common Carrier of Medical Gases or Medical Gas Related Equipment" means any person or entity who undertakes, whether directly or by any other arrangement, to transport, load, or offload property including Medical Gas or Medical Gas Related Equipment for compensation.

(d) "Designated Representative of Medical Gas or Medical Gas Related Equipment Wholesale Distributors" means any and all individuals designated by the Wholesale Distributor of Medical Gases or Medical Gas Related Equipment who will serve as a responsible individual of such Wholesale Distributor with the Board who is actively involved in and aware of the actual daily operation of the such Wholesale Distributor.

(e) "Distribute Medical Gas or Medical Gas Related Equipment" or "Distribution of Medical Gas or Medical Gas Related Equipment" means to sell, offer to sell, deliver, offer to deliver, broker, give away, or transfer a Medical Gas or Medical Gas Related Equipment, whether by passage of title, physical movement, or both. The term does not include:

(1) to Dispense or Administer; or

(2) delivering or offering to deliver a Medical Gas or Medical Gas Related Equipment by a common carrier in the usual course of business as a common carrier.

(f) "Emergency Medical Reasons for the Distribution of Medical Gases or Medical Gas Related Equipment" include, but are not limited to, transfers of a Medical Gas or Medical Gas Related Equipment between a Wholesale Distributor of Medical Gases or Medical Gas Related Equipment or Pharmacy to alleviate a temporary shortage of a Medical Gas or Medical Gas Related Equipment arising from delays in or interruption of regular distribution schedules; sales to nearby emergency medical services, ie, ambulance companies and firefighting organizations in the same state or same marketing or service area, or nearby licensed Practitioners allowed to dispense Medical Gases or Medical Gas Related Equipment for use in the treatment of acutely ill or injured Persons; provision of minimal emergency supplies of Medical Gases or Medical Gas Related Equipment to nearby nursing homes for use in emergencies or during hours of the day when necessary Medical Gases or Medical Gas Related Equipment cannot be obtained; and transfers of

Medical Gases or Medical Gas Related Equipment by a retail Pharmacy to another retail Pharmacy to alleviate a temporary shortage.

(g) "Emergency Use Oxygen" means Oxygen USP administered in emergency situations without a prescription. The container must be labeled in accordance with federal FDA requirements: "For emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation. For all other medical applications, Rx Only."

(h) "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.

(i) "Federal Act" means the Federal Food, Drug, and Cosmetic Act.

(j) "Health Care Entity" means any Person that provides diagnostic, medical, surgical, dental treatment, or rehabilitative care, including home respiratory care providers and (in the case of Oxygen USP) to an authorized administrator of "Emergency Use Oxygen," but does not include any retail Pharmacy or Wholesale Distributor.

(k) "Immediate Container for Medical Gases" means compressed gas cylinders and liquid containers containing a Medical Gas, but does not include large bulk liquid or high pressure containers such as storage tanks, vehicle mounted vessels, trailers, and/or railcars.

(l) "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.

(m) "Label for Medical Gases" means a display of written, printed, or graphic matter upon the immediate container of any Medical Gas.

(n) "Label for Medical Gas Related Equipment" means a display of written, printed, or graphic matter upon the immediate container of any Medical Gas Related Equipment.

(o) "Legally Authorized to Receive" means persons that are licensed Manufacturers of Medical Gases or Medical Gas Related Equipment, Wholesale Distributors of Medical Gases or Medical Gas Related Equipment, home respiratory care companies, and Pharmacies. Also includes Health Care Entities, persons authorized to receive Emergency Use Oxygen without a prescription, and companies that require the use of a Medical Gas in the installation and refurbishment of piping and equipment, including Medical Gas Related Equipment that will be used to distribute or contain a Medical Gas.

(p) "Medical Gas" means gases (including liquefied gases) classified by FDA as drugs or devices that are used for medical applications and which may be stored and administered through the use of Medical Gas Related Equipment, which may or may not be required under Federal or State law for the immediate container to bear the label, "Rx only" or "Caution: Federal or State law prohibits dispensing without a prescription."

(q) "Manufacturer of Medical Gases" means persons manufacturing bulk medical gases or persons transferring gas or liquefied gas product from one container to another (eg, liquid to gas, gas to gas, liquid to liquid).

(r) "Medical Gas Related Equipment" means a device used as a component part or accessory used to contain or control the flow, delivery and/or pressure during the administration of a medical gas (eg, liquid oxygen base and portable units, pressure regulators and flow meters, oxygen concentrators, etc).

(s) "Misbranded Medical Gas or Medical Gas Related Equipment" means a Medical Gas or Medical Gas Related Equipment 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 the case of a Medical Gas; or the label does not show an accurate monograph for the Medical Gas.

(t) "Prescription Medical Gas" means a Medical Gas which is required under law to be labeled with the following statement: "Rx Only."

(u) "Product Labeling" means all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article.

(v) "USP Standards" means standards published in the current official United States Pharmacopeia or National Formulary.

(w) "Wholesale Distribution of Medical Gases or Medical Gas Related Equipment" means the Distribution of Medical Gas or Medical Gas Related Equipment, by Wholesale Distributors of Medical Gases or Medical Gas Related Equipment to Persons other than consumers or patients. To the extent permitted by the Prescription Drug Marketing Act, Wholesale Distribution of Medical Gases, or Medical Gas Related Equipment does not include:

(1) the sale, purchase, or trade of a Medical Gas or Medical Gas Related Equipment, an offer to sell, purchase, or trade a Prescription Drug or Device, or the Dispensing of a Medical Gas or Medical Gas Related Equipment pursuant to a Prescription;

(2) the sale, purchase, or trade of a Medical Gas or Medical Gas Related Equipment or an offer to sell, purchase, or trade a Medical Gas or Medical Gas Related Equipment for Emergency Medical Reasons;

(3) intracompany Transactions, unless in violation of own use provisions;

(4) the sale, purchase, or trade of a Medical Gas or Medical Gas Related Equipment or an offer to sell, purchase, or trade a Medical Gas or Medical Gas Related Equipment among hospitals, Pharmacies, or other health care entities that are under common control;

(5) the sale, purchase, or trade of a Medical Gas or Medical Gas Related Equipment or the offer to sell, purchase, or trade a Medical Gas or Medical Gas Related Equipment 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 Medical Gas or Medical Gas Related Equipment 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 return of residual Medical Gas that may be reprocessed in accordance with Manufacturer's procedures, or the return of recalled, expired, damaged, or otherwise non-salable Medical Gas or Medical Gas Related Equipment, when conducted by a hospital, health care entity, Pharmacy, or charitable institution in accordance with the Board's regulations; or

(8) other transactions excluded from the definition of "wholesale distribution" under 21 CFR 203.3(CC), including any amendments thereto.

(x) "Wholesale Distributor of Medical Gases or Medical Gas Related Equipment" means any Person engaged in Wholesale Distribution of Medical Gas or Medical Gas Related Equipment in or into the State, including but not limited to Manufacturers, own-label

distributors, private-label distributors, warehouses, including Manufacturers' and Distributors' warehouses, and Wholesale Medical Gas or Medical Gas Related Equipment warehouses.

Section 2. Requirements for Licensure.

Wholesale Distributors of Medical Gases or Medical Gas Related Equipment that reside in this state and provide services within this state or other states shall be licensed by the Board and shall periodically renew their license with the Board using an application provided by the Board. Wholesale Distributors of Medical Gases or Medical Gas Related Equipment that provide services within this state though are not residents of this state shall maintain a valid license with the state Board in which they reside and in all states in which they distribute, if required. ~~Wholesale Distributors of Medical Gases or Medical Gas Related Equipment that provide services within this state though are not residents of this state shall maintain a valid license with this state Board if they are not required to be licensed by the state Board in which they reside.~~ Wholesale Distributors cannot operate from a place of residence, except when that place of residence is used for "on call" delivery of homecare oxygen and oxygen related equipment by a home respiratory care technician. Where Wholesale Distribution operations are conducted at more than one location within this state, each such location shall be licensed by the Board of Pharmacy.

(a) Subject to the Federal Act and all applicable federal law and regulations, an FDA-registered Medical Gas or Medical Gas Related Equipment manufacturer, including its affiliates, subsidiaries, agents and other entities under common ownership and control of the manufacturer, that exclusively distributes its own Medical Gas or Medical Gas Related Equipment, may be exempted from the requirements for licensure.

(b) Every Wholesale Distributor who engages in the Wholesale Distribution of Medical Gases or Medical Gas Related Equipment shall license 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 (includes "doing business as (dba)" and "formerly known as"), which cannot be identical to the name used by another unrelated Wholesale Distributor licensed to purchase Medical Gas or Medical Gas Related Equipment in the State;

(2) name(s) of the owner and operator of the licensee (if not the same person), including:

(i) if a Person: the name, business address, Social Security number, and date of birth;

(ii) if a partnership: the name, business address, and Social Security number, and date of birth of each partner, the name of the partnership, and federal employer identification number;

(iii) if a corporation: the name, business address, and title of each corporate officer and director, the corporate names, the state of incorporation, federal employer identification number, and the name and business address of the parent company, if any;

(iv) if a sole proprietorship: the full name and business address of the sole proprietor and the name and federal employer identification number of the business entity;

(v) if a limited liability company: the name, business address, and title of each company officer, 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

(vi) any other relevant information that the Board requires.

(3) name(s), business address(es), and telephone number(s) of a person(s) to serve as the Designated Representative(s) for each facility of the Wholesale Distributor that engages in the Wholesale Distribution of Medical Gas /or Medical Gas Related Equipment and additional information as required in Section 10 (Recordkeeping);

(4) a list of all State and Federal licenses, registrations, or permits, including the license, registration, or permit numbers issued to the Wholesale Distributor by any other state and federal authority that authorizes the Wholesale Distributor to purchase, possess, and Wholesale Distributes Medical Gas or Medical Gas Related Equipment in this state;

(5) a list of all disciplinary actions pertinent to Wholesale Distributors of Medical Gases or Medical Gas Related Equipment by any State and Federal agencies against the Wholesale Distributor distributing Medical Gas or Medical Gas Related Equipment into the state as well as any such actions against principals, owners, directors, or officers;

(6) an address and description of each facility and warehouse, including all locations utilized for Medical Gas or Medical Gas Related Equipment storage or Wholesale Distribution including a description of the security system.

(7) information regarding general and product liability insurance, including copies of relevant policies;

(8) a description of import and export activities;

(9) a copy of the Wholesale Distributor's written policies and procedures as required in Section 11 (Policies and Procedures); and

(10) the information collected by the Board pursuant to Section 1(a)(6) shall be made available only to the Board, a third party recognized by the Board, and to State and Federal law enforcement officials. The Board shall make provisions for protecting the confidentiality of the information collected under this section.

(c) A "surety" bond of not less than $100,000, or other equivalent means of security acceptable to the Board or a third party recognized by the Board such as insurance, an irrevocable letter of credit, or funds deposited in a trust account or financial institution, to secure payment of any administrative penalties imposed by the Board and any fees or costs incurred by the Board regarding that licensee when those penalties, fees, or costs are authorized under state law and the licensee fails to pay thirty (30) days after the penalty, fee, or costs becomes final. A separate "surety" bond or other equivalent means of security is not required for each company's separate locations or for affiliated companies/groups when such separate locations or affiliated companies/groups are required to apply for or renew their Wholesale Distributor of Medical Gases or Medical Gas Related Equipment license with the Board. The Board may make a claim against such bond or other equivalent means of security until one year after the Wholesale Distributor's license ceases to be valid

or until sixty (60) days after any administrative or legal proceeding before or on behalf of the Board that involves the Wholesale Distributor is concluded, including any appeal, whichever occurs later. Manufacturers of Medical Gases shall be exempt from securing a "surety" bond or other equivalent means of security acceptable to the Board. The Board may waive the bond requirement, if the Wholesale Distributor of Medical Gases or Medical Gas Related Equipment:

(1) has previously obtained a comparable surety bond or other equivalent means of security for the purpose of licensure in another state, where the wholesale distributor possesses a valid license in good standing; or

(2) is a publicly held company.

(d) Every Wholesale Distributor of Medical Gases or Medical Gas Related Equipment who engages in Wholesale Distribution of Medical Gases or Medical Gas Related Equipment shall submit a reasonable fee to be determined by the Board.

(e) Manufacturing facilities of Medical Gases are exempt from inspection by the Board, if the Manufacturing facilities:

(1) are currently registered with FDA in accordance with Section 510 of the Federal Act and can provide proof of such registration, such as a copy of the online verification page; and

(2) can provide proof of inspection by the FDA, or other regulatory body within the past three (3) years;

(f) The Board may require each facility that engages in Wholesale Distribution of Medical Gases or Medical Gas Related Equipment to undergo an inspection in accordance with Section 15 of this rule and in accordance with a schedule to be determined by the Board. Wholesale Distributors of Medical Gas or Medical Gas Related Equipment do not qualify for the Verified-Accredited Wholesale Distributors (VAWD).

(g) All Wholesale Distributors of Medical Gases or Medical Gas Related Equipment must publicly display or have readily available all state 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, or to a third party recognized by the Board, within 30 days of such change (unless otherwise noted).

(i) Information submitted by the Wholesale Distributor of Medical Gases or Medical Gas Related Equipment to the Board or a third party recognized by the Board that is considered trade secret or proprietary information, as defined under this State's privacy and trade secret/proprietary statutes, shall be maintained by the Board or a third party recognized by the Board as private or trade secret/proprietary information and be exempt from public disclosure.

Section 3. Minimum Qualifications.

(a) The Board will consider the following factors in determining the eligibility for, and renewal of, licensure of Persons who engage in the Wholesale Distribution of Medical Gas or Medical Gas Related Equipment:

(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 or the Wholesale Distribution of Medical Gases or Medical Gas Related Equipment;

(2) any criminal convictions of the applicant under Federal, State, or local laws;
(3) the applicant's past experience in the Manufacture or Wholesale Distribution of Medical Gases or Medical Gas Related Equipment;
(4) the furnishing by the applicant of false or fraudulent material in any application made in connection with the or Manufacturing or Wholesale Distribution of Medical Gases or Medical Gas Related Equipment;
(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 Medical Gas or Medical Gas Related Equipment;
(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 Distributors of Medical Gases or Medical Gas Related Equipment; 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 and financial background check of the applicant, including but not limited to, all key personnel involved in the operations of the Wholesale Distributor of Medical Gases or Medical Gas Related Equipment, including the most senior Person responsible for facility operations, purchasing, and inventory control and the Person or Persons they report to; and all company officers, key management, principals, and owners with ten percent (10%) or greater ownership 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 of Medical Gases or Medical Gas Related Equipment have committed criminal acts that would constitute grounds for denial of licensure. The background check will be conducted in compliance with any applicable state and Federal laws, at the applicant's expense, and will be sufficient to include all states of residence since the Person has been an adult. Manufacturers of Medical Gases or Medical Gas Related Equipment shall be exempt from criminal and financial background checks.

(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 Medical Gases or Medical Gas Related Equipment or an affirmation and attestation that the applicant has not been involved in, or convicted of, any criminal or prohibited acts.

Section 4. Personnel.

Each Person that is issued an initial or renewal license as a Wholesale Distributor of Medical Gases or Medical Gas Related Equipment, whether in state or out of state, must designate in writing, Person(s) for each facility to serve as Designated Representatives of such Wholesale Distributor. The members of the quality control unit, per 21 CFR 211.22, shall act as the Designated Representatives for the Wholesale Distributer.

(a) To be certified as a Designated Representative for a Wholesale Distributor of Medical Gases or Medical Gas Related Equipment, a Person:

(1) must have the appropriate amount of education, training and experience or any combination thereof to perform the functions required to serve as the Designated Representative of such Wholesale Distributor; and

(2) must be actively involved in and aware of the daily operations of the Wholesale Distributor location(s) including all policies and procedures pertaining to those operations and may cover multiple locations. The Designated Representative is therefore not required to be present at each site during normal business hours.

(b) The information collected pursuant to Section 3(a) shall be made available only to the Board, a third party recognized by the Board, and to State and Federal law enforcement officials. The Board and a third party recognized by the Board shall make provisions for protecting the confidentiality of the information collected under this section.

(c) Each licensed Wholesale Distributor of Medical Gases or Medical Gas Related Equipment located outside of this State that Wholesale Distributes Medical Gases or Medical Gas Related Equipment in this State shall designate a registered agent in this State for service of process. Any licensed Wholesale Distributor of Medical Gases or Medical Gas Related Equipment 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 processes in any action or proceeding against such licensed Wholesale Distributor growing out of or arising from such Wholesale 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.

(d) A Designated Representative must complete either:

(1) continuing education programs specified by the Board regarding Federal and State laws in regard to the Wholesale Distribution, handling, and storage of Medical Gases or Medical Gas Related Equipment; or

(2) training programs that address applicable Federal and State laws and are provided by qualified in-house specialists, outside counsel, or consulting specialists with capabilities to help ensure compliance.

Section 5. Minimum Requirements for the Storage and Handling of Medical Gases or Medical Gas Related Equipment and for Establishment and Maintenance of Medical Gas or Medical Gas Related Equipment Records.

The following are required for the storage, handling, transport, and shipment of Medical Gases or Medical Gas Related Equipment and for the establishment and maintenance of Wholesale Distribution records by Wholesale Distributors of Medical Gases and Medical Gas Related Equipment and their officers, agents, representatives, and employees.

(a) All facilities at which a Medical Gas or Medical Gas Related Equipment is received, stored, warehoused, handled, held, offered, marketed, displayed, or transported from shall:

(1) be of suitable construction to ensure that all Medical Gases or Medical Gas Related Equipment in the facilities are maintained in accordance with the Product Labeling of such Medical Gas or Medical Gas Related Equipment, or in compliance with official compendium standards such as the USP-NF;

(2) be of suitable size and construction to facilitate cleaning, maintenance, and proper Wholesale Distribution operations;
(3) have adequate storage areas with appropriate lighting, ventilation, sanitation, space, equipment, and security conditions;
(4) have a quarantine area for storage of Medical Gas or Medical Gas Related Equipment that are suspected of being outdated, Misbranded, or Adulterated, or otherwise unfit for Distribution or Wholesale Distribution;
(5) be maintained in a clean and orderly condition;
(6) be free from infestation that may impact the identity, strength, quality, or purity of the Medical Gas;
(7) be a commercial location and not a personal dwelling or residence, except when that personal dwelling is used for "on call" delivery of Oxygen USP and oxygen related equipment for homecare use;
(8) 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; and
(9) provide and maintain appropriate inventory controls in order to detect and document any theft of nitrous oxide.

Section 6. Security.

(a) All facilities used for Wholesale Distribution of Medical Gases or Medical Gas Related Equipment 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; and
(3) entry into areas where Medical Gas or Medical Gas Related Equipment are held shall be limited to authorized personnel; all facilities shall be equipped with a system to detect or deter entry after hours.
(b) All facilities shall be equipped with a system that will provide suitable protection against theft. When appropriate, the system shall provide protection against theft that is facilitated or hidden by tampering with computers or electronic records.
(c) All facilities shall be equipped with inventory management and control systems that protect against, detect, and document any instances of theft of nitrous oxide.
(d) Where Wholesale Distributors of Medical Gases or Medical Gas Related Equipment use electronic distribution records. they shall employ, train, and document the training of personnel in the proper use of such technology and equipment.
(e) 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.
(f) Vehicles utilized for on call delivery of Oxygen USP and oxygen related equipment for home care use by home care providers may be parked at a place of residence and shall be locked and equipped with an audible alarm while not attended.
(g) All Wholesale Distributors of Medical Gases or Medical Gas Related Equipment shall maintain records documenting from whom Medical Gases or Medical Gas Related Equipment are received and to whom Medical Gases and/or Medical Gas Related

Equipment are distributed with information sufficient to perform a recall of Medical Gases or Medical Gas Related Equipment received and distributed in compliance with 21 CFR 150b, 21 CFR 211.196, and 21 CFR 820.160b.

Section 7. Storage.

All Medical Gases or Medical Gas Related Equipment shall be stored under appropriate conditions in accordance with regulations or, in the absence of regulations, in accordance with applicable industry standards, and the manufacturers' recommendations on the product labeling.

(a) Packaging of the Medical Gas or Medical Gas Related Equipment should be in accordance with an official compendium such as USP-NF, if applicable.

(b) The recordkeeping requirements in Section 10 (Recordkeeping) shall be followed for the Wholesale Distribution of all Medical Gases or Medical Gas Related Equipment.

Section 8. Examination of Materials.

(a) Upon receipt, each Medical Gas container and related equipment shall be visually examined for identity and to determine if it is damaged or otherwise unfit for Wholesale Distribution. This examination shall be adequate to reveal container damage that would suggest possible Adulteration or Misbranding.

(b) The Medical Gas or Medical Gas Related Equipment found to be unacceptable under paragraph (a) should be quarantined from the rest of stock until the examination and determination that the Medical Gas or Medical Gas Related Equipment are not Misbranded or Adulterated.

(c) Each outgoing shipment shall be carefully inspected for identity of the Medical Gas or Medical Gas Related Equipment and to ensure that there is no Delivery of Medical Gas or Medical Gas Related Equipment that have been damaged in storage or held under improper conditions.

(d) Upon receipt, a Wholesale Distributor of Medical Gases or Medical Gas Related Equipment must review records for the acquisition of Medical Gases or Medical Gas Related Equipment for accuracy and completeness.

(e) The recordkeeping requirements in Section 10 (Recordkeeping) shall be followed for all incoming and outgoing Medical Gases or Medical Gas Related Equipment.

Section 9. Returned, Damaged, and Outdated Medical Gases or Medical Gas Related Equipment.

(a) Medical Gas that has left the control of the Wholesale Distributor may be returned to the Wholesale Distributor or Manufacturer from which it was acquired but may not be resold as a Medical Gas even if the integrity of the product is maintained, unless it is reprocessed by the Manufacturer employing proper and adequate controls to ensure the identity, strength, quality, and purity of the reprocessed Medical Gas.

(b) Reusable Medical Gas Related Equipment that has left the control of the Wholesale Distributor may be returned to Wholesale Distributor or Manufacturer for inspection. The Medical Gas Related Equipment may be repaired and or refurbished, if necessary, provided the Manufacturer or Wholesale Distributor employs proper and adequate controls to return the Medical Gas Related Equipment to proper condition.

(c) Any Medical Gas, including its container, that is damaged, Misbranded, or Adulterated shall be quarantined and physically separated from other Medical Gases until it is destroyed or returned to either the Manufacturer or Wholesale Distributor from which it was acquired. External contamination to Medical Gas containers or closure system, not impacting the integrity of the Medical Gas, is not considered damage, or Adulteration for purposes of this paragraph. When Medical Gas or Medical Gas Related Equipment are Adulterated, Misbranded, or suspected of being Adulterated, or Misbranded, notice of the Adulteration, Misbranding, or suspected Adulteration, or Misbranding shall be provided to the manufacturer or wholesale distributer from which they were acquired and also the appropriate boards and federal regulatory bodies.

(d) Any Medical Gas container that has been opened or used, but is not Adulterated or Misbranded, shall be considered empty, quarantined and physically separated from non-empty Medical Gas containers and returned to the Manufacturer for destruction or reprocessing.

(e) Any Medical Gas, its container, or Medical Gas Related Equipment including its associated documentation or labeling, suspected of being involved in a criminal activity shall be retained and not destroyed until its disposition is authorized by the Board, or applicable law enforcement agency.

(f) The recordkeeping requirements in Section 10 (Recordkeeping) of this rule shall be followed for all Misbranded or Adulterated Medical Gases.

Section 10. Due Diligence.

A Wholesale Distributor of Medical Gases or Medical Gas Related Equipment licensed in accordance with these Rules shall comply with the following Due Diligence requirements:

(a) Prior to the initial Wholesale Distribution or acquisition of a Medical Gases or Medical Gas Related Equipment to or from any Wholesale Distributor (or prior to any Wholesale Distribution to a Wholesale Distributor by a Manufacturer), the Distributing Wholesale Distributor (or Manufacturer) shall provide the following information to the acquiring Wholesale Distributor:

(1) If a Manufacturer is distributing to a wholesale distributor, evidence that the manufacturer is registered, and the Medical Gas or Medical Gas Related Equipment is listed with FDA;

(2) If a Wholesale Distributor is distributing to a wholesale distributor, evidence that the wholesale distributor supplying the Medical Gas or Medical Gas Related Equipment is licensed to provide product into the State, if required by the State;

(3) the name(s) of the responsible facility contact person(s) at the supplying Manufacturer or Wholesale Distributor; and

(4) a certification that the Manufacturer or Wholesale Distributor's policies and procedures comply with this Act.

(b) A Manufacturer or Wholesale Distributor that Wholesale Distributes or acquires Medical Gases or Medical Gas Related Equipment to or from another Wholesale Distributor of Medical Gases or Medical Gas Related Equipment shall provide to or obtain from the distributing or acquiring entities as applicable the information set forth in Section 10 (Recordkeeping).

(c) Wholesale Distributors of Medical Gases or Medical Gas Related Equipment are exempt from inspecting and obtaining the information from Manufacturers of Medical Gases or Medical Gas Related Equipment as required in Section 9 (Due Diligence) when the Manufacturer is registered with FDA in accordance with Section 510 of the Federal Act and can:

(1) provide proof of such registration; and

(2) either:

(i) can provide proof of inspection by the FDA, or other regulatory body within the past three (3) years; or

(ii) in the event that no regulatory body has inspected within the past three (3) years, conformance with industry standards or guidelines, as identified by the board.

Section 11. Recordkeeping.

(a) Wholesale Distributors of Medical Gases or Medical Gas Related Equipment shall establish and maintain records of all transactions regarding the receipt and Wholesale Distribution or other disposition of Medical Gases or Medical Gas Related Equipment. These records shall include:

(1) dates of receipt and Wholesale Distribution or other disposition of the Medical Gas or Medical Gas Related Equipment; and

(2) Information sufficient to perform a recall of Medical Gases or Medical Gas Related Equipment received and distributed.

(b) Such 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:

(1) three (3) years following their creation date for high pressure Medical Gases;

(2) one (1) year following their creation date for cryogenic or refrigerated liquid Medical Gases; and

(3) three (3) years following their creation date for Medical Gas Related Equipment.

(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 (2) working days of a request by an authorized official of any State or Federal governmental agency charged with enforcement of these rules.

(d) Wholesale Distributors and Manufacturers of Medical Gases or Medical Gas Related Equipment should maintain an ongoing list of Persons from whom they receive or to whom they distribute Medical Gases /or Medical Gas Related Equipment.

(e) Wholesale Distributors of Medical Gases or Medical Gas Related Equipment shall maintain a system for the mandatory reporting of any theft, suspected theft, or other

significant loss of Nitrous Oxide to the Board and other appropriate law enforcement agencies.

Section 12. Policies and Procedures.

Wholesale Distributors of Medical Gases or Medical Gas Related Equipment shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, transport, and shipping and Wholesale Distribution of Medical Gases or Medical Gas Related Equipment, including policies and procedures for maintaining inventories, identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories associated with nitrous oxide. Wholesale Distributors of Medical Gases or Medical Gas Related Equipment shall include in their written policies and procedures the following:

(a) A procedure to be followed for handling recalls and withdrawals of Medical Gases or Medical Gas Related Equipment. Such procedure shall be adequate to deal with recalls and withdrawals due to:
  (1) Any action initiated at the request of FDA or any other federal, state, or local law enforcement or other government agency, including the Board of Pharmacy; or
  (2) Any volunteer action by the Manufacturer of Medical Gases or Medical Gas Related Equipment to remove defective or potentially defective Medical Gases or Medical Gas Related Equipment from the market.

(b) A procedure to ensure that Wholesale Distributors of Medical Gases or Medical Gas Related Equipment 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 for reporting criminal or suspected criminal activities involving the inventory of nitrous oxide to the Board, and applicable law enforcement agencies, within three (3) business days of becoming aware of the criminal or suspect criminal activity.

(d) A procedure for verifying security provisions of Common Carriers.

Section 13. Prohibited Acts.

It is unlawful for a Person to knowingly and willfully 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 any Medical Gas or Medical Gas Related Equipment that is Adulterated, Misbranded, or has otherwise been rendered unfit for Distribution or Wholesale Distribution;

(b) the Adulteration, or Misbranding of any Medical Gas or Medical Gas Related Equipment;

(c) the receipt of any Medical Gas or Medical Gas Related Equipment that is Adulterated, Misbranded, stolen, obtained by fraud or deceit, or the delivery or proffered delivery of such Medical Gas or Medical Gas Related Equipment for pay or otherwise;

(d) the Alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the Product Labeling of a Medical Gas or Medical Gas Related Equipment or the willful commission of any other act with respect to a Medical Gas or Medical Gas Related Equipment that results in the Medical Gas or Medical Gas Related Equipment being Misbranded;

(e) the purchase or receipt of a Medical Gas or Medical Gas Related Equipment from a Person that is not licensed to Wholesale Distribute Medical Gas or Medical Gas Related Equipment to that purchaser or recipient;
(f) the sale or transfer of a Medical Gas or Medical Gas Related Equipment to a Person who is not legally authorized to receive a Medical Gas or Medical Gas Related Equipment;
(g) the failure to maintain or provide records as required by this Act and Rules;
(h) 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;
(i) the Wholesale Distribution of any Medical Gas or Medical Gas Related Equipment 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.
(j) the failure to obtain a license or operating without a valid license when a license is required;
(k) the Obtaining of or attempting to obtain a Medical Gas or Medical Gas Related Equipment by fraud, deceit, misrepresentation or engaging in misrepresentation or fraud in the Distribution or Wholesale Distribution of a Medical Gas/or Medical Gas Related Equipment;
(l) the Distributing of a Medical Gas or Medical Gas Related Equipment to a patient without a Prescription or Prescription Order from a Practitioner licensed by law to use or prescribe the Medical Gas or Medical Gas Related Equipment;
(m) the Distributing or Wholesale Distributing of a Medical Gas or Medical Gas Related Equipment that was previously dispensed by a Pharmacy or distributed by a Practitioner;
(n) the Distributing of a Medical Gas or Medical Gas Related Equipment to a patient without providing appropriate information and counseling on use, storage, and disposal;
(o) the failure to report any Prohibited Act as listed in these Rules; or
(p) the failure to exercise Due Diligence as provided in Section 9 (Due Diligence) of these regulations.

Section 14. Criminal Acts.

(a) A Person who, with intent to defraud or deceive, performs the act of Adulteration or Misbranding of any Medical Gas or Medical Gas Related Equipment commits a felony of the third degree.
(b) A Person who engages in the Wholesale Distribution and knowingly purchases or receives Medical Gas or Medical Gas Related Equipment from a Person, not legally authorized to Wholesale Distribute Medical Gas or Medical Gas Related Equipment, in Wholesale Distribution commits a felony of the third degree.
(c) A Person who engages in the Wholesale Distribution and knowingly sells, barters, brokers, or transfers Medical Gases or Medical Gas Related Equipment to a Person not legally authorized to purchase Medical Gases or Medical Gas Related Equipment, under the jurisdiction in which the Person receives the Medical Gas or Medical Gas Related Equipment in Wholesale Distribution, commits a felony of the third degree.

(d) A Person who knowingly falsely creates any Label for a Medical Gas or Medical Gas Related Equipment or who falsely represents any factual matter contained in any Label of a Medical Gas or Medical Gas Related Equipment commits a felony of the third degree.

(e) A Person found guilty of any offense under this section, under the authority of the Court convicting and sentencing the Person, shall be ordered to 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; and

(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 that 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 that led to the conviction.

Section 15. Salvaging and Reprocessing.

(a) Medical Gas or Medical Gas Related Equipment that has been subjected to improper conditions such as a fire, accident or natural disaster, shall not be Salvaged or Reprocessed;

(b) Medical Gas product in a Medical Gas container that has left the control of the Wholesale Distributor may be returned to the Manufacturer and reprocessed provided the Manufacture employs proper and adequate controls to assure the identity, strength, quality and purity of the reprocessed Medical Gas; and

(c) Reusable Medical Gas Related Equipment that has left the control of the Wholesale Distributor may be returned to the Wholesale Distributor or Manufacturer for inspection. The Medical Gas Related Equipment may be repaired and or refurbished (servicing), if necessary, provided the Manufacturer or Wholesale Distributor employs proper and adequate controls to ensure the Medical Gas Related Equipment complies with the manufacturers' design and performance specifications following completion of servicing.

Section 16. Inspection.

(a) The Board shall have the authority to recognize, a third party to inspect Wholesale Distributors of Medical Gases or Medical Gas Related Equipment in that State or in other State(s).

(b) The Board shall have the authority to recognize other State(s) inspections of Wholesale Distributors of Medical Gases or Medical Gas Related Equipment operations in other State(s), if such state's laws are deemed to be substantially equivalent.

(c) The Board may license by reciprocity, a Wholesale Distributor of Medical Gases or Medical Gas Related Equipment that is licensed under the laws of another state, if the requirements of that State are deemed by the Board to be substantially equivalent;.

(d) Any applicant that is denied a license due to an inspection shall have the right of review of the Board's decision.
(e) The Board shall ensure that the proprietary information obtained during the inspection process remains confidential and privileged.
(f) The Board may waive requirements of this Chapter.

Comments

Section 1(c). Comment.

Common carriers frequently use the terms "to load" which means placing property from the shipping location onto the transport vehicle, and "to offload" which means removing property from the transport vehicle at the delivery location.

Section 2(b)(2). Comment.

The risk of diversion and adulteration are not concerns for medical gases. With this in mind, the depth of personal identification information required for licensure of Wholesale Distributors of Medical Gases or Medical Gas Related Equipment is less than that of Wholesale Distributors of Prescription Drugs. In addition, the provision of facility details such as square footage, lease details, and temperature and humidity controls is not required as it is for Wholesale Distributors of Prescription Drugs.

Section 2(f). Comment.

Although a Board may allow a firm to be third party accredited, Wholesale Distributors of Medical Gases or Medical Gas Related Equipment do not qualify for NABP Verified-Accredited Wholesale Distributors (VAWD) program as the inspection criteria is not applicable to Medical Gas or Medical Gas Equipment Related operations.

Section 5(a)(7). Comment.

Some home respiratory care providers provide "on call" services to patients. This requires home respiratory care technicians to keep parked at their personal dwelling the company vehicle stocked with Medical Gases or Medical Gas Related Equipment.

Section 10(c). Comment.

The board may refer to the following industry guideline: CGA M-7, *Guideline for Qualifying Suppliers Used by Medical Gas Manufacturers and Distributors.*

Section 11(b). Comment.

Record retention requirements are determined based on cryogenic and liquefied gas product profiles.

Background:

The Compressed Gas Association (CGA) approached NABP in 2009 to discuss the possibility of developing separate model rules for medical gas wholesale distributors as the existing Model Rules for the Licensure of Wholesale Distributors, in many instances, did not apply to medical gas distributors. NABP staff worked with CGA to develop the above proposed rules to be considered for incorporation into the *Model Act*.

The committee reviewed the Model Rules for the Licensure of Medical Gas and Medical Gas Related Equipment Wholesale Distributors and agreed that separate rules for medical gas distributors should exist.

LE/L Recommendation 4: The Committee Recommends Amending the *Model Act* to Reflect Revisions to 21 Code of Federal Regulations (CFR) 1311 to Address Electronic Prescribing.

The recommended revisions by the committee are denoted by underlines and ~~strikethroughs~~.

National Association of Boards of Pharmacy
Model State Pharmacy Act

Article I

Title, Purpose, and Definitions

…

Section 105. Definitions.

…

~~(a3) "Electronic Transmission" means transmission of information in electronic form or the transmission of the exact visual image of a document by way of electronic equipment.~~

...

Model Rules for the Practice of Pharmacy

…

Section 3. Pharmacy Practice

…

(b) Manner of Issuance of a Prescription Drug Order
A Prescription Drug Order, to be valid, must be issued for a legitimate medical purpose by a Practitioner acting within the course of legitimate professional practice.

(1) A Prescription Drug Order must be communicated to a Pharmacist, or when recorded in such a way that the Pharmacist may review the Prescription Drug Order as transmitted, to a Pharmacy Intern or a Certified Pharmacy Technician, in a licensed Pharmacy. This may be accomplished in one of the following ways. A Prescription Drug Order, including that for a controlled substance listed in Schedules II through V, may be communicated in written form. A Prescription Drug Order, including that for a controlled substance listed in Schedules III through V, and, in certain situations, that for a controlled substance listed in Schedule II, may be communicated orally (including telephone voice communication) or issued electronically ~~by way of Electronic Transmission~~.

(2) The Pharmacist shall not dispense a Prescription Drug if the Pharmacist knows or reasonably should know that the Prescription Drug Order was issued solely on the basis of an Internet-based questionnaire, an Internet-based consultation, or a telephonic consultation, all without a valid Patient-Practitioner relationship.

(3) If communicated orally ~~or by way of Electronic Transmission,~~ the Prescription Drug Order shall be immediately reduced to a form by the Pharmacist~~,~~ or the Pharmacy Intern~~, or Certified Pharmacy Technician~~ that may be maintained for the time required by laws or rules.

(4) A Prescription Drug Order for a Schedule II controlled substance may be communicated orally ~~and/or by way of Electronic Transmission~~ only in the following situations and/or with the following restrictions. Otherwise, a Prescription Drug Order for a Schedule II controlled substance must be communicated in written form or issued electronically.

(i) A Prescription Drug Order for a Schedule II controlled substance may be communicated orally by the Practitioner or the Practitioner's agent ~~by way of Electronic Transmission,~~ provided the original written, signed Prescription Drug Order is presented to the Pharmacist for review prior to the actual Dispensing of the controlled substance, except as noted in paragraph (ii) or (iii) of this Section 3(b)(~~3~~ 4). The original, written Prescription Drug Order shall be maintained in accordance with Section 3(g). (Patient Records).

(ii) In the case of an Emergency Situation, a Prescription Drug Order for a Schedule II controlled substance may be communicated by the Practitioner orally ~~or by way of Electronic Transmission,~~ provided that:

(A) the quantity prescribed and Dispensed is limited to the amount adequate to treat the patient during the emergency period (Dispensing beyond the emergency period must be pursuant to a ~~written~~ Prescription Drug Order either written and signed or electronically issued by the prescribing Practitioner);

(B) the orally communicated Prescription Drug Order shall be immediately reduced to writing by the Pharmacist ~~or Certified Pharmacy Technician, or, if necessary, the Prescription Drug Order communicated by way of Electronic Transmission shall be immediately reduced to a hard copy~~, and ~~either~~ shall contain the information required by Section 3(a). (Prescription Drug Order);

(C) if the prescribing Practitioner is not known to the Pharmacist ~~or Certified Pharmacy Technician,~~ he or she must make a reasonable effort to

determine that the oral authorization came from a registered Practitioner, which may include a callback to the Practitioner using the Practitioner's phone number as listed in the telephone directory and/or other good faith efforts to ensure his or her identity; and

(D) within seven days after authorizing an emergency oral Prescription Drug Order, the Practitioner shall cause a written Prescription Drug Order for the emergency quantity prescribed to be delivered to the Dispensing Pharmacist. In addition to conforming to the requirements of Section 3(a), the Prescription Drug order shall have written on its face "Authorization for Emergency Dispensing," and the date of the orally ~~or electronically~~ transmitted Prescription Drug Order. The written Prescription Drug Order may be delivered to the Pharmacist in Person or by mail, but if delivered by mail, it must be postmarked within the seven (7)-day period. Upon receipt, the Dispensing Pharmacist shall attach this written Prescription Drug Order to the emergency oral Prescription Drug Order, which had earlier been reduced to writing~~, or to the hard copy of the electronically transmitted Prescription Drug Order~~. The Pharmacist shall notify the nearest office of the DEA if the prescribing Practitioner fails to deliver a written Prescription Drug Order.

(iii) The prescribing Practitioner may authorize his or her agent to communicate a Prescription Drug Order orally or by way of Electronic Transmission <u>via facsimile</u> to a Pharmacist, <u>or</u> Pharmacy Intern, ~~or Certified Pharmacy Technician~~ in a licensed Pharmacy, provided that the identity of the transmitting agent is included in the order. In an Institutional Facility, the prescribing Practitioner's agent must be authorized by and in accordance with written policies and procedures of the Facility and applicable state and federal laws.

(5) A Prescription Drug Order for a Schedule II narcotic substance to be Compounded for the direct Administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion may be communicated by the Practitioner or the Practitioner's agent to the Home Infusion Pharmacy ~~by way of Electronic Transmission~~ <u>via facsimile</u>. The hard copy of such ~~Electronic Transmission~~ <u>faxed prescription</u> serves as the original, written Prescription Drug Order for purposes of this Section 3(b)(~~3~~ <u>4</u>)(ii), and it shall be maintained in accordance with Section 3(g). (Patient Records).

(6) A Prescription Drug Order for a Schedule II controlled substance for a resident of a Long-Term Care Facility may be communicated by the Practitioner or the Practitioner's agent ~~by way of Electronic Transmission~~ <u>via facsimile</u>. The hard copy of such <u>faxed prescription</u> ~~Electronic Transmission~~ serves as the original, written Prescription Drug Order for purposes of this Section 3(b)(~~3~~ <u>4</u>) (iii) and it shall be maintained in accordance with Section 3(g). (Patient Records).

(7) All Prescription Drug Orders <u>for a Schedule III-V controlled substance</u> communicated by way of Electronic Transmission <u>via facsimile</u> shall:

(i) be transmitted to a Pharmacist, <u>or</u> Pharmacy Intern~~, or Certified Pharmacy Technician~~ in a licensed Pharmacy of the patient's choice;

(ii) identify the transmitter's phone number or any other suitable means to contact the transmitter for verbal and/or written confirmation, the time and date of transmission, and the identity of the Pharmacy intended to receive the transmission, as well as any other information required by federal or state law;
(iii) be transmitted by an authorized Practitioner or his or her designated agent; and
(iv) be deemed the original Prescription Drug Order, provided it meets the requirements of this subsection.

(8) All Prescription Drug Orders for a Schedule II-V controlled substance issued and processed electronically shall be in compliance with existing federal or state laws and rules.

~~(8)~~ (9) The Pharmacist shall exercise professional judgment regarding the accuracy, validity, and authenticity of the Prescription Drug Order issued electronically or by facsimile to ensure it is ~~communicated by way of Electronic Transmission~~ consistent with existing federal or state laws and rules.

~~(9)~~(10) All electronic equipment for receipt of Prescription Drug Orders issued electronically or by facsimile ~~communicated by way of Electronic Transmission~~ shall be maintained so as to ensure against unauthorized access.

~~(11)~~(12) Persons other than those bound by a confidentiality agreement pursuant to Section 2(a)(2)(xi) shall not have access to Pharmacy records containing Protected Health Information concerning the Pharmacy's patients.

Background:

The committee reviewed and discussed the above section from the *Model Act* and agreed that NABP staff should verify that the above *Model Act* section reflects recent revisions to 21 CFR 1311 that addresses electronic prescribing of controlled substances and revise accordingly. Members also expressed concern that Certified Pharmacy Technicians were allowed to receive oral Prescription Drug Orders. Members discussed the issue in detail and determined that only Pharmacists and Pharmacy Interns and not Certified Pharmacy Technicians should be allowed to do so.

LE/L Recommendation 5: The Committee Recommends Amending the *Model Act* to Address Renewal Provisions for and Responsibilities of Pharmacy Technician and Certified Pharmacy Technician Licensure.

The recommended revisions by the committee are denoted by underlines and ~~strikethroughs~~.

National Association of Boards of Pharmacy
Model State Pharmacy Act

Article I

Title, Purpose, and Definitions

…

Section 105

…

(r) "Certified Pharmacy Technician" means personnel registered with the Board who have completed a certification program approved by the Board and may, under the supervision of a Pharmacist, perform certain activities involved in the Practice of Pharmacy, such as:

(1) receiving ~~new~~ written or electronic Prescription Drug Orders;
~~(2) prescription transfer;~~
~~(3)~~(2) Compounding; and
~~(4)~~(3) assisting in the Dispensing process; and
(4) performing all functions allowed to be performed by pharmacy technicians

but excluding:

(1) Drug Utilization Review (DUR);
(2) clinical conflict resolution;
(3) prescriber contact concerning Prescription Drug Order clarification or therapy modification;
(4) Patient Counseling; ~~and~~
(5) Dispensing process validation~~.~~;
(6) prescription transfer; and
(7) receipt of new oral Prescription drug Orders.

…

(a5) "Pharmacy Technician" means personnel registered with the Board who may, under the supervision of the pharmacist, assist in the pharmacy and perform such functions as:

(1) assisting in the Dispensing process;
(2) processing of medical coverage claims;
(3) stocking of medications; and
(4) cashiering

but excluding:

(1) Drug Utilization Review (DUR);
(2) clinical conflict resolution;
(3) prescriber contact concerning Prescription Drug Order clarification or therapy modification;
(4) Patient Counseling;
(5) Dispensing process validation;
(6) prescription transfer; and
(7) receipt of new oral Prescription Drug Orders.

…

Section 105(r). Comment.

The Model Act defines Certified Pharmacy Technician and Pharmacy Technician separately to distinguish between the activities that can be performed. A Certified Pharmacy Technician is recognized, because of the completion of a Board-approved certification program, as having knowledge and skills that qualify them to assist the Pharmacist in the Practice of Pharmacy with limited patient care tasks that exceed routine Dispensing or Drug storage activities. Pharmacy

Technicians are limited to routine Dispensing activities, Drug storage, medical coverage claims processing, and cashiering. ~~Certification for Pharmacy Technicians is not required because the level of knowledge and skills needed to assist in the pharmacy can be achieved through training programs.~~

Section 105(e5). Comment.

The term Pharmacy Technician will continue to be utilized until 2015. At that time, the Model State Pharmacy Act and Model Rules will be amended to require that all Pharmacy Technicians be certified. The Model Act will also be amended at that time to replace the term Pharmacy Technician with the term Candidate for Certified Pharmacy Technician, which will be redefined to provide a path to certification for non-certified pharmacy technicians. A one-time renewal of the Certified Pharmacy Technician Trainee registration will be allowed.

…

Article III

Licensing

…

Section 305. Renewal of Licenses and Registrations.

(a) Each Pharmacist<u>,</u> ~~and~~ Pharmacy Intern<u>, Certified Pharmacy Technician, and Pharmacy Technician</u> shall apply for renewal of his or her license annually [or at such interval determined by the Board], no later than the first day of _____. A Pharmacist or Pharmacy Intern who desires to continue in the Practice of Pharmacy in this State shall file with the Board an application in such form and containing such data as the Board may require for renewal of the license. If the Board finds that the applicant has been licensed, and that such license has not been Revoked or placed under Suspension, that the applicant has paid the renewal fee, has continued his or her Pharmacy education in accordance with the rules of the Board, and is entitled to continue in the Practice of Pharmacy, the Board shall issue a license to the applicant.

(b) If a Pharmacist fails to make application to the State Board of Pharmacy for renewal of his or her license within a period of three years from the expiration of his or her license, he or she must pass an examination for license renewal; except that a Person who has been licensed under the laws of this State and after the expiration of his or her license, has continually practiced Pharmacy in another State under a license issued by the authority of such State, may renew his or her license upon payment of the designated fee.

(c) A Pharmacist shall apply for renewal of his or her registration to Practice Telepharmacy Across State Lines annually [or at such interval determined by the Board], no later than the first day of (month). A Pharmacist who desires to continue in the Practice of Telepharmacy Across State Lines shall file with the Board an application in such form and containing such data as the Board may require for renewal of the registration. If the Board finds that the applicant has been licensed to Practice Pharmacy in another State and registered to Practice Telepharmacy Across State Lines in this State, that such license and registration have not been Revoked or placed under Suspension, and that the

applicant has paid the renewal fee and is entitled to continue to engage in the Practice of Telepharmacy Across State Lines, the Board shall issue a registration to the applicant.

…

Background:

The committee agreed that license renewal provisions should be added for Certified Pharmacy Technicians and Pharmacy Technicians. The members however, voiced concern that under the *Model Act,* Certified Pharmacy Technicians are allowed to receive oral prescriptions and convey prescription information orally as part of the prescription transfer process. Members discussed these issues and ultimately, due to the perceived risk of increased quality related events, decided to clarify that Certified Pharmacy Technicians may not receive oral Prescription Drug Orders nor may they transfer prescriptions. Members also agreed that it should be affirmatively stated that Certified Pharmacy Technicians may perform all functions that Pharmacy Technicians are allowed to perform in addition to their own.

LE/L Recommendation 6: The Committee Recommends Amending the *Model Act* to Remove the Licensure Provisions for the Practice of Telepharmacy Across State Lines.

The recommended revisions by the committee are denoted by underlines and ~~strikethroughs~~.

National Association of Boards of Pharmacy
Model State Pharmacy Act

Article III

Licensing

...

~~Section 304. Qualifications for Registration to Engage in the Practice of Telepharmacy Across State Lines.~~

~~(a) An applicant applying for registration to engage in the Practice of Telepharmacy Across State Lines shall:~~

~~(1) present to the Board proof of licensure in another State and proof that such license is in good standing;~~

~~(2) submit an application in the form prescribed by the Board;~~

~~(3) pay the fee(s) specified by the Board for the issuance of the Registration; and~~

~~(4) comply with all other requirements of the Board.~~

~~(b) The application required under Section 304(a)(2) shall request of the applicant, at a minimum, the following information:~~

~~(1) name, address, and current Pharmacist licensure information in all other States, including State(s) of licensure and license number(s);~~

~~(2) name, address, phone number, and, if applicable, State of licensure and license number of the site where the Practice of Telepharmacy will originate;~~

~~(3) a statement of the scope of patient services that will be provided;~~

~~(4) a description of the protocol or framework by which patient care will be provided;~~

~~(5) if applicable, any Collaborative Practice Agreements with other health care Practitioners; and~~
~~(6) a statement attesting that the applicant will abide by the Pharmacy laws and regulations of the State in which the patient is located.~~

Section 305. Renewal of Licenses and Registrations.

…

~~(c) A Pharmacist shall apply for renewal of his or her registration to Practice Telepharmacy Across State Lines annually [or at such interval determined by the Board], no later than the first day of (month). A Pharmacist who desires to continue in the Practice of Telepharmacy Across State Lines shall file with the Board an application in such form and containing such data as the Board may require for renewal of the registration. If the Board finds that the applicant has been licensed to Practice Pharmacy in another State and registered to Practice Telepharmacy Across State Lines in this State, that such license and registration have not been Revoked or placed under Suspension, and that the applicant has paid the renewal fee and is entitled to continue to engage in the Practice of Telepharmacy Across State Lines, the Board~~

Background:

The committee discussed the issue and concurred that many states consider telepharmacy to be included in the practice of pharmacy and require no special licensure and agreed to remove these licensing and renewal provisions accordingly.