NABP
National Association of Boards of Pharmacy

REPORT OF THE WORK GROUP TO

CONSIDER EXTENDING WAIVERS

Members Present

Tracy Collier (SC), *chair*; Erick Axcell (KS); Michael Blaire (AZ); Jennifer Chin (MA); Cynthia "Cindy" Fain (AR); Laura Forbes (VI); Mark Klang (NY); Tamara McCants (DC); Eileen Ortega (PR); David "Dave" Rochefort (NH); Lorri Walmsley (AZ); and Cathy Winters (WI).

Others Present

Fred M. Weaver, *Executive Committee liaison;* Lemrey "Al" Carter; William Cover; Melissa Madigan; Eileen Lewalski; Neal Watson; Maureen Schanck; Cameron Orr; and Andrea Busch, *NABP staff*.

Introduction

The committee met virtually on August 25, 2021.

Review of the Work Group Charge

Work group members reviewed their charge and accepted it as follows:

1. Review all provisions waived by the state boards of pharmacy during the coronavirus disease 2019 (COVID-19) public health emergency.
2. Advise which waivers, if any, could safely remain in effect beyond the COVID-19 public health emergency.
3. Amend, if necessary, the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* to reflect the efforts of this work group.

Background and Discussion

The work group reviewed and discussed the various provisions that had been waived by the boards of pharmacy during the past 16 months due to the COVID-19 public health emergency. The waivers had been placed into the following three categories to determine which, if any, in the interest of patient safety and outcomes, should remain in effect indefinitely;

- For permanent consideration (in all circumstances),
- For consideration when special or unusual public health circumstances or concerns occur (eg, drug shortages), and
- Under declared emergency.

Members discussed the categories in order, starting with those considered for permanent status in all circumstances.

Emergency Dispensing and Emergency Refills

The work group first contemplated the difference between emergency dispensing, which it concluded was when a pharmacy has no record on file of any previous dispensing of the medication, as opposed to an emergency refill in which a record of prior dispensing exists. A long and spirited debate ensued regarding the emergency dispensing of medications, including what determines an emergency – a natural disaster, fire, deceased prescriber? Also discussed was whether to allow controlled substances (CS) to be dispensed in such situations, as those drugs are used to treat certain serious maladies such as seizure disorders, which should not be left untreated. The work group members from the Virgin Islands and Puerto Rico shared their boards' past experiences with hurricanes that devastated certain regions of those islands resulting in some health care clinics becoming inaccessible for several months. Virgin Island pharmacists were granted the authority to use professional judgment to determine the validity of the requests for emergency dispensing of maintenance medications, which could include CS. Pharmacists needed proof of a prior prescription and could provide enough medication to bridge the gap until the patient could be seen by a primary care provider. Ultimately, members unanimously agreed that emergency dispensing should be allowed when the prescriber cannot be contacted, and the immediate needs of the patient must be met in order to prevent unnecessary harm and suffering. However, they decided that emergency dispensing should only be allowed when special or unusual public health circumstances or concerns occur, so it was moved to that category. It was further noted that the individual boards should determine the circumstances and duration of time for such dispensing.

Regarding emergency refills, the work group agreed that they should allowed in all circumstances, based on the pharmacist's professional judgment, and that *Model Act* language should be added that mirrors the language for emergency refills contained in the *Model Act's Model Rules for Public Health Emergencies*. Members agreed to limit an emergency refill to no more than a 30-day supply or the smallest available multidose unit for medications such as inhalers or insulin, and that the boards should determine whether to extend any additional refills beyond the initial emergency refill.

Expanded Scope of Practice

The work group then discussed expanded scope of practice and unanimously agreed to support permanent expansion for pharmacists and pharmacy technicians in all circumstances. Members agreed that pharmacists should be allowed to prescribe Clinical Laboratory Improvement Amendments of 1988 (CLIA)-waived tests and prescribe associated medications; and to reflect that intent, the *Model Act* should be amended by removing text addressing this activity from a footnote found in the section addressing Pharmacists Care Services and placing it in the actual provisions for Pharmacist Care Services. Additionally, the work group contemplated expanded scope related to vaccinations and decided to allow all vaccines listed under the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) to be

ordered and administered, but that it should be left to the boards to determine the patient age requirements. Members further agreed to expand pharmacy technician scope of practice to include administration of vaccinations and point-of-care testing. In addition, members agreed that the pharmacist can delegate various activities based on the individual technician's training, skill level, and experience, but excluded clinical care activities.

Remote Prescription Processing and Verification, Expanded Use of Remote Automated Pharmacy Systems, In-Person Counseling Requirements, Pharmacist to Technician Ratios

Members reviewed and discussed the remaining waivers to be permanently extended in all circumstances. They noted that remote order verification for institutional pharmacies has been occurring across states lines for years and that several states recently have allowed for some non-dispensing functions, such as drug utilization review, to occur outside of a licensed pharmacy; as such, they agreed to support permanent allowances for these types of practices. It was further noted that regulatory language pertaining to these practices should be kept broad and that boards should review their state-specific language and revise if necessary. Along those lines, the work group was supportive of expanding the use of remote automated systems to increase patient access to medications, and recommended removing "institutional pharmacies" from the Automated Pharmacy Systems provisions and adding, "and other locations approved by the Board" to allow for broader adoption. Regarding in-person patient counselling, members agreed that the existing *Model Act* language was broad enough, but in determining what is in a patient's best interest, alternative forms of counseling should be available to accommodate individual patient needs.

Regarding pharmacist to technician ratios, although the work group recognized that the *Model Act* does not establish ratios, they decided not to recommend that the waiver of established ratios be extended in all circumstances.

Therapeutic Substitution, Discharge Medications

As part of its discussion of waivers when special or unusual public health circumstances or concerns occur, the work group determined that two of the waived provisions should be allowed in all circumstances. They agreed that pharmacists should be allowed to perform therapeutic substitution within the same Food and Drug Administration (FDA) drug class in all instances unless prohibited by the prescriber. Members also determined that discharged patients should be able to take home multidose medications, such as inhalers, from the hospital in all instances provided that the labels are modified to ensure proper use.

Nonresident Licensure, Expiration Dates, CPE Requirements

Regarding regulatory provisions that should be waived only when special or unusual public health circumstances or concerns occur, including but not limited to drug shortages, the work group began the discussion surrounding nonresident licensure.

Staff shared with members that FDA approached NABP to assist with Moderna's goal to disseminate COVID-19 vaccines to wholesale drug distributors across the country without being licensed by every state. In the effort to expedite the delivery of vaccines to protect the public health, NABP supported temporary emergency wholesale drug distributor licensing. Members agreed that a 90-day temporary provisional wholesale drug distributor license should be an option when special or unusual public health circumstances or concerns occur, such as when life-sustaining medications are in short supply. The work group recommended that the *Model Act* be amended accordingly to include 503B outsourcing facilities, with the emphasis that any entity must have a license in good standing in another state prior to the temporary license being granted. Additionally, members agreed that, when special or unusual public health circumstances or concerns occur, boards could extend any or all license expiration dates, as well as continuing pharmacy education (CPE) deadlines, and waive live CPE activity requirements.

NABP Passport, Electronic Prescribing Requirements, ID and Signature Requirements, Federal and State Waivers

Lastly, the work group considered those waivers that should be allowed only under declared emergencies. Staff shared with the members that the NABP Emergency Passport Program was utilized by 22 states and processed over 8,000 applications that were issued to those whose licenses were in good standing. It was noted that eight percent of all applications were denied for failing to meet the eligibility criteria. The work group agreed that the Passport Program should be retained as is for use in declared emergencies. Members also discussed waivers for electronic prescribing and agreed that under emergency declarations, paper prescriptions should be allowed to be accepted if not restricted by applicable federal laws/rules. It was further agreed that the requirements for identification presentation and signatures for the receipt of drugs could also be waived – if not restricted – by applicable federal laws/rules. To conclude, the work group recommended that the boards of pharmacy should mirror all waivers issued by federal and other state entities, such as the FDA action that relaxed compounding restrictions for the compounding of hand sanitizers. Members also encouraged boards to specifically reflect on what occurred during the current pandemic and review all past waivers made by state and federal agencies to determine whether they are applicable and should be reinstated in the interest of public protection during any future emergencies prior to being officially announced.

After careful review and deliberation, the task force recommended the following:

1. NABP recommends that the state boards of pharmacy consider allowing the following in all circumstances:
    a. Emergency refills of up to a 30-day supply for maintenance medications when no refills exist and the prescriber cannot be contacted. (Boards may decide whether to extend beyond 30 days.)

b. Expansion of pharmacists' scope of practice to have the authority to:
    i. order and administer CLIA-waived, point-of-care testing and prescribe associated medication(s), and;
    ii. order and administer ACIP vaccines pursuant to board's determination of the age requirement.
c. Expansion of pharmacy technician scope of practice by pharmacist delegation, based on training, skill level, and experience, including vaccine administration but excluding clinical care activities.*
d. Remote prescription processing and verification outside of a licensed pharmacy.*
e. Use of patient-accessible remote Automated Pharmacy Systems, including those allowing the dispensing and delivery of prescription drugs.
f. Relaxation of in-person counselling requirements and allowance of alternative forms that are in the patient's best interest.
g. Pharmacist therapeutic substitution within the same FDA drug class unless prohibited by prescriber.
h. Discharged hospitalized patients to take home multidose drug containers (eg, inhalers) with labels that provide directions for use.

2. NABP recommends that the state boards of pharmacy consider allowing the following when special or unusual public health circumstances or concerns occur[1] (eg, drug shortages):
    a. Emergency dispensing of medication to prevent unnecessary harm and suffering until patient can be treated by a primary care provider.
    b. Nonresident licensed manufacturers, wholesale drug distributors (WDDs), third-party logistics providers (3PLs), repackagers, and outsourcing facilities to practice provided they have a state license in good standing.
        i. Manufacturers must be FDA-registered and have had a Current Good Manufacturing Practice (cGMP) inspection within the prior six months.
        ii. WDDs must be limited to a 90-day, temporary provisional license.
    c. Extend pharmacist, pharmacy intern, pharmacy technician, pharmacy, WDD, and 3PL license expiration dates.
    d. Extend CPE deadlines and waive live CPE requirements.
3. NABP recommends that the state boards of pharmacy consider allowing the following under a declared emergency:

[1] The edits to the *Model Act* that reflect this recommendation are also applicable in public health emergency situations, as it would not make sense to recommend these waivers during lesser emergent circumstances only.

a. Nonresident pharmacists and pharmacy technicians who have registered with NABP Emergency Passport to practice.

b. The waiver of requirements for electronic prescribing and acceptance of paper prescriptions if not restricted by applicable federal laws/rules.

c. The waiver of requirements for the presentation of identification and signatures for the receipt of drugs, if not restricted by applicable federal laws/rules.

d. The waiver of rules that reflect those rules waived by federal and other state entities (eg, FDA relaxation of compounding restrictions).

4. Amend the *Model Act* to incorporate the above recommendations. (NOTE: Provisions identified above with an asterisk are currently recognized in the *Model Act,* and thus no *Model Act* edits are necessary.) The amendments recommended by the work group are denoted by underlines and ~~strikethroughs~~.

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

July 2021

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Article I
Title, Purpose, and Definitions

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Section 104. Practice of Pharmacy.

The "Practice of Pharmacy" means, but is not limited to, the interpretation, evaluation, Dispensing, and/or implementation of Medical Orders, and the initiation and provision of Pharmacist Care Services. The Practice of Pharmacy also includes continually optimizing patient safety and quality of services through effective use of emerging technologies and competency-based training. [2]

[2] The definition of the "Practice of Pharmacy" is one of the most important, and perhaps one of the most discussed, clauses in the NABP *Model Act*. The definition is purposely expressed in broad terms to provide substantial latitude to the Board of Pharmacy in the adoption of implementing rules. Inclusion of or authorization for specific activities, such as the Administration of medications, is purposely not delineated in the definition in order to be empowering and not proscriptive. To assist states in the interpretation of the revised definition of the "Practice of

Article III
Licensing

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Section 304. Renewal of Licenses.

(a) Each Pharmacist, Pharmacy Intern, and Certified Pharmacy Technician 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 attested that he or she has no criminal convictions or arrests, 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) Certified Pharmacy Technician Candidates must complete requirements for Certified Pharmacy Technician licensure within 12 months. For good cause shown, the Board may approve one 12-month extension.

(d) The Board may extend a Pharmacist, Pharmacy Intern, or Certified Pharmacy Technician license renewal date in case of a State of Emergency or Unusual Public Health Concern.

Section 305. Continuing Pharmacy Education.

The Board shall, by rule, establish requirements for continuing education in Pharmacy, including the determination of acceptable program content and fees. The Board shall adopt rules necessary to carry out the stated objectives and purposes, to enforce the provisions of this Section, and to ensure

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Pharmacy," the *Model Act* includes the definition of "Pharmacist Care Services" and Model Rules for the Provision of Pharmacist Care Services for those states that need to include specific lists of activities or authorizations due to legislative and/or administrative policies and procedures.

The definition also acknowledges that pharmacy is a dynamic profession and a broad definition of the practice will permit the Board to make necessary changes from time to time to meet the changing practice. Such changes may be affected by new or amended rules, which would be promulgated pursuant to the requirements of the State Administrative Procedures Act, affording all interested parties an opportunity to review and comment on any proposed rules.

continued competence. The Board may extend the date of compliance with continuing pharmacy education provisions in the case of a State of Emergency or Unusual Public Health Concern[3].

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Article V
Licensing of Facilities

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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[4] their license with the Board:[5]

(1) persons engaged in the Practice of Pharmacy (including Telepharmacy);
(2) dispensing Practitioners and Practitioner's facilities including those engaged in nonsterile[6] Compounding;[7]
(3) persons engaged in the Manufacture or Repackaging of Drugs or Devices;
(4) persons engaged in the Wholesale Distribution of Drugs or Devices;
(5) persons engaged in Third-Party Logistics Provider activities of Drugs or Devices;
(6) pharmacies where Drugs or Devices are Dispensed, or Compounded, or Pharmacist Care Services are provided;
(7) Outsourcing Facilities;
(8) Pharmacy Benefits Managers; and
(9) Repository Programs

Where operations are conducted at more than one location, each such location shall be licensed by the Board of Pharmacy.

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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.

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[3] Boards may consider waiving requirements for "live" continuing pharmacy education in the case of a State of Emergency or Unusual Public Health Concern.

[4] The Board may delay a license renewal date in case of a State of Emergency or Unusual Public Health Concern.

[5] State may require additional licensing/registration requirements.

[6] It is contemplated that dispensing Practitioners and Practitioners' facilities should only compound nonsterile human drug products and that sterile compounded human drug products should be obtained from Outsourcing Facilities.

[7] Licensed Practitioners authorized under the laws of this State to Compound Drugs and to Dispense Drugs to their patients in the practice of their respective professions shall meet the same standards, record-keeping requirements, counseling, and all other requirements for the Dispensing of Drugs applicable to Pharmacists.

NABP

Model Rules for the Practice of Pharmacy

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Section 4. Prescription Drug Order Processing.

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(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. The responsibility for the proper prescribing and Dispensing of controlled substances is upon the prescribing Practitioner, but a corresponding responsibility rests with the Pharmacist who fills the prescription.[8]

(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) [9] or issued electronically.[10, 11]

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Section 5. Record Keeping.

(a) Patient Records[12]

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[8] While Pharmacists have a corresponding responsibility to ensure that a controlled substance is Dispensed only pursuant to a valid Prescription Drug Order written for a legitimate medical purpose, this should not impede patients from receiving legitimately prescribed controlled substances or non-controlled substances, as patient care should be the primary consideration.

[9] Policies and procedures should also provide guidance for properly identifying agents of the prescribing Practitioner who are trained and competent in communicating Prescription Drug Orders.

[10] If a state requires prescriptions to be electronically transmitted, consider waiving such requirement and allow issuance of paper prescriptions during a State of Emergency, in compliance with Federal Law.

[11] Electronically transmitted prescriptions should be transmitted from prescriber to Pharmacy with no intervening Persons making illegal alterations that may be considered as engaging in the Practice of Pharmacy without the authority to do so or without being Licensed to do so to such prescriptions. Evolving technologies and systems have alleviated previous concerns regarding the routes by which electronic prescriptions are transmitted, but any attempts to return to illegal prescription altering practices will be halted.

[12] The Pharmacist should have access to clinical and laboratory data concerning each patient, and should monitor each patient's response to his or her Drug therapy. Any unexpected or untoward response should be reported to the prescribing physician. If the Pharmacist is not doing this monitoring, the identity of the health care provider that has assumed this responsibility should be documented in the patient's profile.

It is acceptable for new Prescription Drug Order data to be added to the patient profile, but original entries may not be altered.

(1) A patient record system shall be maintained by all Pharmacies and dispensing Practitioners for patients for whom Prescription Drug Orders are Dispensed. The patient record system shall provide for the immediate retrieval of information necessary for the Dispensing Pharmacist to identify previously Dispensed Drugs at the time a Prescription Drug Order is presented for Dispensing, and be created and stored in a manner to protect against illegal use or disclosure of Protected Health Information. The Pharmacist shall make a reasonable effort to obtain, record, and maintain the following information:
   (i) full name of the patient for whom the Drug is intended;
   (ii) street address and telephone number of the patient;
   (iii) patient's age or date of birth;
   (iv) patient's gender;
   (v) a list of the patient's medications taken during the preceding 24 months; and
   (vi) Pharmacist comments relevant to the individual's Drug therapy, including any other information peculiar to the specific patient or Drug.

(2) The Pharmacist shall make a reasonable effort to obtain from the patient or the patient's agent and shall record any known allergies, Drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other Drugs, including over-the-counter Drugs or Devices currently being used by the patient which may relate to Prospective Drug Review.

(3) A patient record shall be maintained for a period of not less than ten years from the date of the last entry in the profile record. This record may be a hard copy or a computerized form.

(4) Protected Health Information may be used or disclosed as allowed under state and federal privacy rules.

(5) Significant Adverse Drug Reactions shall be reported to the Practitioner and an appropriate entry shall be made in the patient's record.

(b) Records of Dispensing/Delivery[13]

(1) Records of receipt, Dispensing, Delivery, Distribution, or other disposition of all Drugs or Devices are to be made and kept by Pharmacies for five years[14] and shall include, but not be limited to:
   (i) quantity Dispensed for original and refills, if different from original;
   (ii) date of receipt, Dispensing, Delivery, Distribution, or other disposition;
   (iii) serial number (or equivalent if an institution);
   (iv) the identification of the Pharmacist, Certified Pharmacy Technician, or Certified Pharmacy Technician Candidate responsible for Dispensing;

[13] If a Board requires the presentation of identification or patient signature in order for a patient to receive prescribed Drugs, consider waiving such requirements during a State of Emergency, in compliance with Federal Law.

[14] States should check federal laws and ensure that the number of years the state requires Dispensing records to be maintained are at least as many as federal requirements.

(v) name and Manufacturer of Drug Dispensed if Drug Product selection occurs; and
(vi) records of refills to date.

(2) Pharmacies that ship medications by mail, common carrier, or other type of Delivery service shall implement a mechanism to verify that a patient or caregiver has actually received the Delivered medication.[15]

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Section 6. Pharmacist Care Services. ~~16~~

Pharmacist Care Services may include, but are not limited to, Patient assessment and evaluation; assessing health plan and medication eligibility and coverage; Prescribing and Administering Drugs, Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices vaccines, or biologicals; Prescribing and Dispensing for Emergency Use[17]; performing Peer Review and peer consultations; reviewing, selecting, and developing formularies or plan/practice guidelines; performing therapeutic substitution[18]; consulting with other health care professionals; providing patient referrals; performing Medication Therapy Management; ordering and performing Clinical Laboratory Improvement Amendments of 1988-waived lab tests and prescribing associated Drugs and Biologicals[19], as provided by State and Federal law, and reporting results and follow up treatment.

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(b) Patient Counseling[20]

(1) Upon receipt of a Prescription Drug Order and following a review of the patient's record, a Pharmacist shall personally initiate discussion of matters which will enhance or optimize Drug therapy with each patient or caregiver of such patient. Such discussion shall be in Person, whenever practicable, or by telephone or other

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[15] States that require pharmacies that ship medication by mail, common carrier, or other type of Delivery service to implement a mechanism to verify that the patient or caregiver has actually received the Delivered medication may want to consider allowing the mechanism to include a waiver provision that allows the patient or caregiver to request Delivery without Verification and advises the patient or caregiver of the possible consequences of receiving Delivery without Verification.

~~[16] Additional Pharmacist Care Services may include, but are not limited to, Patient assessment and evaluation; assessing health plan and medication eligibility and coverage; Administering Drugs, vaccines, or biologicals; performing Peer Review and peer consultations; reviewing, selecting, and developing formularies or plan /practice guidelines; consulting with other health care professionals; providing patient referrals; performing Medication Therapy Management; ordering lab tests; and performing lab tests as provided by State and Federal law.~~

[17] Pharmacist may prescribe pursuant to specific statewide protocols or standing orders.

[18] Providing it is within the same FDA drug class and not prohibited by the prescriber.

[19] Pharmacist may prescribe associated medications pursuant to specific statewide protocols or standing orders

[20] The intent of this Section is to require that the Pharmacist personally initiate counseling for all new Prescriptions and to exercise his or her professional judgment for refills. Situations may arise, however, where the prescriber specifically indicates that a patient should not be counseled. In such circumstances, it is the responsibility of the Pharmacist to provide the best patient care through appropriate communication with the prescriber and to document the reason(s) for not providing counseling to the patient.

audio/visual means and shall include appropriate elements of Patient Counseling. Such elements may include the following:

(i) the name and description of the Drug;
(ii) the dosage form, dose, route of Administration, and duration of Drug therapy;
(iii) intended use of the Drug and expected action;
(iv) special directions and precautions for preparation, Administration, and use by the patient;
(v) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
(vi) techniques for self-monitoring Drug therapy;
(vii) proper storage and appropriate disposal method(s) of unwanted or unused medication;
(viii) prescription refill information;
(ix) action to be taken in the event of a missed dose; and
(x) Pharmacist comments relevant to the individual's Drug therapy, including any other information peculiar to the specific patient or Drug.

(2) An offer for Patient Counseling can be made by a Certified Pharmacy Technician or Certified Pharmacy Technician Candidate when it is not required by law or deemed necessary that it be done by the Pharmacist.

(3) Alternative forms of patient information may ~~shall~~ be used ~~to supplement~~ for Patient Counseling when appropriate. Examples include written information leaflets, pictogram labels, video programs, etc.

(4) Patient Counseling, as described above and defined in this Act, shall not be required for inpatients of a hospital or institution where other licensed health care professionals are authorized to Administer the Drug(s).

(5) A Pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultation.

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(f) Prescribing and Dispensing for Emergency-Use ~~Dispensing~~

Prescribing and Dispensing Drugs for emergency-use pursuant to a Pharmacist-issued Prescription[21] and appropriate Patient Counseling, including but not limited to:

(1) Opioid overdose reversal agents, such as naloxone;
(2) Epinephrine;
(3) Antidote kits;
(4) Short-acting beta agonist inhalers; and

[21] Pharmacist may prescribe pursuant to specific statewide protocols or standing orders.

(5) Medication-assisted Treatment for the purpose of initiating therapy for opioid use disorder. The Pharmacist must:
(i) obtain a DEA registration and a state controlled substance license or registration, if required; and
(ii) use professional judgment to assess the clinical appropriateness of the patient's request and the length of time until the patient obtains treatment from an authorized Practitioner.[22]

(g) Emergency Refills

A Pharmacist may Dispense a refill of a Prescription Drug, not to exceed a thirty (30)-day supply, without Practitioner authorization if:[23,24]

(1) in the Pharmacist's professional judgment, the Prescription Drug is essential to the maintenance of the Patient's life or to the continuation of therapy;
(2) the Pharmacist makes a good faith effort to reduce the information to a form that may be maintained for the time required by law or rule, indicates it is an "Emergency Refill Prescription," and maintains the record as required by state and federal law, as well as state and federal disaster agencies for consideration for possible reimbursement programs implemented to ensure continued provision of care during a disaster or emergency; and
(3) the Pharmacist informs the Patient or the Patient's agent at the time of Dispensing that the Prescription Drug is being provided without the Practitioner's authorization and that authorization of the Practitioner is required for future refills.

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Section 9. Automated Pharmacy Systems.

(a) Automated Pharmacy Systems can be utilized in licensed pharmacies and Shared Pharmacy Services Pharmacies and other locations approved by the Board. ~~located within an Institutional Facility or clinic~~. A Pharmacist is not required to be physically present at the site of the Automated Pharmacy System if the system is supervised electronically by a Pharmacist. Automated Pharmacy Systems shall comply with the following provisions.

(1) Documentation as to type of equipment, serial numbers, content, policies and procedures, and Shared Pharmacy Services Pharmacy location shall be maintained in the Pharmacy for review . Such documentation shall include, but is not limited to:

[22] It is contemplated that for long-term treatment, Pharmacists should be prescribing under a collaborative practice agreement rather than under an emergency-use provision.

[23] Boards may consider contacting the US Drug Enforcement Administration ahead of time to ensure these provisions are applicable to controlled substances.

[24] Boards may consider extending beyond a thirty (30)-day supply.

(i) name and address of the Pharmacy and the Shared Pharmacy Services Pharmacy where the Automated Pharmacy System (s) is being used;
(ii) Manufacturer's name and model;
(iii) description of how the Automated Pharmacy System is used;
(iv) quality assurance procedures to determine continued appropriate use of the Automated Pharmacy System;
(v) policies and procedures for system operation, safety, security, accuracy, patient confidentiality, access, and malfunction; and
(vi) documentation evidencing that the Automated Pharmacy System has been tested prior to initial use and on a periodic basis at each location to ensure that the Automated Pharmacy System is operating properly.

(2) Automated Pharmacy Systems should be used only in settings where there is an established program of Pharmacist Care Services that ensures medication orders or Prescription Drug Orders are reviewed by a Pharmacist in accordance with established policies and procedures and good Pharmacist Care Services.[25]
(i) A Pharmacist shall be accessible to respond to inquiries or requests pertaining to Drugs Dispensed from the Automated Pharmacy System.[26]
(ii) Any Pharmacy that maintains an Automated Pharmacy System for the purposes of remote Dispensing to outpatients[27] shall maintain a video/auditory communication system to provide for effective communication between the patient and the Pharmacist; the video/auditory communication system shall allow for the appropriate exchange of oral and written communication and Patient Counseling; if the video/auditory communication system malfunctions, then all operations of the Automated Pharmacy System shall cease until the system is fully functional.

(3) All policies and procedures must be maintained in the Pharmacy responsible for the Automated Pharmacy System and, if the Automated Pharmacy System is being used at a different location, at that location as well.

(4) Automated Pharmacy Systems shall have adequate security systems and procedures, evidenced by written policies and procedures[28], to:

[25] Each state should determine whether or not the Dispensing of a "first dose" or an "emergency dose" may take place without prior order review by a Pharmacist but with appropriate security and patient medication management controls in place.

[26] In order to facilitate communication between the Pharmacy and the site where the Automated Pharmacy System is located, a Pharmacy should provide a toll-free telephone number so that the Pharmacist is accessible at all times the Automated Pharmacy System is operational.

[27] Although an "outpatient" generally refers to a Person who receives Drugs for use outside of an Institutional Facility, the definition of "outpatient" must be defined by each state. For example, although the *Model Act* classifies penal institutions as a type of Institutional Facility and therefore its inmates as inpatients, the Pharmacist is exempt from providing Patient Counseling. However, some states may consider inmates of penal institutions as outpatients and therefore should decide if a video/audio communication system is required in such facilities so that the Pharmacist is able to provide Patient Counseling.

[28] The use of Automated Pharmacy Systems requires written policies and procedures in place prior to installation to ensure safety, environmental controls, accuracy, security, and patient confidentiality and to define access and limits to access to equipment and medications.

(i) prevent unauthorized access;
(ii) comply with federal and state regulations; and
(iii) prevent the illegal use or disclosure of Protected Health Information.

(5) Records and/or electronic data kept by Automated Pharmacy Systems shall meet the following requirements.
(i) All events involving the contents of the Automated Pharmacy System must be recorded electronically.
(ii) Records must be maintained by the Pharmacy and must be readily available to the Board. Such records shall include:
(A) identity of system accessed;
(B) identification of the individual accessing the system;
(C) type of Transaction;
(D) name, strength, dosage form, and quantity of the Drug accessed;
(E) name of the patient for whom the Drug was ordered; and
(F) such additional information as the Pharmacist-in-Charge may deem necessary.

(6) Access to and limits on access (eg, security levels) to the Automated Pharmacy System must be defined by policy and procedures and must comply with state and federal regulations. [29]

(7) The Pharmacist-in-Charge shall have the responsibility to:
(i) assign, discontinue, or change access to the system;
(ii) ensure that access to the medications comply with state and federal regulations;
(iii) ensure that the Automated Pharmacy System is filled/stocked accurately and in accordance with established, written policies and procedures.

(8) The filling/stocking of all medications in the Automated Pharmacy System shall be accomplished by qualified personnel under the supervision of a licensed Pharmacist.

(9) A record of medications filled/stocked into an Automated Pharmacy System shall be maintained and shall include identification of the persons filling/stocking and checking for accuracy.[30]

(10) All containers of medications stored in the Automated Pharmacy System shall be packaged and labeled in accordance with federal and state laws and regulations.

(11) All aspects of handling controlled substances shall meet the requirements of all state and federal laws and regulations.

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[29] This section anticipates that decisions regarding which health care professionals may access the Automated Pharmacy System and the level of access allowed (eg, access to medications, access to patient profiles for viewing only, access to patient profiles for modification) will be left up to the individual(s) responsible for the Automated Pharmacy System; however, states may decide to take on this responsibility and define those who may have access to the system and the levels of access allowed.

[30] This section anticipates that states will allow non-Pharmacist personnel to fill/stock Automated Pharmacy Systems under a Pharmacist's supervision; however, the state may decide to only allow a Pharmacist to perform this function. Should the State allow non-Pharmacist personnel to perform this function, it should define the level of Pharmacist supervision necessary (eg, immediate, direct, or general).

(12) The Automated Pharmacy System shall provide a mechanism for securing and accounting for medications removed from and subsequently returned to the Automated Pharmacy System, all in accordance with existing state and federal law.[31]

(13) The Automated Pharmacy System shall provide a mechanism for securing and accounting for wasted medications or discarded medications in accordance with existing state and federal law.

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Model Rules for Institutional Pharmacy

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Section 6. ~~Packaging~~ Relabeling of Previously Dispensed Outpatient Medication for Inpatient Use.

(a) At a patient's or patient's caregiver's request, an Institutional Pharmacy may relabel for inpatient use ~~change the packaging of~~ a Drug previously Dispensed by an outpatient pharmacy to the patient.

(b) ~~Any~~ The Institutional Pharmacy providing ~~packaging~~ relabeling services shall have in place policies and procedures to:

(1) assess whether the medication may be Adulterated or Misbranded; and

(2) package and label the medication in compliance with state and federal requirements and USP standards.

(c) The Institutional Pharmacy that ~~packages~~ relabels a previously Dispensed outpatient ~~medication~~ Drug shall retain all original prescription information in accordance with state record-keeping requirements.

Section 7. Relabeling of Previously Dispensed Inpatient Multidose Medication for Outpatient Use

(a) At a patient's or patient's caregiver's request, an Institutional Pharmacy may relabel for outpatient use a multidose Drug previously Dispensed to an inpatient.

(b) The Institutional Pharmacy providing relabeling services shall have in place policies and procedures to:

1. assess whether the medication may be Adulterated or Misbranded; and
2. package and label the medication in compliance with state and federal requirements and USP standards.

(c) The Institutional Pharmacy that relabels a previously Dispensed multidose Drug shall retain all original Chart Order information in accordance with state record-keeping requirements.

[31] The State may require that each licensed Pharmacy or facility have in place written policies and procedures to address situations in which medications removed from the system remain unused and must be secured and accounted for.

Model Rules for Public Health Emergencies or Unusual Public Health Concerns

Section 1. Purpose and Scope.[32]

By the provision of these rules by the Board, the primary purpose of the section is to enable Pharmacists and Pharmacies to assist in the management and containment of a Public Health Emergency[33] or ~~similar crisis~~ Unusual Public Health Concerns within the confines of a regulatory framework that serves to protect the welfare and health of the public.

Section 2. Definitions.

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[32] States may consider adding the following, more detailed language, which specifically addresses Drug Disposal and reporting requirements in the case of an emergency or disaster, to their emergency rules or guidelines:

Disposal of Prescription Drugs in Pharmacies Affected by Certain Disasters

(a) For Pharmacies that sustain flood and/or fire damage in the Prescription department or other damage resulting in an irrevocable loss of the Drug inventory, the entire Drug inventory, including Drugs awaiting pick up by Patients, becomes unfit for Dispensing. In such a case, an accurate record of Prescription Drug losses should be prepared by the Pharmacy.

(b) For Pharmacies that experience a loss of power for an extended period of time, the Drug inventory must be evaluated for continued Product integrity using USP standards. For example, medications with labeling requiring storage at "controlled room temperature" must be kept at between 68º F and 77º F, with brief deviations of between 56º F and 86ºF. Medication inventories found to have been stored outside of USP standards become unfit for Dispensing. In such a case, an accurate record of Prescription Drug losses should be prepared by the Pharmacy. For Pharmacies with questions on USP Product integrity standards, contact USP at 800/227-8772.

Reporting of Theft or Loss of Controlled Substances During an Emergency or Disaster

(a) In circumstances of theft by looting, burglary, etc., where evidence or witnesses indicate the medications were taken by someone, the nearest DEA Diversion Field Office must be notified by telephone, facsimile, or brief written message of the circumstances of the theft immediately upon discovery. In addition, the pharmacy must complete DEA Form 106 – Report of Theft or Loss of Controlled Substances, found at *www.deadiversion.usdoj.gov*, to formally document the actual circumstances of the theft and the quantity of controlled substances involved, once this information has been conclusively determined.

(b) In circumstances of damage or where drugs were irrevocably lost to flooding or other circumstance, such information must be reported on DEA Form 41 – Registrants Inventory of Drugs Surrendered, found at *www.deadiversion.usdoj.gov*.

(c) The amount stolen or lost may need to be calculated by taking the most recent controlled substances inventory, adding the amount purchased since that date, then subtracting the amount dispensed and distributed since that date. Absent a calculated amount, a best estimate should be reported.

Disposal of Prescription Drugs Irrevocably Lost in an Emergency or Disaster

(a) Controlled Substances
Reverse Distributors, either individually or in concert with other contractors, are equipped to dispose of controlled substances. Contact your primary distributor for their recommendations for a reverse Distributor or contact a reverse Distributor directly.

(b) Contaminated Medical Debris
Non-controlled substance Prescription Drugs and Devices contaminated with flood water or other contaminants should be disposed of using a medical waste transportation, processing, and disposal system vendor. Such vendors must be licensed by the state.

(c) Hazardous Debris
Materials are deemed hazardous if they are ignitable, corrosive, toxic, or reactive. Prescription Drugs considered hazardous include, but are not limited to, epinephrine, nicotine, nitroglycerin, physostigmine, reserpine, selenium sulfide, chloral hydrate, and many chemotherapy agents, such as cyclophosphamide, chlorambucil, and daunomycin. Other hazardous items that might be found in a Pharmacy include paints, varnishes and thinners, alcohol, batteries, mercury thermometers, and blood pressure cuffs. It is recommended that Pharmacies handle all contaminated Prescription medications as hazardous debris and dispose of it using a hazardous waste collection and disposal company. These companies must be licensed by the state.

(d) Commercial Waste
Over-the-counter Drugs and other store shelf material may be disposed of in the commercial waste stream.

[33] During a Public Health Emergency, Boards of Pharmacy should issue waivers that mirror waivers issued by Federal and other state entities.

(a) "Declared Disaster Areas" are areas designated by state or federal authorities as those that have been adversely affected by a natural or man-made disaster and require extraordinary measures to provide adequate, safe, and effective health care for the affected population.

(b) "Emergency Dispensing" means Dispensing of a Prescription Drug, including a controlled substance, during an Unusual Public Health Concern or Public Health Emergency , and:

(i) the prescriber cannot be contacted;

(ii) the Pharmacy has no record on file of prior dispensing of the Drug; and

(iii) the immediate needs of the patient must be met until a primary provider can be seen, so as to prevent unnecessary harm and suffering.

(~~b~~c) "Emergency Standing Prescription Drug Order" means a standing Prescription Drug Order issued by the State Health Officer for Pharmacists to Dispense designated Prescription Drugs during a Public Health Emergency requiring mass Dispensing to expeditiously treat or provide prophylaxis to large numbers of Patients.[34]

(~~c~~d) "Mobile Pharmacy" means a Pharmacy that is self-propelled or movable by another vehicle that is self-propelled.

(e) "NABP Emergency Passport Program" means a program, operated by the National Association of Boards of Pharmacy, that verifies Pharmacists, Pharmacy Technicians, Pharmacy Interns, and Pharmacies meet the standard of licensure and are in good standing in states of licensure in order to practice on a temporary or emergency basis according to state Public Health Emergency orders or as otherwise determined by the state board of pharmacy.

(~~d~~f) "Public Health Emergency" means an imminent threat or occurrence of an illness or health condition caused by terrorism, bioterrorism, epidemic or pandemic disease, novel and highly fatal infectious agent or biological toxin, or natural or man-made disaster, that poses a substantial risk of a significant number of human fatalities or incidents of permanent or long-term disability that is beyond the capacity of local government or nongovernmental organizations to resolve.

(~~e~~g) "State of Emergency" means a governmental declaration, usually issued as a result of a Public Health Emergency, that may suspend certain normal functions of government, alert citizens to alter their normal behaviors, and/or direct government agencies to implement emergency preparedness plans.

(~~f~~h) "Temporary Pharmacy Facility" means a facility established as a result of a Public Health Emergency or State of Emergency to temporarily provide Pharmacy services within or adjacent to Declared Disaster Areas.

(i) "Unusual Public Health Concern" means a potential threat or occurrence of a circumstance or health condition that poses a risk to the health of a significant number of patients that is beyond the capacity of local government or nongovernmental organizations to immediately resolve.

[34] Boards may consider identifying the official who has authority to issue an "Emergency Prescription Drug Order" and reviewing this on a regular basis.

Section 3. Emergency Standing Prescription Drug Order.

(a) For the duration of a State of Emergency issued due to a Public Health Emergency, a Pharmacist may Dispense a Prescription Drug pursuant to an Emergency Standing Prescription Drug Order if the Pharmacist:

(1) performs, to the extent possible, a Prospective Drug Utilization Review (DUR) and Patient Counseling in accordance with these rules;[35]

(2) reduces the information to a form that may be maintained for the time required by law or rule, indicates it is an "Emergency Standing Prescription Drug Order," and files and maintains the record as required by state and federal law.

Section 4. ~~Public Health~~ Emergency Refills ~~Dispensing~~.

(a) For the duration of the State of Emergency issued due to a Public Health Emergency, or for the duration of an Unusual Public Health Concern, in the affected state and in other states engaged in disaster assistance pursuant to a governmental declaration or rule of the Board, a Pharmacist may Dispense a refill of a Prescription Drug, not to exceed a thirty (30)-day supply, without Practitioner authorization if:[36]

(1) in the Pharmacist's professional judgment, the Prescription Drug is essential to the maintenance of the Patient's life or to the continuation of therapy;

(2) the Pharmacist makes a good faith effort to reduce the information to a form that may be maintained for the time required by law or rule, indicates it is an "Emergency Refill Prescription," and maintains the record as required by state and federal law, as well as state and federal disaster agencies for consideration for possible reimbursement programs implemented to ensure continued provision of care during a disaster or emergency; and

(3) the Pharmacist informs the Patient or the Patient's agent at the time of Dispensing that the Prescription Drug is being provided without the Practitioner's authorization and that authorization of the Practitioner is required for future refills.

(b) For the duration of the State of Emergency, in an effort to provide patients with the best possible care in light of limited Drug availability and/or limited information on patients' current Drug therapy, a Pharmacist may initiate or modify Drug therapy and Dispense an amount of such Drug to accommodate a patient's health care needs until that patient may be seen by a Practitioner. Pharmacists performing such activities must utilize currently accepted

[35] Although these services are important, in times of a disaster or emergency, it may not be possible to perform a Prospective Drug Review or provide counseling on Dispensed Drugs.

[36] Boards may consider contacting the US Drug Enforcement Administration ahead of time to ensure these provisions are applicable to controlled substances.

Standards of Care when initiating or modifying Drug therapy. These activities may be undertaken if:

(1) in the Pharmacist's professional judgment, the Prescription Drug is essential to the maintenance of the Patient's life or to the continuation of therapy;

(2) the Pharmacist makes a good faith effort to reduce the information to a form that may be maintained for the time required by law or rule, indicates that drug therapy has been initiated or modified due to a disaster or emergency, and maintains the record as required by state and federal law; and[37]

(3) the Pharmacist informs the Patient or the Patient's agent at the time of Dispensing that the Prescription Drug is being provided without the Practitioner's authorization and that authorization of the Practitioner is required for future refills.

(c) The Practitioner and Pharmacist shall not incur any liability as a result of the performance of these activities in good faith pursuant to this section.

Section 5. Temporary Recognition of Nonresident State Licensure and NABP Emergency Passport for Pharmacists, Certified Pharmacy Technicians, Certified Pharmacy Technician Candidates, and Pharmacy Interns.

~~(a)~~ When a State of Emergency is declared due to a Public Health Emergency:

(1) a Pharmacist not licensed in this State, but currently licensed in another state and registered with the NABP Emergency Passport Program, may Dispense Prescription Drugs in ~~areas affected by the~~ Declared Disaster Areas during the time that the State of Emergency exists if:

(i) an application has been submitted in the form prescribed by the Board of Pharmacy;

(ii) the Board can verify current licensure in good standing of the Pharmacist directly with the state or indirectly via a third-party verification system;[38] ~~and~~

(iii) the fee(s) specified by the Board have been paid; and

(iv) the Pharmacist is engaged in a legitimate relief effort.

If the Board is supplied with proof of an active Emergency Passport, as administered by the National Association of Boards of Pharmacy, compliance with subsections (i) and (ii) above is demonstrated;

(2) a Certified Pharmacy Technician, Certified Pharmacy Technician Candidate, or Pharmacy Intern not licensed in this State, but currently licensed in another state and registered

[37] Boards should be cognizant that state and federal disaster agencies, to ensure continued provision of care during disasters or emergencies, have programs that consider reimbursement requests for medication providers and may request Board assistance in the dispersal of funds. Records of dispensing will likely be needed for possible reimbursement consideration. In addition, records may also be used for post-event evaluation of care.

[38] If the information cannot be verified directly by the state Board of Pharmacy in which the nonresident pharmacist is licensed, the NABP Disciplinary Clearinghouse may be utilized to verify that a nonresident pharmacist has not had disciplinary action taken against his or her license.

with the NABP Emergency Passport Program, may assist the Pharmacist in Dispensing Prescription Drugs in ~~affected~~ Declared Disaster Areas during the time that the State of Emergency exists if:

(i) an application has been submitted in the form prescribed by the Board of Pharmacy;

(ii) the Board can verify current licensure in good standing of the Certified Pharmacy Technician, Certified Pharmacy Technician Candidate, or Pharmacy Intern directly with the state or indirectly via a third-party verification system; ~~and~~

(iii) the fee(s) specified by the Board have been paid; and

(iv) the Certified Pharmacy Technician, Certified Pharmacy Technician Candidate, or Pharmacy Intern is engaged in a legitimate relief effort.

If the Board is supplied with proof of an active Emergency Passport, as administered by the National Association of Boards of Pharmacy, compliance with subsections (i) and (ii) above is demonstrated.

Section 6. Temporary Recognition of Nonresident State Licensure for Manufacturers, Outsourcing Facilities, Repackagers, Third-Party Logistics Providers, and Wholesale Drug Distributors.

When a State of Emergency is declared due to a Public Health Emergency, or when there exists an Unusual Public Health Concern:

(1~~3~~) A Manufacturer, Outsourcing Facility, Repackager, Third-Party Logistics Provider, or Wholesale Drug Distributor, not licensed in this State, but currently licensed in another state, may Distribute Prescription Drugs in affected areas ~~Disaster Areas~~ during the time that the State of Emergency or Unusual Public Health Concern exists if ~~(i)~~ the Board can verify ~~:~~ that the entity is engaged in a legitimate relief effort and has

~~(ii)~~ current licensure in good standing in another state.

(2) ~~of the~~ For Wholesale Drug Distributors, verification of state licensure may take place directly with the state or indirectly via a third-party verification system.~~; and~~

~~(iii)the Wholesale Drug Distributor is engaged in a legitimate relief effort.~~

(~~4~~3)For Wholesale Drug Distributors, the temporary recognition of nonresident licensure or registration shall cease with the termination of the State of Emergency or Unusual Public Health Concern, or after 90 days, whichever comes first.

(4) For Manufacturers, the Board must verify registration with FDA that a Current Good Manufacturing Practice (cGMP) inspection has taken place within the previous six months.

Section 7~~6~~. Temporary Pharmacy Facilities or Mobile Pharmacies.

(a) Pharmacies located in Declared Disaster Areas, nonresident Pharmacies, and Pharmacies licensed in another state but not licensed in this State, if necessary to provide Pharmacy

services during a State of Emergency, may arrange to temporarily locate or relocate to a Temporary Pharmacy Facility or Mobile Pharmacy if the Temporary Pharmacy Facility or Mobile Pharmacy:[39]

(1) is under the control and management of the Pharmacist-in Charge or designated supervising Pharmacist;
(2) is located within the Declared Disaster Area or affected areas;
(3) notifies the Board of its location;[40]
(4) is properly secured to prevent theft and diversion of Drugs;
(5) maintains records in accordance with laws and regulations of the state in which the disaster occurred; and
(6) ceases the provision of services with the termination of the State of Emergency,

unless it is successfully licensed by the Board of Pharmacy in accordance with Article V of this Act.

(b) The Board, in accordance with Board rules, shall have the authority to approve or disapprove Temporary Pharmacy Facilities and Mobile Pharmacies and shall make arrangements for appropriate monitoring and inspection of the Temporary Pharmacy Facilities and Mobile Pharmacies on a case-by-case basis. Approval of Temporary Pharmacy Facilities and Mobile Pharmacies will be based on the need, type, and scope of Public Health Emergency, as well as the ability of the Temporary Pharmacy Facilities or Mobile Pharmacies to comply with state and federal drug law.

(c) A Temporary Pharmacy Facility wishing to permanently operate at its temporary site must be licensed by the Board of Pharmacy in accordance with Article V of this Act.

(d) Mobile Pharmacies, placed in operation during a State of Emergency, may not operate permanently, unless approved by the Board.[41]

[39] Boards may consider contacting the US Drug Enforcement Administration ahead of time to ensure that controlled substances may be delivered to and Dispensed from temporary or mobile pharmacy facilities.

[40] Boards may choose to require "approval" of a Temporary Pharmacy Facility or a Mobile Pharmacy, as opposed to requiring only "notification." "Notification" may imply that the Board of Pharmacy has approved the location of the Temporary Pharmacy Facility or Mobile Pharmacy.

[41] Although many states do not allow the permanent or temporary licensure of Mobile Pharmacies, states that do allow the licensure of Mobile Pharmacies may consider implementing special requirements for permanent licensure; for example, a state may limit Mobile Pharmacies to operation only by nonprofit organizations and only in communities that are medically underserved.