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

August 2014

Preamble and Mission Statement of the National Association of Boards of Pharmacy

Preamble

The National Association of Boards of Pharmacy (NABP) recognizes and supports pharmacists serving as the health care professionals responsible for providing patient care that ensures optimal medication therapy outcomes. NABP also recognizes the ongoing and critical need for patients' medications to be managed by a licensed pharmacist and state regulatory agencies to aggressively enforce standards of care.

NABP Mission Statement

NABP is the independent, international, and impartial Association that assists its member boards and jurisdictions for the purpose of protecting the public health.

NABP Member Boards of Pharmacy

Alabama State Board of Pharmacy
Alaska Board of Pharmacy
Arizona State Board of Pharmacy
Arkansas State Board of Pharmacy
California State Board of Pharmacy
Colorado State Board of Pharmacy
Connecticut Commission of Pharmacy
Delaware State Board of Pharmacy
District of Columbia Board of Pharmacy
Florida Board of Pharmacy
Georgia State Board of Pharmacy
Guam Board of Examiners for Pharmacy
Hawaii State Board of Pharmacy
Idaho State Board of Pharmacy
Illinois Department of Financial and Professional Regulation, Division of Professional Regulation – State Board of Pharmacy
Indiana Board of Pharmacy
Iowa Board of Pharmacy
Kansas State Board of Pharmacy
Kentucky Board of Pharmacy
Louisiana Board of Pharmacy
Maine Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation – Board of Pharmacy
Maryland Board of Pharmacy
Massachusetts Board of Registration in Pharmacy
Michigan Board of Pharmacy
Minnesota Board of Pharmacy
Mississippi Board of Pharmacy
Missouri Board of Pharmacy
Montana Board of Pharmacy
Nebraska Department of Health and Human Services, Division of Public Health, Licensure Unit
Nevada State Board of Pharmacy
New Hampshire Board of Pharmacy
New Jersey State Board of Pharmacy
New Mexico Board of Pharmacy
New York State Board of Pharmacy
North Carolina Board of Pharmacy
North Dakota State Board of Pharmacy
Ohio State Board of Pharmacy
Oklahoma State Board of Pharmacy
Oregon State Board of Pharmacy
Pennsylvania State Board of Pharmacy
Puerto Rico Board of Pharmacy
Rhode Island Board of Pharmacy
South Carolina Department of Labor, Licensing, and Regulation – Board of Pharmacy
South Dakota State Board of Pharmacy
Tennessee Board of Pharmacy
Texas State Board of Pharmacy
Utah Board of Pharmacy
Vermont Board of Pharmacy
Virgin Islands Board of Pharmacy*
Virginia Board of Pharmacy
Washington State Pharmacy Quality Assurance Commission
West Virginia Board of Pharmacy
Wisconsin Pharmacy Examining Board
Wyoming State Board of Pharmacy

Australia:

Pharmacy Board of Australia*

Canada:

Alberta College of Pharmacists*
College of Pharmacists of British Columbia*
College of Pharmacists of Manitoba*
New Brunswick Pharmaceutical Society*
Nova Scotia College of Pharmacists*
Ontario College of Pharmacists*
Quebec Order of Pharmacists*
Saskatchewan College of Pharmacists*

New Zealand:

Pharmacy Council of New Zealand*

*Associate Member

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National Association of Boards of Pharmacy
Model State Pharmacy Act

Article I

Title, Purpose, and Definitions

Introductory Comment to Article I

Article I of the Model State Pharmacy Act and Model Rules of National Association of Boards of Pharmacy (Model Act) *sets forth the foundation upon which the Act is constructed. It clearly declares and acknowledges that safeguarding the public interest is the foremost compelling reason for regulating the Practice of Pharmacy and the Distribution of Drugs and related Devices. It also circumscribes the activities included within the Practice of Pharmacy, as well as the definitions of several other terms used throughout the Act.*

NABP created the Model Act to provide State Boards of Pharmacy with model language that may be used when developing state laws or board rules for the respective States. *NABP believes that it is both desirable and necessary to recognize that the public interest must be the central precept in the* Model Act *and its administration, and that State Boards of Pharmacy must constantly strive to achieve the principles enunciated in Article I of the Act.*

An ACT concerning the regulation of the Practice of Pharmacy in this State and related matters.

Be it enacted. . . .

Section 101. Title of Act.

This Act shall be known as the "_____ Pharmacy Practice Act."

Section 102. Legislative Declaration.

The Practice of Pharmacy in the State of _____ is declared a professional practice affecting the public health, safety, and welfare and is subject to regulation and control in the public interest.[1] It is further declared to be a matter of public interest and concern that the Practice of Pharmacy, as defined in this Act, merit and receive the confidence of the public and that only qualified persons be permitted to engage in the Practice of Pharmacy, and to ensure the quality of Drugs and related Devices Distributed in the State of _____. This Act shall be liberally construed to carry out these objectives and purposes.

Section 103. Statement of Purpose.

It is the purpose of this Act to promote, preserve, and protect the public health, safety, and welfare by and through the effective control and regulation of the Practice of Pharmacy; the licensure of Pharmacists; the registration of Pharmacy Technicians; the licensure, control, and

[1] Pharmacy is a learned profession affecting public health and welfare and should be declared as such by the State Legislature. The Practice of Pharmacy, from time to time, has been erroneously viewed, even by government agencies, as a commercial business rather than a profession. The status of Pharmacy as a profession has been, and will continue to be, of particular importance in litigation.

regulation of all sites or Persons, in or out of this State, that Distribute, Manufacture, or sell Drugs (or Devices used in the Dispensing and Administration of Drugs), within this State, and the regulation and control of such other materials as may be used in the diagnosis, treatment, and prevention of injury, illness, and disease of a patient or other individual.[2]

Section 104. Practice of Pharmacy.

The "Practice of Pharmacy" means the interpretation, evaluation, and implementation of Medical Orders; the accepting, processing, or Dispensing of Prescription Drug Orders; participation in Drug and Device selection; Drug Administration; Drug Utilization Review (DUR); the Practice of Telepharmacy within and across state lines; Drug or Drug-related research; the provision of Patient Counseling; the provision of those acts or services necessary to provide Pharmacist Care in all areas of patient care, including Primary Care, Medication Therapy Management, Collaborative Pharmacy Practice, the ordering, conducting, and interpretation of appropriate tests, and the recommendation and Administration of immunizations; and the responsibility for Compounding and Labeling of Drugs and Devices (except Labeling by a Manufacturer, Repackager, or Distributor of Non-Prescription Drugs and commercially packaged Legend Drugs and Devices), proper and safe storage of Drugs and Devices, and maintenance of required records. The practice of pharmacy also includes continually optimizing patient safety and quality of services through effective use of emerging technologies and competency-based training.

(See comment list.)

Section 105. Definitions.

(a) "Active Ingredients" refer to chemicals, substances, or other Components of articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases in humans or animals or for use as nutritional supplements.

(b) "Added Substances" mean the ingredients necessary to prepare the Drug product but are not intended or expected to cause a human pharmacologic response if administered alone in the amount or concentration contained in a single dose of the Compounded Drug product. The term "added substances" is usually used synonymously with the terms "inactive ingredients," "excipients," and "pharmaceutic ingredients."

(c) "Administer" means the direct application of a Drug to the body of a patient or research subject by injection, inhalation, ingestion, or any other means.

(d) "Adulterated": A Drug or Device shall be deemed to be Adulterated:

(1) if:

(i) it consists in whole or in part of any filthy, putrid, or decomposed substance; or

(ii) it has been produced, prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or if the methods used in, or the facilities

[2] The Statement of Purpose is designed to define the general scope of the Pharmacy Act. It provides for the control and regulation of the Practice of Pharmacy and the licensure of facilities engaged in the Distribution of Drugs and related Devices. A Board will have full knowledge of the whereabouts of Drugs in the legitimate stream of intrastate and interstate commerce, providing it with the ability to better prevent diversion, effectuate recalls, ensure the quality of Drugs Dispensed or Administered to patients, and effectively protect the public.

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 Drug or Device meets the requirements of this part as to safety and has the identity and strength, and meets the quality and purity characteristics that it purports or is represented to possess; or

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

(iv) it bears or contains, for purposes of coloring only, a color additive that is unsafe within the meaning of the Federal Food, Drug, and Cosmetic Act (Federal Act); or it is a color additive, the intended use of which is for purposes of coloring only, and is unsafe within the meaning of the Federal Act;

(2) if it purports to be or is represented as a Drug, the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in the compendium. Such a determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in the compendium, or in the absence of or inadequacy of these tests or methods of assay, those prescribed under authority of the Federal Act. No Drug defined in an official compendium shall be deemed to be Adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefore set forth in the compendium, if its difference in strength, quality, or purity from that standard is plainly stated on its label. Whenever a Drug is recognized in both the United States Pharmacopeia (USP) and the Homeopathic Pharmacopoeia of the United States it shall be subject to the requirements of the USP unless it is labeled and offered for sale as a homeopathic Drug, in which case it shall be subject to the Homeopathic Pharmacopoeia of the United States and not those of the USP;

(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; or

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

(e) "Affiliated Entity" means legally separate covered entities that are affiliated and that designate themselves as a single covered entity for the purposes of this section.

(f) "Authenticate" means to affirmatively verify that each transaction listed on the Pedigree and any other accompanying documentation has occurred, in accordance with the Rules of the Board.[3]

(g) "Authentication of Product History" means, but is not limited to, identifying the purchasing source, the ultimate fate, and any intermediate handling of any Component of a radiopharmaceutical.

(h) "Automated Pharmacy Systems" include, but are not limited to, mechanical systems that perform operations or activities, other than Compounding or Administration, relative to the storage, packaging, Dispensing, or Distribution of medications, and which collect, control, and maintain all transaction information.

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[3] Although Pedigrees record each transaction of a Prescription Drug and are, therefore, primarily used in Authenticating, "other accompanying documents" such as purchase orders and invoices should also be utilized to assist in Authenticating. For example, when such "accompanying documents" seem false or misleading, every attempt should be made to Authenticate the Prescription Drug before it is further wholesale distributed. The Board should also establish standards and procedures for Manufacturers and Wholesale Distributors to complete the Authentication process. These standards should provide consistency among Manufacturers and Wholesale Distributors.

(i) "Beyond-Use Date" means a date placed on a prescription label at the time of Dispensing that is intended to indicate to the patient or caregiver a time beyond which the contents of the prescription are not recommended to be used.[4]

(j) "Bioburden" means the total number of microorganisms associated with a specific item prior to sterilization.

(k) "Biological Safety Cabinet" means a containment unit suitable for the preparation of low to moderate risk agents where there is a need for protection of the product, personnel, and environment, according to National Sanitation Foundation (NSF) Standard 49.

(l) "Board of Pharmacy" or "Board" means the governmental regulatory body empowered to regulate pharmaceutical practices including granting and disciplining licenses of individuals and companies.

(m) "Cease and Desist" is an order of the Board prohibiting a licensee or other Person or entity from continuing a particular course of conduct that violates the Pharmacy Practice Act or its rules and regulations.[5]

(n) "Censure" is a severe formal reproof of a licensee for violation of the Pharmacy Practice Act or rules and regulations, and may require specific redress; for example, restitution of fees.

(o) "Centralized Performance Database" means aggregate data from a large number of pharmacies concerning Quality-Related Events and patients for whom pharmaceutical products and services have been provided at the pharmacies, and from which patient identifiers have been removed.

(p) "Certified Pharmacy Technician"[6] 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) Compounding; and
(4) assisting in the Dispensing process; and
(5) 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.

(q) "Chain Pharmacy Warehouse" means a permanent physical location for Drugs and/or Devices that acts as a central warehouse and performs intracompany sales and transfers of Prescription Drugs or Devices to chain Pharmacies, which are members

[4] In determining a Beyond-Use Date for a specific Drug product, the Pharmacist may use the recommendations provided in the most recent edition of the United States Pharmacopeia-National Formulary (USP-NF).

[5] No proof of actual damage is required for issuance of a Cease and Desist order.

[6] 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.

of the same affiliated group, under common ownership and control. Chain Pharmacy Warehouses must be licensed as Wholesale Distributors.

(r) "Chart Order" means a lawful order entered on the chart or a medical record of an inpatient or resident of an Institutional Facility by a Practitioner or his or her designated agent for a Drug or Device and shall be considered a Prescription Drug Order provided that it contains:

(1) the full name of the patient;
(2) date of issuance;
(3) name, strength, and dosage form of the Drug prescribed;
(4) directions for use; and
(5) if written, the prescribing Practitioner's signature or the signature of the Practitioner's agent (including the name of the prescribing Practitioner); or if electronically submitted, the prescribing Practitioner's electronic or digital signature.

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

(t) "Co-licensee" means a pharmaceutical manufacturer that has entered into an agreement with another pharmaceutical manufacturer to engage in a business activity or occupation related to the manufacture or distribution of a Prescription Drug.

(u) "Collaborative Pharmacy Practice" is that Practice of Pharmacy whereby one or more Pharmacists have jointly agreed, on a voluntary basis, to work in conjunction with one or more Practitioners under protocol and in collaboration with Practitioner(s) to provide patient care services to achieve optimal medication use and desired patient outcomes.

(v) "Collaborative Pharmacy Practice Agreement" is a written and signed agreement between one or more Pharmacists and one or more Practitioners that provides for Collaborative Pharmacy Practice as defined by law and the Rules of the Board.

(w) "Common Carrier" means any person or entity who undertakes, whether directly or by any other arrangement, to transport property including Prescription Drugs for compensation.[7]

(x) "Component" means any Active Ingredient or Added Substance intended for use in the Compounding of a Drug product, including those that may not appear in such product.

(y) "Compounding" means the preparation of Components into a Drug product (1) as the result of a Practitioner's Prescription Drug Order or initiative based on the Practitioner/patient/Pharmacist relationship in the course of professional practice, or (2) for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or Dispensing. Compounding includes the preparation of Drugs or Devices in anticipation of receiving Prescription Drug Orders based on routine, regularly observed prescribing patterns.[8]

(z) "Consumer Survey" means a systematic record of consumer perceptions of the quality of pharmaceutical products and services provided at a pharmacy.

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[7] The definition of "Common Carrier" specifically excludes Wholesale Distributors, which are defined separately.

[8] Nothing in these definitions of "Compounding" and "Manufacturing" shall preclude a Pharmacist from informing Practitioners or patients of the ability to Compound or the availability of Compounding services. (See Appendix B, Good Compounding Practices Applicable to State Licensed Pharmacies.)

(a2) "Continuous Quality Improvement Program" means a system of standards and procedures to identify and evaluate quality-related events, and to constantly enhance the efficiency and effectiveness of the structures and processes of a pharmacy system that determine the outcomes of medication use. All information, communications, or data maintained as a component of such a system shall be privileged and confidential and not subject to discovery in civil litigation.[9]

(b2) "Contraband Device" means a Device that is Counterfeit, stolen, Misbranded, obtained by fraud, purchased by a nonprofit institution for its own use and placed in commerce in violation of the own use agreement for that Device, or for which the documentation in existence has been forged, Counterfeited, falsely created, or contains any altered, false, or misrepresented information.

(c2) "Contraband Drug" means a Drug which is Counterfeit, stolen, Misbranded, obtained by fraud, purchased by a nonprofit institution for its own use and placed in commerce in violation of the own use agreement for that Drug, or for which a Pedigree (if required) does not exist, or for which the Pedigree in existence has been forged, Counterfeited, falsely created, or contains any altered, false, or misrepresented information.

(d2) "Costs/Administrative Costs" is a monetary amount assessed a licensee to cover the cost of investigation and prosecution of a disciplinary action.

(e2) "Counterfeit Device" means a Device which, or the container, shipping container, seal, or Product Labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or any likeness thereof, of a Manufacturer, processor, packer, or Distributor other than the Person or Persons who in fact Manufactured, processed, packed, Distributed, or Wholesale Distributed such Device and which thereby falsely purports or is represented to be the product of, or to have been packed, Distributed, or Wholesale Distributed by, such other Manufacturer, processor, packer, or Distributor.

(f2) "Counterfeit Drug" means a Drug which, or the container, shipping container, seal, or Product Labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or Device, or any likeness thereof, of a Manufacturer, processor, packer, or Distributor other than the Person or Persons who in fact Manufactured, processed, packed, Distributed, or Wholesale Distributed such Drug and which thereby falsely purports or is represented to be the product of, or to have been packed, Distributed, or Wholesale Distributed by, such other Manufacturer, processor, packer, or Distributor.

(g2) "Critical Areas" means areas designed to maintain sterility of sterile materials. Sterilized product, container/closures, and equipment may be exposed in critical areas.

(h2) "Critical Surfaces" are surfaces that may come into contact with or directly impact sterilized product or containers/closures.

(i2) "Cytotoxic" means a pharmaceutical that has the capability of killing living cells.

(j2) "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.

(k2) "De-identified Health Information" means Health Information that does not identify an individual and with respect to which there is no reasonable basis to believe that the

[9] States should continue efforts to develop and implement requirements for Continuous Quality Improvement (CQI) Programs in pharmacies, recognizing that CQI Programs enhance patient safety and operate most effectively when privilege of discovery laws and/or regulations protecting CQI data and information are enacted and included as a component of the CQI process.

information can be used to identify an individual. De-identified health information must meet the specifications of the de-identified health information described in the HIPAA privacy rules (45 CFR §164.514(b)).
(See comment list.)

(l2) "Deliver" or "Delivery" means the actual, constructive, or attempted transfer of a Drug or Device from one Person to another, whether or not for a consideration.

(m2) "Designated Record Set" means:

(1) A group of records maintained by or for a Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board that is:
   (i) the medical records and billing records about patients maintained by or for a Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board;
   (ii) the enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or
   (iii) used, in whole or in part, by or for the Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board to make decisions about patients.

(2) For purposes of this paragraph, the term "record" means any item, collection, or grouping of information that includes Protected Health Information and is maintained, collected, used, or disseminated by or for a Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board.

(n2) "Designated Representative" means an individual designated by the Wholesale Distributor who will serve as the responsible individual of the Wholesale Distributor with the Board who is actively involved in and aware of the actual daily operation of the Wholesale Distributor.[10]

(o2) "Device" means an instrument, apparatus, implement, machine, contrivance, implant, or other similar or related article, including any component part or accessory, which is required under Federal law to bear the label, "Caution: Federal or State law requires Dispensing by or on the order of a physician."[11]

(p2) "Digital Signature" means an electronic signature based upon cryptographic methods of originator authentication, and computed by using a set of rules and a set of parameters so that the identity of the signer and the integrity of the data can be verified.[12]

(q2) "Disinfection" means the process by which surface Bioburden is reduced to a safe level or eliminated.

(r2) "Dispense" or "Dispensing" means the interpretation, evaluation, and implementation of a Prescription Drug Order, including the preparation, final verification, and Delivery of a Drug or Device to a patient or patient's agent in a suitable container appropriately labeled for subsequent Administration to, or use by, a patient.[13]

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[10] The "Designated Representative" should serve as a liaison to the Board who is extremely knowledgeable about and involved in the daily operations of the Wholesale Distributor. If a Wholesale Distributor is licensed by multiple states, it is not necessary for the Wholesale Distributor to have multiple Designated Representatives. One Designated Representative per Wholesale Distributor facility is sufficient.

[11] States at their option may want to consider limiting the definition of "Devices" to those Devices associated with the Dispensing. Administration, or use of Drugs.

[12] Public Key Infrastructure (PKI) technology is an example of a system that provides the mechanisms to make digital signatures and encryption of messages possible.

[13] "Dispensing" includes the Delivery of a Drug or Device to the patient or the patient's agent by the Pharmacist or the Pharmacist's agent. Under the statutory definition of "Dispense" in Section 105(u2), Drugs and/or Devices mailed or shipped to a patient are not Dispensed until the Drugs and/or Devices are actually received by the patient or the patient's agent.

(s2) "Distribute" or "Distribution" means to sell, offer to sell, deliver, offer to deliver, broker, give away, or transfer a Drug, whether by passage of title, physical movement, or both. The term does not include:

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

(t2) "Drop Shipment" means the sale, by a Manufacturer, that Manufacturer's Co-Licensee, that Manufacturer's Third-Party Logistics Provider, or that Manufacturer's Exclusive Distributor, of the Manufacturer's Prescription Drug, to a Wholesale Distributor whereby the Wholesale Distributor takes title but not possession of such Prescription Drug and the Wholesale Distributor invoices the Pharmacy and the Pharmacy receives Delivery of the Prescription Drug directly from the Manufacturer, that Manufacturer's Co-Licensee, that Manufacturer's Third-Party Logistics Provider, or that Manufacturer's Exclusive Distributor, of such Prescription Drug. Drop Shipments shall be part of the "Normal Distribution Channel."

(u2) "Drug" means:

(1) articles recognized as Drugs in any official compendium, or supplement thereto, designated from time to time by the Board for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals;[14]
(2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals;
(3) articles (other than food) intended to affect the structure or any function of the body of humans or other animals; and
(4) articles intended for use as a Component of any articles specified in clause (1), (2), or (3) of this definition.

(v2) "Drug Utilization Review (DUR)" includes but is not limited to the following activities:

(1) Evaluation of the Prescription Drug Order(s) and patient record(s) for:
    (i) known allergies;
    (ii) rational therapy contraindications;
    (iii) reasonable dose, duration of use, and route of Administration, considering age, gender, and other patient factors;[15]
    (iv) reasonable directions for use;
    (v) potential or actual adverse Drug reactions;
    (vi) Drug-Drug interactions;

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[14] The official compendium recognized by Food and Drug Administration (FDA) and many State Boards of Pharmacy is the USP-NF.

[15] A "reasonable" dose, duration of use, and route of administration under "Drug Utilization Review" would be determined by taking into consideration patient-specific factors, including but not limited to, age, gender, and other patient factors, but dependent upon the information about the patient known to the pharmacist.

DUR is also known to mean "Drug Use Review"; however, "Drug Utilization Review" is the preferred term.

(vii) Drug-food interactions;
(viii) Drug-disease contraindications;
(ix) therapeutic duplication;
(x) proper utilization (including over- or under-utilization), and optimum therapeutic outcomes; and
(xi) abuse/misuse.

(w2) "Electronic Signature" means an electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record.[16]

(x2) "Emergency Medical Reasons" include, but are not limited to, transfers of a prescription Drug between a Wholesale Distributor or Pharmacy to alleviate a temporary shortage of a prescription Drug arising from delays in or interruption of regular distribution schedules; sales to nearby emergency medical services, ie, ambulance companies and firefighting organizations in the same state or same marketing or service area, or nearby licensed Practitioners of Prescription Drugs for use in the treatment of acutely ill or injured Persons; provision of minimal emergency supplies of Prescription Drugs to nearby nursing homes for use in emergencies or during hours of the day when necessary Prescription Drugs cannot be obtained; and transfers of Prescription Drugs by a retail Pharmacy to another retail Pharmacy to alleviate a temporary shortage.

(y2) "Emergency 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.

(z2) "Emergency Situations," for the purposes of authorizing an oral Prescription Drug Order of a Schedule II controlled substance, means those situations in which the prescribing Practitioner determines (1) that immediate Administration of the controlled substance is necessary for proper treatment of the patient, (2) that no appropriate alternative treatment is available, including Administration of a Drug that is not a Schedule II controlled substance, and (3) that it is not reasonably possible for the prescribing Practitioner to provide a written Prescription Drug Order to be presented to the Person Dispensing the substance, prior to the Dispensing.

(a3) "Enteral" means within or by way of the gastrointestinal tract or intestine.

(b3) "Equivalent Drug Product" means a Drug product which has the same established name, active ingredient(s), strength or concentration, dosage form, and route of Administration and which is formulated to contain the same amount of active ingredient(s) in the same dosage form and to meet the same compendial or other applicable standards (eg, strength, quality, purity, and identity), but which may differ in characteristics, such as shape, scoring, configuration, packaging, excipients (including colors, flavors, and preservatives), and expiration time.

(c3) "Exclusive Distributor" means an entity that:

(1) contracts with a Manufacturer to provide or coordinate warehousing, Wholesale Distribution, or other services on behalf of a Manufacturer and who takes title to that Manufacturer's Prescription Drug, but who does not have general

[16] The term "Electronic Signature" may have different meanings in various State laws and regulations. It is important to distinguish between "Electronic Signatures" and "Digital Signatures," which provide a much higher level of security for electronically transmitted information. It is anticipated that federal controlled substance regulations will soon allow for the transmission of controlled substance prescriptions provided that Digital Signatures are used. At that time, states may want to consider requiring Digital signatures as part of all electronically transmitted prescriptions.

responsibility to direct the sale or disposition of the Manufacturer's Prescription Drug; and

(2) is licensed as a Wholesale Distributor under this chapter.

(d3) "External Entities" means those organizations that exist outside of the pharmacist-patient relationship and that participate in the implementation of Patient Compliance and Patient Intervention Programs. External Entities include, but are not limited to, health insurance carriers, health benefit management companies, and health care marketing enterprises. [Note: Depending on the activities conducted by External Entities, they may be construed as "business associates" as defined under HIPAA and its related privacy rules (45 CFR Part 160). If so, HIPAA and its privacy rules that apply to those External Entities acting as business associates shall take precedence over contrary state law. In addition, "business associate agreements," as defined under HIPAA and its privacy rules, shall be required between a Pharmacist or Pharmacy and the External Entity acting as a business associate so as to prevent the unauthorized use or disclosure of Protected Health Information.]

(e3) "FDA" means 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.

(f3) "Federal Act" means the Federal Food, Drug, and Cosmetic Act.

(g3) "Fill date" means the actual date a new or refilled prescription is dispensed but not necessarily delivered to a patient from a pharmacy.

(h3) "Fine/Civil Penalty" is a monetary penalty assessed a licensee for violation of the Pharmacy Practice Act or rules and regulations.

(i3) "Health Care Entity" means any Person that provides diagnostic, medical, surgical, dental treatment, or rehabilitative care but does not include any retail Pharmacy or Wholesale Distributor.

(j3) "Health Care Operations" means any of the following activities of the Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board to the extent that the activities are related to the provision of Pharmacist Care services:

(1) conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities; population-based activities relating to improving health or reducing health care costs, protocol development, case management and care coordination, contacting of health care providers and patients with information about treatment alternatives; and related functions that do not include treatment;

(2) reviewing the competence or qualifications of health care professionals, evaluating practitioner and provider performance, health plan performance, conducting training programs in which students, trainees, or practitioners in areas of health care learn under supervision to practice or improve their skills as health care providers, training of non-health care professionals, accreditation, certification, licensing, or credentialing activities;

(3) underwriting, premium rating, and other activities relating to the creation, renewal, or replacement of a contract of health insurance or health benefits, and ceding, securing, or placing a contract for reinsurance of risk relating to claims for health care (including stop-loss insurance and excess of loss insurance),[17]

[17] 45 CFR §164.514(g) reads:
Standard: uses and disclosures for underwriting and related purposes. If a health plan receives protected heath information for the purpose of underwriting, premium rating, or other activities relating to the creation, renewal, or replacement of a contract of health

provided that the requirements of 45 CFR §164.514(g) are met, if applicable;

(4) conducting or arranging for medical review, legal services, and auditing functions, including fraud and abuse detection and compliance programs;

(5) business planning and development, such as conducting cost-management and planning-related analyses related to managing and operating the entity, including formulary development and Administration, development, or improvement of methods of payment or coverage policies; and

(6) business management and general administrative activities, including, but not limited to:

(i) management activities relating to implementation of and compliance with the requirements of this Act;

(ii) customer service, including the provision of data analyses for policy holders, plan sponsors, or other customers, provided that Protected Health Information is not disclosed to such policy holder, plan sponsor, or customer;

(iii) resolution of internal grievances;

(iv) the sale, transfer, merger, or consolidation of all or part of the Pharmacy, Pharmacy Benefits Manager, or other entity that is or will be licensed or registered by the Board with another Pharmacy, Pharmacy Benefits Manager, or other entity licensed or registered by the Board and due diligence related to such activity; and

(v) creating de-identified health information or a limited data set, and fundraising for the benefit of the Pharmacy, Pharmacy Benefits Manager, or other entity licensed or registered by the Board.[18]

(k3) "Health Information" means any information, whether oral or recorded in any form or medium, that:

(1) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse, and

(2) relates to the past, present, or future physical or mental health or condition of an individual; or the past, present, or future payment for the provision of health care to an individual.

(l3) "HIPAA" is the federal Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191) and any amendments thereof.

(m3) "Home Infusion Pharmacy" means a Pharmacy that Compounds solutions for direct Administration to a patient in a private residence, Long-Term Care Facility, or hospice setting by means of parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion.

(n3) "Immediate Container" means a container and does not include package liners.

(o3) "Individually Identifiable Health Information" is information that is a subset of Health Information, including demographic information collected from an individual and

(1) is created or received by a health care provider, health plan, employer, or health care clearinghouse; and

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insurance or health benefits, and if such health insurance or health benefits are not placed with the health plan, such health plan may not use or disclose such protected health information for any other purpose, except as may be required by law.

[18] The word "fundraising" is contemplated to refer to generation of revenue through the sale of data, and is not intended to be used in the charitable sense.

(2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and
   (i) that identifies the individual; or
   (ii) with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

(p3) "Institutional Facility" means any organization whose primary purpose is to provide a physical environment for patients to obtain health care services, including but not limited to a(n):
(1) hospital;
(2) Long-Term Care Facility;
(3) convalescent home;
(4) nursing home;
(5) extended care facility;
(6) mental health facility;
(7) rehabilitation center;
(8) psychiatric center;
(9) developmental disability center;
(10) Drug abuse treatment center;
(11) family planning clinic;
(12) penal institution;
(13) hospice;
(14) public health facility; and
(15) athletic facility.

(q3) "Institutional Pharmacy" means any place that is registered with the State Board of Pharmacy pursuant to Article V of the Pharmacy Practice Act that provides Pharmacist Care to an Institutional Facility and where Drugs, Devices, and other materials used in the diagnosis and treatment of injury, illness, and disease (hereinafter referred to as "Drugs") are Dispensed, Compounded, and Distributed.

(r3) "Internal Test Assessment" means, but is not limited to, conducting those tests of quality assurance necessary to ensure the integrity of the test.

(s3) "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.

(t3) "ISO Class" means the description of an atmospheric environment characterized by the number of particles within a diameter per cubic foot of air.

(u3) "Isolator" means a decontaminated unit, supplied with ISO Class 5 or higher air quality that provides uncompromised, continuous isolation of its interior from the external environment (eg, surrounding cleanroom air and Compounding Pharmacy personnel).

(v3) "Label" means a display of written, printed, or graphic matter upon the immediate container of any Drug or Device.

(w3) "Labeling" means the process of preparing and affixing a label to any Drug container exclusive, however, of the Labeling by a Manufacturer, packer, or Distributor of a Non Prescription Drug or commercially packaged Legend Drug or Device. Any such label shall include all information required by Federal and State law or rule.

(x3) "Long-Term Care Facility" means a nursing home, retirement care, mental care, or other facility or institution that provides extended health care to resident patients.

(y3) "Manufacturer" means a Person engaged in the Manufacture of Drugs or Devices.[19]

(z3) "Manufacturing" means the production, preparation, propagation, conversion, or processing of a Drug or Device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis. Manufacturing includes the packaging or repackaging of a Drug or Device or the Labeling or relabeling of the container of a Drug or Device for resale by pharmacies, Practitioners, or other Persons.[20]

(a4) "Marketing" means:

(1) To make a communication about a product or service that encourages recipients of the communication to purchase or use the product or service, unless the communication is made:

(i) to describe a health-related product or service (or payment for such product or service) that is provided by, or included in a plan of benefits of, the covered entity making the communication, including communications about the entities participating in a health care provider network or health plan network; replacement of, or enhancements to, a health plan; and health-related products or services available only to a health plan enrollee that add value to, but are not part of, a plan of benefits;

(ii) for treatment of the patient; or

(iii) for case management or care coordination for the patient, or to direct or recommend alternative treatments, therapies, health care providers, or settings of care to the patient.

(2) An arrangement between a Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board, and any other entity whereby the Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board discloses Protected Health Information to the other entity in exchange for direct or indirect remuneration, for the other entity or its affiliate to make a communication about its own product or service that encourages recipients of the communication to purchase or use that product or service.

(b4) "Medical Order" means a lawful order of a Practitioner that may or may not include a Prescription Drug Order.

(c4) "Medication Adherence Monitoring Service" is defined as any structured activity that complements or supplements the existing responsibilities regarding the Dispensing of prescriptions and associated Patient Counseling, and that uses Protected Health Information to contact the patient or caregiver via phone, print, electronic media, or other means of communication, in order to improve patient compliance with and adherence to prescribed medication therapy and that involves the collection and analysis of data related to patient medication use.[21] Medication Adherence

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[19] "Manufacturer" is also defined as a Wholesale Distributor in the *Model Act*. Therefore, all of the conditions, requirements, and prohibited and criminal acts would apply to Manufacturers in states where applicable definitions and sections of the *Model Act* were adopted. An integral component of the licensing of Manufacturers as Wholesale Distributors to prevent or detect Counterfeit or Contraband Drugs or Devices is the requirement for the development, maintenance, and release of the Manufacturer's approved list of Authorized Distributors or Authorized Distributors of Record. Failure to do so would preclude licensure and, if the Manufacturer is licensed, could be grounds for suspension or revocation of the license.

[20] Nothing in these definitions of "Compounding" and "Manufacturing" shall preclude a Pharmacist from informing Practitioners or patients of the ability to Compound or the availability of Compounding services. (See Appendix B, Good Compounding Practices Applicable to State Licensed Pharmacies.)

[21] Compliance refers to taking actions necessary to ensure patients receive prescribed medications initially, whereas adherence refers to taking actions necessary to ensure that medication therapy is continued.

Monitoring Services may incorporate such efforts as refill reminder and patient education programs.

(d4) "Medication Synchronization" refers to a component of Medication Therapy Management that provides authority, at the patient's direction, for the pharmacist to adjust a patient's medication quantity or refill schedule, and the authority to provide the patient with a one-time synchronization refill, in order to manage a patient's maintenance medications and coordinate the dosing schedules to complement the patient's life schedule, unless deemed inappropriate by the prescribing Practitioner.

(See comment list.)

(e4) "Medication Therapy Management" is a distinct service or group of services that optimize therapeutic outcomes for individual patients. Medication Therapy Management services are independent of, but can occur in conjunction with, the provision of a medication or a medical device. Medication Therapy Management encompasses a broad range of professional activities and responsibilities within the licensed Pharmacist's scope of practice. These services may include, but are not limited to, the following, according to the individual needs of the patient:

(1) performing or obtaining necessary assessments of the patient's health status;
(2) formulating a medication treatment plan;
(3) selecting, initiating, modifying, or administering medication therapy;
(4) monitoring and evaluating the patient's response to therapy, including safety and effectiveness;
(5) performing a comprehensive medication review to identify, resolve, and prevent medication-related problems, including adverse drug events;
(6) documenting the care delivered and communicating essential information to the patient's other primary care providers;
(7) providing verbal education and training designed to enhance patient understanding and appropriate use of his or her medications;
(8) providing information, support services and resources designed to enhance patient adherence with his or her therapeutic regimens, such as Medication Synchronization;
(9) coordinating and integrating Medication Therapy Management services within the broader health care management services being provided to the patient; and
(10) such other patient care services as may be allowed by law.

(f4) "Misbranded": A Drug or Device shall be deemed to be misbranded if the label is false or misleading in any particular; or the label does not bear the name and address of the Manufacturer, packer, or Distributor and does not have an accurate statement of the quantities of the active ingredients in the case of a Drug; or the label does not show an accurate monograph for Prescription Drugs.

(g4) "Mobile Pharmacy" means a Pharmacy that is self-propelled or movable by another vehicle that is self-propelled.

(h4) "National Association of Boards of Pharmacy (NABP)" means the association whose members are the Boards of Pharmacy, which association was established to assist Boards in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health.

(i4) "Non-Prescription Drug" means a Drug that may be sold without a prescription and that is labeled for use by the consumer in accordance with the requirements of the laws and rules of this State and the Federal government.

(j4) "Nonresident Pharmacy" means a Pharmacy located outside this State.

(k4) "Normal Distribution Channel" means a chain of custody for a Prescription Drug that goes from a Manufacturer of the Prescription Drug, the Manufacturer's Co-Licensee,

the Manufacturer's Third-Party Logistics Provider, or the Manufacturer's Exclusive Distributor to:

(1) a Wholesale Distributor to a Pharmacy to a patient or other designated persons authorized by law to dispense or administer such Prescription Drug to a patient; or

(2) a Wholesale Distributor to a Chain Pharmacy Warehouse to that Chain Pharmacy Warehouse's intracompany Pharmacy to a patient or other designated persons authorized by law to dispense or administer such Prescription Drug to a patient; or

(3) a Chain Pharmacy Warehouse to that Chain Pharmacy Warehouse's intracompany Pharmacy to a patient or other designated persons authorized by law to dispense or administer such Prescription Drug to a patient; or

(4) as prescribed by the Board's regulations.

(l4) "Nuclear Pharmacy" means a Pharmacy providing radiopharmaceutical services or, as provided in the Model Rules for Nuclear/Radiologic Pharmacy, appropriate area of any Institutional Facility.

(m4) "Parenteral" means by some other route than through the gastrointestinal tract such as, but not limited to, intravenous, subcutaneous, or intramuscular routes.

(n4) "Patient Counseling" means the oral communication by the Pharmacist of information, as defined in the rules of the applicable Board, to the patient or caregiver, in order to ensure proper use of Drugs and Devices.

(o4) "Patient Intervention Program" is defined as any structured activity that complements or supplements the existing responsibilities regarding the Dispensing of prescriptions and associated Patient Counseling, and that uses Protected Health Information to contact the patient or caregiver via phone, print, electronic media, or other means of communication, to discuss, inform, and/or affect patient therapy or choice of medications.

(p4) "Pedigree" means a statement or record in a written form or electronic form, approved by the Board, that records each Wholesale Distribution of any given Prescription Drug (excluding Veterinary Prescription Drugs), which leaves the Normal Distribution Channel. Effective December 31, 2007, Pedigrees shall electronically record, for all Prescription Drugs, each Wholesale Distribution starting with the sale by a Manufacturer through acquisition and sale by any Wholesale Distributor, until final sale to a Pharmacy or other authorized Person Administering or Dispensing the Prescription Drug.[22] The Pedigree shall minimally include the following information for each transaction:

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

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[22] The "Pedigree" should contain the names and addresses of each person certifying delivery or receipt of the Prescription Drug. "Certifying" is to attest and confirm the actual delivery and receipt of the Drug via a signature or other acceptable means as approved by the Board on the Pedigree.

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

NABP recognizes that technology must be available in order for a Wholesale Distributor to comply with the electronic Pedigree requirements. States should monitor the availability of technology in developing statutes and rules and allow for variances if the technologies needed to comply with the requirements of the Pedigree provisions are not available. In addition, consideration must be given related to the large-scale implementation of this technology across the supply chain and the technology must be proven to have no negative impact on the safety and efficacy of pharmaceutical product; however, implementation should not be unnecessarily delayed.

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

(q4) "Peer Review" means a process that is part of an outcome-based, continuous quality improvement process that involves:
(1) the setting and periodic re-evaluation of standards for quality by which a pharmacy operation will be evaluated:
(2) the collection of data necessary to identify when those standards are not being met and data necessary to evaluate the reason(s) the deficiency occurred;
(3) an objective review of the data by an appropriate peer review committee to make recommendations for quality improvement; and
(4) an appropriate feedback mechanism to ensure that the process is operating in a manner that continually improves the quality of care provided to patients.
(i) Peer review should not be a punitive activity or a performance evaluation.

(r4) "Peer Review Committee" [23]means:
(1) a committee that is authorized to evaluate the quality of pharmacy services or the competence of pharmacists and suggest improvements in pharmacy systems to enhance patient care; or
(2) a committee established by a person who owns a pharmacy or employs pharmacists that is authorized to evaluate the quality of pharmacy services or the competence of pharmacists and suggest improvements in pharmacy systems to enhance patient care.

(s4) "Person" means an individual, corporation, subsidiary, partnership, association, organization, affiliate organization, or any other legal entity, including government.

(t4) "Pharmacist" means an individual currently licensed by this State to engage in the Practice of Pharmacy. A Pharmacist is entitled to engage in the Practice of Pharmacy, as defined in this chapter, within or outside of a licensed Pharmacy, as defined in the Rules of the Board.

(u4) "Pharmacist Care" is the provision by a Pharmacist of patient care activities, as defined by the Rules of the Board, with or without the Dispensing of Drugs or Devices, intended to achieve outcomes related to the cure or prevention of a disease,

[23] A Peer Review Committee may be established to evaluate the quality of Pharmacy services or the competence of pharmacists and suggest improvements in Pharmacy systems to enhance patient care. Peer Review Committees may review documentation of quality-related activities in a pharmacy, assess system failures and personnel deficiencies, determine facts, and make recommendations or issue decisions in a written report that can be used for Continuous Quality Improvement purposes. A Peer Review Committee may include the members, employees, and agents of the committee, including assistants, investigators, attorneys, and any other agents that serve the committee in any capacity.

elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process.[24]

(v4) "Pharmacist-in-Charge" means a Pharmacist currently licensed in this State who accepts responsibility for the operation of a Pharmacy in conformance with all laws and rules pertinent to the Practice of Pharmacy and the Distribution of Drugs, and who is personally in full and actual charge of such Pharmacy and personnel.

(w4) "Pharmacist's Scope of Practice Pursuant to the Collaborative Pharmacy Practice Agreement" means those duties and limitations of duties placed upon one or more Pharmacists by the collaborating Practitioner or Practitioners, the Board, and applicable law, and includes the limitations implied by the scope of practice of the collaborating Practitioner or Practitioners.

(x4) "Pharmacy" means any place within this State where Drugs are Dispensed and Pharmacist Care is provided and any place outside of this State where Drugs are Dispensed and Pharmacist Care is provided to residents of this State.

(See comment list.)

(y4) "Pharmacy Benefits Manager" means a Person that Administers the Prescription Drug/Device portion of health insurance plans on behalf of plan sponsors, such as self-insured employers, insurance companies, and health maintenance organizations, and that engages in or directs the Practice of Pharmacy.

(See comment list.)

(z4) "Pharmacy Intern"[25] means an individual who is:

(1) currently licensed by this State to engage in the Practice of Pharmacy while under the supervision of a Pharmacist and is enrolled in a professional degree program of a school or college of pharmacy that has been approved by the Board and is satisfactorily progressing toward meeting the requirements for licensure as a Pharmacist; or

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

(3) a qualified applicant awaiting examination for licensure or meeting Board requirements for re-licensure; or

(4) an individual participating in a residency or fellowship program.

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[24] Objectives of Pharmacist Care include cure of a disease, elimination or reduction of a patient's symptomatology, arresting or slowing of a disease process, or prevention of a disease or symptomatology. Pharmacist Care should be provided by all Pharmacists to the extent of their abilities regardless of the practice setting.

[25] Most Pharmacy Interns are either enrolled in a professional degree program or postgraduate program (residency or fellowship), or have graduated from a Board-approved professional degree program and are awaiting examination. In some cases, however, Boards of Pharmacy also designate pharmacists whose licenses have lapsed or been inactive for a significant period of time as "Pharmacy Intern," allowing these pharmacists to obtain practical experience so that their licenses can be reactivated. Additionally, Boards may grant the "Pharmacy Intern" designation to those Pharmacists seeking practical experience following a period of license suspension or revocation.

Boards of Pharmacy may consider limiting the Pharmacy Interns' duration of registration especially if the boards find that Pharmacy Interns are not successfully progressing toward Pharmacist Licensure in an acceptable and reasonable time frame.

(a5) "Pharmacy Technician"[26] 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.

(b5) "Positive Patient Outcomes" include the cure or prevention of disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process so as to improve the patient's quality of life.

(c5) "Practice Accountability Audit" means an evaluation of the Centralized Performance Database to determine which pharmacies are consistently in violation of Criteria and/or standards.

(d5) "Practice of Telepharmacy" means the provision of Pharmacist Care by registered Pharmacies and Pharmacists located within US jurisdictions through the use of telecommunications or other technologies to patients or their agents at distances that are located within US jurisdictions.[27]

(e5) "Practice of Telepharmacy Across State Lines" means the Practice of Telepharmacy when the patient is located within a US jurisdiction and the pharmacist is located in a different US jurisdiction.

(f5) "Practitioner" means an individual currently licensed, registered, or otherwise authorized by the appropriate jurisdiction to prescribe and Administer Drugs in the course of professional practice.[28]

(g5) "Preceptor" means an individual who is currently licensed as a Pharmacist by the Board of Pharmacy, meets the qualifications as a Preceptor under the Rules of the Board, and participates in the instructional training of Pharmacy Interns.[29]

(h5) "Prepackaging" means the act of transferring a Drug, manually or by use of an Automated Pharmacy System, from a Manufacturer's or Distributor's original

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[26] 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.

[27] The "Practice of Telepharmacy" is deemed to occur within the jurisdiction in which the patient is located and the jurisdiction(s) in which the pharmacist and, if applicable, pharmacy are located; therefore, such practice will be subject to the Pharmacy practice regulations of all jurisdictions' Boards of Pharmacy.

[28] The definition of "Practitioner" anticipates that those persons other than Pharmacists who are permitted to prescribe and Administer Drugs will be specifically so authorized in other legislation.

[29] Preceptors should be appropriately qualified and possess ample experience for the proper instructional training of Pharmacy Interns. It is strongly encouraged that Preceptors pursue continuing professional development for their practitioner-educator role expectations.

container to another container in advance of receiving a Prescription Drug Order or for a Patient's immediate need for Dispensing by a Pharmacy or Practitioner authorized to Dispense in the establishment in which the Prepackaging occurred.

(i5) "Prescription Drug" or "Legend Drug" means a Drug that is required under Federal law to be labeled with either of the following statements prior to being Dispensed or Delivered: (1) "Rx Only"; or (2) "Caution: Federal law restricts this Drug to use by, or on the order of, a licensed veterinarian"; or (3) a Drug that is required by any applicable Federal or State law or rule to be Dispensed pursuant only to a Prescription Drug Order or is restricted to use by Practitioners only.

(j5) "Prescription Drug Order" means a lawful order from a Practitioner for a Drug or Device for a specific patient, including orders derived from Collaborative Pharmacy Practice, where a valid Patient-Practitioner relationship exists, that is communicated to a Pharmacist in a licensed Pharmacy.

(k5) "Primary Care" is the first level of contact of individuals, the family, and the community with the health care delivery system, bringing health care as close as possible to where people live and work, and constitutes the first element of a continuing health care process. (Areas of Primary Care where Pharmacists provide Pharmacist Care include, but are not limited to, the following: chronic disease management; smoking cessation; maternal and child health; immunizations; family planning; self-care consulting; Drug selection under protocol; treatment of common diseases and injuries; nutrition; and general health education and promotion.)

(l5) "Probation" is a restriction of Pharmacy practice for a specified period of time.[30]

(m5) "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.

(n5) "Product Quality and Characteristics" include sterility, potency, identity, strength, quality, and purity associated with environmental quality, preparation activities, and checks and tests.

(o5) "Professional Performance Evaluation" means a peer review process in which a competency assessment is made of a pharmacist by another pharmacist for the purpose of improving the quality of the evaluated pharmacist's performance.

(p5) "Prospective Drug Utilization Review (DUR)" means a review of the patient's Drug therapy and Prescription Drug Order as part of a Drug Utilization Review, as defined in the rules of the Board, prior to Dispensing the Drug.

(q5) "Protected Health Information" means Individually Identifiable Health Information:

(1) Except as provided in paragraph (2) of this definition, that is:
   (i) transmitted by electronic media;
   (ii) maintained in any medium described in the definition of electronic media at §162.103 of the HIPAA privacy rules (45 CFR Part 160);
   (iii) transmitted or maintained in any other form or medium.

(2) Protected health information excludes individually identifiable health information in:
   (i) education records covered by the Family Educational Right and Privacy Act, as amended 20 USC 1232(g);
   (ii) records described at 20 USC 1232(g)(4)(B)(iv); and
   (iii) employment records held by a licensee in its role as an employer.

(See comment list.)

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[30] Licensee may be placed on Probation for a period of time subject to specific conditions determined by the Board. Probation may result from the Board's decision to stay a license Revocation or Suspension judgment. The licensee may be permitted to continue practice only within conditions established by the Board, and violation of those conditions will end the stay and result in Revocation or Suspension.

(r5) "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 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.

(s5) "Qualified Licensed Professional" means a non-Pharmacist individual (such as a physician, nurse, or technologist) who possesses a current state license, if applicable, and who has sufficient training and experience to safely handle and Dispense radiopharmaceuticals as defined by the respective requirements of [cite appropriate Nuclear Regulatory Commission (NRC) or Agreement State and State Board of Pharmacy law(s)].

(t5) "Qualified Nuclear Pharmacist" means a currently licensed Pharmacist in the State of practice, who is certified as a Nuclear Pharmacist by the State Board of Pharmacy or by a certification Board recognized by the State Board of Pharmacy, or who meets the following standards:

(1) Minimum standards of training for "authorized user status" of radioactive material [cite State Radiation Control Agency or NRC licensure guide].
(2) Completed a minimum of 200 contact hours of instruction in nuclear Pharmacy and the safe handling and the use of radioactive materials from a program approved by the State Board of Pharmacy, with emphasis in the following areas:
    (i) radiation physics and instrumentation;
    (ii) radiation protection;
    (iii) mathematics of radioactivity;
    (iv) radiation biology; and
    (v) radiopharmaceutical chemistry.
(3) Attained a minimum of 500 hours of clinical nuclear Pharmacy training under the supervision of a qualified nuclear Pharmacist.

(u5) "Quality-Related Event" means any departure from the appropriate Dispensing of a prescribed medication that is or is not corrected prior to the Delivery and/or Administration of the medication.[31] The term "Quality-Related Event" includes:

(1) a variation from the prescriber's prescription drug order, including, but not limited to:
    (i) incorrect Drug;
    (ii) incorrect Drug strength;
    (iii) incorrect dosage form;
    (iv) incorrect patient; or
    (v) inadequate or incorrect packaging, labeling, or directions;
(2) a failure to identify and manage:
    (i) over-utilization or under-utilization;
    (ii) therapeutic duplication;
    (iii) drug-disease contraindications;
    (iv) drug-drug interactions;
    (v) incorrect drug dosage or duration of drug treatment;
    (vi) drug-allergy interactions; or
    (vii) clinical abuse/misuse.
(3) The term also includes packaging or warnings that fail to meet recognized standards, the Delivery of a medication to the wrong patient, and the failure to

[31] Quality-Related Events may be recorded using the Community Pharmacy Quality-Related Event Data Collection Form found in Appendix F.

detect and appropriately manage a significant actual or potential problem with a patient's drug therapy.

(v5) "Quality Self-Audit" means an internal evaluation at a pharmacy to assess the effectiveness of the Continuous Quality Improvement (CQI) Program.

(w5) "Radiopharmaceutical Quality Assurance" means, but is not limited to, the performance of appropriate chemical, biological, and physical tests on potential radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals, including internal test assessment, authentication of product history, and the keeping of proper records.

(x5) "Radiopharmaceutical Service" means, but shall not be limited to, the procurement, storage, handling, preparation, Labeling, quality assurance testing, Dispensing, Delivery, record keeping, and disposal of radiopharmaceuticals and other Drugs.

(y5) "Radiopharmaceuticals" are radioactive Drugs as defined by Food and Drug Administration (FDA) and the State Board of Pharmacy [cite appropriate law(s)].

(z5) "Repackage" means changing the container, wrapper, quantity, or Product Labeling of a Drug or Device to further the Distribution of the Drug or Device.

(a6) "Repackager" means a Person who Repackages.

(b6) "Repository Program" means a program that is established to receive previously dispensed medications and redispense such to qualified individuals and/or to facilitate the proper disposal of unacceptable medications in compliance with state and environmental regulations.

(c6) "Reprimand" is a formal reproof of a licensee for violation of the Pharmacy Practice Act or rules and regulations.

(d6) "Revocation" is the withdrawal of the license to practice Pharmacy. The Person no longer has the privilege to practice in the State.

(e6) "Risk Level" of the Sterile Pharmaceutical means the level assigned to a Sterile Pharmaceutical by a Pharmacist that represents the probability that the Sterile Pharmaceutical will be contaminated with microbial organisms, spores, endotoxins, foreign chemicals, or other physical matter.

(f6) "Sales Unit" means the unit of measure the manufacturer uses to invoice its customer for the particular product.

(g6) "Shared Pharmacy Services" means a system that allows a participating Pharmacist or Pharmacy pursuant to a request from another participating Pharmacist or Pharmacy to process or fill a Prescription Drug Order, which may include preparing, packaging, Labeling, Compounding for specific patients, Dispensing, performing Drug Utilization Reviews, conducting claims adjudication, obtaining refill authorizations, reviewing therapeutic interventions, and/or reviewing institutional facility orders.

(h6) "Significant Adverse Drug Reaction" means any Drug-related incident that may result in serious harm, injury, or death to the patient.

(i6) "Significant Quality-Related Event" means any Quality-Related Event that results in serious harm, injury, or death to the patient.

(j6) "Significant Loss" means any loss of a Prescription Drug that exceeds a reasonable level established by like persons, which requires that loss to be reported to the Board or as required by Drug Enforcement Administration (DEA) or other state and/or federal agencies for Prescription Drugs and controlled substances.[32]

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[32] Some factors to consider in determining a Significant Loss include:
(a) the actual quantity of Prescription Drugs or controlled substances lost in relation to the type of business;
(b) the specific Prescription Drugs or controlled substances lost;

(k6) "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.

(l6) "Sterile Pharmaceutical" means any dosage form of a drug, including but not limited to, parenterals (eg, injectables, surgical irrigants, and ophthalmics) devoid of viable microorganisms.

(m6) "Summary Suspension" is the Suspension of a license, which requires a licensee to cease Pharmacy practice immediately pending the results of a timely hearing.[33]

(n6) "Suspension" is the withdrawal of the license to practice Pharmacy in the State for a specified period of time.

(o6) "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.

(p6) "Third-Party Logistics Provider" means an entity that:

(1) Provides or coordinates warehousing, Distribution, or other services on behalf of a Manufacturer, but does not take title to the Prescription Drug or have general responsibility to direct the Prescription Drug's sale or disposition; and

(2) Is licensed as a Wholesale Distributor under this chapter.

(q6) "USP Standards" means standards published in the current official United States Pharmacopeia or National Formulary.

(See comment list.)

(r6) "Valid Patient-Practitioner Relationship" means the following have been established:

(1) a Patient has a medical complaint;

(2) a medical history has been taken;

(3) a face-to-face physical examination adequate to establish the medical complaint has been performed by the prescribing practitioner or in the instances of telemedicine through telemedicine practice approved by the appropriate Practitioner Board; and

(4) some logical connection exists between the medical complaint, the medical history, and the physical examination and the Drug prescribed.

(s6) "Warning" is a written notice issued to a licensee addressing possible errant conduct.[34]

(t6) "Wholesale Distribution" means the Distribution of Prescription Drugs or Devices by Wholesale Distributors to Persons other than consumers or patients, and includes the transfer, Distribution, or sale of Prescription Drugs by a Pharmacy to another Pharmacy or from a Pharmacy to a Practitioner, only for the purpose of Dispensing or Administration, but not for resale; if the value of the goods transferred exceeds five

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(c) whether the loss of the Prescription Drugs or controlled substances can be associated with access to those Prescription Drugs or controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the Prescription Drugs or controlled substances;

(d) a pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses;

(e) whether the specific Prescription Drugs or controlled substances are likely candidates for diversion; and

(f) local trends and other indicators of the diversion potential of the missing Prescription Drug or controlled substance.

If it is determined that the loss is not significant, a record of the occurrence should be kept for future reference. When a Significant Loss occurs in a Pharmacy that is registered in multiple states, all applicable Boards should be notified.

[33] If the Board believes it necessary to protect the public health and safety, it may summarily Suspend a license and order a prompt hearing on the matters in question.

[34] A Warning may require that the licensee provide the Board with clarifying information. (May also be known as a Letter of Concern or Letter of Admonition.)

percent (5%) of total Prescription Drug sales revenue of either the transferor or transferee Pharmacy during any consecutive twelve (12)-month period, providing that such transfers are compliant with federal law. To the extent permitted by the Prescription Drug Marketing Act, Wholesale Distribution does not include[35]:

(1) the sale, purchase, or trade of a Prescription Drug or Device, an offer to sell, purchase, or trade a Prescription Drug or Device, or the Dispensing of a Prescription Drug or Device pursuant to a Prescription;
(2) the sale, purchase, or trade of a Prescription Drug or Device or an offer to sell, purchase, or trade a Prescription Drug or Device for Emergency Medical Reasons;
(3) Intracompany Transactions, unless in violation of own use provisions;
(4) the sale, purchase, or trade of a Prescription Drug or Device or an offer to sell, purchase, or trade a Prescription Drug or Device among hospitals, Chain Pharmacy Warehouses, Pharmacies, or other health care entities that are under common control;
(5) the sale, purchase, or trade of a Prescription Drug or Device or the offer to sell, purchase, or trade a Prescription Drug or Device by a charitable organization described in 503(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;
(6) the purchase or other acquisition by a hospital or other similar health care entity that is a member of a group purchasing organization of a Prescription Drug or Device for its own use from the group purchasing organization or from other hospitals or similar health care entities that are members of these organizations;
(7) the transfer of Prescription Drugs or Devices between Pharmacies pursuant to a Centralized Prescription Processing agreement;
(8) the sale, purchase, or trade of blood and blood components intended for transfusion;
(9) the return of recalled, expired, damaged, or otherwise non-salable Prescription Drugs, when conducted by a hospital, health care entity, Pharmacy, or charitable institution in accordance with the Board's regulations;
(10) the sale, transfer, merger, or consolidation of all or part of the business of a retail Pharmacy or Pharmacies from or with another retail Pharmacy or Pharmacies, whether accomplished as a purchase and sale of stock or business assets, in accordance with the Board's regulations; or
(11) other transactions excluded from the definition of "Wholesale Distribution" under 21 CFR 203.3(CC), including any amendments thereto.

(u6) "Wholesale Distributor" means any Person engaged in Wholesale Distribution of Prescription Drugs or Devices in or into the State, including but not limited to Manufacturers, Repackagers, own-label distributors, private-label distributors, jobbers, brokers, warehouses, including Manufacturers' and Distributors' warehouses, Co-licensees, Exclusive Distributors, Third-Party Logistics Providers, Chain

[35] Although "Devices" is included in both definitions of "Wholesale Distribution" and "Wholesale Distributor," federal law and some State laws do not define "Wholesale Distribution" as such. Wherever appropriate under the Model Rules, the term is included and recognized that Wholesale Distribution also includes Devices. A disparity could be caused if those persons that only distribute Devices are not currently licensed by the State and, therefore, not subject to regulation by the Board. Different requirements and standards would exist for these persons than would apply for persons who Distribute both Drugs and Devices. It is NABP's position that persons that Manufacture and/or Distribute Devices should be licensed with the Board and adhere to the same requirements as those in place for persons that Manufacture and/or Distribute Drugs. In developing laws and rules, states may need to review their current regulations regarding licensure for persons that solely Manufacture and/or Distribute Devices in order to determine the applicability of the Model Rules to persons that Manufacture and/or Distribute Devices.

Pharmacy Warehouses, and Wholesale Drug warehouses, independent Wholesale Drug traders, and retail Pharmacies that conduct Wholesale Distributions.[36]

[36] "Wholesale Distributor" may be used interchangeably with Wholesaler and, as defined by the Prescription Drug Marketing Act of 1987, includes Manufacturers.

Comments

Section 104. Comment.

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. Additionally, the definition limits certain activities to performance by Pharmacists only, while allowing qualified personnel to assist Pharmacists in practice. That distinction is noted by listing activities that must be performed by the Pharmacist, such as the interpretation, evaluation, and implementation of Medical Orders; the Dispensing of Prescription Drug Orders; Drug and Device selection; Drug Administration; Drug Utilization Review (DUR); the Practice of Telepharmacy within and across state lines; Drug or Drug-related research; Patient Counseling; Pharmacist Care; and other tasks that the Pharmacist has responsibility for, such as Compounding and Labeling of Drugs and Devices; the proper and safe storage of Drugs and Devices, and maintenance of proper records. The deliberate distinction between the terms "must perform" and "is responsible for" intends to allow delegation of tasks to Certified Pharmacy Technicians or Pharmacy Technicians.

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.

NABP recognizes that protection of the public health should extend across state borders. Accordingly, the NABP *Model Act* incorporates the Practice of Telepharmacy Across State Lines within the scope of the "Practice of Pharmacy."

Section 105(k2). Comment.

45 CFR §164.514(b) reads:

> "requirements for de-identification of protected health information. A covered entity may determine that health information is not individually identifiable health information only if:
> (1) A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable:
> (i) Applying such principles and methods, determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information; and
> (ii) Documents the methods and results of the analysis that justify such determination; or
> (2)(i) The following identifiers of the individual or of relatives, employers, or household members of the individual, are removed:
> (A) Names;
> (B) All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:
> (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and

(2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
(C) All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
(D) Telephone numbers;
(E) Fax numbers;
(F) Electronic mail addresses;
(G) Social security numbers;
(H) Medical record numbers;
(I) Health plan beneficiary numbers;
(J) Account numbers;
(K) Certificate/license numbers;
(L) Vehicle identifiers and serial numbers, including license plate numbers;
(M) Device identifiers and serial numbers;
(N) Web Universal Resource Locators (URLs);
(O) Internet Protocol (IP) address numbers;
(P) Biometric identifiers, including finger and voice prints;
(Q) Full face photographic images and any comparable images; and
(R) Any other unique identifying number, characteristic, or code, except as permitted by paragraph (c) of this section; and
(ii) The covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information."

Section 105(d4). Comment.

Medication Synchronization can be effective in improving medication adherence and eliminating gaps in therapy by reducing the number of Pharmacy visits for patients on multiple-medication regimens. Patients receive their synchronized refills by appointment with their Pharmacist each month, which allows for increased patient-Pharmacist interaction and the provision of comprehensive Medication Therapy Management services for chronic illnesses. In addition to facilitating medication adherence and maximizing health benefits, Medication Synchronization may also offer Pharmacies a mechanism to improve workload and inventory control. Other possible advantages of medication synchronization include minimization of overall health costs and increased convenience for patients.

"Medication Refill Consolidation," "Medication Schedule Synchronization," and "Medication Refill Synchronization" are other terms used for these types of services.

Medication Synchronization is used in the Dispensing of medications for patients with chronic illnesses. Chronic illnesses are those diseases or conditions that are of long duration, require ongoing treatment, and can be controlled but not completely cured. The US National Center for Health Statistics defines a chronic disease as a condition lasting for three or more months. According to the Centers for Medicare and Medicaid Services, the most common chronic conditions among Medicare beneficiaries are hypertension, high cholesterol, heart disease, diabetes, and arthritis. Other common chronic illnesses include heart failure, depression, chronic kidney disease, osteoporosis, Alzheimer's disease, chronic obstructive pulmonary disease, atrial fibrillation, cancer, asthma, and stroke.

Section 105(x4) (and [y4]). Comment.

It is the performance of activities that encompass the Practice of Pharmacy that distinguishes Pharmacy Benefits Managers from Pharmacy Benefits Processors. The activities that may encompass the Practice of Pharmacy by Pharmacy Benefits Managers include, but are not limited to, the following:

- Disease state management
- Disease compliance management
- Drug adherence management
- Drug interaction management
- Drug utilization management
- Formulary management
- Generic alternative program management
- Generic incentive program management
- Medical and/or Drug data analysis
- Patient Drug Utilization Review (DUR) services
- Prior authorization services
- Provider profiling and outcomes assessment
- Refill reminder program management
- Therapy guidelines management
- Stop therapy protocol management
- Wellness management
- Maintenance of confidential patient information
- Direction or design of the clinical programs for a Pharmacy or a group of Pharmacies

Section 105(q5). Comment.

45 CFR §162.103 reads as follows:

> Electronic media means the mode of electronic transmission. It includes the Internet (wide-open), Extranet (using Internet technology to link a business with information only accessible to collaborating parties), leased lines, dial-up lines, private networks, and those transmissions that are physically moved from one location to another using magnetic tape, disk, or compact disk media.

20 USC §1232g reads as follows:

> Sec. 1232g. Family educational and privacy rights
> (a) Conditions for availability of funds to educational agencies or institutions; inspection and review of education records; specific information to be made available; procedure for access to education records; reasonableness of time for such access; hearings; written explanations by parents; definitions
> (1)(A) No funds shall be made available under any applicable program to any educational agency or institution which has a policy of denying, or which effectively prevents, the parents of students who are or have been in attendance at a school of such agency or at such institution, as the case may be, the

right to inspect and review the education records of their children. If any material or document in the education record of a student includes information on more than one student, the parents of one of such students shall have the right to inspect and review only such part of such material or document as relates to such student or to be informed of the specific information contained in such part of such material. Each educational agency or institution shall establish appropriate procedures for the granting of a request by parents for access to the education records of their children within a reasonable period of time, but in no case more than forty-five days after the request has been made.
(B) No funds under any applicable program shall be made available to any State educational agency (whether or not that agency is an educational agency or institution under this section) that has a policy of denying, or effectively prevents, the parents of students the right to inspect and review the education records maintained by the State educational agency on their children who are or have been in attendance at any school of an educational agency or institution that is subject to the provisions of this section.
(C) The first sentence of subparagraph (A) shall not operate to make available to students in institutions of postsecondary education the following materials:
(i) financial records of the parents of the student or any information contained therein;
(ii) confidential letters and statements of recommendation, which were placed in the education records prior to January 1, 1975, if such letters or statements are not used for purposes other than those for which they were specifically intended;
(iii) if the student has signed a waiver of the student's right of access under this subsection in accordance with subparagraph (D), confidential recommendations ─
(I) respecting admission to any educational agency or institution,
(II) respecting an application for employment, and
(III) respecting the receipt of an honor or honorary recognition
(D) A student or a person applying for admission may waive his right of access to confidential statements described in clause (iii) of subparagraph (C), except that such waiver shall apply to recommendations only if
(i) the student is, upon request, notified of the names of all persons making confidential recommendations and
(ii) such recommendations are used solely for the purpose for which they were specifically intended. Such waivers may not be required as a condition for admission to, receipt of financial aid from, or receipt of any other services or benefits from such agency or institution.
(2) No funds shall be made available under any applicable program to any educational agency or institution unless the parents of students who are or have been in attendance at a school of such agency or at such institution are provided an opportunity for a hearing by such agency or institution, in accordance with regulations of the Secretary, to challenge the content of such student's education records, in order to insure that the records are not inaccurate, misleading, or otherwise in violation of the privacy rights of students, and to provide an opportunity for the correction or deletion of any such inaccurate, misleading or otherwise inappropriate data contained therein and to insert into such records a written explanation of the parents respecting the content of such records.
(3) For the purposes of this section the term "educational agency or institution" means any public or private agency or institution which is the recipient of funds under any applicable program.
(4)(A) For the purposes of this section, the term "education records" means, except as may be provided otherwise in subparagraph (B), those records, files, documents, and other materials which ─
(i) contain information directly related to a student; and
(ii) are maintained by an educational agency or institution or by a person acting for such agency or institution.
(B) The term "education records" does not include ─
(i) records of instructional, supervisory, and administrative personnel and educational personnel ancillary thereto which are in the sole possession of the maker thereof and which are not accessible or revealed to any other person except a substitute;
(ii) records maintained by a law enforcement unit of the educational agency or institution that were created by that law enforcement unit for the purpose of law enforcement;
(iii) in the case of persons who are employed by an educational agency or institution but who are not in attendance at such agency or institution, records made and maintained in the normal course of

business which relate exclusively to such person in that person's capacity as an employee and are not available for use for any other purpose; or
(iv) records on a student who is eighteen years of age or older, or is attending an institution of postsecondary education, which are made or maintained by a physician, psychiatrist, psychologist, or other recognized professional or paraprofessional acting in his professional or paraprofessional capacity, or assisting in that capacity, and which are made, maintained, or used only in connection with the provision of treatment to the student, and are not available to anyone other than persons providing such treatment, except that such records can be personally reviewed by a physician or other appropriate professional of the student's choice.
(5)(A) For the purposes of this section the term "directory information" relating to a student includes the following: the student's name, address, telephone listing, date and place of birth, major field of study, participation in officially recognized activities and sports, weight and height of members of athletic teams, dates of attendance, degrees and awards received, and the most recent previous educational agency or institution attended by the student.
(B) Any educational agency or institution making public directory information shall give public notice of the categories of information which it has designated as such information with respect to each student attending the institution or agency and shall allow a reasonable period of time after such notice has been given for a parent to inform the institution or agency that any or all of the information designated should not be released without the parent's prior consent.
(6) For the purposes of this section, the term "student" includes any person with respect to whom an educational agency or institution maintains education records or personally identifiable information, but does not include a person who has not been in attendance at such agency or institution.
(b) Release of education records; parental consent requirement; exceptions; compliance with judicial orders and subpoenas; audit and evaluation of federally-supported education programs; recordkeeping
(1) No funds shall be made available under any applicable program to any educational agency or institution which has a policy or practice of permitting the release of education records (or personally identifiable information contained therein other than directory information, as defined in paragraph (5) of subsection (a) of this section) of students without the written consent of their parents to any individual, agency, or organization, other than to the following ─
(A) other school officials, including teachers within the educational institution or local educational agency, who have been determined by such agency or institution to have legitimate educational interests, including the educational interests of the child for whom consent would otherwise be required;
(B) officials of other schools or school systems in which the student seeks or intends to enroll, upon condition that the student's parents be notified of the transfer, receive a copy of the record if desired, and have an opportunity for a hearing to challenge the content of the record;
(C)(i) authorized representatives of (I) the Comptroller General of the United States, (II) the Secretary, or
(III) State educational authorities, under the conditions set forth in paragraph (3), or
(ii) authorized representatives of the Attorney General for law enforcement purposes under the same conditions as apply to the Secretary under paragraph (3);
(D) in connection with a student's application for, or receipt of, financial aid;
(E) State and local officials or authorities to whom such information is specifically allowed to be reported or disclosed pursuant to State statute adopted ─
(i) before November 19, 1974, if the allowed reporting or disclosure concerns the juvenile justice system and such system's ability to effectively serve the student whose records are released, or
(ii) after November 19, 1974, if ─
(I) the allowed reporting or disclosure concerns the juvenile justice system and such system's ability to effectively serve, prior to adjudication, the student whose records are released; and
(II) the officials and authorities to whom such information is disclosed certify in writing to the educational agency or institution that the information will not be disclosed to any other party except as provided under State law without the prior written consent of the parent of the student.
(F) organizations conducting studies for, or on behalf of, educational agencies or institutions for the purpose of developing, validating, or administering predictive tests, administering student aid programs, and improving instruction, if such studies are conducted in such a manner as will not permit the personal identification of students and their parents by persons other than representatives of

such organizations and such information will be destroyed when no longer needed for the purpose for which it is conducted;
(G) accrediting organizations in order to carry out their accrediting functions;
(H) parents of a dependent student of such parents, as defined in section 152 of title 26;
(I) subject to regulations of the Secretary, in connection with an emergency, appropriate persons if the knowledge of such information is necessary to protect the health or safety of the student or other persons; and
(J)(i) the entity or persons designated in a Federal grand jury subpoena, in which case the court shall order, for good cause shown, the educational agency or institution (and any officer, director, employee, agent, or attorney for such agency or institution) on which the subpoena is served, to not disclose to any person the existence or contents of the subpoena or any information furnished to the grand jury in response to the subpoena; and
(ii) the entity or persons designated in any other subpoena issued for a law enforcement purpose, in which case the court or other issuing agency may order, for good cause shown, the educational agency or institution (and any officer, director, employee, agent, or attorney for such agency or institution) on which the subpoena is served, to not disclose to any person the existence or contents of the subpoena or any information furnished in response to the subpoena. Nothing in clause (E) of this paragraph shall prevent a State from further limiting the number or type of State or local officials who will continue to have access thereunder.
(2) No funds shall be made available under any applicable program to any educational agency or institution which has a policy or practice of releasing, or providing access to, any personally identifiable information in education records other than directory information, or as is permitted under paragraph (1) of this subsection, unless ─
(A) there is written consent from the student's parents specifying records to be released, the reasons for such release, and to whom, and with a copy of the records to be released to the student's parents and the student if desired by the parents, or
(B) except as provided in paragraph (1)(J), such information is furnished in compliance with judicial order, or pursuant to any lawfully issued subpoena, upon condition that parents and the students are notified of all such orders or subpoenas in advance of the compliance therewith by the educational institution or agency.
(3) Nothing contained in this section shall preclude authorized representatives of (A) the Comptroller General of the United States, (B) the Secretary, or (C) State educational authorities from having access to student or other records which may be necessary in connection with the audit and evaluation of Federally-supported education programs, or in connection with the enforcement of the Federal legal requirements which relate to such programs: Provided, That except when collection of personally identifiable information is specifically authorized by Federal law, any data collected by such officials shall be protected in a manner which will not permit the personal identification of students and their parents by other than those officials, and such personally identifiable data shall be destroyed when no longer needed for such audit, evaluation, and enforcement of Federal legal requirements.
(4)(A) Each educational agency or institution shall maintain a record, kept with the education records of each student, which will indicate all individuals (other than those specified in paragraph (1)(A) of this subsection), agencies, or organizations which have requested or obtained access to a student's education records maintained by such educational agency or institution, and which will indicate specifically the legitimate interest that each such person, agency, or organization has in obtaining this information. Such record of access shall be available only to parents, to the school official and his assistants who are responsible for the custody of such records, and to persons or organizations authorized in, and under the conditions of, clauses (A) and (C) of paragraph (1) as a means of auditing the operation of the system.
(B) With respect to this subsection, personal information shall only be transferred to a third party on the condition that such party will not permit any other party to have access to such information without the written consent of the parents of the student. If a third party outside the educational agency or institution permits access to information in violation of paragraph (2)(A), or fails to destroy information in violation of paragraph (1)(F), the educational agency or institution shall be prohibited from permitting access to information from education records to that third party for a period of not less than five years.

(5) Nothing in this section shall be construed to prohibit State and local educational officials from having access to student or other records which may be necessary in connection with the audit and evaluation of any federally or State supported education program or in connection with the enforcement of the Federal legal requirements which relate to any such program, subject to the conditions specified in the proviso in paragraph (3).
(6)(A) Nothing in this section shall be construed to prohibit an institution of postsecondary education from disclosing, to an alleged victim of any crime of violence (as that term is defined in section 16 of title 18), or a nonforcible sex offense, the final results of any disciplinary proceeding conducted by such institution against the alleged perpetrator of such crime or offense with respect to such crime or offense.
(B) Nothing in this section shall be construed to prohibit an institution of postsecondary education from disclosing the final results of any disciplinary proceeding conducted by such institution against a student who is an alleged perpetrator of any crime of violence (as that term is defined in section 16 of title 18), or a nonforcible sex offense, if the institution determines as a result of that disciplinary proceeding that the student committed a violation of the institution's rules or policies with respect to such crime or offense.
(C) For the purpose of this paragraph, the final results of any disciplinary proceeding
(i) shall include only the name of the student, the violation committed, and any sanction imposed by the institution on that student; and
(ii) may include the name of any other student, such as a victim or witness, only with the written consent of that other student.
(7)(A) Nothing in this section may be construed to prohibit an educational institution from disclosing information provided to the institution under section 14071 of title 42 concerning registered sex offenders who are required to register under such section.
(B) The Secretary shall take appropriate steps to notify educational institutions that disclosure of information described in subparagraph
(A) is permitted.
(c) Surveys or data-gathering activities; regulations not later than 240 days after October 20, 1994, the Secretary shall adopt appropriate regulations or procedures, or identify existing regulations or procedures, which protect the rights of privacy of students and their families in connection with any surveys or data-gathering activities conducted, assisted, or authorized by the Secretary or an administrative head of an education agency. Regulations established under this subsection shall include provisions controlling the use, dissemination, and protection of such data. No survey or data-gathering activities shall be conducted by the Secretary, or an administrative head of an education agency under an applicable program, unless such activities are authorized by law.
(d) Students' rather than parents' permission or consent; for the purposes of this section, whenever a student has attained eighteen years of age, or is attending an institution of postsecondary education, the permission or consent required of and the rights accorded to the parents of the student shall thereafter only be required of and accorded to the student.
(e) Informing parents or students of rights; under this section, no funds shall be made available under any applicable program to any educational agency or institution unless such agency or institution effectively informs the parents of students, or the students, if they are eighteen years of age or older, or are attending an institution of postsecondary education, of the rights accorded them by this section.
(f) Enforcement; termination of assistance; the Secretary shall take appropriate actions to enforce this section and to deal with violations of this section, in accordance with this chapter, except that action to terminate assistance may be taken only if the Secretary finds there has been a failure to comply with this section, and he has determined that compliance cannot be secured by voluntary means.
(g) Office and review board; creation; functions the Secretary shall establish or designate an office and review board within the Department for the purpose of investigating, processing, reviewing, and adjudicating violations of this section and complaints which may be filed concerning alleged violations of this section. Except for the conduct of hearings, none of the functions of the Secretary under this section shall be carried out in any of the regional offices of such Department.

Section 105(q6). Comment.

A Valid Patient-Practitioner Relationship includes a relationship with a consulting Practitioner or a Practitioner to which a patient has been referred, or a covering Practitioner, or an appropriate Practitioner-Board-approved telemedicine Practitioner providing that a physical examination had been previously performed by the patient's primary Practitioner.

To best protect the public, the issue of a Valid Patient-Practitioner Relationship should be addressed in each jurisdiction's Medical Practice Act and the Consumer Fraud Protection Act or their equivalent.

A face-to-face physical examination is not required to establish a Valid Patient-Practitioner relationship if:

(a) the prescribing Practitioner is issuing a prescription or Dispensing a non-controlled substance legend drug in accordance with the Expedited Partner Therapy in the Management of Sexually Transmitted Diseases Guidance document issued by the United States Centers for Disease Control and Prevention;

(b) the prescription, Administration, or Dispensing is through a public health clinic or other distribution mechanism approved by the state health authority in order to prevent, mitigate, or treat a pandemic illness, infectious disease outbreak, or intentional or accidental release of a biological, chemical, or radiological agent; or

(c) the prescribing Practitioner is issuing a prescription through a telemedicine practice approved by the appropriate state agency that provides health care delivery, diagnosis, consultation, or treatment by means of audio, video, or data communications. Standard telephone, facsimile transmission, or both, in the absence of other integrated information or data, do not constitute telemedicine practices.

Article II

Board of Pharmacy

Introductory Comment to Article II

Before it can regulate the Practice of Pharmacy, the State must first establish and empower the Board of Pharmacy. Accordingly, Article II of the Model Act *defines and creates the Board of Pharmacy by specifying elements necessary to its formation, organization, and operation.*

Each of the sections contained in this article covers elements that NABP felt necessary to the proper formation and efficient operation of the Board. Several of these sections, especially those that contain innovative or infrequently utilized provisions, are supplemented by individual explanatory comments.

Among the sections of Article II that may be of particular interest to users of the Model Act *are the following: Sections 202 and 203(b), pertaining to the inclusion of public members as Board members; Section 207, which provides grounds and procedures for removal of Board members; and Section 213(c)(2), which enables Boards to avail themselves of research and study grants and other non-State monies.*

It is also important to note that Section 212 specifically empowers the Board to make such rules as are necessary to fully administer and implement the Act. This is a most significant feature of the Model Act*. The underlying philosophy of this approach is that the statute should create objectives, guidelines, and policies in general areas, and permit the Board to provide the specifics in its rules. This approach recognizes that it is impossible for State legislatures to enact comprehensive provisions regarding all of the matters with which a Board of Pharmacy may be confronted or to anticipate the rapidly changing conditions of the professions and the delivery of health care. Consequently, NABP recommends that Boards have adequate power to adopt and amend rules with the greatest possible flexibility and autonomy. Section 212 of the* Model Act *accomplishes this objective.*

As noted in the findings of the 1990 report on the "State Discipline of Pharmacists" by the Federal Health and Human Services Department, Office of Inspector General (OIG), "The ability of many State Pharmacy Boards to protect the public is hampered by limitations in their legal authorities, administrative processes, and resources." Based on these findings, the OIG recommended that, "State governments should ensure that State Pharmacy Boards have adequate resources and authority for carrying out their enforcement responsibilities effectively."

Section 201. Designation.

The responsibility for enforcement of the provisions of this Act is hereby vested in the Board of Pharmacy. The Board shall have all of the duties, powers, and authority specifically granted by or necessary for the enforcement of this Act, as well as such other duties, powers, and authority as it may be granted from time to time by applicable law. In the event of a declared State of Emergency, the Board may waive the requirements of this Act in order to protect the public

health, safety, or welfare of its citizens and to facilitate the provision of Drugs, Devices, and Pharmacist Care services to the public.[37]

[37] In states where centralized prescription filling or centralized prescription processing are not permitted, states may consider allowing the performance of such activities in a declared State of Emergency.

Section 202. Membership.

The Board of Pharmacy shall consist of _____ members, _____ of whom shall be a representative of the public, and the remainder] [each] of whom shall be Pharmacists who possess the qualifications specified in Section 203.[38]

Section 203. Qualifications.

(a) Each Pharmacist member of the Board of Pharmacy shall at the time of appointment[39]:

(1) be a resident of this State for not less than six months;
(2) be currently licensed and in good standing to engage in the Practice of Pharmacy in this State;
(3) be actively engaged in the Practice of Pharmacy in this State;
(4) have five (5) years of experience in the Practice of Pharmacy in this State after licensure.

(b) The public member of the Board of Pharmacy shall be a resident of this State who has attained the age of majority and shall not be, nor shall ever have been, a Pharmacist, or the spouse of a Pharmacist, or a Person who has ever had any material financial interest in the provision of Pharmacy services or who has engaged in any activity directly related to the Practice of Pharmacy.[40]

Section 204. Appointment.

(a) The Governor shall appoint the members of the Board of Pharmacy in accordance with other provisions of this Section and the State Constitution.

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[38] The number of Board members should be determined by each individual state according to its particular requirements. Individual states may wish to consider a Board composition that represents the diversity of practice sites and interests within a state. Variable factors, such as state population, number of Pharmacists, number of pharmacies, and other local considerations, may all be relevant in determining the number of Board members needed to most effectively enforce the Act. In the event a state prefers to limit the Board membership to currently licensed Pharmacists, the bracketed language pertaining to a public member should be deleted, as should Section 203(b). In this event, the alternative "each" should be selected, and Section 203(a) should be renumbered as Section 203.

[39] Section 203(a) of the Act requires that a Pharmacist be engaged in the Practice of Pharmacy at the time of his or her appointment as a Board member and that he or she have at least five (5) years of experience in the Practice of Pharmacy in the state prior thereto. Since the Practice of Pharmacy is defined in Section 104 in broad terms, it renders a Pharmacist actively engaged in almost any phase of the practice eligible for appointment. This provides for candidates who have divergent backgrounds and experiences and who are knowledgeable in the affairs of the profession.
However, it should be noted from the definition of Pharmacy Practice in Section 104 that those persons actively engaged in the Practice of Pharmacy would basically be limited to those individuals who are working within settings where medications/Devices are Dispensed and Pharmacist Care is provided. To include persons who are in positions related to the practice but who are not engaged in Dispensing and Pharmacist Care functions would wrongfully cause the inclusion of individuals, such as personnel employed by Drug Manufacturers, Wholesale Distributors, and the like, who may be licensed to practice but who do not practice Pharmacy under the terms of the applicable Practice Act. The determination as to whether or not an individual is actively engaged in the Practice of Pharmacy will undoubtedly be rendered on a case-by-case basis. The general Criteria described above, however, would most probably be applicable in making the determination. Under the terms of a Practice Act, which includes a definition of Pharmacy practice, only those persons who are actively engaged in the basic functions set forth in the definition would be individuals "actively engaged in the Practice of Pharmacy."

[40] Specific qualifying Criteria for the public member have been deliberately omitted from this section. Reliance has been placed in the Governor to determine what attributes an individual should possess in order to meaningfully serve on a Board of Pharmacy. In order to help ensure that such a member would be truly independent in his or her judgments, those persons who have a possible substantial relationship with the profession are rendered ineligible by this Section.

(b) Nominations for appointment to the Board may be made to the Governor by any individual, association, or any other entity. Such nominations shall be recommendations only and shall not be binding in any manner upon the Governor.[41]

Section 205. Terms of Office.

(a) Except as provided in subsection (b), members of the Board of Pharmacy shall be appointed for a term of _____ years, except that members of the Board who are appointed to fill vacancies that occur prior to the expiration of a former member's full term shall serve the unexpired portion of such term.

(b) The terms of the members of the Board shall be staggered, so that the terms of no more than _____ member(s) shall expire in any year. Each member shall serve until a successor is appointed and qualified.
   (1) The present members of the Board shall serve the balance of their terms.
   (2) Any present Board member appointed initially for a term of less than _____ years shall be eligible to serve for _____ additional full terms.

(c) No member of the Board shall serve more than _____ consecutive full terms. The completion of the unexpired portion of a full term shall not constitute a full term for purposes of this Section.

Section 206. Vacancies.

Any vacancy that occurs in the membership of the Board for any reason, including expiration of term, removal, resignation, death, disability, or disqualification, shall be filled by the Governor in the manner prescribed by Section 204.

Section 207. Removal.[42]

(a) A Board member may be removed pursuant to the procedures set forth in subsection (b) herein, upon one or more of the following grounds:

   (1) the refusal or inability for any reason of a Board member to perform his or her duties as a member of the Board in an efficient, responsible, and professional manner;
   (2) the misuse of office by a member of the Board to obtain personal, pecuniary, or material gain or advantage for himself or herself or another through such office;
   (3) the violation by any member of the laws governing the Practice of Pharmacy or the Distribution of Drugs and/or Devices.

(b) Removal of a member of the Board of Pharmacy shall be in accordance with the Administrative Procedures Act of this State, or other applicable laws.

Section 208. Organization.

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[41] The purpose of Section 204(b) is to provide a mechanism through which any interested Person or group may designate a candidate for the Board. Since nominations are recommendations only, the Governor retains complete discretion in regard to the appointees. As an alternative to appointment of Board of Pharmacy members by the Governor, some state laws call for the election of such members by the states' Pharmacists.

[42] In certain jurisdictions, there may be general statutory provisions that establish the procedures and grounds for the removal of appointed public officials. In these jurisdictions, you may wish to disregard Section 207.

(a) The Board of Pharmacy shall elect from its members a President and such other officers as it deems appropriate and necessary to the conduct of its business. The President of the Board of Pharmacy shall preside at all meetings of the Board and shall be responsible for the performance of all of the duties and functions of the Board required or permitted by this Act. Each additional officer elected by the Board shall perform those duties normally associated with his or her position and such other duties assigned to him or her from time to time by the Board.

(b) Officers elected by the Board shall serve terms of one (1) year commencing with the day of their election and ending upon election of their successors and shall serve no more than _____ consecutive full terms in each office to which they are elected.

(c) The Board shall employ a Pharmacist to serve as a full time employee of the Board in the position of Executive Director. The Executive Director shall be responsible for the performance of the administrative functions of the Board and such other duties as the Board may direct.[43]

Section 209. Compensation of Board Members.

Each member of the Board of Pharmacy shall receive as compensation the sum of $_____ per day for each day on which the member is engaged in performance of the official duties of the Board, and shall be reimbursed for all reasonable and necessary expenses incurred in connection with the discharge of such official duties.

Section 210. Meetings.

(a) The Board of Pharmacy shall meet at least once every _____ months to transact its business. The Board shall meet at such additional times as it may determine. Such additional meetings may be called by the President of the Board or by two-thirds (2/3) of the members of the Board.

(b) The Board shall meet at such place as it may from time to time determine. The place for each meeting shall be determined prior to giving notice of such meeting and shall not be changed after such notice is given without adequate prior notice.

(c) Notice of all meetings of the Board shall be given in the manner and pursuant to requirements prescribed by the State's Administrative Procedures Act.

(d) A majority of the members of the Board shall constitute a quorum for the conduct of a Board meeting and, except where a greater number is required by this Act or by any rule of the Board, all actions of the Board shall be by a majority of a quorum.

(e) All Board meetings and hearings shall be open to the public. The Board may, in its discretion and according to law, conduct any portion of its meeting in executive session, closed to the public.[44]

Section 211. Employees.

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[43] NABP urges that every Board have a permanent administrative official, an Executive Director who is a currently licensed Pharmacist, to perform and supervise the administrative duties and functions for which the Board is responsible on a day-to-day basis. The responsibilities of the Executive Director should include the hiring of necessary staff to assist in fulfilling the responsibilities of the Board.

[44] Many states have adopted "sunshine" laws that provide for open meetings. Section 210(e) may not be necessary or may need revision to eliminate or to curtail the use of executive sessions.

The Board of Pharmacy may, at its discretion, employ persons, in addition to the Executive Director, in such other positions or capacities as it deems necessary to the proper conduct of Board business and to the fulfillment of the Board's responsibilities as defined by this Act.[45]

Section 212. Rules.

The Board of Pharmacy shall make, adopt, amend, and repeal such rules as may be deemed necessary by the Board from time to time for the proper Administration and enforcement of this Act. Such rules shall be promulgated in accordance with the procedures specified in the Administrative Procedures Act of this State.

Section 213. Powers and Responsibilities.

(a) The Board of Pharmacy shall be responsible for the control and regulation of the Practice of Pharmacy in this State including, but not limited to, the following[46]:

(1) the licensing by examination or by license transfer of applicants who are qualified to engage in the Practice of Pharmacy under the provisions of this Act;
(2) the renewal of licenses to engage in the Practice of Pharmacy;
(3) the establishment and enforcement of compliance with professional standards and rules of conduct of Pharmacists engaged in the Practice of Pharmacy;
(4) the determination and issuance of standards for recognition and approval of degree programs of schools and colleges of Pharmacy whose graduates shall be eligible for licensure in this State, and the specification and enforcement of requirements for practical training, including Pharmacy practice experience[47];
(5) the enforcement of those provisions of this Act relating to the conduct or competence of Pharmacists practicing in this State; the Revocation, Summary Suspension, Suspension, Probation, Censure, or Reprimand of, or the issuance of Warnings or the assessment of Fines/Civil Penalties or Costs/Administrative Costs against licenses to engage in the Practice of Pharmacy; and the issuance of Cease and Desist orders against any Person or entity;
(6) the licensure and regulation of the training, qualifications, and employment of Pharmacy Interns and Pharmacy Technicians;

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[45] Inspectors employed by the Board of Pharmacy may be Pharmacists. Boards may wish to consider whether inspectors must be Pharmacists.

[46] The "Practice of Pharmacy in this State" includes shipping Prescription Drugs into this State from another jurisdiction. However, this is not meant to be construed as a licensure requirement for every Pharmacist that is employed at a Nonresident Pharmacy unless they are specifically engaged in the Practice of Pharmacy and provide services to residents in this State (see Sections 104 and 501(a) of this Act).

[47] Great care should be exercised by the Boards with respect to this Section. Many states have statutes or rules which provide that approved or accredited degree programs of schools or colleges of Pharmacy are those approved by the Accreditation council for pharmacy education (ACPE).

It is a well-established rule of administrative law that any delegation of governmental power must carry with it appropriate limitations and procedural safeguards for affected individuals. Thus, a direct, unequivocal grant of the accreditation function to a private organization, such as ACPE, might be deemed an unauthorized, improper, and invalid delegation of Board or legislative authority. An NABP study of this question discovered at least one case where a court overturned a Board action based upon such invalid delegation to a private body. See Garces v Department of Registration and Education, 254 N.E.2d 622 (Ill, 1969).

NABP urges all Boards to adopt, in their Rules, the Standards of Accreditation established from time to time by the ACPE, the nationally recognized accrediting agency for Pharmacy degree programs.

(7) the collection of professional demographic data;
(8) the right to seize any such Drugs and Devices found by the Board to constitute an imminent danger to the public health and welfare;
(9) establishing minimum specifications for the physical facilities, technical equipment, environment, supplies, personnel, and procedures for the storage, Compounding and/or Dispensing of such Drugs or Devices, for the monitoring of Drug therapy, and for the Manufacture and Distribution of Drugs and Devices;
(10) establishing minimum standards for the purity and quality of such Drugs, Devices, and other materials within the Practice of Pharmacy;
(11) the issuance and renewal of licenses for Pharmacies located within this State, or outside this State if providing services to patients within this State, that Compound or Dispense Drugs or Devices or provide Pharmacist Care.
(12) the issuance and renewal of licenses of all Manufacturers and Distributors of Drugs and Devices located within this State, or outside this State if providing such services within this State;
(13) inspection at all reasonable hours of the facility and appropriate records of any licensed Person or licensed facility and any Person or facility seeking licensure for the purpose of determining if any provisions of the laws governing licensure, the legal Distribution of Drugs or Devices, or the Practice of Pharmacy are being violated, including the inspection of Protected Health Information. The Board of Pharmacy, its officers, inspectors, and representatives shall cooperate with all agencies charged with the enforcement of the laws of the United States, of this State, and of all other states relating to Drugs, Devices, and the Practice of Pharmacy;
(14) establishing minimum standards for maintaining the integrity and confidentiality of prescription information and other patient health care information; and[48]
(15) the approval of Pharmacy practice initiatives that improve the quality of or access to Pharmacist Care, but which fall outside the scope of present regulations. This subsection shall not be construed to expand the definition of the Practice of Pharmacy as defined in this Act.

(b) Centralized Performance Database

(1) The Board of Pharmacy shall utilize a Centralized Performance Database. The Centralized Performance Database shall be maintained in such a way as to permit an evaluator to apply Criteria and Standards to data from one pharmacy, and determine whether, over time, outcomes from that pharmacy compare favorably with outcomes from other pharmacies.
(2) The Board of Pharmacy shall conduct a Practice Accountability Audit at least once every six months to identify pharmacies that consistently violate Criteria and/or standards. The Board of Pharmacy shall require that pharmacies so

[48] Under this Act, "Protected Health Information" may be used or disclosed without acknowledgement, authorization, or opportunity to agree or object in the situations described in 45 CFR 164.512(a) – (l), and which include:

- As required by law
- For certain public health activities
- For certain health oversight activities
- Pursuant to judicial or administrative proceedings
- For law enforcement purposes
- For military or national security purposes
- As necessary to comply with worker compensation laws
- In situations presenting a serious threat to health or safety

Investigative activities of the Boards of Pharmacy are considered health oversight activities and, therefore, fall under this disclosure exemption.

identified provide an explanation of the reason for their consistent violation of Criteria and/or standards.

(c) The Board of Pharmacy shall have such other duties, powers, and authority as may be necessary to the enforcement of this Act and to the enforcement of Board rules made pursuant thereto, which shall include, but are not limited to, the following:

(1) The Board may join such professional organizations and associations organized exclusively to promote the improvement of the standards of the Practice of Pharmacy for the protection of the health and welfare of the public and/or whose activities assist and facilitate the work of the Board.

(2) The Board may receive and expend funds, in addition to its [annual/biennial] appropriation, from parties other than the State, provided:

(i) such funds are awarded for the pursuit of a specific objective which the Board is authorized to accomplish by this Act, or which the Board is qualified to accomplish by reason of its jurisdiction or professional expertise;

(ii) such funds are expended for the pursuit of the objective for which they are awarded;

(iii) activities connected with or occasioned by the expenditures of such funds do not interfere with the performance of the Board's duties and responsibilities, and do not conflict with the exercise of the Board's powers as specified by this Act;

(iv) such funds are kept in a separate, special account; and

(v) periodic reports are made concerning the Board's receipt and expenditure of such funds.

(3) The Board may establish a Bill of Rights for patients concerning the health care services a patient may expect in regard to Pharmacist Care.[49]

(4) Any investigation, inquiry, or hearing which the State Board of Pharmacy is empowered to hold or undertake may be held or undertaken by or before any member or members of the Board and the finding or order of such member or members shall be deemed to be the order of said Board when approved and confirmed as noted in Section 210(d).

(5) Embargo.[50]

(i) Notwithstanding anything in this Act to the contrary, whenever a duly authorized representative of the Board finds, or has probable cause to believe, that any Drug or Device is adulterated or misbranded within the meaning of the (State) Food and Drug Act, he or she shall affix to such Drug or Device a tag or other appropriate marking giving notice that such article is or is suspected of being adulterated or misbranded, has been detained or embargoed, and Warning all Persons not to remove or dispose of such article by sale or otherwise until provision for removal or disposal is given by the Board, its agent, or the Court. No Person shall remove or dispose of such embargoed Drug or Device by sale or otherwise without the permission of the Board or its agent or, after summary proceedings have been instituted, without permission from the Court.

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[49] A Patient's Bill of Rights establishes the professional services that a patient may expect when obtaining Drugs or Devices from a Pharmacist. The Bill of Rights would normally contain patient expectations that could translate into standards of professional practice and/or codes of conduct for the Pharmacist. Accordingly, if a Board should choose to establish a Patient's Bill of Rights, the Bill should be consistent with standards of practice, codes of ethics, and regulations that the Board has adopted under the Pharmacy Practice Act. If care is not taken, a Board could inadvertently expand the role and the responsibilities of the Pharmacist through the establishment of a Patient's Bill of Rights.

[50] The purpose of this subsection is to ensure quality, purity, and correct Labeling of Drugs, Devices, and other materials.

(ii) When a Drug or Device detained or embargoed under Paragraph (i) of this subsection (5) has been declared by such representative to be adulterated or misbranded, the Board shall, as soon as practical thereafter, petition the Judge of the _____ Court in which jurisdiction the article is detained or embargoed for an order for condemnation of such article. If the judge determines that the Drug or Device so detained or embargoed is not adulterated or misbranded, the Board shall direct the immediate removal of the tag or other marking.

(iii) If the Court finds the detained or embargoed Drug or Device is adulterated or misbranded, such Drug or Device, after entry of the decree, shall be destroyed at the expense of the owner under the supervision of a Board representative and all court costs and fees, storage, and other proper expense shall be borne by the owner of such Drug or Device. When the adulteration or misbranding can be corrected by proper Labeling or processing of the Drug or Device, the Court, after entry of the decree and after such costs, fees, and expenses have been paid and a good and sufficient bond has been posted, may direct that such Drug or Device be Delivered to the owner thereof for such Labeling or processing under the supervision of a Board representative. Expense of such supervision shall be paid by the owner. Such bond shall be returned to the owner of the Drug or Device on representation to the Court by the Board that the Drug or Device is no longer in violation of the embargo and the expense of supervision has been paid.

(iv) It is the duty of the Attorney General [State's Attorney] to whom the Board reports any violation of Section 213(c)(5) to cause appropriate proceedings to be instituted in the proper court without delay and to be prosecuted in the manner required by law. Nothing in this subparagraph (iv) shall be construed to require the Board to report violations whenever the Board believes the public's interest will be adequately served in the circumstances by a suitable written notice or Warning.

(6) The Board may place under seal all Drugs or Devices that are owned by or in the possession, custody, or control of a licensee at the time his or her license is Suspended or Revoked or at the time the Board refuses to renew his license. Except as otherwise provided in this section, Drugs or Devices so sealed shall not be disposed of until appeal rights under the Administrative Procedures Act have expired, or an appeal filed pursuant to that Act has been determined. The court involved in an appeal filed pursuant to the Administrative Procedures Act may order the Board, during the pendency of the appeal, to sell sealed Drugs that are perishable. The proceeds of such a sale shall be deposited with that court.

(7) Except as otherwise provided to the contrary, the Board shall exercise all of its duties, powers, and authority in accordance with the State Administrative Procedures Act.

(8) In addition to the fees specifically provided for herein, the Board may assess additional reasonable fees for services rendered to carry out its duties and responsibilities as required or authorized by this Act or Rules adopted hereunder. Such services rendered shall include, but not be limited to, the following:

(i) issuance of duplicate certificates or identification cards;

(ii) mailing lists or reports of data maintained by the Board;

(iii) copies of any documents;

(iv) certification of documents;

(v) notices of meetings;

(vi) licensure transfer;

(vii) examination Administration to a licensure applicant; and
(viii) examination materials.

(9) Cost Recovery.[51]

(i) If any order issues in resolution of a disciplinary proceeding before the Board of Pharmacy, the Board may request the _____ to direct any licensee found guilty of a charge involving a violation of any Drug laws or rules, to pay to the Board a sum not to exceed the reasonable costs of the investigation and prosecution of the case and, in any case, not to exceed twenty-five thousand dollars ($25,000).

(ii) In the case of a Pharmacy or Wholesale Distributor, the order may be made as to the corporate owner, if any, and as to any Pharmacist, officer, owner, or partner of the Pharmacy or Wholesale Distributor who is found to have had knowledge of or have knowingly participated in one or more of the violations set forth in this section.

(iii) The costs to be assessed shall be fixed by the _____ and shall not be increased by the Board; where the Board does not adopt a proposed decision and remands the case to a(n) _____ , the _____ shall not increase any assessed costs.

(iv) Where an order for recovery of costs is made and timely payment is not made as directed in the Board's decision, the Board may enforce the order for payment in the Court in the county where the administrative hearing was held. This right of enforcement shall be in addition to any other rights the Board may have as to any Person directed to pay costs.

(v) In any action for recovery of costs, proof of the Board's decision shall be conclusive proof of the validity of the order of payment and the terms for payment.

[51] The "_____" interspersed throughout this section may be filled with the terms: "administrative law judge," "hearing officer," or "presiding officer," as determined by individual states.

Article III

Licensing

Introductory Comment to Article III

Article III of the Model Act *specifies the requirements for initial licensure of Pharmacists, transfer of licensure, and renewal of licenses and registrations. In each of these areas, the Act sets forth basic Criteria and delegates to the Board the authority for implementing those Criteria. The Board does this by utilizing appropriate administrative enforcement mechanisms and by the issuance of specific rules.*

Section 301 establishes the basis for this Article by making it unlawful for any unlicensed Person to engage in the Practice of Pharmacy, and by enabling the Board to exact penalties for unlawful practice.

In the area of initial licensure (Section 302), the Board must implement the Act by approving degree programs of Pharmacy, by specifying the examination to be employed (Section 302[b]), by establishing Pharmacy practice experience standards (Section 302[c]), and by ensuring that all other prerequisites are met by each applicant to whom it issues a license.

The Act also reflects the efforts of NABP to continue uniform standards for transfer of licensure (Section 303).

Section 301. Unlawful Practice.

(a) Except as otherwise provided in this Act, it shall be unlawful for any individual, whether located in or outside this State, to engage in the Practice of Pharmacy in this State unless currently licensed to practice under any facet of the provisions of this Act.

(b) The provision of Pharmacist Care services to an individual in this State, through the use of telecommunications, the Internet, or other technologies, regardless of the location of the pharmacist, shall constitute the Practice of Pharmacy and shall be subject to regulation.[52]

(1) Licensed Pharmacies located outside this State that provide Pharmacist Care services to individuals in this State must be licensed within this State under Article V of this Act.

(2) Pharmacists located outside this State who are providing Pharmacist Care services outside of a licensed Pharmacy to individuals located in this State must register with this State to engage in the nonresident Practice of Pharmacy.

(c) 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, and all other requirements for the Dispensing of Drugs applicable to Pharmacists.

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[52] NABP recognizes that protection of the public health should extend across State borders. Accordingly, the NABP *Model Act* incorporates the Practice of Telepharmacy Across State Lines within the scope of the "Practice of Pharmacy" and requires an independently practicing pharmacist located outside this State to register to Practice Telepharmacy Across State Lines, rather than obtain full licensure for providing Pharmacist Care services from outside the State to patients within the State. Pharmacists located outside this State who are providing Pharmacist Care services from a Pharmacy or nonresident Pharmacy licensed in this State need not register with this State to Practice Telepharmacy Across State Lines.

((See comment list.))

(d) It shall be unlawful for any individual to perform the activities of a Certified Pharmacy Technician or Pharmacy Technician unless currently registered to do so under the provisions of this Act.

(e) (1) The Board may in its own name issue a Cease and Desist order to stop an individual from engaging in an unauthorized Practice of Pharmacy.

(2) Except as otherwise indicated in this Act, any individual who, after due process, shall be found by the Board to have unlawfully engaged in the Practice of Pharmacy shall be subject to a Fine to be imposed by the Board not to exceed $____ for each offense. Each such violation of this Act or the rules promulgated hereunder pertaining to unlawfully engaging in the Practice of Pharmacy shall also constitute a misdemeanor punishable upon conviction as provided in the criminal code of this State.

(3) Except as otherwise indicated in this Act, any individual who, after due process, shall be found by the Board to have unlawfully engaged in the Practice of Pharmacy that resulted in harm to an individual shall be subject to a Fine to be imposed by the Board not to exceed $____ for each offense. Each such violation of this Act or the rules promulgated hereunder pertaining to unlawfully engaging in the Practice of Pharmacy that resulted in harm to an individual shall also constitute a felony punishable upon conviction as provided in the criminal code of this State.

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 an 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;[53]
(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;[54]
(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

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[53] It is contemplated that Boards will approve those programs whose standards are at least equivalent to the standards required by the ACPE. This would include college-structured pharmacy practice experience programs and continuing education programs. See Comment to Section 213(a)(4) above for further discussion of the Board's proper role in the accreditation process.

[54] Boards should avoid mention of specific examinations or other contracted services in their practice act and regulations to avoid challenges related to an unconstitutional delegation of authority. It is contemplated that Boards will utilize the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®) as part of their assessment of pharmacy education equivalence.

(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.

(b) Examinations.

(1) The examination for licensure required under Section 302(a)(7) of the Act shall be given by the Board at least two (2) times during each year. The Board shall determine the content and subject matter of each examination and approve the site and date of the Administration of the examination.

(2) The examination shall be prepared to measure the competence of the applicant to engage in the Practice of Pharmacy. The Board may employ, cooperate, and contract with any organization or consultant in the preparation and grading of an examination, but shall retain the sole discretion and responsibility for determining which applicants have successfully passed such an examination.

(c) Pharmacy Practice Experience Programs and Other Training Programs.[55]

(1) All applicants for licensure by examination shall obtain practical experience in the Practice of Pharmacy concurrent with or after college attendance, or both, under such terms and conditions as the Board shall determine.[56]

(2) The Board shall establish such licensure requirements for Pharmacy Interns and standards for Pharmacy practice experiences, or any other experiential program necessary to qualify an applicant for the licensure examination, and shall also determine the qualifications of Preceptors used in practical experience programs.[57]

Section 303. Qualifications for Licensure Transfer.[58]

(a) In order for a Pharmacist currently licensed in another jurisdiction to obtain a license as a Pharmacist by license transfer in this State, an applicant shall:[59]

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[55] As college-based Pharmacy practice experience programs become uniform under the most recent revision of the ACPE *Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree* (effective July 1, 2007), and when boards of pharmacy are convinced that schools and colleges of pharmacy are meeting these Accreditation Standards and Guidelines and the competency requirements set out by Boards, Boards should begin to broadly accept and recognize college-based Pharmacy practice experience programs completed by students in other jurisdictions and eliminate requirements that such students obtain additional Pharmacy practice experience hours in addition to those obtained as part of the college of pharmacy curriculum. Because of the potential lack of uniformity among non-college-based Pharmacy practice experience programs, it is recommended that Boards exercise their prerogative to accept only at their discretion non-college based Pharmacy practice experiences completed by Pharmacy Interns in other jurisdictions.

[56] Although Boards of Pharmacy mandate a specified number of hours of Pharmacy practice experiences as a prerequisite to licensure, Boards of Pharmacy are also encouraged to deem those requirements met if Boards find that the college-based Pharmacy practice experiences meet or exceed the hourly Pharmacy practice experience requirements.

As indicated in the Model Rules for Pharmacy Interns, applicants for licensure as Pharmacists shall submit evidence that they have satisfactorily completed: (1) an objective assessment mechanism intended to evaluate achievement of desired competencies as delineated in the ACPE Accreditation Standards and Guidelines and (2) not less than 1,740 hours of Pharmacy practice experience credit under the instruction and supervision of a Preceptor. Boards may consider moving away from requiring a specific number of contact hours should it be determined that the ACPE Accreditation Standards and Guidelines result in appropriate preparation for students and objective assessment mechanisms demonstrate such.

[57] Boards of Pharmacy are strongly encouraged to utilize the ACPE Accreditation Standards and Guidelines as a basis for establishment and revision of Board standards for Pharmacy practice experiences. These Accreditation Standards and Guidelines also contain additional guidance on the desired behaviors, qualities, and values of preceptors.

[58] See the NABP Model Rules for Public Health Emergencies for language that addresses the temporary recognition of nonresident pharmacist licensure in the case of a declared State of Emergency issued due to a Public Health Emergency.

[59] It is intended that NABP's National Disciplinary Clearinghouse would be utilized by state Boards for verifying information provided by applicants.

(1) have submitted an application in the form prescribed by the Board of Pharmacy;
(2) have attained the age of majority;
(3) have good moral character;
(4) have possessed at the time of initial licensure as a Pharmacist all qualifications necessary to have been eligible for licensure at that time in this State;
(5) have engaged in the Practice of Pharmacy for a period of at least one (1) year or have met the Pharmacy practice experience requirements of this State within the one (1) year period immediately previous to the date of such application;
(6) have presented to the Board proof of initial licensure by examination and proof that such license is in good standing;
(7) have presented to the Board proof that any other license granted to the applicant by any other state has not been Suspended, Revoked, or otherwise restricted for any reason, except nonrenewal or for the failure to obtain the required continuing education credits, in any state where the applicant is currently licensed but not engaged in the Practice of Pharmacy; and
(8) have paid the fees specified by the Board.

(b) No applicant shall be eligible for license transfer unless the state in which the applicant was initially licensed as a Pharmacist also grants licensure transfer to Pharmacists duly licensed by examination in this State, under like circumstances and conditions.[60]

Section 304. Renewal of Licenses and Registrations.

(a) Each Pharmacist, Pharmacy Intern, Certified Pharmacy Technician, and 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.

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

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[60] Endorsement states may wish to consider the removal of Subparagraph (b) in this Section.

to carry out the stated objectives and purposes, to enforce the provisions of this Section, and to ensure continued competence.

Section 306. Pharmacy Practice Experience Program Standards; Pharmacy Intern Licensure.

The Board of Pharmacy shall establish standards for Pharmacy practice experience programs for the purpose of providing the practice experience necessary for licensure as a Pharmacist. The Board shall grant a Pharmacy Intern license to Pharmacy students, authorizing those students to engage in the Practice of Pharmacy under the supervision of a Pharmacist. The Board of Pharmacy shall adopt rules regarding the licensure of Pharmacy Interns and the standards for Pharmacy practice experience programs.[61]

Section 307. Registration of Certified Pharmacy Technicians.

(a) In order to be registered as a Certified Pharmacy Technician in this State, an applicant shall:[62]

(1) have submitted an 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[63]:
  (i) graduated from a competency-based pharmacy technician education and training program approved by the Board of Pharmacy;[64] 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;[65]
(6) have successfully passed an examination developed using nationally recognized and validated psychometric and pharmacy practice standards approved by the Board of Pharmacy;

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[61] Boards of Pharmacy are strongly encouraged to utilize the ACPE Accreditation Standards and Guidelines as a basis for establishment and revision of board standards for Pharmacy practice experiences. These Accreditation Standards and Guidelines also contain additional guidance on the desired behaviors, qualities, and values of preceptors.

[62] In 2015, the *Model State Pharmacy Act and Model Rules* will be amended to require persons seeking to become Certified Pharmacy Technicians to complete each of the requirements outlined in Sections 307(a)(5)(i), 307(a)(5)(ii), and 307(a)(6).

[63] Boards should avoid mention of specific examinations or other contracted services in their practice act and regulations to avoid challenges related to an unconstitutional delegation of authority. It is contemplated that Boards will utilize the Pharmacy Technician Certification Board examination as part of their assessment of technician competence to assist in the practice of pharmacy.

[64] It is recommended that states adopt this requirement, if not currently required, through a process that incorporates provisions for grandfathering.

[65] It is contemplated that Boards will approve those pharmacy technician training programs whose standards are at least equivalent to the minimum standards being developed by an accrediting organization recognized by state Boards, such as ACPE. See Comment to Section 213(a)(4) above for further discussion of the Board's proper role in the accreditation process.

(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.[66]

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

Section 308. Registration of Pharmacy Technicians.[67]

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

(1) have submitted an 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.[68]

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

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[66] 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.

[67] In 2015, the *Model State Pharmacy Act and Model Rules* will be amended to remove the term Pharmacy Technician and incorporate 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 Candidate for Certified Pharmacy Technician will be allowed.

[68] 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.

Comments

Section 301(c). Comment.

Boards of Pharmacy are often confronted with the problem of preventing unlicensed individuals from engaging in one or more facets of the Practice of Pharmacy. The regulation of the Practice of Pharmacy, including the control of unlicensed practice in the profession, has a reasonable and rational relationship to public health, safety, and welfare. See, for example, *State v Wakeen*, 57 N.W.2d 364 (Wis, 1953). cf. *State v VanKeegan*, 113 A.2d 141 (Conn, 1955) and *Williamson v Lee Optical of Oklahoma*, 348 U.S. 483 (1955), concerning prohibitions on the unlicensed practice of ophthalmology. For this reason, vesting the power in the Board to regulate the illicit practice would not appear to violate the constitutional due process requirements. Monetary fines are another enforcement action Boards can utilize to protect the public health. Although monetary fines are not generally considered criminal sanctions, it can be forcibly argued that there are no constitutional barriers impeding the imposition of fines by a Board of Pharmacy. See, for example, *Helvering v Mitchell*, 303 U.S. 376 (1938); *City of Waukegan v Pollution Control Board*, 311 N.E.2d 146 (Ill, 1974); *County Council for Montgomery County v Investors Funding Corp*, 312 A.2d 225 (Md, 1973); and *Rody v Hollis*, 500 P.2d 97 (Wash, 1972).

One area that could present a serious question of law in regard to Section 301(b), however, involves the constitutional limitation on the delegation of authority to administrative agencies. It is likely that the delegation contemplated in Article III of the *Model Act* would be valid in a majority of jurisdictions. See, for example, *Jordan v Board of Insurance*, 334 S.W. 2d 278 (Tex, 1960); *Sutherland v Ferguson*, 397 P. 2d 335 (Kan, 1964); and *Kovack v Licensing Board of City of Waterville*, 173 A. 2d 554 (Me, 1961); see generally L. Davis, Administrative Law Treatise, Section 2.10 (1970 Suppl.). Be cautioned, however, that certain jurisdictions require very specific standards in a delegation of authority that could render Section 301(b) constitutionally suspect. See, for example, *People v Tibbits*, 305 N.E. 2d 152 (Ill, 1973); *Sarasota County v Barg*, 302 So. 2d 737 (Fla, 1974). In these jurisdictions, revisions of Article III may be necessary.

Article IV

Discipline

Introductory Comment to Article IV

At the very heart of any Pharmacy Act is the enforcement power of the Board of Pharmacy. The Board must have authority to discipline and/or prohibit Pharmacies, Pharmacists, Pharmacy Interns, Certified Pharmacy Technicians, or Pharmacy Technicians who violate this Act or Rules from continuing to threaten the public if it is to fulfill its responsibilities. The Board must have the ability to stop wrongdoers, either permanently or temporarily, discipline them, and, where appropriate, to guide and assist errant licensees in rehabilitating themselves.

The Model Act *disciplinary provisions are contained in Article IV. They were drafted with the purpose of granting to the Board the widest possible scope within which to perform its disciplinary functions. Standardized disciplinary action terms and definitions were developed to facilitate the accurate reporting of disciplinary actions taken by Boards of Pharmacy and to avoid confusion associated with state-to-state variations in terms and definitions. The grounds for disciplinary action were developed to ensure protection of the public, while reserving to the Board the power to expand upon them and adapt them to changing or local conditions as necessary. The penalties permitted under the* Model Act *will afford the Board the flexibility to conform and relate discipline to offenses.*

Section 401. Disciplinary Action Terms.

The following is a list of disciplinary actions that may be taken, issued, or assessed by the Board of Pharmacy: Revocation, Summary Suspension, Suspension, Probation, Censure, Reprimand, Warning, Cease and Desist, Fine/Civil Penalty, Costs/Administrative Costs.[69]

Section 402. Grounds, Penalties, and Reinstatement.[70]

(a) The Board of Pharmacy may refuse to issue or renew, or may Revoke, Summarily Suspend, Suspend, place on Probation, Censure, Reprimand, issue a Warning against, or issue a Cease and Desist order against, the licenses or the registration of, or assess a Fine/Civil Penalty or Costs/Administrative Costs against any Person Pursuant to the procedures set forth in Section 403 herein below, upon one or more of the following grounds:

(1) unprofessional conduct as that term is defined by the rules of the Board;[71]

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[69] Guidelines for the imposition of sanctions for certain designated offenses can be found in Appendix D: Guidelines for Disciplinary Sanctions of the *Model Act*.

[70] The penalties provided in Section 402 give the Board wide latitude to make the disciplinary action fit the offense. The "reasonable intervals" in 402(c) would be determined by the Board.

[71] It is particularly important to emphasize the need for specificity in defining the grounds upon which a Pharmacist's or Pharmacy Intern's license to practice Pharmacy, or a Certified Pharmacy Technician's or Pharmacy Technician's registration to assist in the Practice of Pharmacy, may be Revoked or Suspended. The term "unprofessional conduct" is particularly susceptible to judicial challenge for being unconstitutionally vague. Each offense included within the meaning of this term must be capable of being understood with reasonable precision by the Persons regulated so that it can be readily enforced and relied upon during disciplinary proceedings, and so that those regulated by it may easily conform their professional conduct to its meaning(s).

(2) incapacity that prevents a licensee from engaging in the Practice of Pharmacy or a registrant from assisting in the Practice of Pharmacy, with reasonable skill, competence, and safety to the public;
(3) being guilty of one (1) or more of the following:
    (i) a felony;
    (ii) any act involving moral turpitude or gross immorality; or
    (iii) violations of the Pharmacy or Drug laws of this State or rules and regulations pertaining thereto; or of laws, rules, and regulations of any other state; or of the Federal government;
(4) disciplinary action taken by another state or jurisdiction against a license or other authorization to Practice Pharmacy based upon conduct by the licensee similar to conduct that would constitute grounds for actions as defined in this section;
(5) failure to report to the Board any adverse action taken by another licensing jurisdiction (United States or foreign), government agency, law enforcement agency, or court for conduct that would constitute grounds for action as defined in this section;
(6) failure to report to the Board one's surrender of a license or authorization to Practice Pharmacy in another state or jurisdiction while under disciplinary investigation by any of those authorities or bodies for conduct that would constitute grounds for action as defined in this section;
(7) failure to report to the Board any adverse judgment, settlement, or award arising from a malpractice claim arising related to conduct that would constitute grounds for action as defined in this section;
(8) knowing or suspecting that a Pharmacist or Pharmacy Intern is incapable of engaging in the Practice of Pharmacy or that a Pharmacy Technician is incapable of assisting in the Practice of Pharmacy, with reasonable skill, competence, and safety to the public, and failing to report any relevant information to the Board of Pharmacy;
(9) misrepresentation of a material fact by a licensee in securing the issuance or renewal of a license or registration;
(10) fraud by a licensee in connection with the Practice of Pharmacy;
(11) affiliating with websites that may deceive or defraud patients or that violate Pharmacy or Drug laws of this State or rules and regulations pertaining thereto; or of laws, rules, and regulations of any other state; or of the Federal government;
(12) engaging, or aiding and abetting an individual to engage in the Practice of Pharmacy without a license; assisting in the Practice of Pharmacy or aiding and abetting an individual to assist in the Practice of Pharmacy without having registered with the Board of Pharmacy; or falsely using the title of Pharmacist, Pharmacy Intern, Certified Pharmacy Technician, or Pharmacy Technician;
(13) <u>requiring Pharmacy personnel to meet production and/or performance metrics and/or quotas that negatively impact patient safety.[72]</u>

These potential problems make it essential for Boards to issue appropriate rules making the grounds for disciplinary action specific, understandable, and reasonable. In addition, the Boards must ensure that such rules are published for the benefit of all licensees within their jurisdiction. Only by doing so can Boards be assured of authority to take successful and meaningful disciplinary actions that will not later be overturned by the courts.

This section must be examined in light of other state laws since some states, for example, restrict the circumstances under which a license may be denied to an individual because of the commission of a felony. In addition, an individual who has been convicted of a felony or an act involving gross immorality and who has paid his debt to society has restored constitutional protections that may curtail a strict application of Section 402(a)(3).

[72] This is not intended to include performance metrics that may be related to the ability and competency of Pharmacy personnel.

(14) failing to pay the costs assessed in a disciplinary hearing pursuant to Section 213(c)(9);
(15) engaging in any conduct that subverts or attempts to subvert any licensing examination or the Administration of any licensing examination;[73]
(16) being found by the Board to be in violation of any of the provisions of this Act or rules adopted pursuant to this Act;
(17) illegal use or disclosure of Protected Health Information;
(18) failure to furnish to the Board, its investigators, or representatives any information legally requested by the Board.

(b)

(1) The Board may defer action with regard to an impaired licensee who voluntarily signs an agreement, in a form satisfactory to the Board, agreeing not to practice Pharmacy and to enter an approved treatment and monitoring program in accordance with this Section, provided that this Section should not apply to a licensee who has been convicted of, pleads guilty to, or enters a plea of nolo contendere to a felonious act prohibited by _____ or a conviction relating to a controlled substance in a court of law of the United States or any other state, territory, or country. A licensee who is physically or mentally impaired due to addiction to Drugs or alcohol may qualify as an impaired Pharmacist and have disciplinary action deferred and ultimately waived only if the Board is satisfied that such action will not endanger the public and the licensee enters into an agreement with the Board for a treatment and monitoring plan approved by the Board, progresses satisfactorily in such treatment and monitoring program, complies with all terms of the agreement and all other applicable terms of subsection (b)(2). Failure to enter such agreement or to comply with the terms and make satisfactory progress in the treatment and monitoring program shall disqualify the licensee from the provisions of this Section and the Board shall activate an immediate investigation and disciplinary proceedings. Upon completion of the rehabilitation program in accordance with the agreement signed by the Board, the licensee may apply for permission to resume the Practice of Pharmacy upon such conditions as the Board determines necessary.
(2) The Board may require a licensee to enter into an agreement that includes, but is not limited to, the following provisions:
    (i) Licensee agrees that his or her license shall be Suspended or Revoked indefinitely under subsection (b)(1).

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[73] It is recommended that the following rule be adopted defining subversion or the attempt to subvert any licensing examination.
(a) Conduct which subverts or attempts to subvert any licensing examination or the administration of any examination shall include, but not be limited to, the following:
    (1) Conduct which violates the security of the examination materials; removing from the examination room any examination materials without authorization; the unauthorized reproduction by any means of any portion of the actual licensing examination; aiding by any means the unauthorized reproduction of any portion of the actual licensing examination; paying or using professional or paid examination takers for the purpose of reconstructing any portion of the licensing examination; obtaining examination questions or other examination materials, except by specific authorization either before, during, or after an examination; or selling, Distributing, buying, receiving, or having unauthorized possession of any portion of a future, current, or previously administered licensing examination.
    (2) Unauthorized communication of examination information with any other examinee during the administration of a licensing examination; copying answers from another examinee or permitting one's answers to be copied by another examinee; having in one's possession during the administration of the licensing examination any books, equipment, notes, written or printed materials, or data of any kind other than the examination materials Distributed, or otherwise authorized to be in one's possession during the examination; or impersonating any examinee or having an impersonator take the licensing examination on one's behalf.

(ii) Licensee will enroll in a treatment and monitoring program approved by the Board.

(iii) Licensee agrees that failure to satisfactorily progress in such treatment and monitoring program shall be reported to the Board by the treating professional, who shall be immune from any liability for such reporting made in good faith.

(iv) Licensee consents to the treating physician or professional of the approved treatment and monitoring program reporting to the Board on the progress of licensee at such intervals as the Board deems necessary and such Person making such report will not be liable when such reports are made in good faith.

(3) The ability of an impaired Pharmacist to practice shall only be restored and charges dismissed when the Board is satisfied by the reports it has received from the approved treatment program that licensee can resume practice without danger to the public.

(4) Licensee consents, in accordance with applicable law, to the release of any treatment information from anyone within the approved treatment program.

(5) The impaired licensee who has enrolled in an approved treatment and monitoring program and entered into an agreement with the Board in accordance with subsection (b)(1) hereof shall have his license Suspended or Revoked, but enforcement of this Suspension or Revocation shall be stayed by the length of time the licensee remains in the program and makes satisfactory progress, and complies with the terms of the agreement and adheres to any limitations on his practice imposed by the Board to protect the public. Failure to enter into such agreement or to comply with the terms and make satisfactory progress in the treatment and monitoring program shall disqualify the licensee from the provisions of this Section and the Board shall activate an immediate investigation and disciplinary proceedings.

(6) Any Pharmacist who has substantial evidence that a licensee has an active addictive disease for which the licensee is not receiving treatment under a program approved by the Board pursuant to an agreement entered into under this Section, is diverting a controlled substance, or is mentally or physically incompetent to carry out the duties of his or her license, shall make or cause to be made a report to the Board. Any Person who reports pursuant to this Section in good faith and without malice shall be immune from any civil or criminal liability arising from such reports. Failure to provide such a report within a reasonable time from receipt of knowledge may be considered grounds for disciplinary action against the licensee so failing to report.

(c) Any Person whose license to practice Pharmacy in this State has been Revoked, Summarily Suspended, Suspended, placed on Probation, Censured, Reprimanded, issued a Warning against, or issued a Cease and Desist order against, the licenses or the registration of, or assessed a Fine/Civil Penalty or Costs/Administrative Costs against pursuant to this Act, whether voluntarily or by action of the Board, shall have the right, at reasonable intervals, to petition the Board for reinstatement of such license.[74] Such petition shall be made in writing and in the form prescribed by the

[74] A Pharmacist who is under investigation or who has been charged with a violation of the Pharmacy Practice Act may agree to voluntarily surrender his or her license. When this occurs, the Board should formally enter stipulated findings and an order describing the terms and conditions of the surrender including any agreed upon time limitations. This establishes statutory grounds that would support disciplinary action, and prevents a Pharmacist who has surrendered a license from applying for reinstatement within a time frame unacceptable to the Board.

Board. Upon investigation and hearing, the Board may, at its discretion, grant or deny such petition, or it may modify its original finding to reflect any circumstances that have changed sufficiently to warrant such modifications. The Board, also at its discretion, may require such Person to pass an examination(s) for reentry into the Practice of Pharmacy.

(d) Nothing herein shall be construed as barring criminal prosecutions for violations of this Act.

(e) All final decisions by the Board shall be subject to judicial review pursuant to the Administrative Procedures Act.

(f) Any individual or entity whose license to practice Pharmacy, or registration to assist in the Practice of Pharmacy, is Revoked, Suspended, or not renewed shall return his or her license or registration certificate to the offices of the State Board of Pharmacy within 10 days after receipt of notice of such action.

Section 403. Procedure.[75]

(a) Notwithstanding any provisions of the State Administrative Procedures Act, the Board may, without a hearing, Summarily Suspend a license for not more than 60 days if the Board finds that a Pharmacist, Pharmacy Intern, Certified Pharmacy Technician, or Pharmacy Technician has violated a law or rule that the Board is empowered to enforce, and if continued practice by the Pharmacist, Pharmacy Intern, Certified Pharmacy Technician, or Pharmacy Technician would create an imminent risk of harm to the public. The Suspension shall take effect upon written notice to the Pharmacist, Pharmacy Intern, Certified Pharmacy Technician, or Pharmacy Technician specifying the statute or rule violated. At the time it issues the Suspension notice, the Board shall schedule a disciplinary hearing to be held under the Administrative Procedures Act within 20 days thereafter. The Pharmacist, Pharmacy Intern, Certified Pharmacy Technician, or Pharmacy Technician shall be provided with at least 10 days notice of any hearing held under this subsection.

(b) Notwithstanding any provisions of the State Administrative Procedures Act, the Board may, in its own name, issue a Cease and Desist order to stop an individual from engaging in an unauthorized Practice of Pharmacy or violating or threatening to violate a statute, rule, or order that the Board has issued or is empowered to enforce. The Cease and Desist order must state the reason for its issuance and give notice of the individual's right to request a hearing under applicable procedures as set forth in the Administrative Procedures Act. Nothing herein shall be construed as barring criminal prosecutions for violations of this Act.

[75] The procedures which must be followed before disciplinary action can be taken in many of the states are determined by the Administrative Procedures Act. The *Model Act* was drafted on the assumption that such an Act was in effect.

Article V

Licensing of Facilities

Introductory Comment to Article V

The fifth and last substantive Article of the Model Act *concerns licensure of Pharmacies, Manufacturers, Wholesale Distributors, and the like. The licensure requirements of this Article will provide a Board with knowledge of all facilities involved in the storage, Distribution, and sale of Drugs or Devices within the state and those located outside the state that are shipping Drugs or Devices into the state. They will permit a Board to better ensure against Drug or Device diversion from the legitimate channels of commerce and provide the necessary data for effective recalls and the dissemination of information.*

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) dispensing Practitioners and Practitioner's facilities;[76]
   (3) persons engaged in the Manufacture, production, sale, or Distribution or Wholesale Distribution of Drugs or Devices;
   (4) pharmacies where Drugs or Devices are Dispensed, or Pharmacist Care is provided;
   (5) Pharmacy Benefits Managers; and
   (6) Repository Programs

   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.[77]

(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 and/or pharmacy permit holder and the Pharmacist-in-Charge of the Pharmacy, whether the owner and/or pharmacy permit holder is a sole proprietor, partnership, association, corporation, or otherwise.

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[76] 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.

[77] Section 501(b) contemplates that the Criteria for licensure, beyond minimum requirements for all Persons and Pharmacies, established in an individual entity classification could differ. For example, the Criteria that must be met by a nuclear Pharmacy will certainly differ from that of the community Pharmacy. This type of latitude places the responsibility on the Board to adopt appropriate rules to meet the situation at hand. It also provides a forum for change to meet the changing concepts of professional practice and the Distribution of Drugs and/or Devices.

(d) Each licensed Person located outside of this State who ships, mails, Distributes, Wholesale Distributes, or Delivers Drugs or Devices in this State, or Pharmacy located outside of this State who ships, mails, Distributes, or Delivers Drugs or Devices in this State, shall comply with the laws of patients' domicile, and shall designate a registered agent in this state for service of process. Any such licensed Person or Pharmacy who 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 whom may be served all legal process in any action or proceeding against such licensed Person growing out of or arising from such Delivery. A copy of any such service of process shall be mailed to such Person or Pharmacy by the Board by certified mail, return receipt requested, postage prepaid, at the address such licensed Person has designated on its application for licensure in this State. If any such Person is not licensed in this State, service on the Secretary of State only shall be sufficient service.[78]

(e) The Board may enter into agreements with other states or with third parties for the purpose of exchanging information concerning the licensure and inspection of entities located in this jurisdiction and those located outside this State.

(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. For facilities that Compound Sterile Pharmaceuticals, an initial or an annual inspection shall be required for purposes of licensure or licensure renewal. For facilities that do not Compound Sterile Pharmaceuticals, an initial inspection or an inspection that takes place not more than every 24 months shall be required for purposes of licensure or licensure renewal. Such inspection shall be performed by the following:

(1) the Board or its duly authorized agent;
(2) a duly authorized agent of a third party approved by the Board; or
(3) for Nonresident Pharmacies, the resident state Board of Pharmacy, if the resident Board's inspection is substantially equivalent to inspection in this State.

Section 502. Application.

(a) The Board shall specify by rule the licensure procedures to be followed, including but not limited to, specification of forms for use in applying for such licensure and times, places, and applicable fees.

(b) Applicants for licensure to Distribute, Wholesale Distribute, Manufacture, sell, purchase, transfer, and/or produce Drugs or Devices, and applicants for licensure as a Pharmacy Benefits Manager, shall file with the Board of Pharmacy a verified application containing such information as the Board requires of the applicant relative to the qualifications for a license.

(c) Licenses issued by the Board pursuant to this Act shall not be transferable or assignable.

(d) The Board shall specify by rule minimum standards for responsibility of any Person, Pharmacy, or Pharmacy Benefits Manager that has employees or personnel engaged in the Practice of Pharmacy, or Manufacture, Distribution, Wholesale Distribution, production, sale, or use of Drugs or Devices in the conduct of their business. If the licensed Person is a Pharmacy located in this state, that portion of the facility to which

[78] This section provides for service of process on any Person who Dispenses, Distributes, or Delivers Drugs or Devices within the State.

such license applies shall be operated only under the direct supervision of a Pharmacist licensed to practice in this State.

(e) 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 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 shall be exempt from securing a "surety" bond or other equivalent means of security acceptable to the Board or a third party recognized by the Board. The Board may waive the bond requirement, if the wholesale distributor:

(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.

(See comment list.)

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;
(5) any criminal conviction or pleas of guilty or nolo contendere of all licensed or registered personnel;
(6) disasters, accidents, or any theft, destruction, or loss of records required to be maintained by State or Federal law;
(7) occurrences of Significant Quality-Related Events;
(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.

(b) All licensed Persons shall report to the Board of Pharmacy, or its authorized agent, the occurrence of any Pharmacy or Pharmacy-related inspection conducted by any state or Federal regulatory agency or authorized agent thereof, and shall provide a copy of the report of such inspection, including applicable documents relating to corrective actions.

Section 504. Grounds, Penalties, and Reinstatement.

(a) No Person, Pharmacy, or Pharmacy Benefits Manager designated in Section 501 of this Act shall operate until a license has been issued to said Person, Pharmacy, or Pharmacy Benefits Manager by the Board.

(b) Except where otherwise permitted by law, it shall be unlawful for a Manufacturer or a Wholesale Distributor to Distribute or Deliver Drugs or Devices to any Person in this State not licensed under this statute. Any Person who shall Distribute or Deliver Drugs or Devices to a Person not licensed shall be subject to a fine to be imposed by the Board not to exceed one thousand dollars ($1,000) for each offense in addition to such other disciplinary action the Board may take under this Act. Except as otherwise indicated in this Act, each such violation shall also constitute a misdemeanor punishable upon conviction as provided in the criminal code of this State.

(c) The Board may Suspend, Revoke, deny, or refuse to renew the license of any Person, Wholesale Distributor, Pharmacy, or Pharmacy Benefits Manager on any of the following grounds:[79]

(1) the finding by the Board of violations of any Federal, State, or local laws relating to the Practice of Pharmacy, Drug samples, Wholesale or retail Drug or Device Distribution, or Distribution of controlled substances;
(2) any felony convictions under Federal, State, or local laws;
(3) the furnishing of false or fraudulent material in any application made in connection with Drug or Device Manufacturing or Distribution;
(4) suspension or Revocation by Federal, State, or local government of any license currently or previously held by the applicant for the Manufacture or Distribution of any Drugs or Devices, including controlled substances;
(5) obtaining any remuneration by fraud, misrepresentation, or deception;
(6) affiliating with websites that may deceive or defraud patients or that violate Pharmacy or Drug laws of this State or rules and regulations pertaining thereto; or of laws, rules, and regulations of any other state; or of the Federal government;
(7) dealing with Drugs or Devices that he or she knows or should have known are Counterfeit, Contraband, or stolen Drugs or Devices;[80]
(8) purchasing or receiving of a Drug or Device from a source other than a Person or pharmacy licensed under the laws of the State, except where otherwise provided;
(9) the transfer during any consecutive twelve (12)-month period by a Pharmacy to a Wholesale Distributor or to another Pharmacy of more than five percent (5%) of the total amount of Prescription Drugs or Devices purchased by the Pharmacy in the immediately preceding twelve (12)-month period. The following are not subject to the provisions of this subsection:
    (i) Prescription Drugs or Devices that are returned by a pharmacy for credit, in an amount equal to or less than the actual purchase price, to the Wholesale Distributor or Manufacturer from which those products were purchased;
    (ii) Intracompany sales;
    (iii) The sale, purchase, or trade of a Drug or an offer to sell, purchase, or trade a Drug among hospitals or other health care entities that are under common control;

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[79] The Prescription Drug Marketing Act of 1987 (PDMA) requires that the state licensing laws provide for the Suspension or Revocation of licenses upon conviction for violation of federal, state, or local Drug laws or rules pertaining to the unlawful Distribution of Drugs at wholesale. The PDMA defines fines, imprisonment, or civil penalties.

[80] This section restricts Distribution of Drugs or Devices to licensed entities to help ensure against clandestine Distribution to unauthorized and unlicensed Persons.

(iv) The sale, purchase, or trade of a Drug or the offer to sell, purchase, or trade a Drug 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;

(v) The purchase or other acquisition by a hospital or other similar health care entity that is a member of a group purchasing organization of a Drug for its own use from the group purchasing organization or from other hospitals or similar health care entities that are members of these organizations; and

(vi) The transfer of Prescription Drugs or Devices between Pharmacies pursuant to a Centralized Prescription Processing or Filling agreement.

(10) the transfer during any consecutive twelve (12)-month period by a Wholesale Distributor to a Wholesale Distributor of more than five percent (5%) of the total amount of prescription Drugs or Devices purchased by Wholesale Distributor in the immediately preceding twelve (12)-month period;

(11) Wholesale Drug Distributors other than pharmacies Dispensing or Distributing Drugs or Devices directly to patients;

(12) violations of any of the provisions of this Act or of any of the Rules adopted by the Board under this Act; or

(13) illegal use or disclosure of Protected Health Information.

(d) Reinstatement of a license that has been Suspended, Revoked, or restricted by the Board may be granted in accordance with the procedures specified by Section 401 of this Act.

Section 505. Criminal Offense; Forfeiture of Property.

(a) Violation of any of the provisions of Article V of this Act by any person engaged in the Wholesale Distribution of Drugs and Devices shall constitute a Class three felony, provided that any such violation that results in the death of a Person shall constitute a Class one felony.

(b) A Person engaged in the Wholesale Distribution of Drugs and Devices convicted by a criminal court of this State of violating any of the provisions of Article V may be ordered by the court 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; or

(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 the 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 the 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.

Comments

Section 502. Comment.

Boards may want to consider requesting the following information on applications for pharmacy and wholesale distributor licensure:

(a) personal information;
(b) marital information;
(c) family information (parents, siblings, in-laws);
(d) education;
(e) military information;
(f) arrests, detentions, litigations, and arbitrations;
(g) residences (past 25 years);
(h) employment (back to age 18);
(i) character references;
(j) safe deposit box or other depository information;
(k) privileged, occupational, or professional licensure;
(l) out-of-state business, venture, or industry licensure or financial interest in such;
(m) appearances before any licensing agency or similar authority in or outside the state;
(n) denials of a personal license, permit, certificate, or registration for a privileged, occupational, or professional activity;
(o) denials of a business or industry license or related finding of suitability, or participation in a group that has been denied a business or industry license or related finding of suitability;
(p) Administrative actions or proceedings related to the pharmaceutical industry or participation in a group that has been the subject of such administrative actions or proceedings;
(q) guilty findings or pleadings or pleas of nolo contendere to any offense, federal or state, related to prescription Drugs and/or controlled substances or participation in a group that has been found or pled guilty or that has pled nolo contendere to any such offense;
(r) surrender, voluntary or otherwise, of licensure, permit, or certificate of registration relating to the pharmaceutical industry, or participation in a group that has surrendered, voluntary or otherwise, any such licensure, permit, or certificate of registration; and
(s) any relatives within the fourth degree of consanguinity associated with or employed in the pharmaceutical or Drug-related industry.

Article VI

Other

Section 601. Severability.

If any provision of this Act is declared unconstitutional or illegal, or the applicability of this Act to any Person, Pharmacy, or circumstance is held invalid by a court of competent jurisdiction, the constitutionality or legality of the remaining provisions of this Act and the application of this Act to other Persons, Pharmacies, and circumstances shall not be affected and shall remain in full force and effect without the invalid provision or application.

Section 602. Effective Date.

This Act shall be in full force and effect on _____.

National Association of Boards of Pharmacy Model Rules

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.[81] 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;

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

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

Section 2. Identification.

The Pharmacy Intern shall be so designated in his or her professional relationships, and shall in no manner falsely assume, directly or by inference, to be a Pharmacist. The Board shall issue to the Pharmacy Intern a license for purposes of identification and verification of his or her role as a Pharmacy Intern, which license shall be surrendered to the Board upon discontinuance of Pharmacy practice experiences for any reason including licensure as a Pharmacist. No individual not properly licensed by the Board as a Pharmacy Intern shall take, use, or exhibit the title of Pharmacy Intern, or any other term of similar like or import.

Section 3. Supervision.

A Pharmacy Intern shall be allowed to engage in the Practice of Pharmacy provided that such activities are under the supervision of a Pharmacist. A Pharmacist shall be in contact with, and

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[81] The ACPE *Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree* (effective July 1, 2007) requires schools and colleges of Pharmacy seeking and maintaining ACPE accreditation to incorporate introductory Pharmacy practice experiences within their professional curricula, and such experiences must account for not less than 5% of the total curricular length (not less than 300 contact hours). Under the supervision of a Preceptor and usually taken throughout the first three academic years of the professional program, these introductory Pharmacy practice experiences expose students to and allow students to participate in activities such as processing/Dispensing Medication Orders, conducting Patient interviews, or presenting Patient cases in an organized format.

It is also encouraged that Boards of Pharmacy allow Pharmacy students to be registered as Pharmacy Interns as early as initial enrollment in a Board-approved professional program as long as the Pharmacy student has begun to take professional degree courses.

actually giving instructions to, the Pharmacy Intern during all professional activities throughout the entire Pharmacy practice experience period. The Pharmacist is responsible for supervising all the Practice of Pharmacy activities performed by the Pharmacy Intern, including but not limited to the accurate Dispensing of the Drug.[82]

Section 4. Change of Address.

All Pharmacy Interns shall notify the Board immediately upon change of employment and residential address.

Section 5. Evidence of Completion.

Applicants for licensure as Pharmacists shall submit evidence that they have satisfactorily completed: (1) an objective assessment mechanism intended to evaluate achievement of desired competencies; and (2) not less than 1,740 hours of Pharmacy practice experience credit under the instruction and supervision of a Preceptor.[83]

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[82] According to the ACPE Accreditation Standards and Guidelines, most Pharmacy practice experiences must be under the supervision of a qualified Pharmacist Preceptor licensed in the United States. Realizing that in some cases non-Pharmacist Preceptors can also provide valuable learning opportunities, it is hoped that Boards of Pharmacy recognize these experiences and that schools and colleges of pharmacy ensure, in most cases through faculty, that the desired competencies are being met.

Supervision includes an actual review of the Prescription Drug Order and the dispensed Drug or product to ensure public protection.

[83] These requirements coincide with the ACPE Accreditation Standards and Guidelines. Boards of pharmacy are strongly encouraged to utilize these Accreditation Standards and Guidelines as a basis for the establishment and revision of Board standards for Pharmacy practice experiences.
Introductory Pharmacy practice experiences, which are not less than 300 contact hours, are in addition to the advanced practice experiences taken during the final professional year, which account for not less than 25 % of the curricular length or 1,440 contact hours. The total Pharmacy practice experience hour requirement, therefore, is not less than 1,740 hours. Boards may consider moving away from requiring a specific number of contact hours should it be determined that the ACPE Accreditation Standards and Guidelines result in appropriate preparation for students and objective assessment mechanisms demonstrate such.

Model Standards for

Pharmacy Practice Experience Programs

Section 1. Preceptor.

(a) The Pharmacy Intern, excluding those who are currently enrolled in a professional degree program of a school or college of pharmacy approved by the Board and satisfactorily progressing toward meeting the requirements for licensure as a Pharmacist, shall notify the Board of Pharmacy within two weeks of beginning practice as a Pharmacy Intern, on a form provided by the Board, of the identity of the Pharmacy practice experience site and of the Preceptor.

(b) A Preceptor may be responsible for the training of more than one Pharmacy Intern. The number of Pharmacy Interns engaged in the Practice of Pharmacy at any time is limited to the number of Pharmacy Interns the Pharmacist can appropriately precept as approved by the Board.

Section 2. Pharmacy Practice Experience Programs.[84]

(a) The Pharmacy at which a Pharmacy Intern is being trained shall provide an environment that is conducive to the learning of the Practice of Pharmacy by a Pharmacy Intern. Pharmacy practice experience sites shall meet the standards approved by the Board.

(b) Pharmacy practice experience in non-traditional practice sites (eg, industry-sponsored programs) must be approved by the Board of Pharmacy prior to granting of credit.

(c) When a Pharmacy Intern desires to obtain credit for training received in a state other than this State, the Pharmacy Intern shall abide by all the provisions of the Pharmacy practice experience rules in that state, and shall provide evidence from that state's Board of Pharmacy of the number of clock hours of experience actually participated in by the Pharmacy Intern.

[84] Boards of pharmacy are strongly encouraged to utilize the ACPE Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree (effective July 1, 2007) as a basis for the establishment and revision of Board standards for Pharmacy practice experiences.

Model Rules for Institutional Pharmacy

Section 1. Applicability.

The following Rules are applicable to all Institutional Facilities and Institutional Pharmacies as defined in Section 2 below.

Section 2. Definitions.

(a) "Chart Order"[85] means a lawful order entered on the chart or a medical record of an inpatient or resident of an Institutional Facility by a Practitioner or his or her designated agent for a Drug or Device and shall be considered a Prescription Drug Order provided that it contains:
(1) the full name of the patient;
(2) date of issuance;
(3) name, strength, and dosage form of the Drug prescribed;
(4) directions for use; and
(5) if written, the prescribing Practitioner's signature or the signature of the Practitioner's agent (including the name of the prescribing Practitioner); or if electronically submitted, the prescribing Practitioner's electronic or digital signature.

(b) "Institutional Facility"[86] means any organization whose primary purpose is to provide a physical environment for patients to obtain health care services, including but not limited to a(n):
(1) hospital;
(2) Long-Term Care Facility;
(3) convalescent home;
(4) nursing home;
(5) extended care facility;
(6) mental health facility;
(7) rehabilitation center;
(8) psychiatric center;
(9) developmental disability center;
(10) Drug abuse treatment center;
(11) family planning clinic;
(12) penal institution;
(13) hospice;
(14) public health facility;
(15) athletic facility.

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[85] Chart Orders that are written by the Practitioner's agent shall be countersigned by the prescribing Practitioner within the required time period as required by state law or rule.

[86] Although the definition of Institutional Facility is broad and may encompass an array of facilities that provide long-term medical care and services for its residents, some states may also recognize residential assisted living facilities or residential group homes as such.

(c) "Institutional Pharmacy"[87] means any place which is registered with the State Board of Pharmacy pursuant to Article V of the Pharmacy Practice Act that provides Pharmacist Care to an Institutional Facility and where Drugs, Devices, and other materials used in the diagnosis and treatment of injury, illness, and disease (hereinafter referred to as *Drugs*) are Dispensed, Compounded, and Distributed.[88]

Section 3. Personnel.

(a) Each Institutional Pharmacy shall be directed by a Pharmacist, hereinafter referred to as the *Pharmacist-in-Charge*, who is licensed to engage in the Practice of Pharmacy in this State.

Section 4. Absence of Pharmacist.

(a) During such times as an Institutional Pharmacy may be unattended by a Pharmacist, arrangements shall be made in advance by the Pharmacist-in-Charge for provision of Drugs to the medical staff and other authorized personnel of the Institutional Facility by use of night cabinets and, in emergency circumstances, by access to the Pharmacy. A Pharmacist must be "on call" during all absences.

(b) In the absence of a Pharmacist, Drugs shall be stored in a locked cabinet or other enclosure constructed and located outside of the Pharmacy area, to which only specifically authorized personnel may obtain access by key or combination, and which is sufficiently secure to deny access to unauthorized persons. The Pharmacist-in-Charge shall, in conjunction with the appropriate committee of the Institutional Facility, develop inventory listings of those Drugs to be included in such cabinet(s) and determine who may have access, and shall ensure that:
   (1) Drugs are properly Labeled;
   (2) only prepackaged Drugs are available, in amounts sufficient for immediate therapeutic requirements;
   (3) whenever access to the cabinet occurs, written Practitioner's orders and proofs-of-use are provided;
   (4) all Drugs therein are inventoried no less than once per week;
   (5) a complete audit of all activity concerning such cabinet is conducted no less than once per month; and
   (6) written policies and procedures are established to implement the requirements of this Section 4.

(c) Whenever any Drug is not available from floor supplies or night cabinets, and such Drug is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, such Drug may be obtained from the Pharmacy in accordance with the requirements of this Section 4. One supervisory nurse in any given eight-hour shift is responsible for obtaining Drugs from the Pharmacy. The responsible nurse shall be designated in writing by the appropriate committee of the Institutional Facility. Removal of any Drug from the Pharmacy by an authorized nurse must be recorded on a suitable form showing the patient name, room number, name of

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[87] Although traditionally characterized as being physically part of an Institutional Facility, the Model Rules recognize that an Institutional Pharmacy may or may not be physically attached to an Institutional Facility.

[88] States should recognize that hospitals, in order to prepare for a disaster or emergency, may be stocking emergency supplies of medications in areas outside the licensed pharmacy. Hospitals should be encouraged to expand the space allotted to the licensed pharmacy area to accommodate the need to store emergency supplies.

Drug, strength, amount, date, time, and signature of nurse. The form shall be left with the container from which the Drug was removed.

(d) Emergency kit Drugs may be provided for use by authorized personnel of the Institutional Facility provided, however, such kits meet the following requirements:

(1) Emergency kit Drugs are those Drugs which may be required to meet the immediate therapeutic needs of patients and which are not available from any other authorized source in sufficient time to prevent risk of harm to patients by delay resulting from obtaining such Drugs from such other sources.

(2) All emergency kit Drugs shall be provided and sealed by a Pharmacist;

(3) The supplying Pharmacist and the medical staff of the Institutional Facility shall jointly determine the Drugs, by identity and quantity, to be included in emergency kits.

(4) Emergency kits shall be stored in secured areas to prevent unauthorized access, and to ensure a proper environment for preservation of the Drugs within them.

(5) The exterior of each emergency kit shall be labeled so as to clearly indicate that it is an emergency Drug kit and that it is for use in emergencies only. The label shall contain a listing of the Drugs contained in the kit, including name, strength, quantity, and expiration date of the contents, and the name, address(es), and telephone number(s) of the supplying Pharmacist.

(6) Drugs shall be removed from emergency kits only pursuant to a valid Chart Order.

(7) Whenever an emergency kit is opened, the supplying Pharmacist shall be notified and the Pharmacist shall restock and reseal the kit within a reasonable time so as to prevent risk of harm to patients.[89]

(8) The expiration date of an emergency kit shall be the earliest date of expiration of any Drug supplied in the kit. Upon the occurrence of the expiration date, the supplying Pharmacist shall replace the expired Drug.

Section 5. Drug Distribution and Control.

(a) The Pharmacist-in-Charge shall establish written procedures for the safe and efficient Distribution of Drugs and for the provision of Pharmacist Care. An annual updated copy of such procedures shall be on hand for inspection by the Board of Pharmacy.

(b) Drugs brought into an Institutional Facility by a patient shall not be Administered unless they can be identified and the quality of the Drug assured. If such Drugs are not to be Administered, then the Pharmacist-in-Charge shall, according to procedures specified in writing, have them turned in to the Pharmacy, which shall package and seal them and return them to an adult member of the patient's immediate family, or store and return them to the patient upon discharge.

(c) Investigational Drugs shall be stored in and Dispensed from the Pharmacy only. All information with respect to investigational Drugs shall be maintained in the Pharmacy.[90]

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[89] When the Pharmacist restocks and reseals the emergency kit Drugs, it is recommended that a lock or other similar device be used to assure that unauthorized access to the kit is minimized.

[90] Regarding the use of investigational Drugs in an institution, it is necessary that the institution ensure that such studies contain adequate safeguards for the patient, the institution, and the scientific integrity of the study. The institution must have written policies and procedures for the approval, management, and control of investigational Drug studies. All patients who participate in investigational Drug studies must freely consent, in writing, to treatment with these Drugs. The Pharmacist is responsible to the institution and to the principal investigator for seeing that procedures for the control of investigational Drug use are developed and implemented.

Section 6. Shared Pharmacy Services Utilization for Immediate Need.[91]

(a) In accordance with the Model Rules for the Practice of Pharmacy and Shared Pharmacy Services, an Institutional Pharmacy may outsource services to another Pharmacy for the limited purpose of ensuring that Drugs or Devices are attainable to meet the immediate needs of patients and residents of the Institutional Facility or when the Institutional Pharmacy cannot provide services on an ongoing basis, provided that the Institutional Pharmacy:

(1) has obtained approval from the Institutional Facility to outsource Shared Pharmacy Services for its inpatients and residents; and

(2) provides a valid Chart Order to the Pharmacy it has contracted with for the Shared Pharmacy Services.

[91] Although Institutional Pharmacies primarily outsource services to another Pharmacy for the purposes of meeting the immediate needs of patients and residents when the Institutional Pharmacy is closed, it is also recognized that other services may be outsourced that the Institutional Pharmacy is not able to provide on an ongoing basis.

Model Rules for the Practice of Pharmacy

Introductory Comment

The Board finds that in the interest of protecting the public health and welfare, in order to ensure optimum effect of Drug therapy, and to maximize the quality of Pharmacist Care, the following rules are essential.

Section 1. Facility.

(a) To obtain a license for a Pharmacy, an applicant shall:
- (1) have submitted an 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 or authorized agent thereof; and

(d) Possess the following 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.
- (2) Each Pharmacy shall maintain an area designated for the provision of Patient Counseling services. This area shall be designed to provide a reasonable expectation of privacy of Protected Health Information.
- (3) Each Pharmacy shall have ready access to references applicable to the services provided, to include at least one current reference[92] in each of the following in each of the following categories:
  - (i) State and Federal Drug laws relating to the Practice of Pharmacy and the legal Distribution of Drugs and any rules or regulations adopted pursuant thereto;
  - (ii) pharmacology;
  - (iii) dosage and toxicology;
  - (iv) general.
- (4) Each Pharmacy shall maintain patient-oriented reference material for guidance in proper Drug usage.[93]
- (5) Each Person involved in the development, maintenance, or use of a Drug formulary shall maintain a currently accepted reference containing guidelines for a sound Drug formulary system.
- (6) All areas where Drugs and Devices are stored shall be dry, well lighted, well ventilated, and maintained in a clean and orderly condition. Storage areas shall be maintained at temperatures which will ensure the integrity of the Drugs prior to their Dispensing as stipulated by the United States Pharmacopeia–National

[92] Boards may wish to give examples in each of these categories of reference texts.
[93] Patient-oriented reference material can include publications such as Facts and Comparisons' Patient Drug Facts, or the United States Pharmacopoeia Dispensing Information (USPDI).

Formulary (USP-NF) and/or the Manufacturer's or Distributor's Product Labeling unless otherwise indicated by the Board.

(7) Each Pharmacy shall have access to a sink with hot and cold running water that is convenient to the Compounding area for the purpose of hand scrubs prior to Compounding.

(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. In the event of separation of employment of an employee due to any confirmed Drug-related reason, including diversion, or other acts involving dishonesty, suitable action shall be taken to ensure the security of the pharmacy.

(iii) Prescription and other patient health care information shall be maintained in a manner that protects the integrity and confidentiality of such information as provided by the rules of the Board.

(9) Equipment/Supplies.
The Pharmacy shall carry and utilize the equipment and supplies necessary to conduct a Pharmacy in a manner that is in the best interest of the patients served and to comply with all State and Federal laws.

(10) The Pharmacy shall provide a means for patients to prevent disclosure of Confidential Information or personally identifiable information that was obtained or collected by the Pharmacist or Pharmacy incidental to the Delivery of Pharmacist Care other than as authorized by law or rules of the Board.

(11) The Pharmacy, if conducting business over the Internet, shall be accredited by a program approved by the Board.

(e) Upon renewal, the licensee shall provide to the Board the NABP e-Profile ID of the Pharmacy and the Pharmacist-in-Charge

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:[94]

(A) Policies and procedures addressing the following:

(-a-) the provision of Pharmacy services;[95]

[94] The owner and/or pharmacy permit holder, along with the Pharmacist-in-Charge, are responsible for these policies and procedures.

[95] The Pharmacist-in-Charge, as part of the responsibilities to manage as effectively as possible a patient's therapy to avoid a harmful interruption of therapy because of a shortage or limited Distribution of medications, can proactively improve Pharmacy operations by developing a systematic approach to address such circumstances. References such as the American Society of Health-System Pharmacists (ASHP) Guidelines in Managing Drug Product Shortages could be used as resources for developing policies and

(-b-) the procurement, storage, security, and disposition of Drugs and Devices, particularly controlled substances and drugs of concern;
(-c-) computerized recordkeeping systems;
(-d-) Automated Pharmacy Systems;
(-e-) preventing the illegal use or disclosure of Protected Health Information, or verifying the existence thereof and ensuring that all employees of the Pharmacy read, sign, and comply with such established policies and procedures;
(-f-) operation of the Pharmacy in the event of a fire, flood, pandemic, or other natural or man-made disaster or emergency, to the extent that the Pharmacy can be safely and effectively operated and the Drugs contained therein can be safely stored and Dispensed. Such policies and procedures shall include reporting to the Board the occurrence of any fire, flood, or other natural or man-made disaster or emergency within 10 days of such occurrence[96];
(-g-) the proper management of Drug recalls which may include, where appropriate, contacting patients to whom the recalled Drug product(s) have been Dispensed;
(-h-) the duties to be performed by Certified Pharmacy Technicians and Pharmacy Technicians. The duties and responsibilities of these personnel shall be consistent with their training and experience and shall address the method and level of necessary supervision specific to the practice site. These policies and procedures shall, at a minimum, specify that Certified Pharmacy Technicians and Pharmacy Technicians are not assigned duties that may be performed only by a Pharmacist. Such policies and procedures shall also specify that Pharmacy Technicians shall not be assigned duties that may be performed only by Certified Pharmacy Technicians.

(B) Policies and procedures that address the following activities related to prescription medication shipment by mail or common carrier:
(-a-) properly transferring prescription information to an alternative Pharmacy of the patient's choice in situations where the medication is not Delivered or Deliverable;
(-b-) verifying 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-) tracking all shipments; and
(-d-) ensuring that Drugs do not become adulterated in transit

(C) Quality assurance programs addressing the following:
(-a-) Pharmacy services. The quality assurance program should be designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue

procedures if appropriate. Additionally, Food and Drug Administration maintains a list of current and resolved drug shortages, as well as discontinued drugs on the agency's Drug Shortages Web page at www.fda.gov/cder/drug/shortages.

[96] States should recognize that hospitals, in order to prepare for a disaster or emergency, may be stocking emergency supplies of medications in areas outside the licensed pharmacy. Hospitals should be encouraged to expand the space allotted to the licensed pharmacy area to accommodate the need to store emergency supplies.

opportunities to improve patient care, and resolve identified problems;

(-b-) Automated Pharmacy Systems. The quality assurance program should monitor the performance of the Automated Pharmacy System, ensure the Automated Pharmacy System is in good working order and accurately Dispenses the correct strength, dosage form, and quantity of the Drug prescribed, while maintaining appropriate record keeping and security safeguards; and;

(-c-) The prevention and detection of Drug diversion.[97]

(ii) Ensuring that:

(A) all Pharmacists and Pharmacy Interns employed at the Pharmacy are currently licensed and that all Certified Pharmacy Technicians and Pharmacy Technicians employed at the Pharmacy are currently registered with the Board of Pharmacy.

(iii) Notifying the Board of Pharmacy, immediately and in writing, of any of the following[98] 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 confirmed Drug-related reason, including but not limited to, Adulteration, abuse, theft, or 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 shall notify the Board of Pharmacy;

(C) change of ownership of the Pharmacy;

(D) change of address of the Pharmacy;

(E) permanent closing of the Pharmacy;

(F) Significant Quality-Related Events;

(G) the installation or removal of Automated Pharmacy Systems. Such notice must include, but is not limited to:

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[97] As part of a quality assurance program designed to prevent and detect drug diversion, the Pharmacist-in-Charge is 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; and
- 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.

[98] 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.

(-a-) the name and address of the Pharmacy;
(-b-) the location of the Automated Pharmacy System; and
(-c-) the identification of the responsible Pharmacist.
(-d-) Such notice must be must occur prior to the installation or removal of the system.

(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.

(3) The Pharmacist-in-Charge shall be assisted by a sufficient number of Pharmacists, Certified Pharmacy Technicians, and Pharmacy Technicians as may be required to competently and safely provide Pharmacy services.

(i) The Pharmacist-in-Charge shall maintain and file with the Board of Pharmacy, on a form provided by the Board, a current list of all Certified Pharmacy Technicians and Pharmacy Technicians assisting in the provision of Pharmacy services.

(ii) The Pharmacist-in-Charge shall develop or adopt, implement, and maintain written policies and procedures to specify the duties to be performed by Certified Pharmacy Technicians and Pharmacy Technicians. The duties and responsibilities of these personnel shall be consistent with their training and experience and shall address the method and level of necessary supervision specific to the practice site. These policies and procedures shall, at a minimum, specify that Certified Pharmacy Technicians and Pharmacy Technicians are not assigned duties that may be performed only by a Pharmacist. Such policies and procedures shall also specify that Pharmacy Technicians shall not be assigned duties that may be performed only by Certified Pharmacy Technicians.

(iii) The Pharmacist-in-charge shall develop or adopt, implement, and maintain a Pharmacy Technician training program that is site-specific to the practice setting of which he or she is in charge for all individuals employed by the Pharmacy who will assist in the Practice of Pharmacy. The Pharmacist-in-Charge shall utilize a Pharmacy Technician training manual as part of the training program. The Pharmacist-in-Charge shall be responsible for maintaining a record of all Certified Pharmacy Technicians and Pharmacy Technicians successfully completing the Pharmacy's Technician site-specific training program and an objective assessment mechanism. The Pharmacist-in-Charge shall attest to the Board of Pharmacy, in a timely manner, those persons who, from time to time, have met the training requirements necessary for registration with the Board.[99]

(b) Professional Performance Evaluation

Each Pharmacist who performs any of the acts described within the definition of "Practice of Pharmacy" is responsible for ensuring that he or she is the subject of a Professional Performance Evaluation at least once each year. Each Pharmacy is

[99]All training programs should be subject to approval by the Board of Pharmacy.

responsible for ensuring that every Pharmacist who practices at the Pharmacy for more than 40 hours during any twelve (12)-month period and who performs any of the acts described within the definition of "Practice of Pharmacy" is the subject of a Professional Performance Evaluation at least once each year.

(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.

Section 3. Prescription Drug Order Processing.

(a) Prescription Drug Order

A Prescription Drug Order shall contain the following information at a minimum:

(1) full name, date of birth, and street address of the patient;
(2) name, prescribing Practitioner's license designation, address, and, if required by law or rules of the Board, DEA registration number of the prescribing Practitioner;
(3) date of issuance;
(4) name, strength, dosage form, and quantity of Drug prescribed;
(5) directions for use;
(6) refills authorized, if any;
(7) if a written Prescription Drug Order, prescribing Practitioner's signature;
(8) if an electronically transmitted Prescription Drug Order, prescribing Practitioner's electronic or digital signature;
(9) if a hard copy Prescription Drug Order generated from electronic media, prescribing Practitioner's electronic or manual signature. For those with electronic signatures, such Prescription Drug Orders shall be applied to paper that utilizes security features[100] that will ensure the Prescription Drug Order is not subject to any form of copying and/or alteration.

(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) [101] or issued electronically.[102]

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[100] Examples of security features for prescription paper include those that prevent copying, such as hidden background words or darker-colored areas of the paper (which, when photocopied appear as black), those that prevent adulteration, such as solvent dye and brownstain features, and those that verify authenticity, such as the incorporation of fluorescent threads or watermarks.

[101] 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.

[102] 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

(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, the Prescription Drug Order shall be immediately reduced to a form by the Pharmacist, 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 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 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). The original, written Prescription Drug Order shall be maintained in accordance with state and federal recordkeeping requirements.

(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, 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 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, and shall contain the information required by state and federal law;

(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. The Prescription Drug order shall have written on its face "Authorization for Emergency Dispensing," and the date of the orally 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

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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.

Prescription Drug Order, which had earlier been reduced to writing. 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 via facsimile to a Pharmacist, 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 via facsimile. The hard copy of such faxed prescription serves as the original, written Prescription Drug Order and it shall be maintained in accordance with state and federal recordkeeping requirements.

(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 via facsimile. The hard copy of such faxed prescription serves as the original, written Prescription Drug Order and it shall be maintained in accordance with state and federal recordkeeping requirements.

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

(i) be transmitted to a Pharmacist, 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.

(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 consistent with existing federal or state laws and rules.

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

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

(c) Transfer of a Prescription Drug Order

Pharmacies utilizing automated data-processing systems shall satisfy all information requirements of a manual mode for Prescription Drug Order transferal, except as noted below for those pharmacies accessing a common electronic file. The transfer of original Prescription Drug Order information for the purpose of refill Dispensing is permissible between Pharmacies subject to the following requirements:

(1) The information is communicated directly between Pharmacists or Certified Pharmacy Technicians and the transferring Pharmacist or Certified Pharmacy Technician records the following information:
    (i) write the word "VOID" on the face of the invalidated Prescription Drug Order;
    (ii) record on the reverse side of the invalidated Prescription Drug Order the name and address of the Pharmacy to which it was transferred and the name of the Pharmacist or Certified Pharmacy Technician receiving the Prescription Drug Order;
    (iii) record the date of the transfer and the name of the Pharmacist or Certified Pharmacy Technician transferring the information; and
    (iv) the computer record shall reflect the fact that the original Prescription Drug Order has been voided and shall contain all the other information required above.

(2) The Pharmacist or Certified Pharmacy Technician receiving the transferred Prescription Drug Order information shall reduce to writing the following:
    (i) Write the word "TRANSFER" on the face of the transferred Prescription Drug Order.
    (ii) Provide all information required to be on a Prescription Drug Order pursuant to state and federal laws and rules, and include:
        (A) date of issuance of original Prescription Drug Order;
        (B) original number of refills authorized on original Prescription Drug Order;
        (C) date of original Dispensing;
        (D) number of valid refills remaining and date of last refill;
        (E) Pharmacy's name, address, and original prescription number from which the Prescription Drug Order information was transferred; and
        (F) name of transferring Pharmacist or Certified Pharmacy Technician.
    (iii) Systems providing for the electronic transfer of information shall not infringe on a patient's freedom of choice as to the provider of Pharmacist Care.

(3) Both the original and transferred Prescription Drug Order shall be maintained for a period of five years from the date of last refill.

(4) Pharmacies accessing a common electronic file or database used to maintain required Dispensing information are not required to transfer Prescription Drug Orders or information for Dispensing purposes between or among Pharmacies participating in the same common prescription file, provided, however, that any such common file shall contain complete records of each Prescription Drug Order and refill Dispensed, and, further, that a hard copy record of each Prescription Drug Order transferred or accessed for purposes of refilling shall be generated and maintained at the Pharmacy refilling the Prescription Drug Order or to which the Prescription Drug Order is transferred and shall protect against the illegal use or disclosure of Protected Health Information.

(5) In an emergency, a Pharmacy may transfer original Prescription Drug Order information for a non-controlled substance to a second Pharmacy for the purpose

of Dispensing up to a 72-hour supply without voiding the original Prescription Drug Order.

(d) Drug Product Selection by the Pharmacist

(1) A Pharmacist Dispensing a Prescription Drug Order for a Drug product prescribed by its brand name may select any Equivalent Drug Product provided that the Manufacturer or Distributor holds, if applicable, either an approved New Drug Application (NDA) or an approved Abbreviated New Drug Application (ANDA), unless other approval by law or from the Federal Food and Drug Administration is required.

(2) The Pharmacist shall not select an Equivalent Drug Product if the Practitioner instructs otherwise, either orally or in writing, on the Prescription Drug Order.

(3) The Pharmacist shall notify the patient or patient's agent if a Drug other than the brand name Drug prescribed is Dispensed.

(4) Whenever Drug product selection is performed by a Pharmacist, the Pharmacist shall Dispense the Equivalent Drug Product in a container Labeled in accordance with Section 3(e) (Labeling).

(e) Labeling

(1) All Drugs Dispensed to ambulatory or outpatients, including Drugs Dispensed by Practitioners shall have a label affixed to the container in which such Drug is Dispensed. The label shall include the following: [103]

(i) Critical Information for Patients – Critical information must appear on the label with emphasis (highlighted or bolded), in a sans serif typeface (such as "arial"), minimum 12-point size, and in "sentence case." Field size and font size may be increased in the best interest of patient care. Critical information text should never be truncated and shall include:

(A) patient name

(-a-) legal name of the patient; or

(-b-) if patient is an animal, include the last name of the owner, name of the animal, and animal species.

(B) directions for use

(-a-) directions for use as indicated by the prescriber and medication purpose/indication if included on prescription drug order[104]; and

(-b-) language should be simplified, avoiding unfamiliar words and medical jargon; when applicable, use numeric instead of alphabetic characters.

(C) drug name

(-a-) if written for a brand name and a generic drug is dispensed, include phrase "Generic for [brand name];"and

(-b-) include drug name suffixes, such as CD, SR, XL, XR, etc.

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[103] 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.

[104] Boards of pharmacy and licensees should recognize that "take as directed" may not provide sufficient information for the appropriate use of the medication. "Take as directed" is appropriate when specific directions are included on a unit-of-use package or dispensed package or in situations when directions are not able to be included on the label and the pharmacist presents directions to the patient and documents that such directions were given. "Take as directed" should not be used in lieu of patient counseling.

It is understood that prescription drug orders often do not include the indication for use.

(D) drug strength, expressed in the metric system whenever possible
(E) "use by" date
(-a-) date after which medication should be used; not expiration date of medication or expiration date of prescription; and
(-b-) format as – "Use by: MM/DD/YY."

(ii) Important information for patients – Must appear on the label but should not supersede critical information for patients and shall include: [105]

(A) pharmacy name or dispensing practitioner's entity name[106];
(B) pharmacy telephone number[107];
(C) prescriber name;
(-a-) format as – "Prescriber: [prescriber name]."
(D) "fill date" [108];
(-a-) format as – "Date filled: MM/DD/YY."
(E) prescription number;
(F) drug quantity;
(-a-) format as – "Qty: [number]."
(G) number of remaining refills;
(-a-) format as – "Refills: [number remaining]" or "No refills," using whole numbers only and managing partial fills through the pharmacy record keeping system;
(H) written or graphic product description;
(I) auxiliary information[109];
(J) any cautions and other provisions which may be required by federal or state law.

(iii) The following additional information for Patients – may appear on the label:
(A) bar codes;
(B) pharmacy address; and
(C) store number. [110]

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[105] Information traditionally included on the patient label must continue to be maintained and safeguarded by the record-keeping system. Boards of Pharmacy should require that record-keeping systems prohibit any alteration or modification of these data unless an appropriate audit trail and justification exists. Record-keeping systems should also prohibit any deletion of information except in accordance with state and federal requirements for data management and retention.

[106] Boards of Pharmacy should recognize that some pharmacies "do business as" a name other than the corporate name.

[107] Include phone number of the dispensing pharmacy, recognizing that a pharmacy providing shared services may be involved in the filling process; Boards of Pharmacy should not require more than one telephone number on the label.

[108] "Fill date" and "use by" date should be the only dates appearing on the prescription label. Other dates often found on labels, such as the original and expiration dates of the prescription drug order can be misunderstood by patients and clutter the label with unnecessary information.

[109] Auxiliary information, including auxiliary labels, should be evidence based, standardized, and demonstrated to complement the prescription label.

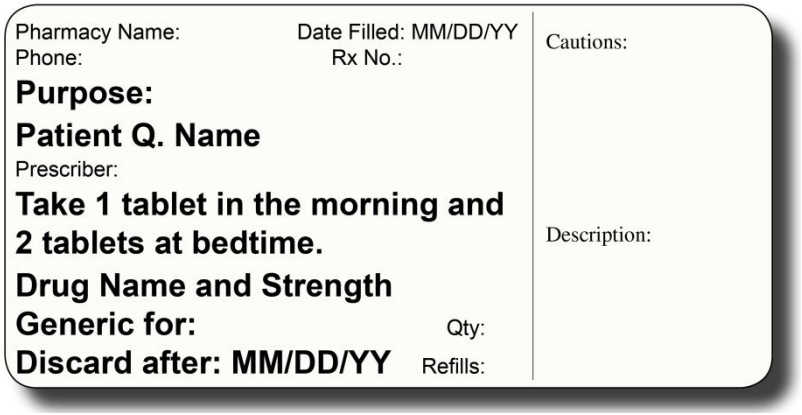
[110] Boards of pharmacy may consider utilizing these suggested labeling formats provided below.

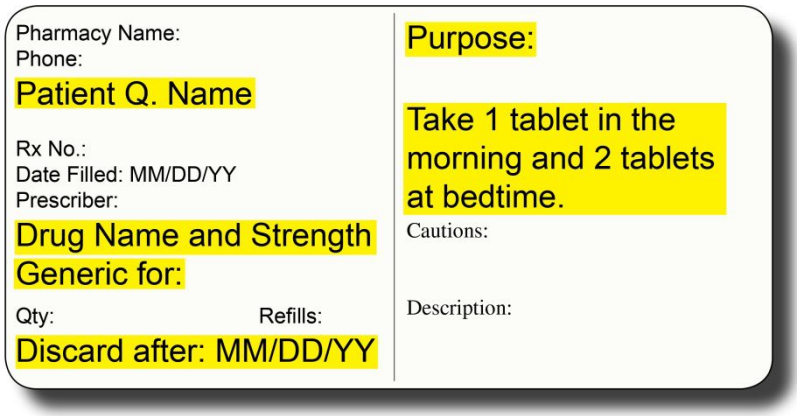
Section 4. Recordkeeping

(a) Patient Records[111]

(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





[111] 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.

(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

(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[112] 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 responsible for Dispensing;

(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.[113]

(c) Electronic Recordkeeping

(1) Systems Policies and Procedures

An up-to-date policy and procedure manual shall be developed by the Pharmacist-in-Charge that explains the operational aspects of the computerized recordkeeping system and shall:

(i) include examples of all required output documentation provided by the computerized recordkeeping system;

(ii) outline steps to be followed when the computerized recordkeeping system is not operational due to scheduled or unscheduled system interruption;

(iii) outline regular and routine backup file procedure and file maintenance;

(iv) outline audit procedures, personnel code assignments, and personnel responsibilities; and

(v) provide a quality assurance mechanism for data entry validation.

(2) Data Storage and Retrieval.

(i) the system shall have the capability of producing sight-readable information on all original and refill Prescription Drug Orders. The term "sight-

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[112] 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.

[113] 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.

readable" means that an authorized individual shall be able to examine the record and read the information from the cathode ray tube (CRT), microfiche, microfilm, printout, or other method acceptable to the Board of Pharmacy; and

(ii) the system shall provide online retrieval (via CRT display or hard copy printout) of original Prescription Drug Order information. Such information shall include, but not be limited to, the Prescription Drug Order requirements and records of Dispensing as indicated in Section 3 of this Rule; and

(iii) the storage and retrieval of refill information for original paper prescription orders for controlled substances in Schedule III and IV are subject to the following conditions:

(A) the system must provide online retrieval (via computer monitor or hard-copy printout) of original prescription order information for those prescription orders that are currently authorized for refilling. This shall include, but is not limited to, data such as the original prescription number; date of issuance of the original prescription order by the Practitioner; full name and address of the patient; name, address, and DEA registration number of the Practitioner; and the name, strength, dosage form, quantity of the controlled substance prescribed (and quantity dispensed if different from the quantity prescribed), and the total number of refills authorized by the prescribing Practitioner;

(B) the system must also provide online retrieval (via computer monitor or hard copy printout) of the current refill history for Schedule III or IV controlled substance prescription orders (those authorized for refill during the past six months). This refill history shall include, but is not limited to, the name of the controlled substance, the date of refill, the quantity Dispensed, the identification code, or name or initials of the Dispensing Pharmacist for each refill and the total number of refills Dispensed to date for that prescription order;

(C) Documentation of the fact that the refill information entered into the computer each time a Pharmacist refills an original paper, fax, or oral prescription order for a Schedule III or IV controlled substance is correct must be provided by the individual pharmacist who makes use of such an application. If such an application provides a hard copy printout of each day's controlled substance prescription order refill data, that printout shall be verified, dated, and signed by the individual Pharmacist who refilled such a prescription order. The individual Pharmacist must verify that the data indicated are correct and then sign this document in the same manner as he would sign a check or legal document (eg, J.H. Smith, or John H. Smith). This document shall be maintained in a separate file at that Pharmacy for a period of two years from the Dispensing date. This printout of the day's controlled substance prescription order refill data must be provided to each Pharmacy using such a computerized application within 72 hours of the date on which the refill was Dispensed. It must be verified and signed by each Pharmacist who is involved with such dispensing. In lieu of such a printout, the Pharmacy shall maintain a bound logbook, or separate file, in which each individual Pharmacist involved in such Dispensing shall sign a statement (in the manner previously described) each day, attesting to the fact that the refill information entered into the

computer that day has been reviewed by him or her and is correct as shown. Such a book or file must be maintained at the pharmacy employing such an application for a period of years after the date of Dispensing the appropriately authorized refill;

(D) the electronic recordkeeping system shall have the capability of producing a printout of any Prescription Drug Order data. The system shall provide a refill-by-refill audit trail for any specified strength and dosage form of any Drug. Such an audit trail shall be by printout, and include the name of the prescribing Practitioner, name and location of the patient, quantity Dispensed on each refill, date of Dispensing of each refill, name or identification code of the Dispensing Pharmacist, and unique identifier of the Prescription Drug Order; and

(E) any facility maintaining centralized prescription records shall be capable of sending a requested printout to the Pharmacy within 48 hours.

(iv) if a prescription is created, signed, transmitted, and received electronically, all records related to that prescription must be retained electronically and are subject to the following:

(A) records must be maintained electronically for years from the date of their creation or receipt;

(B) records regarding controlled substances prescriptions must be readily retrievable from all other records. Electronic records must be easily readable or easily rendered into a format that a person can read;

(C) records required by this section part must be made available to the state and federal agencies upon request;

(D) if the Pharmacy discontinues or changes the electronic prescription service provider or transfers the electronic Prescription Drug Order records to another Pharmacy, the Pharmacy must ensure that the records are stored in a format that can be retrieved, displayed, and printed in a readable format; and

(E) digitally signed prescription records must be transferred or migrated with the digital signature.

(3) Security

To maintain the confidentiality of patient records, the system shall have adequate security and systems safeguards designed to prevent and detect unauthorized access, modification, or manipulation of patient records. Once the Drug has been Dispensed, any alterations in Prescription Drug Order data shall be documented, including the identification of the Pharmacist responsible for the alteration.

(4) System Backup (Auxiliary Records Maintenance)

(i) In the event of an unscheduled system interruption, sufficient patient data and Prescription Drug Order data should be available to permit reconstruction of such data within a two-hour time period for the Pharmacist to Dispense Drugs with sound professional judgment.

(ii) An auxiliary system shall be established for the documentation of refills if the automated data processing system is inoperative for any reason and to ensure that all refills are authorized by the original Prescription Drug Order and that the maximum number of refills is not exceeded.

(iii) The auxiliary system shall be in place to provide for the maintenance of all necessary patient Drug information (as outlined in this rule) until the automated system becomes operational. However, nothing in this section

shall preclude the Pharmacist from using professional judgment for the benefit of a patient's health and safety.

(iv) When the automated system is restored to operation, the information regarding Prescription Drug Orders Dispensed and refilled during the inoperative period shall be entered into the automated system within 96 hours.

(v) Routine backup systems and procedures (hard copy, copy, disk, etc) shall be in place and operational to ensure against loss of patient data.

(vi) In the event that permanent Dispensing information is lost due to unscheduled system interruption, the Board of Pharmacy shall be notified within 24 hours.

Section 5. Pharmacist Care

(a) Prospective Drug Utilization Review (DUR)[114]

A Pharmacist shall review the patient record and each Prescription Drug Order for:

(1) known allergies;
(2) rational therapy contraindications;
(3) reasonable dose, duration of use, and route of Administration, considering age, gender, and other patient factors;
(4) reasonable directions for use;
(5) potential or actual adverse Drug reactions;
(6) Drug-Drug interactions;
(7) Drug-food interactions;
(8) Drug-disease contraindications;
(9) therapeutic duplication;
(10) proper utilization (including over- or under-utilization), and optimum therapeutic outcomes; and
(11) abuse/misuse.

Upon recognizing any of the above, the Pharmacist shall take appropriate steps to avoid or resolve the problem which shall, if necessary, include consultation with the Practitioner.

(b) Patient Counseling[115]

(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 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;

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[114] Pharmacists should be permitted to use computer software, if available, to accomplish this review.

[115] 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.

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

(3) 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).

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

(c) Medication Adherence Monitoring Services and Intervention Programs

Medication Adherence Monitoring Services and Intervention Programs designed to promote improved medication use behaviors, such as compliance and adherence, appropriate monitoring and self-reporting, increased patient knowledge, and improved therapy options, shall comply with established Guidelines for the Appropriate Use and Disclosure of Protected Health Information in Medication Adherence Monitoring Services and Patient Intervention Programs. (See Appendix E for Guidelines for the Appropriate Use and Disclosure of Protected Health Information in Medication Adherence Monitoring Services and Patient Intervention Programs.)

(d) Collaborative Pharmacy Practice

(1) Collaborative Pharmacy Practice Agreement

A Pharmacist planning to engage in Collaborative Pharmacy Practice shall have on file at his or her place of practice the written Collaborative Pharmacy Practice Agreement. The initial existence and subsequent termination of any such agreement and any additional information the Board may require concerning the Collaborative Pharmacy Practice Agreement, including the agreement itself, shall be made available to the Board for review upon request. The Agreement may allow the Pharmacist, within the Pharmacist's Scope of Practice Pursuant to the Collaborative Pharmacy Practice Agreement, to conduct activities approved by the Practitioner, and as defined by law and by the Rules of the Board. The collaboration that the Practitioner agrees to conduct with the Pharmacist must be within the scope of the Practitioner's current practice. Patients or caregivers shall be advised of such agreement.

(2) Contents

The Collaborative Pharmacy Practice Agreement shall include:

(i) identification of the Practitioner(s) and Pharmacist(s) who are parties to the Agreement;
(ii) the types of decisions that the Pharmacist is allowed to make may include:
(A) a detailed description of the types of diseases, Drugs, or Drug categories involved, and the activities allowed in each case;

(B) a detailed description of the methods, procedures, decision criteria, and plan the Pharmacist is to follow when conducting allowed activities; and

(C) a detailed description of the activities the Pharmacist is to follow, including documentation of decisions made and a plan or appropriate mechanism for communication, feedback, and reporting to the Practitioner concerning specific decisions made. In addition to the Agreement, documentation shall occur on the prescription record, patient profile, a separate log book, or in some other appropriate system.

(iii) a method for the Practitioner to monitor compliance with the Agreement and clinical outcomes and to intercede where necessary;

(iv) a description of the Continuous Quality Improvement Program used to evaluate effectiveness of patient care and ensure positive patient outcomes;

(v) a provision that allows the Practitioner to override a Collaborative Practice decision made by the Pharmacist whenever he or she deems it necessary or appropriate;

(vi) a provision that allows either party to cancel the Agreement by written notification;

(vii) an effective date; and

(viii) signatures of all collaborating Pharmacists and Practitioners who are party to the agreement, as well as dates of signing.

Amendments to a Collaborative Pharmacy Practice Agreement must be documented, signed, and dated.

(3) Initiation of the Collaborative Pharmacy Practice Agreement
The Collaborative Pharmacy Practice Agreement must be coupled with a medical order from the Practitioner to initiate allowed activities for any particular patient.

(4) Documentation of Pharmacist activities
Documentation of allowed activities must be kept as part of the patient's permanent record and be readily available to other health care professionals providing care to that patient and who are authorized to received it. Documentation of allowed activities shall be considered Protected Health Information.

(5) Review
At a minimum, the written agreement shall be reviewed and renewed and, if necessary, revised every year.

Section 6. Continuous Quality Improvement Program

(a) Continuous Quality Improvement Program

(1) Compliance with this section may be considered by the Board as a mitigating factor in the investigation and evaluation of a Quality-Related Event (QRE).

(2) Each Pharmacy shall establish a Continuous Quality Improvement (CQI) Program for the purpose of detecting, documenting, assessing, and preventing QREs. At a minimum, a CQI Program shall include provisions to:

(i) designate an individual or individuals responsible for implementing, maintaining, and monitoring the CQI Program, which is managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form;

(ii) initiate documentation of QREs as soon as possible, but no more than three days, after determining their occurrence;

(iii) analyze data collected in response to QREs to assess causes and any contributing factors such as staffing levels, workflow, and technological support;
(iv) use the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs and increase good outcomes for patients;
(v) provide ongoing CQI education at least annually to all pharmacy personnel;
(vi) for those Persons utilizing a Drug formulary, a periodic review of such formulary shall be undertaken to ensure that appropriate medications are being offered/selected in the best interest of patients.

(3) As a component of its CQI Program, each Pharmacy shall ensure that periodic meetings are held, at least annually, by staff members of the Pharmacy to consider the effects on quality of the Pharmacy system due to staffing levels, workflow, and technological support. Such meetings shall review data showing evidence of the quality of care for patients served by the Pharmacy and shall develop plans for improvements in the system of Pharmacy Practice so as to increase good outcomes for patients.

(4) Appropriately-blinded incidents of QREs shall be reported to a nationally recognized error reporting program designated by the Board.

(5) Quality Self-Audit
Each Pharmacy shall conduct a Quality Self-Audit at least quarterly to determine whether the occurrence of QREs has decreased and whether there has been compliance with preventative procedures, and to develop a plan for improved adherence with the CQI Program in the future. Each pharmacy shall conduct a Quality Self-Audit upon change of Pharmacist-in-Charge to familiarize that Person with the Pharmacy's CQI Program.

(6) Consumer Survey
As a component of its CQI Program, each Pharmacy should conduct a Consumer Survey of patients who receive pharmaceutical products and services at the Pharmacy. A Consumer Survey should be conducted at least once per year. A statistically valid sampling technique may be used in lieu of surveying every patient. Each Pharmacy should use the results of its Consumer Survey to evaluate its own performance at a particular time and over a period of time.

(7) Protection from Discovery[116]
All information, communications, or data maintained as a component of a pharmacy CQI Program are privileged and confidential. This shall not prevent review of a pharmacy's CQI Program and records maintained as part of a system by the Board, pursuant to subpoena, as necessary to protect the public health and safety. All information, communications, or data furnished to any Peer Review Committee, and any findings, conclusions, or recommendations resulting from the proceedings of such committee, board, or entity are privileged. The records and proceedings of any Peer Review Committee, are confidential and shall be used by such committee, and the members thereof, only in the exercise of the proper functions of the committee and shall not be public records nor be available for court subpoena or for discovery proceedings. The disclosure of confidential, privileged Peer Review Committee information during advocacy, or as a report to the Board of Pharmacy, or to the affected Pharmacist or Pharmacy

[116] Boards of pharmacy may have more or less authority to inspect CQI records, depending on state law. When authorizing the implementation of CQI Programs the extent of authority needed to obtain these materials must be determined.

auxiliary personnel under review does not constitute a waiver of either confidentiality or privilege.

(8) Compliance with Subpoena
All persons shall comply fully with a subpoena issued by the Board for documents or information as otherwise authorized by law. The disclosure of documents or information under subpoena does not constitute a waiver of the privilege associated with a CQI Program. Failure to comply with the subpoena is grounds for disciplinary action against the Person by the appropriate licensing board.

Section 7. Shared Pharmacy Services.

(a) General Requirements[117, 118]

(1) The Pharmacy must possess a resident or nonresident permit issued by the Board prior to engaging in Shared Pharmacy Services.[119]

(2) A Pharmacy may provide or utilize Shared Pharmacy Services only if the Pharmacies involved:

(i) have the same owner; or

(ii) have a written contract or agreement that outlines the services provided and the shared responsibilities of each party in complying with federal and state pharmacy laws and rules; and

(iii) share a common electronic file or technology that allows access to information necessary or required to perform Shared Pharmacy Services in conformance with the pharmacy act and the Board's rules.

(3) A Pharmacy engaged in Shared Pharmacy Services shall comply with appropriate federal and state controlled substance registrations for each Pharmacy if controlled substances are maintained.

(4) A Pharmacy engages in Shared Pharmacy Services shall notify the Board in writing within 10 days of a change of location, discontinuance of service, or closure of a Pharmacy.

(b) Operations

(1) Pharmacies engaging in Shared Pharmacy Services, or a Pharmacist acting independently of a Pharmacy and participating in Shared Pharmacy Services shall:

(i) maintain records identifying, individually, for each Prescription Drug Order processed, the name of each Pharmacist, or Pharmacy Intern who took part in the Drug Utilization Review, refill authorization, or therapeutic intervention functions performed at that Pharmacy and the

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[117] The Board may want to consider the extent to which this General Requirements Section is applicable to institutional-based Shared Pharmacy Services Pharmacies, as such application may be subject to interpretation of existing state and federal law governing Institutional Facilities.

[118] In order to ensure accountability, the Pharmacist-in-Charge of a Pharmacy engaging in Shared Pharmacy Services must possess a license to practice Pharmacy in all jurisdictions that he/she is engaging in such series until such a time in which provisions for multistate practice exist.

[119] Often the terms "licensure," "registration," and "permit" are used interchangeably throughout the *Model Act*. In the case of Shared Pharmacy Services Pharmacies that utilize Automated Pharmacy Systems, Boards may determine that it is appropriate to issue a permit for the Automated Pharmacy System but not for the physical site where the Automated Pharmacy System is located.

name of any Certified Pharmacy Technician or Pharmacy Technician if they assisted in any of those functions;

(ii) maintain records identifying individually, for each Prescription Drug Order filled or dispensed, the name of each Pharmacist or Pharmacy Intern who took part in the filling, dispensing, and counseling functions performed at that Pharmacy and the name of any Certified Pharmacy Technician or Pharmacy Technician if they assisted in any of those functions;

(iii) report to the Board as soon as practical the results of any disciplinary action taken by another state's Board of Pharmacy involving Shared Pharmacy Services;

(iv) maintain a mechanism for tracking the Prescription Drug Order during each step of the processing and filling procedures performed at the Pharmacy;

(v) maintain a mechanism for the patient to identify all Pharmacies involved in filling the Prescription Drug Order; and

(vi) be able to obtain for inspection any required record or information within 72 hours of any request by the Board or its designee.

(2) Notification to Patients

(i) Pharmacies engaging in Shared Pharmacy Services shall notify patients that their Prescription Drug Orders may be processed or filled by another Pharmacy unless the Prescription Drug is delivered to patients in Institutional Facilities where a licensed health care professional is responsible for administering the Prescription Drug to the patient.

(c) Drug Storage and Security

(1) Drugs shall be stored in compliance with state and federal laws and in accordance with these Rules, including those addressing temperature, proper containers, and the handling of outdated drugs.

(2) Drugs stored at Shared Pharmacy Services Pharmacies shall be stored in an area that is:

(i) separate from any other Drugs used by the health care facility; and

(ii) secured, so as to prevent access by unauthorized personnel.

(3) Access to the area where Drugs are stored at the Shared Pharmacy Services Pharmacy must be limited to:

(i) Pharmacists, Certified Pharmacy Technicians, Pharmacy Technicians, or Pharmacy Interns who are employed by the Shared Pharmacy Services Pharmacy; or

(ii) Personnel employed at the Institutional Facility or clinic where the Shared Pharmacy Services Pharmacy is located who:

(A) are licensed health care providers;

(B) are designated in writing by the Pharmacist-in-Charge or the Person responsible for the supervision and on-site operation of the facility where the Automated Pharmacy System is located; and

(C) have completed documented training concerning their duties associated with the Shared Pharmacy Services Pharmacy.

(4) Shared Pharmacy Services Pharmacies shall have adequate security to:

(i) comply with federal and state laws and regulations; and

(ii) Protect the confidentiality and integrity of Protected Health Information.

(d) Policies and Procedures

(1) Each participant in Shared Pharmacy Services shall jointly develop, implement, review, revise, and comply with joint policies and procedures for Shared Pharmacy Services. Each participant is required to maintain this portion of the

joint policies and procedures that relate to that participant's operations. The policies and procedures shall:

(i) outline the responsibilities of each of the pharmacies;

(ii) include a list of the name, address, telephone numbers, and all license and permit numbers of the pharmacies involved in Shared Pharmacy Services; and

(iii) include policies and procedures for:

(A) notifying patients that their Prescription Drug Orders may be processed or filled by another Pharmacy and providing the name of the Pharmacy;

(B) protecting the confidentiality and integrity of Protected Health Information;

(C) dispensing Prescription Drug Orders when the filled Prescription Drug Order is not received or the patient comes in before the Prescription Drug Order is received:

(D) maintaining required manual or electronic records to identify the name, initials or identification code and specific activity or activities of each Pharmacist, Certified Pharmacy Technician, Pharmacy Technician, or Pharmacy Intern who performed any Shared Pharmacy Services;

(E) complying with federal and state laws; and

(F) operating a Continuous Quality Improvement Program for Shared Pharmacy Services, designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems.

(e) Individual Practice

(1) Nothing in this Section shall prohibit an individual Pharmacist licensed in the state, who is an employee of or under contract with a Pharmacy, or a licensed Certified Pharmacy Technician, Pharmacy Technician, or Pharmacy Intern, working under the supervision of the Pharmacy, from accessing that Pharmacy's electronic database from inside or outside the Pharmacy and performing the Prescription Drug Order processing functions permitted by the Pharmacy Act, if both of the following conditions are met:

(i) the Pharmacy establishes controls to protect the confidentiality and integrity of Protected Health Information; and

(ii) no part of the database is duplicated, downloaded, or removed from the Pharmacy's electronic database.

Section 8. Automated Pharmacy Systems.

(a) Automated Pharmacy Systems can be utilized in licensed pharmacies and Shared Pharmacy Services Pharmacies 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:

(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 that ensures medication orders or Prescription Drug Orders are reviewed by a Pharmacist in accordance with established policies and procedures and good Pharmacist Care. [120]
(i) A Pharmacist shall be accessible to respond to inquiries or requests pertaining to Drugs Dispensed from the Automated Pharmacy System.[121]
(ii) Any Pharmacy that maintains an Automated Pharmacy System for the purposes of remote Dispensing to outpatients[122] 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[123], to:
(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.

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[120] 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.

[121] 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.

[122] 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.

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

(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. [124]

(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.[125]

(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.

(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.[126]

(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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[124] 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.

[125] 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).

[126] 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.

Section 9. Return and Reuse of Prescription Drugs.

(a) Prescription Drugs may only be returned and reused providing that the Prescription Drugs:
  (1) were removed from the Pharmacy for delivery by Pharmacy staff, or a Pharmacy contracted delivery service and returned because the Prescription Drugs were not deliverable or the patient refused delivery, and such Prescription Drugs did not leave the control of the Pharmacy; and
  (2) Prescription Drugs were packaged in:
    (i) the manufacturer's original, sealed, and tamper-evident bulk, unit-of-use, or unit-dose packaging; or
    (ii) the dispensing pharmacy's original packaging; and
    (iii) returned to the pharmacy immediately after the unsuccessful delivery attempt.
  (3) If a Pharmacy attempts, but is not able, to deliver Prescription Drugs using an approved common carrier, then such Prescription Drugs may be returned and reused by the Pharmacy if packaged in:
    (i) the manufacturer's original, sealed, and tamper-evident bulk, unit-of-use[127], or unit-dose packaging; or
    (ii) the dispensing pharmacy's original, sealed, and tamper-evident packaging that maintains the product quality as per United States Pharmacopeia (USP) standards.

(b) All returned packaging must indicate that the Prescription Drug's integrity and stability has been maintained.
(c) All returned Prescription Drugs must have been returned on the same day as the attempted delivery and must be evaluated by appropriate Pharmacy staff to ensure such Prescription Drugs are not adulterated or misbranded.
(d) A state-licensed Pharmacist must verify compliance with all of the above elements.

Section 10. Prescription Drug Repository Programs.

(a) Repository Programs must have written policies and procedures, which include at a minimum:
  (1) Qualifications of acceptable medications for reuse. Such qualifications must include the following provisions:
    (i) only non-controlled medications will be accepted
    (ii) all medications will be inspected and determined to be:
      (A) unadulterated;
      (B) unexpired; and
      (C) in unopened unit dose or manufacturer's tamper-resistant original packaging
    (iii) maintenance of a separate physical inventory;
    (iv) completion of a monthly expiration date review for all medications;
    (v) prohibition of charging or accepting compensation for medications except for administrative or minimal dispensing fees;
    (vi) dispensing by a pharmacist or a practitioner within the practitioner's scope of practice; and

[127]Unit-of-use is not intended to include co-mingled, multi-medication unit-of-use packages also known as compliance packs.

(vii) record keeping, including the source and dispensation of all medication.

Section 11. Disposal of Controlled Substances.[128]

(a) Any Persons legally authorized to possess controlled substances in the course of their professional practice or the conduct of their business shall dispose of such Drugs by the following procedures and in compliance with federal law:

(1) The responsible individual shall send the Board of Pharmacy a list of the controlled substances to be disposed of, including the name(s) and quantity of the Drug(s).

(2) The Board shall authorize and instruct the applicant to dispose of the controlled substances in one of the following manners:

(i) by Delivery to an agent of the Board of Pharmacy or the Board of Pharmacy office;

(ii) by destruction of the Drugs in the presence of a Board of Pharmacy officer, agent, inspector, or other authorized individual; or

(iii) by such other means as the Board of Pharmacy may determine to ensure that the Drugs do not become available to unauthorized Persons.

Section 12. Prepackaging

(a) A Pharmacy may Prepackage Drugs under the following circumstances:

(1) written policies and procedures have been developed that address the processes of Prepackaging within the Pharmacy;

(2) the Prepackaging processes are conducted under conditions that ensure the integrity of the Drug and under the direct supervision of a Pharmacist;

(3) the Prepackaged Drugs are labeled with the following components:

(i) Drug Name;

(ii) Drug Strength;

(iii) Pharmacy Control and Manufacturer lot number;

(iv) Name of the Manufacturer or Distributor of the Drug; and

(v) Beyond-Use Date.

(iv) Records of all Prepackaging operations are maintained and include the following:

(A) the name (nonproprietary and proprietary name), strength, dosage form, quantity per container, and quantity of containers of the Drug being Prepackaged;

(B) the name of the Manufacturer or Distributor of the Drug;

(C) Pharmacy Control and Manufacturer lot number;

(D) expiration date of the Drug according to the original Manufacturer or Distributor container and the Beyond-Use Date;

(E) the name or initials of the Certified Pharmacy Technician or Pharmacy Technician that Prepackaged the Drug and the name or initials of the Pharmacist that verified the appropriateness of the Prepackaged Drug; and

(F) the date the Drug is Prepackaged.

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[128]Boards may give hospitals the authority to dispose of wasted quantities of controlled substances without prior authorization under specified conditions.

(v) All Drugs Prepackaged are stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the Labeling of such Drugs, or with requirements in the current edition of an official compendium.

Section 13. Provision of Pharmacist Care Outside of a Licensed Pharmacy.

(a) A Pharmacist providing Pharmacist Care services outside the premises of a licensed Pharmacy shall maintain the records or other patient-specific information used in such activities in a readily retrievable form in a system that is secured and managed by the pharmacy with whom the pharmacist is providing such services or, if acting independent of a pharmacy, a secure system maintained by the pharmacist. Such records or information shall:

(1) provide accountability and an audit trail;
(2) be provided to the Board upon request;
(3) be preserved for a period of at least five years from the date relied upon or consulted for the purposes of performing any such function; and
(4) secure from unauthorized access and use.

Section 14. Approval of Pharmacy Practice Initiatives.

(a) Application. [129]

An application for approval of a Pharmacy practice initiative that improves the quality of or access to Pharmacist Care, but which falls outside the scope of present regulations, shall be submitted to the Board and shall contain at least the following information:

(1) the name, address, telephone number, and the license number of the Pharmacist responsible for overseeing the initiative;
(2) the specific location and, if a Pharmacy, the Pharmacy name, address, telephone, and license number where the proposed Pharmacy practice initiative will be conducted; and
(3) a detailed summary of the proposed Pharmacy practice initiative, which includes:
    (i) the goals and/or objectives of the proposed Pharmacy practice initiative;
    (ii) a full explanation of the initiative and how it will be conducted;
    (iii) the time frame for the Pharmacy practice initiative, including the proposed start date;
    (iv) background information or literature review to support the proposal, if applicable;
    (v) the rule(s) that will have to be waived in order to complete the Pharmacy practice initiative and a request to waive the rule(s); and

[129] Boards may want to develop language addressing the time frame within which they will take action on an application for approval of a Pharmacy practice initiative.

(vi) procedures to be used during the Pharmacy practice initiative to ensure that the public's health and safety are not compromised as a result of the rule waiver.

(b) Approval by the Board.

The Board shall approve a Pharmacy practice initiative if it determines that:

(1) the Pharmacy practice initiative will improve the quality of or access to Pharmacist Care;

(2) the Pharmacy practice initiative will not adversely affect, directly or indirectly, the health, safety, or well-being of the public; and

(3) the alternative measures to be taken, if any, are equivalent or superior to those prescribed in the part for which the rule waiver is requested.

The Board shall deny, Revoke, or refuse to renew an application for a Pharmacy practice initiative if the Board determines that the above requirements have not been met. In issuing an approval for a Pharmacy practice initiative, the Board may impose such terms and conditions it deems appropriate to carry out the purposes of Section 213(a)(14) of this Act and the rules adopted thereunder.

(c) Notification.

The Board shall notify the applicant in writing within 60 days of the Board's decision. If an approval is granted, the notification shall specify the period of time for which the approval and rule waiver will be effective and any conditions to be met by the applicant.

(d) Extension of Approval of Pharmacy Practice Initiatives.

A request for an extension of an approval of a Pharmacy practice initiative shall be submitted in writing at least (_____) days prior to the expiration date of the existing approval. Renewal requests shall contain the information specified in subsection (a). An approval of a Pharmacy practice initiative shall be renewed by the Board if the applicant continues to satisfy the Criteria contained in subsection (b) and demonstrates compliance with the alternative measures or conditions imposed at the time the original Pharmacy practice initiative was approved.

Section 15. Unprofessional Conduct.

Unprofessional conduct shall include, but is not limited to, the following acts of a Pharmacist or Pharmacy:

(a) the publication or circulation of false, misleading, or otherwise deceptive statements concerning the Practice of Pharmacy;

(b) unreasonably refusing to Compound or Dispense Prescription Drug Orders that may be expected to be Compounded or Dispensed in Pharmacies by Pharmacists;

(c) attempting to circumvent the Patient Counseling requirements, or discouraging the patient from receiving Patient Counseling concerning their Prescription Drug Orders;

(d) the illegal use or disclosure of Protected Health Information;

(e) failure to maintain adequate records, systems, and security to protect against the illegal use or disclosure of Protected Health Information;

(f) failure to maintain adequate records to account for disclosures of Protected Health Information;

(g) selling, giving away, or otherwise disposing of accessories, chemicals, or Drugs or Devices found in illegal Drug traffic when the Pharmacist knows or should have known of their intended use in illegal activities;

(h) engaging in conduct likely to deceive, defraud, or harm the public, or demonstrating a willful or careless disregard for the health, welfare, or safety of a patient, or engaging

in conduct which substantially departs from the standards of care ordinarily exercised by a Pharmacist, with proof of actual injury not having to be established;

(i) selling a Drug for which a Prescription Drug Order from a Practitioner is required, without having received a Prescription Drug Order for the Drug;

(j) willfully and knowingly failing to maintain complete and accurate records of all Drugs received, Dispensed, or disposed of in compliance with the Federal laws and regulations and State laws and rules;

(k) obtaining any remuneration by fraud, misrepresentation, or deception, including, but not limited to, receiving remuneration for amending or modifying, or attempting to amend or modify, a patient's Pharmacist Care, absent a clear benefit to the patient, solely in response to promotion or marketing activities.

Model Rules for Public Health Emergencies

Section 1. Purpose and Scope.

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 or similar crisis within the confines of a regulatory framework that serves to protect the welfare and health of the public.

(See comment list.)

Section 2. Definitions.

(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 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.[130]

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

(d) "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) "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) "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.

Section 3. Emergency 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 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;[131]

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

[131] 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.

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

Section 4. Public Health Emergency Refill Dispensing.

(a) For the duration of the State of Emergency issued due to a Public Health Emergency 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:[132]

(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 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[133]

(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 Licensure.

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

[133] 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.

(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, may Dispense Prescription Drugs in areas affected by the Declared Disaster during the time that the State of Emergency exists if:

(i) the Board can verify current licensure in good standing of the Pharmacist directly with the state or indirectly via a third-party verification system; and[134]

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

(2) a Certified Pharmacy Technician, Pharmacy Technician, or Pharmacy Intern not registered or licensed in this State, but currently registered or licensed in another state, may assist the Pharmacist in Dispensing Prescription Drugs in affected Disaster Areas during the time that the State of Emergency exists if:

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

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

(3) a Wholesale Drug Distributor not licensed in this State, but currently licensed in another state, may Distribute Prescription Drugs in affected Disaster Areas during the time that the State of Emergency exists if:

(i) the Board can verify current licensure in good standing of the Wholesale Drug Distributor directly with the state or indirectly via a third-party verification system; and

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

(4) the temporary recognition of nonresident licensure or registration shall cease with the termination of the State of Emergency.

Section 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:[135]

(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;[136]

(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

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[134] 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.

[135] 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.

[136] 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.

(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.[137]

[137] 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.

Comments

Section 1. Comment.

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.

Model Rules for Nuclear/Radiologic Pharmacy

Section 1. Purpose and Scope.

The Practice of Nuclear/Radiologic Pharmacy is hereby recognized as a specialty of Pharmacy practice, regulated by State Boards of Pharmacy. As such, the following model rules are included to address those areas specific or unique to this specialty practice. Nuclear/Radiologic Pharmacy Practice refers to a patient-oriented service that embodies the scientific knowledge and professional judgment required to improve and promote health through the assurance of the safe and efficacious use of radiopharmaceuticals and other Drugs.

Section 2. Definitions.

(a) "Authentication of Product History" means, but is not limited to, identifying the purchasing source, the ultimate fate, and any intermediate handling of any Component of a radiopharmaceutical.

(b) "Internal Test Assessment" means, but is not limited to, conducting those tests of quality assurance necessary to ensure the integrity of the test.

(c) "Nuclear Pharmacy" means a Pharmacy providing radiopharmaceutical services or, as provided in Section 3 of these Rules, an appropriate area of any Institutional Facility.

(d) "Qualified Licensed Professional" means a non-Pharmacist individual (such as a physician, nurse, or technologist) who possesses a current state license, if applicable, and who has sufficient training and experience to safely handle and Dispense radiopharmaceuticals as defined by the respective requirements of [cite appropriate Nuclear Regulatory Commission (NRC) or Agreement State and State Board of Pharmacy law(s)].

(e) "Qualified Nuclear Pharmacist" means a currently licensed Pharmacist in the State of practice, who is certified as a Nuclear Pharmacist by the State Board of Pharmacy or by a certification Board recognized by the State Board of Pharmacy, or who meets the following standards:

(1) Minimum standards of training for "authorized user status" of radioactive material [cite State Radiation Control Agency or NRC licensure guide].

(2) Completed a minimum of 200 contact hours of instruction in nuclear Pharmacy and the safe handling and the use of radioactive materials from a program approved by the State Board of Pharmacy, with emphasis in the following areas:

(i) radiation physics and instrumentation;

(ii) radiation protection;

(iii) mathematics of radioactivity;

(iv) radiation biology; and

(v) radiopharmaceutical chemistry.

(3) Attained a minimum of 500 hours of clinical nuclear Pharmacy training under the supervision of a qualified nuclear Pharmacist.

(f) "Radiopharmaceutical Quality Assurance" means, but is not limited to, the performance of appropriate chemical, biological, and physical tests on potential radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals, including internal test assessment, authentication of product history, and the keeping of proper records.

(g) "Radiopharmaceutical Service" means, but shall not be limited to, the procurement, storage, handling, preparation, Labeling, quality assurance testing, Dispensing, Delivery, record keeping, and disposal of radiopharmaceuticals and other Drugs.

(h) "Radiopharmaceuticals" are radioactive Drugs as defined by Food and Drug Administration and the _____ State Board of Pharmacy [cite appropriate law(s)].

Section 3. General Requirements for Pharmacies Providing Radiopharmaceutical Services.

(a) Nuclear Pharmacy License. A license to operate a Pharmacy providing radiopharmaceutical services shall only be issued to a Qualified Nuclear Pharmacist. All personnel performing tasks in the preparation and Distribution of radioactive Drugs shall be under the direct supervision of a Qualified Nuclear Pharmacist. A Qualified Nuclear Pharmacist shall be responsible for all operations of the Pharmacy and shall be in personal attendance at all times that the Pharmacy is open for business. In emergency situations when a Qualified Nuclear Pharmacist is not present, designated Qualified Licensed Professionals may have access to the licensed area. These individuals may prepare single doses of radiopharmaceuticals for the immediate emergency, and must document such activities.

(b) Nuclear Pharmacies shall have adequate space and equipment, commensurate with the scope of services required and provided, meeting minimal space requirements established for all pharmacies in the State or as otherwise defined by the _____ State Board of Pharmacy.

(c) The Nuclear Pharmacy area shall be secured from unauthorized personnel.

(d) Nuclear Pharmacies shall maintain records of acquisition, inventory, and disposition of all radioactive Drugs and other radioactive materials in accordance with [cite appropriate Pharmacy and radiological control agency or NRC Statute(s)].

(e) All pharmacies handling radiopharmaceuticals shall provide a radioactive storage and product decay area. Detailed floor plans shall be submitted to the State Board of Pharmacy and the State Radiation Control Agency or NRC before approval of the license.

(f) Radiopharmaceuticals are to be Dispensed only upon a Prescription Drug Order from a Practitioner authorized to possess, use, and Administer radiopharmaceuticals.

(g) The permit to operate a Nuclear Pharmacy is conditioned upon an approved State Radiation Control Agency (RCA) or NRC license. Copies of the RCA or NRC inspection reports shall be made available upon request for Board inspection.

(h) Labeling

(1) No radiopharmaceutical may be Dispensed unless a label is affixed to the immediate container bearing the following information:
   (i) the standard radiation symbol;
   (ii) the words "Caution – Radioactive Material"; and
   (iii) the prescription number.

(2) No radiopharmaceutical may be Dispensed unless a label is affixed to the outer or Delivery container bearing the following information:
   (i) the standard radiation symbol;
   (ii) the words "Caution – Radioactive Material";
   (iii) the radionuclide and chemical form;
   (iv) the activity and date and time of assay;
   (v) the volume, if in liquid form;

(vi) the requested activity and the calibrated activity;
(vii) the prescription number;
(viii) patient name or space for patient name. Where the patient's name is not available at the time of Dispensing, a 72-hour exemption is allowed to obtain the name of the patient. No later than 72 hours after Dispensing the radiopharmaceutical, the patient's name shall become a part of the Prescription Drug Order to be retained for a period of three years;
(ix) the name and address of the nuclear Pharmacy;
(x) the name of the Practitioner; and
(xi) the lot number of the prescription.

Section 4. Other Requirements.

All Nuclear/Radiologic Pharmacies shall also adhere to the principles outlined in the Rules for Pharmacist Care as these pertain to the practice of Nuclear Pharmacy. (See Appendix A for Model Inspection Form for Nuclear Pharmacies.)

Model Rules for Sterile Pharmaceuticals

Section 1. Purpose and Scope.

The purpose of this section is to ensure positive patient outcomes through the provision of standards for (1) Pharmacist Care; (2) the preparation, Labeling, and Distribution of Sterile Pharmaceuticals by Pharmacies; and (3) Product Quality and Characteristics. These standards are intended to apply to all Sterile Pharmaceuticals, notwithstanding the location of the patient (eg, home, hospital, nursing home, hospice, doctor's office). All Compounding Pharmacies and Pharmacists shall practice in accordance with these Rules, the Board's Good Compounding Practices Applicable to State Licensed Pharmacies, and the current United States Pharmacopeia-National Formulary (USP-NF) chapters on Compounding and sterile pharmaceutical preparations.

Section 2. Definitions.

(a) "Beyond-Use Date" means a date placed on a prescription label at the time of Dispensing that is intended to indicate to the patient or caregiver a time beyond which the contents of the prescription are not recommended to be used.

(b) "Bioburden" means the total number of microorganism associated with a specific item prior to sterilization.

(c) "Biological Safety Cabinet" means a containment unit suitable for the preparation of low to moderate risk agents where there is a need for protection of the product, personnel, and environment, according to National Sanitation Foundation (NSF) Standard 49.

(d) "Critical Areas" means areas designed to maintain sterility of sterile materials. Sterilized product, container/closures, and equipment may be exposed in critical areas.

(e) "Critical Surfaces" – Surfaces which may come into contact with or directly impact sterilized product or containers/closures.

(f) "Cytotoxic" means a pharmaceutical that has the capability of killing living cells.

(g) "Disinfection" means the process by which surface bioburden is reduced to a safe level or eliminated. [138]

(h) "Enteral" means within or by way of the gastrointestinal tract or intestine.

(i) "ISO Class" means the description of an atmospheric environment characterized by the number of particles within a diameter per cubic foot of air.[139]

(j) "Isolator" means a decontaminated unit, supplied with ISO Class 5 or higher air quality that provides uncompromised, continuous isolation of its interior from the external environment (eg, surrounding cleanroom air and Compounding Pharmacy personnel).

(k) "Parenteral" means by some other route than through the gastrointestinal tract such as, but not limited to, intravenous, subcutaneous or intramuscular routes.

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[138] Some disinfection agents are effective only against vegetative microbes, while others possess additional capability to effectively kill bacterial and fungal spores.

[139] For example, "ISO Class 5" means an atmospheric environment that contains fewer than 100 particles 0.5 microns in diameter per cubic foot or air.

(l) "Positive Patient Outcomes" include the cure or prevention of disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process so as to improve the patient's quality of life.

(m) "Product Quality and Characteristics" include sterility, potency, identity, strength, quality, and purity associated with environmental quality, preparation activities, and checks and tests.

(n) "Risk Level" of the Sterile Pharmaceutical means the level assigned to a Sterile Pharmaceutical by a Pharmacist that represents the probability that the Sterile Pharmaceutical will be contaminated with microbial organisms, spores, endotoxins, foreign chemicals, or other physical matter.[140]

(o) "Sterile Pharmaceutical" means any dosage form of a drug, including but not limited to, parenterals (eg, injectables, surgical irrigants, and ophthalmics) devoid of viable microorganisms.

Section 3. Policy and Procedure Manual.

A policy and procedure manual shall be prepared and maintained for the Compounding, Dispensing, Delivery, Administration, storage, and use of Sterile Pharmaceutical Prescription Drugs. The policy and procedure manual shall:

(a) include a quality assurance program for the purpose of monitoring patient care and Pharmacist Care outcomes, adverse Drug reactions, personnel qualifications, training and performance, product integrity, equipment, facilities, Disinfection, personnel cleansing and gowning, and guidelines regarding patient education;

(b) be current and available for inspection by a Board of Pharmacy-designated agent;

(c) include a plan designed to prevent microbiological contamination of sterile Drug products and procedures concerning the validation of any sterilization process;

(d) include training and other requirements for Pharmacy Compounding personnel involved in aseptic manipulations to ensure adherence to the basic principles of aseptic technique;

(e) address the management and proper disposal of Cytotoxic and/or infectious waste, if applicable; and

(f) address how supervisory personnel will monitor the ongoing adherence to procedures and sound practices.

Section 4. Physical Requirements.

(a) The Pharmacy shall have a designated area with entry restricted to designated personnel for preparing Sterile Pharmaceuticals. This area shall be structurally isolated from other areas with restricted entry or access, and must be designed to avoid unnecessary traffic and airflow disturbances from activity within the controlled facility. It shall be used only for the preparation of these specialty products. It shall be of sufficient size to accommodate a laminar flow hood and to provide for the proper

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[140] According to the USP Chapter 797 (27th revision of the USP), the Risk Levels of operations should guide the health care professional in determining the appropriate procedures necessary to ensure a safe Compounding process. Correspondingly, based upon the Risk Level, health care professionals are responsible for determining the procedural and environmental quality practices and attributes that are necessary for the Risk Level associated with the Sterile Pharmaceutical.

Boards may consider referencing USP Chapter 797; the revised version went into effect June 1, 2008, after consideration of recommendations received from USP internal expert committees and the professional community.

storage of Drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation, and security.

(b) The Pharmacy preparing Sterile Pharmaceuticals shall have:
  (1) appropriate environmental control Devices capable of maintaining at least ISO Class 5 conditions in the workplace where Critical Areas and Critical Surfaces are exposed and critical activities are performed and providing for appropriate environment control in accord with USP Chapter 797. Furthermore, these Devices are capable of maintaining ISO Class 5 conditions during all Compounding activities and include laminar airflow hoods and zonal laminar flow of High Efficiency Particulate Air (HEPA) filtered air; use of an Isolator shall also be considered;
  (2) floors, walls, and ceilings of smooth, hard surfaces that are easily cleanable;
  (3) appropriate disposal containers for used needles, syringes, etc, and, if applicable, for Cytotoxic waste from the preparation of chemotherapy agents and infectious wastes;
  (4) when Cytotoxic Drug products are prepared, appropriate environmental control also includes appropriate biohazard cabinetry;
  (5) temperature-controlled delivery container;
  (6) infusion devices, if appropriate.

(c) The Pharmacy shall maintain supplies adequate to ensure an environment suitable for the aseptic preparation of Sterile Pharmaceuticals.

(d) The Pharmacy shall have sufficient current reference materials related to sterile products to meet the needs of Pharmacy staff.

Section 5. Records and Reports.

In addition to standard record and reporting requirements, the following records and reports must be maintained for sterile pharmaceuticals:[141]

(a) Maintenance schedules, including a system for cleaning and disinfecting the room and equipment;

(b) Compounding records, as described by Good Compounding Practices Applicable to State Licensed Pharmacies, Appendix B, Subpart I;

(c) Records demonstrating that adequate disinfection (or Sterilization) was performed for the laminar flow hood and supplies used in the aseptic Compounding operation; and

(d) Dispensing or Distribution records to document who received the Compounded prescriptions.

Section 6. Delivery Service.

The Pharmacist-in-Charge shall ensure the environmental control and stability of all products shipped. Therefore, any Compounded, Sterile Pharmaceutical must be shipped or Delivered to a patient or patient's agent in appropriate temperature-controlled (as defined by USP Standards) delivery containers and stored appropriately. Information on appropriate storage shall be provided to the patient or patient's agent.

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[141] Boards may consider exempting lot number documentation for institutions that have an adequate mechanism in place to recall products. Such mechanisms may include bar coding and other technologies that may contain the necessary information that is effectively needed to recall products.

Section 7. Disposal of Cytotoxic and/or Hazardous Wastes.

The Pharmacist-in-Charge is responsible for ensuring that there is a system for the disposal of Cytotoxic and/or infectious waste in a manner so as not to endanger the public health.

Section 8. Emergency Kit.

When Sterile Pharmaceuticals are provided to home care patients, the Dispensing Pharmacy may supply the nurse or patient with emergency Drugs, if the physician has authorized the use of these Drugs by a protocol, in an emergency situation (eg, anaphylactic shock).

Section 9. Cytotoxic Drugs.

In addition to the minimum requirements for a Pharmacy established by rules of the Board, the following requirements are necessary for those pharmacies that prepare Cytotoxic Drugs to ensure the protection of the personnel involved.

(a) All Cytotoxic Drugs should be Compounded in a vertical flow, Class II, Biological Safety Cabinet. Other products should not be Compounded in this cabinet.

(b) Protective apparel shall be worn by personnel Compounding Cytotoxic Drugs. This shall include disposable masks, gloves, and gowns with tight cuffs.

(c) Appropriate safety and containment techniques for Compounding Cytotoxic Drugs shall be used in conjunction with the aseptic techniques required for preparing sterile products.

(d) Disposal of Cytotoxic waste shall comply with all applicable local, State, and Federal requirements.

(e) Written procedures for handling both major and minor spills of Cytotoxic agents must be developed and must be included in the policy and procedure manual.

(f) Prepared doses of Cytotoxic Drugs must be Dispensed, labeled with proper precautions inside and outside, and shipped in a manner to minimize the risk of accidental rupture of the primary container.

Section 10. Patient Education and Training.

If appropriate, the Pharmacist must demonstrate or document the patient's training and competency in managing this type of therapy provided by the Pharmacist to the patient in the home environment. A Pharmacist must be involved in the patient training process in any area that relates to Drug Compounding, Labeling, Administration, storage, stability, compatibility, or disposal. If appropriate, the Pharmacist must be responsible for seeing that the patient's competency in the above areas is reassessed on an ongoing basis.

Section 11. Quality Assurance/Compounding and Preparation of Sterile Pharmaceuticals.

There shall be a documented, ongoing quality assurance control program that monitors personnel performance, component verification and usage, Disinfection, sterilization, equipment, and facilities that are appropriate to the Risk Level of the Sterile Pharmaceutical(s) being prepared. Appropriate samples of finished products shall be examined to ensure that the Pharmacy is capable of consistently preparing Sterile Pharmaceuticals meeting specifications.

(a) All clean rooms and laminar flow hoods shall be certified by an independent contractor according to the International Organization of Standardization Classification of Particulate Matter in Room Air (ISO14644-1) for operational efficiency at least every six months. Appropriate records shall be maintained.

(b) There shall be written procedures requiring sampling on a frequent basis and special measures taken when microbial contamination is suspected.

(c) If bulk Compounding of sterile solutions is performed using chemicals that initially are nonsterile, extensive end-product microbial testing must be documented prior to the release of the product from quarantine. This process must include appropriate tests for particulate matter, pyrogens, and microbes.

(d) There shall be written justification of the chosen Beyond-Use Dates for Compounded products.

(e) There shall be documentation of quality assurance audits at regular, planned intervals, including infection control and sterile technique audits. Intervals shall be based on the type of operations performed and shall increase as the Risk Level increases.

(f) There shall be policies and procedures on the retraining or recertification of trained Pharmacy Compounding personnel in various aspects of aseptic behavior. The training program shall include a demonstration of ongoing competency. Training to ensure skills such as aseptic technique, cleanroom behavior, and knowledge of the hazards posed by contaminated drugs shall be conducted.

(g) Pharmacy Compounding Personnel shall wear sterile garb if conducting one or more aseptic manipulation of sterilized equipment or product.

(h) An effective Disinfection program shall be implemented, including adequate provisions for preventing emergence of unsafe levels of sporeforming organisms.

(i) A system shall be in place for monitoring Pharmacy Compounding personnel and environmental conditions.

(j) A system shall be in place for maintaining any equipment or Devices used to control aseptic conditions.

Section 12. Pharmacist Care Outcomes.

There shall be a documented, ongoing quality assurance control program that monitors patient care and Pharmacist Care outcomes, including but not limited to, the following:

(a) routine performance of Prospective Drug Utilization Review (DUR) and patient monitoring functions by a Pharmacist, as defined in the Rules of the Board;

(b) patient monitoring plans that include written outcome measures and systems for routine patient assessment (examples include infection rates, rehospitalization rates, and the incidence of adverse Drug reactions);

(c) documentation of patient training as specified in Section 10; and

(d) appropriate collaboration with other health care professionals.

Model Rules for the Licensure of Wholesale Distributors

Definitions.

(a) "Adulterated": A Drug or Device shall be deemed to be Adulterated:

(1) if:

(i) it consists in whole or in part of any filthy, putrid, or decomposed substance; or

(ii) it has been produced, prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or 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 Drug or Device meets the requirements of this part as to safety and has the identity and strength, and meets the quality and purity characteristics that it purports or is represented to possess; or

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

(iv) it bears or contains, for purposes of coloring only, a color additive that is unsafe within the meaning of the Federal Food, Drug, and Cosmetic Act (Federal Act); or it is a color additive, the intended use of which is for purposes of coloring only, and is unsafe within the meaning of the Federal Act;

(2) if it purports to be or is represented as a Drug, the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in the compendium. Such a determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in the compendium, or in the absence of or inadequacy of these tests or methods of assay, those prescribed under authority of the Federal Act. No Drug defined in an official compendium shall be deemed to be Adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefore set forth in the compendium, if its difference in strength, quality, or purity from that standard is plainly stated on its label. Whenever a Drug is recognized in both the United States Pharmacopeia (USP) and the Homeopathic Pharmacopoeia of the United States it shall be subject to the requirements of the USP unless it is labeled and offered for sale as a homeopathic Drug, in which case it shall be subject to the Homeopathic Pharmacopoeia of the United States and not those of the USP;

(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; or

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

(b) "Authenticate" means to affirmatively verify that each transaction listed on the Pedigree and any other accompanying documentation has occurred, in accordance with the Rules of the Board.[142]

(c) "Authorized Distributor of Record" 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 on no less than a monthly basis.

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

(e) "Chain Pharmacy Warehouse" means a permanent physical location for Drugs and/or Devices that acts as a central warehouse and performs intracompany sales and transfers of Prescription Drugs or Devices to chain Pharmacies, which are members of the same affiliated group, under common ownership and control. Chain Pharmacy Warehouses must be licensed as Wholesale Distributors.

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

(g) "Co-licensee" means an instance where two or more parties have the right to engage in the manufacturing and/or marketing of a Prescription Drug, consistent with the FDA's implementation of the Prescription Drug Marketing Act.

(h) "Common Carrier" means any person or entity who undertakes, whether directly or by any other arrangement, to transport property including Prescription Drugs for compensation.[143]

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

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

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[142] Although Pedigrees record each transaction of a Prescription Drug and are, therefore, primarily used in Authenticating, "other accompanying documents" such as purchase orders and invoices should also be utilized to assist in Authenticating. For example, when such "accompanying documents" seem false or misleading, every attempt should be made to Authenticate the Prescription Drug before it is further Wholesale Distributed. The Board should also establish standards and procedures for Manufacturers and Wholesale Distributors to complete the Authentication process. These standards should provide consistency among Manufacturers and Wholesale Distributors.

[143] The definition of "Common Carrier" specifically excludes wholesale distributors which are defined separately.

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

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

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

(n) "Device" means an instrument, apparatus, implement, machine, contrivance, implant, or other similar or related article, including any component part or accessory, which is required under Federal law to bear the label, "Caution: Federal or State law requires Dispensing by or on the order of a physician."

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

(1) to Dispense or Administer;

(2) delivering or offering to deliver a Drug by a common carrier in the usual course of business as a common carrier; or

(3) providing a Drug sample to a patient by a Practitioner licensed to prescribe such Drug; a health care professional acting at the direction and under the supervision of a Practitioner; or the Pharmacy of a hospital or of another health care entity that is acting at the direction of such a Practitioner and that received such sample in accordance with the Act and regulations to administer or dispense.

(p) "Drop Shipment" means the sale by a Manufacturer, that Manufacturer's Co-Licensee, that Manufacturer's Third-Party Logistics Provider, or that Manufacturer's Exclusive Distributor, of the Manufacturer's Prescription Drug, to an Authorized Distributor of Record whereby the Authorized Distributor of Record takes title but not possession of such Prescription Drug and the Wholesale Distributor invoices the Pharmacy and the Pharmacy receives Delivery of the Prescription Drug directly from the Manufacturer, that Manufacturer's Co-Licensee, that Manufacturer's Third-Party Logistics Provider, or that Manufacturer's Exclusive Distributor, of such Prescription Drug. Drop Shipments shall be part of the "Normal Distribution Channel."

(q) "Drug" means:

(1) articles recognized as Drugs in any official compendium, or supplement thereto, designated from time to time by the Board for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals;

(2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals;

(3) articles (other than food) intended to affect the structure or any function of the body of humans or other animals; and
(4) articles intended for use as a Component of any articles specified in clause (1), (2), or (3) of this definition.

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

(s) "Exclusive Distributor" means an entity that:
(1) contracts with a Manufacturer to provide or coordinate warehousing, Wholesale Distribution, or other services on behalf of a Manufacturer and who takes title to that Manufacturer's Prescription Drug, but who does not have general responsibility to direct the sale or disposition of the Manufacturer's Prescription Drug; and
(2) is licensed as a Wholesale Distributor under this chapter; and
(3) to be considered part of the Normal Distribution Channel, must also be an Authorized Distributor of Record.

(t) "FDA" means 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.

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

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

(w) "Immediate Container" means a container and does not include package liners.

(x) "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.

(y) "Label" means a display of written, printed, or graphic matter upon the immediate container of any Drug or Device.

(z) "Manufacturer" means a Person engaged in the Manufacture of Drugs or Devices.

(a2) "Misbranded": A Drug or Device shall be deemed to be misbranded if the label is false or misleading in any particular; or the label does not bear the name and address of the Manufacturer, packer, or Distributor and does not have an accurate statement of the quantities of the active ingredients in the case of a Drug; or the label does not show an accurate monograph for Prescription Drugs.

(b2) "Normal Distribution Channel" means a chain of custody for a Prescription Drug that goes, directly or by drop shipment, from a Manufacturer of the Prescription Drug, the Manufacturer's Co-Licensee, the Manufacturer's Third-Party Logistics Provider, or the Manufacturer's Exclusive Distributor to:
(1) an Authorized Distributor of Record to a Pharmacy to a patient or other designated persons authorized by law to dispense or administer such Prescription Drug to a patient; or

(2) an Authorized Distributor of Record to a Chain Pharmacy Warehouse to that Chain Pharmacy Warehouse's intracompany Pharmacy to a patient or other designated persons authorized by law to dispense or administer such Prescription Drug to a patient; or
(3) a Chain Pharmacy Warehouse to that Chain Pharmacy Warehouse's intracompany Pharmacy to a patient or other designated persons authorized by law to dispense or administer such Prescription Drug to a patient; or
(4) a Pharmacy to a patient or other designated persons authorized by law to dispense or administer such drug to a patient; or
(5) as prescribed by the Board's regulations.

(c2) "Pedigree" means a statement or record in a written form or electronic form, approved by the Board, that records each Wholesale Distribution of any given Prescription Drug (excluding Veterinary Prescription Drugs). The Pedigree shall minimally include the following information for each transaction:
(1) the source of the Prescription Drug(s), including the name and principal address of the seller;
(2) the proprietary and established name of the Prescription Drug, the amount of the Prescription Drug, its dosage form and dosage strength, the date of the purchase, the sales invoice number, container size, number of containers, expiration date(s), and lot number(s) or control number(s) of the Prescription Drug;
(3) the business name and address of each owner of the Prescription Drug and its shipping information, including the name and address of the facility of each Person certifying delivery or receipt of the Prescription Drug;
(4) information that states that the Wholesale Distributor has conducted Due Diligence of the Wholesale Distributor(s) from which the Wholesale Distributor purchased; and
(5) a certification from the Designated Representative of the Wholesale Distributor that the information contained therein is true and accurate under penalty of perjury.

(d2) "Prescription Drug" or "Legend Drug" means a Drug which is required under Federal law to be labeled with either of the following statements prior to being Dispensed or Delivered:
(1) "Rx Only"; or
(2) "Caution: Federal law restricts this Drug to use by, or on the order of, a licensed veterinarian"; or
(3) a Drug which is required by any applicable Federal or State law or rule to be Dispensed pursuant only to a Prescription Drug Order or is restricted to use by Practitioners only.

(e2) "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.

(f2) "Repackage" means changing the container, wrapper, quantity, or Product Labeling of a Drug or Device to further the Distribution of the Drug or Device.

(g2) "Repackager" means a Person who Repackages.

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

(i2) "Sales Unit" means the unit of measure the manufacturer uses to invoice its customer for the particular product.

(j2) "Significant Loss" means any loss of a Prescription Drug that exceeds a reasonable level established by like persons which requires that loss to be reported to the Board

or as required by Drug Enforcement Administration or other state and/or federal agencies for Prescription Drugs and controlled substances.

(k2) "Third-Party Logistics Provider" means an entity that:

(1) provides or coordinates warehousing, Distribution, or other services on behalf of a Manufacturer, but does not take title to the Prescription Drug or have general responsibility to direct the Prescription Drug's sale or disposition; and

(2) is licensed as a Wholesale Distributor under this chapter; and

(3) to be considered part of the Normal Distribution Channel, must also be an Authorized Distributor of Record.

(l2) "USP Standards" means standards published in the current official United States Pharmacopeia or National Formulary.

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

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

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

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

(n2) "Wholesale Distribution" means the Distribution of Prescription Drugs or Devices by Wholesale Distributors to Persons other than consumers or patients, and includes the transfer, distribution, or sale of Prescription Drugs by a Pharmacy to another Pharmacy or from a Pharmacy to a Practitioner, only for the purpose of dispensing or Administration, but not for resale; if the value of the goods transferred exceeds five percent (5%) of total Prescription Drug sales revenue of either the transferor or transferee Pharmacy during any consecutive twelve (12)-month period, providing that such transfers are compliant with federal law. To the extent permitted by the Prescription Drug Marketing Act, Wholesale Distribution does not include:

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

(2) the sale, purchase, or trade of a Prescription Drug or Device or an offer to sell, purchase, or trade a Prescription Drug or Device for Emergency Medical Reasons;

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

(4) the sale, purchase, or trade of a Prescription Drug or Device or an offer to sell, purchase, or trade a Prescription Drug or Device among hospitals, Chain Pharmacy Warehouses, Pharmacies, or other health care entities that are under common control;

(5) the sale, purchase, or trade of a Prescription Drug or Device or the offer to sell, purchase, or trade a Prescription Drug or Device by a charitable organization described in 503(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(6) the purchase or other acquisition by a hospital or other similar health care entity that is a member of a group purchasing organization of a Prescription Drug or Device for its own use from the group purchasing organization or from other hospitals or similar health care entities that are members of these organizations;

(7) the transfer of Prescription Drugs or Devices between Pharmacies pursuant to a Centralized Prescription Processing agreement;

(8) the sale, purchase, or trade of blood and blood components intended for transfusion;
(9) the return of recalled, expired, damaged, or otherwise non-salable Prescription Drugs, when conducted by a hospital, health care entity, Pharmacy, or charitable institution in accordance with the Board's regulations;
(10) the sale, transfer, merger, or consolidation of all or part of the business of a retail Pharmacy or Pharmacies from or with another retail Pharmacy or Pharmacies, whether accomplished as a purchase and sale of stock or business assets, in accordance with the Board's regulations; or
(11) other transactions excluded from the definition of "wholesale distribution" under 21 CFR 203.3(CC), including any amendments thereto.

(o2) "Wholesale Distributor" means any Person engaged in Wholesale Distribution of Prescription Drugs or Devices in or into the State, including but not limited to Manufacturers, Repackagers, own-label distributors, private-label distributors, jobbers, brokers, warehouses, including Manufacturers' and Distributors' warehouses, Co-Licensees, Exclusive Distributors, Third-Party Logistics Providers, Chain Pharmacy Warehouses, and Wholesale Drug warehouses, independent Wholesale Drug traders, Reverse Distributors, and retail Pharmacies that conduct Wholesale Distributions. [144]

Section 1. Requirements for Licensure.

Wholesale Distributors that provide services within this State, whether the Wholesale Distributor is located within this State or outside this State, shall be licensed by the Board and shall annually renew their license with the Board using an application provided by the Board. Wholesale Distributors cannot operate from a place of residence. Where Wholesale Distribution operations are conducted at more than one location, each such location shall be licensed by the Board of Pharmacy. [145]

(a) Every Wholesale Distributor who engages in the Wholesale Distribution of Prescription Drugs or Devices shall license annually with the Board by application and provide information required by the Board on an application approved by the Board, including but not limited to:
(1) all trade or business names used by the licensee (includes "is doing business as" and "formerly known as"), which cannot be identical to the name used by another unrelated Wholesale Distributor licensed to purchase Prescription Drugs or Devices in the State;
(2) name(s) of the owner and operator of the licensee (if not the same person), including:

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[144] In their regulation of Wholesale Distributors, many states have decided to license FDA-approved manufacturers separately from Wholesale Distributors, or in some cases exempt them from licensure altogether, because some of the licensing requirements are duplicative of the FDA's manufacturing licensure processes. Some states have had difficulty in distinguishing who should and who should not be subject to the Wholesale Distributor licensing requirements. For states that wish to exempt Manufacturers from particular licensing requirements, NABP suggests using the following language:

> Subject to the Federal Food, Drug, and Cosmetic Act and all applicable federal law and regulation, an FDA-approved manufacturer, including its affiliates, subsidiaries, agents and other entities under common ownership and control of the manufacturer, that exclusively distributes its own FDA-approved prescription drug and/or biologic product, and that has not left the manufacturer's chain of custody shall be exempt from the requirements of the [this section]…

[145] The application and screening process for licensing Wholesale Distributors represents a critical point in efforts to prevent the introduction of Counterfeit and Contraband products into the medication distribution system. An application that requires detailed information about the applicant and key individuals involved in the operations of the Wholesale Distributor is critical.

(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, and the name of the partnership and federal employer identification number;
(iii) if a corporation: the name, business address, Social Security number and date of birth, and title of each corporate officer and director, the corporate names, the state of incorporation, federal employer identification number, and the name of the parent company, if any; the name, business address, and Social Security number of each shareholder owning ten percent (10%) or more of the voting stock of the corporation, including over-the-counter (OTC) stock, unless the stock is traded on a major stock exchange and not OTC;
(iv) if a sole proprietorship: the full name, business address, Social Security number, and date of birth of the sole proprietor and the name and federal employer identification number of the business entity;
(v) if a limited liability company: the name of each member, the name of each manager, the name of the limited liability company and federal employer identification number, and the name of the state in which the limited liability company was organized; and
(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 Prescription Drugs or Devices and additional information as required in Section 10 (Record Keeping);
(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 Distribute Prescription Drugs;
(5) a list of all disciplinary actions by State and Federal agencies against the Wholesale Distributor as well as any such actions against principals, owners, directors, or officers;
(6) a full description of each facility and warehouse, including all locations utilized for Prescription Drug storage and/or Wholesale Distribution. The description should include the following:
(i) square footage;
(ii) security and alarm system descriptions;
(iii) terms of lease or ownership;
(iv) address; and
(v) temperature and humidity controls.
(7) a copy of the deed for the property on which the Wholesale Distributor's establishment is located, if the property is owned by the Wholesale Distributor, or a copy of the Wholesale Distributor's lease for the property on which the establishment is located that has an original term of not less than one (1) calendar year, if the establishment is not owned by the Wholesale Distributor;
(8) information regarding general and product liability insurance, including copies of relevant policies;
(9) a description of the Wholesale Distributor's Drug import and export activities; and
(10) a copy of the Wholesale Distributor's written policies and procedures as required in Section 11 (Policies and Procedures).

(11) the information collected pursuant to Section 1(a)(6) and (a)(10) 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.

(b) 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 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 shall be exempt from securing a "surety" bond or other equivalent means of security acceptable to the Board or a third party recognized by the Board. The Board may waive the bond requirement, if the Wholesale Distributor:[146]

(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.

(c) Every Wholesale Distributor who engages in Wholesale Distribution shall submit a reasonable fee to be determined by the Board.

(d) Each facility that engages in Wholesale Distribution must undergo an inspection by the Board or a third party recognized by the Board for the purpose of inspecting the Wholesale Distribution operations prior to initial licensure and periodically thereafter in accordance with a schedule to be determined by the Board but not less than once every three (3) years. Manufacturing facilities are exempt from inspection by the Board if the Manufacturing facilities are currently registered with FDA in accordance with Section 510 of the Federal Act.

(e) All Wholesale Distributors must publicly display or have readily available all licenses and the most recent inspection report administered by the Board.

(f) 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).

(g) Information submitted by the Wholesale Distributor 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

[146] Although Wholesale Distributors may be licensed in multiple states, it is not intended for Wholesale Distributors to procure a separate "surety" bond (or other equivalent means) for each state of licensure. States should consider waiving this requirement if the Wholesale Distributor has procured a "surety" bond (or other equivalent means) for the purposes of licensure in another state, or if the wholesaler is a publicly traded company.

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.[147]

Section 2. 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 Drugs or Devices:

(1) any findings by the Board that the applicant has violated or been disciplined by a regulatory agency in any state for violating any Federal, State, or local laws relating to Drug or Device Wholesale Distribution;
(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 Drugs or Devices;
(4) the furnishing by the applicant of false or fraudulent material in any application made in connection with Drug or Device Manufacturing or Wholesale Distribution;
(5) Suspension, sanction, or Revocation by federal, State, or local government against any license currently or previously held by the applicant or any of its owners for violations of State or Federal laws regarding Drugs or Devices;
(6) compliance with previously granted licenses of any kind;
(7) compliance with the requirements to maintain and/or make available to the Board licensing authority or to Federal, State, or local law enforcement officials those records required to be maintained by Wholesale Distributors; and
(8) any other factors or qualifications the Board considers relevant to and consistent with the public health and safety.

(b) The Board shall consider the results of a criminal and financial background check of the applicant, including but not limited to, all key personnel involved in the operations of the Wholesale Distributor, 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 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 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 Drugs or Devices or an affirmation and attestation that the applicant has not been involved in, or convicted of, any criminal or prohibited acts.

Section 3. Personnel.

[147] The Board may designate a third party to conduct inspections and ensure that all requirements for licensure established by the legislature and Board are fulfilled. The NABP Verified-Accredited Wholesale Distributors® (VAWD®) program is available to the states.

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

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

(1) submit an application on a form furnished by the Board and provide information that includes, but is not limited to:

(i) information required to complete the criminal and financial background checks required under Section 2(b);[148]

(ii) date and place of birth;

(iii) occupations, positions of employment, and offices held during the past seven (7) years;

(iv) principal business and address of any business corporation, or other organization in which each such office of the Person was held or in which each such occupation or position of employment was carried on;

(v) whether the Person, during the past seven (7) years, has been enjoined, either temporarily or permanently, by a court of competent jurisdiction from violating any Federal or State law regulating the possession, control, or Wholesale Distribution of Prescription Drugs or Devices, together with details of such events;

(vi) description of any involvement by the Person with any business, including any investments, other than the ownership of stock in a publicly traded company or mutual fund, during the past seven (7) years, which Manufactured, Administered, Prescribed, Wholesale Distributed, or stored Prescription Drugs and Devices in which such businesses were named as a party in a lawsuit;

(vii) description of any criminal offense (not including minor traffic violations) of which the Person, as an adult, was found guilty, regardless of whether adjudication of guilt was withheld or whether the Person pled guilty or nolo contendere. If the Person indicates that a criminal conviction is under appeal and submits a copy of the notice of appeal of the criminal offense, the applicant must, within 15 days after the disposition of the appeal, submit to the Board a copy of the final written order of disposition;

(viii) photograph of the Person taken within the previous 30 days under procedures as specified by the Board;

(ix) name, address, occupation, and date and place of birth for each member of the Person's immediate family, unless the Person is employed by a Wholesale Distributor that is a publicly held company. As used in this subparagraph, the term "member of the immediate family" includes the Person's spouse(s), children, parents, siblings, the spouses of the Person's children, and the spouses of the Person's siblings; and

(x) any other information the Board deems relevant.

(2) have a minimum of two years of verifiable full-time managerial or supervisory experience in a Pharmacy or Wholesale Distributor licensed in this State or another state, where the Person's responsibilities included but were not limited to record keeping, storage, and shipment of Prescription Drugs or Devices;

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

(3) may serve as the Designated Representative for only one Wholesale Distributor at any one time, except where more than one licensed Wholesale Distributor is co-located in the same facility and such Wholesale Distributors are members of an affiliated group, as defined in Section 1504 of the Internal Revenue Code;
(4) be actively involved in and aware of the actual daily operations of the Wholesale Distributor:
    (i) employed full-time in a managerial position by the Wholesale Distributor;
    (ii) physically present at the Wholesale Distributor during normal business hours, except for time periods when absent due to illness, family illness or death, scheduled vacation, or other authorized absence; and
    (iii) aware of, and knowledgeable about, all policies and procedures pertaining to the operations of the Wholesale Distributor.

(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 located outside of this State that Wholesale Distributes Prescription Drugs or Devices in this State shall designate a registered agent in this State for service of process. Any licensed Wholesale Distributor that does not so designate a registered agent shall be deemed to have designated the Secretary of State of this State to be its true and lawful attorney, upon who may be served all legal 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:[149]
(1) continuing education programs specified by the Board regarding Federal and State laws in regard to the Wholesale Distribution, handling, and storage of Prescription Drugs or Devices; or
(2) if no formal continuing education is specified by the Board, 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 4. Minimum Requirements for the Storage and Handling of Prescription Drugs and for Establishment and Maintenance of Prescription Drug Records.

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

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

(a) All facilities at which Prescription Drugs and Devices are received, stored, warehoused, handled, held, offered, marketed, displayed, or transported from shall:
  (1) be of suitable construction to ensure that all Prescription Drugs and Devices in the facilities are maintained in accordance with the Product Labeling of such Prescription Drugs and Devices, or in compliance with official compendium standards such as the United State Pharmacopeia–USP-NF;
  (2) be of suitable size and construction to facilitate cleaning, maintenance, and proper Wholesale Distribution operations;
  (3) have adequate storage areas to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;
  (4) have a quarantine area for storage of Prescription Drugs and Devices that are outdated, damaged, deteriorated, Misbranded, or Adulterated, Counterfeit, or suspected of being Counterfeit, otherwise unfit for Distribution or Wholesale Distribution, or that are in immediate or sealed secondary containers that have been opened;
  (5) be maintained in a clean and orderly condition;
  (6) be free from infestation of any kind;
  (7) be a commercial location and not a personal dwelling or residence;
  (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;
  (9) provide and maintain appropriate inventory controls in order to detect and document any theft, Counterfeiting, or diversion of Prescription Drugs or Devices.

(b) Wholesale Distributors involved in the Wholesale Distribution of controlled substances shall be duly registered with Drug Enforcement Administration (DEA) and appropriate state controlled substance agency and in compliance with all applicable laws and rules for the storage, handling, transport, shipment, and Wholesale Distribution of controlled substances.

Section 5. Security and Anti-Counterfeiting.

(a) All facilities used for Wholesale Distribution shall be secure from unauthorized entry:
  (1) access from outside the premises shall be kept to a minimum and be well-controlled;
  (2) the outside perimeter of the premises shall be well-lighted; and
  (3) entry into areas where Prescription Drugs or Devices are held shall be limited to authorized personnel; all facilities shall be equipped with an alarm system to detect entry after hours.

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

(c) All facilities shall be equipped with inventory management and control systems that protect against, detect, and document any instances of theft, diversion, or Counterfeiting.

(d) All common carriers used by a Wholesale Distributor shall ensure security via one of the following:
  (1) a verifiable security system; or
  (2) a Board-approved accreditation or certification program.

(e) At a date at which such technology is required to be maintained, Wholesale Distributors shall possess and maintain in good working order technology and equipment that allows the Wholesale Distributor to Authenticate, track, and trace Prescription Drugs. The technology and equipment shall satisfy standards set by the Board for such technology and equipment. The technology and equipment shall be used, as required by the Board, to conduct tracking, tracing, and Authentication of Prescription Drugs. Wholesale Distributors shall employ, train, and document the training of personnel in the proper use of such technology and equipment.[150]

(f) All facilities shall be equipped with security systems to protect the integrity and confidentiality of data and documents and make such data and documents readily available to the Board and other state and federal law enforcement officials. (g) Authentication of Pedigrees: [151]

(1) Wholesale Distributors that acquire Prescription Drugs from other Wholesale Distributors outside the Normal Distribution Channel shall Authenticate the Pedigrees of at least ten percent (10%) of all such Prescription Drugs, unless an electronic pedigree and track and trace system, which documents each transaction, is in place.

(2) Wholesale Distributors and Manufacturers from whom Wholesale Distributors have acquired Prescription Drugs shall cooperate with Pedigree Authentication efforts and provide the requested information in a timely manner. The Board shall provide Authentication standards and procedures.

(3) Each Wholesale Distributor that has Distributed a Prescription Drug for which an acquiring Wholesale Distributor is conducting a Pedigree Authentication, shall provide to the acquiring Wholesale Distributor, upon request, detailed information regarding its acquisition of the Prescription Drug, including:
   (i) Date of acquisition;
   (ii) Lot number or control number;
   (iii) Acquisition invoice number; and
   (iv) Name, address, telephone number, and e-mail address (if available) of the Manufacturer or Wholesale Distributor from which the Prescription Drug was acquired.

(4) If the Wholesale Distributor attempting to Authenticate the Pedigree of the Prescription Drug is unable to Authenticate the Pedigree, the Wholesale Distributor shall quarantine the Prescription Drug and file a report with the Board and FDA within three (3) business days after completing the attempted Authentication; and

(5) If the Wholesale Distributor attempting to Authenticate the Pedigree of the Prescription Drug is able to Authenticate the Pedigree, the Wholesale Distributor shall maintain records of the Authentication for three (3) years, and shall produce them to the Board upon request.

Section 6. Storage.

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

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

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

(a) If no storage requirements are established for a Prescription Drug, the Prescription Drug may be held at "controlled" room temperature, as defined in an official compendium such as USP-NF, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(b) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment and/or logs shall be utilized to document proper storage of Prescription Drugs and Devices.

(c) Packaging of the Prescription Drugs and Devices should be in accordance with an official compendium such as USP-NF and identify any compromise in the integrity of the Prescription Drugs or Devices due to tampering or adverse storage conditions.

(d) Controlled substance Drugs should be isolated from non-controlled substance Drugs and stored in a secure area in accordance with Drug Enforcement Administration security requirements and standards.

(e) The record keeping requirements in Section 10 (Record Keeping) shall be followed for the Wholesale Distribution of all Prescription Drugs and Devices.

Section 7. Examination of Materials.

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

(b) The Prescription Drugs or Devices found to be unacceptable under paragraph (a) should be quarantined from the rest of stock until the examination and determination that the Prescription Drugs and Devices are not outdated, damaged, deteriorated, Misbranded, Counterfeited, Contraband, or Adulterated and the determination that they are fit for human use.

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

(d) Upon receipt, a Wholesale Distributor must review records for the acquisition of Prescription Drugs or Devices for accuracy and completeness, considering the total facts and circumstances surrounding the transactions and the Wholesale Distributors involved.

(e) The record keeping requirements in Section 10 (Record Keeping) shall be followed for all incoming and outgoing Prescription Drugs and Devices.

Section 8. Returned, Damaged, and Outdated Prescription Drugs.

(a) Appropriate documentation shall be completed and any necessary notations made to the Pedigree if any Prescription Drug that was ordered in excess of need by the Wholesale Distributor, if identified as such, and which the integrity has been

maintained, that is returned to the Manufacturer or Wholesale Distributor from which it was acquired.

(b) Any Prescription Drug or Device that is outdated, damaged, deteriorated, Misbranded, Counterfeited, Contraband, suspected of being Counterfeited or Contraband, Adulterated, or otherwise deemed unfit for human consumption shall be quarantined and physically separated from other Prescription Drugs and Devices until it is destroyed or returned to either the Manufacturer or Wholesale Distributor from which it was acquired. When Prescription Drugs and Devices are Adulterated, Counterfeited, Contraband, Misbranded, or suspected of being Adulterated, Counterfeit, Contraband, or Misbranded, notice of the Adulteration, Counterfeiting, Contrabandage, Misbranding, or suspected Adulteration, Counterfeiting, Contrabandage, or Misbranding shall be provided within three (3) business days of that determination to the Board, FDA, and Manufacturer or Wholesale Distributor from which they were acquired. Any Prescription Drug or Device returned to a Manufacturer or Wholesale Distributor shall be kept under proper conditions for storage, handling, transport, shipment, and documentation showing that proper conditions were maintained and shall be provided to the Manufacturer or Wholesale Distributor to which the Prescription Drugs or Devices are returned.

(c) Any Prescription Drug or Device whose immediate or sealed outer or secondary containers or Product Labeling are Adulterated, Misbranded, Counterfeited, Contraband, or suspect of being Counterfeit or Contraband shall be quarantined and physically separated from other Prescription Drugs or Devices until it is destroyed or returned to either the Manufacturer or Wholesale Distributor from which it was acquired. When the immediate or sealed outer or secondary containers or Product Labeling of any Prescription Drug or Device are Adulterated, Misbranded, Counterfeited, Contraband, or suspect of being Counterfeit or Contraband, notice of the Adulteration, Misbranding, Counterfeiting, Contrabandage, or suspected Counterfeiting or Contrabandage shall be provided within three (3) business days of that determination to the Board, FDA, and Manufacturer or Wholesale Distributor from which it was acquired.

(d) Any Prescription Drug or Device that has been opened or used, but is not Adulterated, Misbranded, Counterfeited, Contraband, or suspect of being Counterfeit or Contraband, shall be identified as such, and shall be quarantined and physically separated from other Prescription Drugs or Devices until it is destroyed or returned to the Manufacturer or Wholesale Distributor from which acquired.

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

(f) Contraband, Counterfeit, or suspected to be Counterfeit or Contraband Drugs and Devices, other evidence of criminal activity, and accompanying documentation shall be retained and not destroyed until its disposition is authorized by the Board and FDA.

(g) The shipping, immediate, or sealed outer or secondary container or Product Labeling, and accompanying documentation, suspected of or determined to be Counterfeit, Contraband, or otherwise fraudulent shall not be destroyed until its disposition is authorized by the Board and FDA.

(h) The record keeping requirements in Section 10 (Record Keeping) of this rule shall be followed for all outdated, damaged, deteriorated, Counterfeit, Contraband, Misbranded, or Adulterated Prescription Drugs.

Section 9. Due Diligence.

If a Wholesale Distributor is licensed in accordance with these Rules or provides documentation that the Due Diligence procedures are in place and monitored by the Board or a third party recognized by the Board, then the following Due Diligence requirements may be waived by the Board:

(a) Prior to the initial Wholesale Distribution or acquisition of Prescription Drugs 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) a list of states in which the Wholesale Distributor is licensed, and into which it ships Prescription Drugs;
(2) copies of all State and Federal regulatory licenses and registrations;
(3) the Wholesale Distributor's most recent facility inspection reports;
(4) information regarding general and product liability insurance, including copies of relevant policies;
(5) a list of other names under which the Wholesale Distributor is doing business, or was formerly known;
(6) a list of corporate officers;
(7) a list of managerial employees directly involved in the day-to-day operations of Wholesale Distribution;
(8) a list of all owners of the Wholesale Distributor that own more than ten percent (10%) of the Wholesale Distributor, unless the Wholesale Distributor is publicly traded;
(9) a list of all secured common carriers approved by the Wholesale Distributor;
(10) a list of all disciplinary actions by State and Federal agencies;
(11) a description, including the address, dimensions, and other relevant information, of each facility or warehouse used for Prescription Drug storage and Wholesale Distribution;
(12) a description of Prescription Drug import and export activities of the Wholesale Distributor; and
(13) a description of the Wholesale Distributor's policies and procedures to comply with this Act.

(b) Prior to the initial Wholesale Distribution or acquisition of Prescription Drugs to or from any Wholesale Distributor, the Distributing or acquiring Wholesale Distributor shall:

(1) conduct a criminal background check of all of the Wholesale Distributor's personnel, shareholders, and owners involved in operations and management as specified in Section 2 (Minimum Qualifications), and require that all Common Carriers contracted with or utilized by the Wholesale Distributor conduct

criminal background checks of the employees whose responsibilities include the handling of Prescription Drugs; or

(2) verify that the Wholesale Distributor has been accredited by a third party recognized by the Board.

(c) If a Wholesale Distributor's facility has not been inspected by the Board or a third party recognized by the Board within three (3) years of the contemplated transaction, any Wholesale Distributor choosing to do business with that facility shall conduct an inspection of the former Wholesale Distributor's facility prior to the first transaction to ensure compliance with applicable laws and regulations relating to the storage and handling of Prescription Drugs or Devices. A third party may be engaged to conduct the site inspection on behalf of the latter Wholesale Distributor. If the Wholesale Distributor's facility has been inspected by the Board or a third party recognized by the Board, within a three (3) year time period, the inspection report is sufficient to meet the requirements of this subsection.

(d) At least annually, a Wholesale Distributor that Wholesale Distributes or acquires Prescription Drugs to or from another Wholesale Distributor shall update the information set forth in Section 10 (Record Keeping).

(e) At least once every three (3) years, a Wholesale Distributor that Wholesale Distributes or acquires Prescription Drugs to or from another Wholesale Distributor shall inspect, or engage a third party to inspect, the premises of the facility or facilities of the Wholesale Distributor to or from whom it is Distributing or acquiring Prescription Drugs. If the Distributing or acquiring Wholesale Distributor's facility has been inspected by the Board or a third party recognized by the Board within the three (3)-year time period, the inspection report is sufficient to meet the requirements of this subsection.

(f) Wholesale Distributors are exempt from inspecting and obtaining the information from Manufacturers of Prescription Drugs as required in Section 9 (Due Diligence) when the Manufacturer is registered with FDA in accordance with Section 510 of the Federal Act.

Section 10. Record Keeping.

(a) Wholesale Distributors shall establish and maintain inventories and records of all transactions regarding the receipt and Wholesale Distribution or other disposition of Prescription Drugs and Devices. These records shall include:

(1) dates of receipt and Wholesale Distribution or other disposition of the Prescription Drugs and Devices;

(2) pedigrees for all Prescription Drugs that are Wholesale Distributed outside the Normal Distribution Channel; and[152]

(3) effective at a date set by the Board no sooner than July 1, 2009, Pedigrees shall be maintained for each wholesale distribution of a prescription drug starting with the sale by a Manufacturer through acquisition and sale by any Wholesale Distributor, until final sale to a Pharmacy or other authorized Person Administering or Dispensing the Prescription Drug. Pedigrees may be implemented through an approved, uniform, and universally available system that electronically tracks and traces the prescription drug. This electronic tracking

[152] The utilization of the "Normal Distribution Channel" is not meant to be a permanent solution for a pedigree system. Its purpose is to provide state boards of pharmacy with an interim solution, until the technology for an electronic pedigree system for all prescription drugs is available on a large scale and across the supply chain.

system will be deemed to be readily available only upon there being available a standardized system originating at the Manufacturer and capable of being used on a wide scale across the entire health care industry, which includes manufacturers, wholesale distributors, and pharmacies. Also, consideration must be given to:[153]

(i) the large-scale implementation of this technology across the supply chain;
(ii) the technology must be proven to have no negative impact on the safety and efficacy of the pharmaceutical product; and
(iii) the findings and recommendations from FDA regarding the use of track-and-trace technology and a standardized numerical identifier. Nevertheless, implementation should not be unnecessarily delayed. Implementation of this subsection shall satisfy the requirements under Section 10 (a)(2).

(b) Such records shall include the Inventories and records and shall be made available for inspection and photocopying by any authorized official of any State, Federal, or local governmental agency for a period of three (3) years following their creation date.

(c) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (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 should maintain an ongoing list of Persons with whom they do business.

(e) All facilities shall establish and maintain procedures for reporting Counterfeit and Contraband or suspected Counterfeit and Contraband Drugs or Devices or Counterfeiting and Contraband or suspected Counterfeiting and Contraband activities to the Board and FDA.

(f) Wholesale Distributors shall maintain a system for the mandatory reporting of any theft, suspected theft, diversion, or other significant loss of any Prescription Drug or Device to the Board and FDA, and, where applicable, to DEA.[154]

Section 11. Policies and Procedures.

Wholesale Distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, transport, and shipping and Wholesale Distribution of Prescription Drugs, including policies and procedures for identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in

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[153] NABP recognizes that technology must be available in order for a Wholesale Distributor to comply with these requirements. Information received by NABP indicates that the June 1, 2009 implementation date is a realistic goal for enacting the requirements of this section. However, states should monitor the availability of technology in developing statutes and rules and allow for variances if the technologies needed to comply with the requirements of the Pedigree provisions are not available. Consideration must be given, however, to the large-scale implementation of this technology across the supply chain and the technology must be proven to have no negative impact on the safety and efficacy of the pharmaceutical product. Nevertheless, implementation should not be unnecessarily delayed.

[154] This information should be reported to NABP, if serving as a data collection repository, in addition to the other relevant authorities.

inventories. Wholesale Distributors shall include in their written policies and procedures the following:[155]

(a) A procedure to be followed for handling recalls and withdrawals of Prescription Drugs and Devices. 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 to remove defective or potentially defective Prescription Drugs or Devices from the market.

(b) A procedure to ensure that Wholesale Distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of a strike, fire, flood, or other natural disaster, or other situations of local, State, or national emergency.

(c) A procedure to ensure that any outdated Prescription Drugs shall be segregated from other Prescription Drugs and either returned to the Manufacturer or destroyed in accordance with Federal and State laws, including all necessary documentation and the appropriate witnessing. This procedure shall provide for written documentation of the disposition of outdated Prescription Drugs. This documentation shall be maintained for two (2) years after disposition of the outdated Prescription Drugs.

(d) A procedure for the destruction of outdated Prescription Drugs in accordance with federal and state laws, including all necessary documentation, maintained for a minimum of three (3) years, and the appropriate witnessing of the destruction of outdated Prescription Drugs in accordance with all applicable Federal and State requirements.

(e) A procedure for the disposing and destruction of containers, Labels, and packaging to ensure that the containers, Labels, and packaging cannot be used in Counterfeiting activities, including all necessary documentation, maintained for a minimum of three (3) years, and the appropriate witnessing of the destruction of any Labels, packaging, Immediate Containers, or containers in accordance with all applicable Federal and State requirements.

(f) A procedure for identifying, investigating and reporting significant Prescription Drug inventory discrepancies involving Counterfeit, suspect of being Counterfeit, Contraband, or suspect of being Contraband, in the inventory and reporting of such discrepancies within ten (10) business days to the Board and/or appropriate Federal or State agency upon discovery of such discrepancies.

(g) A procedure for reporting criminal or suspected criminal activities involving the inventory of Prescription Drug(s) and Device(s) to the Board, FDA, and, if applicable, DEA, within the three (3) business days.

(h) A procedure for conducting Authentication of Pedigrees in accordance with Section 5 (Security and Anti-Counterfeiting) and standards adopted by the Board.

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

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[155] In developing policies and procedures for the management and quality improvement of the Wholesale Distribution activities of a Wholesale Distributor, the Board may want to refer to the Healthcare Distribution Management Association and the National Association of Chain Drug Stores.

Section 12. Prohibited Acts.[156]

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 Prescription Drug or Device that is Adulterated, Misbranded, Counterfeit, suspected of being Counterfeit, or has otherwise been rendered unfit for Distribution or Wholesale Distribution;

(b) the Adulteration, Misbranding, or Counterfeiting of any Prescription Drug or Device;

(c) the receipt of any Prescription Drug or Device that is Adulterated, Misbranded, stolen, obtained by fraud or deceit, Counterfeit, or suspected of being Counterfeit, or the delivery or proffered delivery of such Prescription Drug or Device for pay or otherwise;

(d) the Alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the Product Labeling of a Prescription Drug or Device or the commission of any other act with respect to a Prescription Drug or Device that results in the Prescription Drug or Device being Misbranded;

(e) the forging, Counterfeiting, simulating, or falsely representing of any Prescription Drug or Device without the authority of the Manufacturer, or using any mark, stamp, tag, label, or other identification device without the authorization of the Manufacturer;

(f) the purchase or receipt of a Prescription Drug or Device from a Person that is not licensed to Wholesale Distribute Prescription Drugs or Devices to that purchaser or recipient;

(g) the sale or transfer of a Prescription Drug or Device to a Person who is not legally authorized to receive a Prescription Drug or Device;

(h) the sale or transfer of a Prescription Drug or Device from Pharmacies to Wholesale Distributors for resale;[157]

(i) the failure to maintain or provide records as required by this Act and Rules;

(j) 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;

(k) the Wholesale Distribution of any Prescription Drug or Device that was:
  (1) purchased by a public or private hospital or other health care entity;
  (2) donated or supplied at a reduced price to a charitable organization; or
  (3) stolen or obtained by fraud or deceit.

(l) the failure to obtain a license or operating without a valid license when a license is required;

(m) the Obtaining of or attempting to obtain a Prescription Drug or Device by fraud, deceit, misrepresentation or engaging in misrepresentation or fraud in the Distribution or Wholesale Distribution of a Prescription Drug or Device;

(n) the Distributing of a Prescription Drug or Device to the patient without a Prescription or Prescription Order from a Practitioner licensed by law to use or prescribe the Prescription Drug or Device;

(o) the failure to obtain, Authenticate, or pass on a Pedigree when required under these Rules;

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[156] Boards should be advised that statutory amendments may be necessary in the State practice acts in order to properly integrate the prohibited and criminal acts. It is highly recommended that boards confer with Board Counsel before adopting the Model Rules to make certain that the appropriate statutory language exists in the state pharmacy practice act to support the Model Rules.

[157] Returned purchases from Pharmacies to Wholesale Distributors are not considered to be "transfers, Distributions, or sales," and are not affected by this language.

(p) the receipt of a Prescription Drug or Device pursuant to a Wholesale Distribution without first receiving a Pedigree, when required, that was attested to as accurate and complete by the Wholesale Distributor;
(q) the Distributing or Wholesale Distributing of a Prescription Drug or Device that was previously dispensed by a Pharmacy or distributed by a Practitioner;
(r) the failure to report any Prohibited Act as listed in these Rules; or
(s) the failure to exercise Due Diligence as provided in Section 9 (Due Diligence) of these regulations.

Section 13. Criminal Acts.[158]

(a) A Person who, with intent to defraud or deceive, performs the act of Adulteration, Misbranding, or Counterfeiting of any Prescription Drug or Device commits a felony of the third degree.
(b) A Person who engages in the Wholesale Distribution of Prescription Drug(s) who, with intent to defraud or deceive, fails to deliver to another Person a complete and accurate Pedigree, when required, concerning a Prescription Drug prior to transferring the Prescription Drug to another Person commits a felony of the third degree.
(c) A Person who engages in the Wholesale Distribution of Prescription Drug(s) who, with intent to defraud or deceive, fails to acquire a complete and accurate Pedigree, when required, concerning a Prescription Drug prior to obtaining the Prescription Drug from another Person commits a felony of the third degree.
(d) A Person who engages in the Wholesale Distribution of Prescription Drug(s) and knowingly destroys, alters, conceals, or fails to maintain a complete and accurate Pedigree concerning any Prescription Drug in his possession commits a felony of the third degree.
(e) A Person who engages in the Wholesale Distribution of Prescription Drug(s) who is in possession of a Pedigree, as required by the Board, and who knowingly fails to Authenticate the Pedigree as required, and who nevertheless Wholesale Distributes or attempts to further Wholesale Distribute Prescription Drug(s) commits a felony of the third degree.
(f) A Person who engages in the Wholesale Distribution of Prescription Drug(s) who, with intent to defraud or deceive, falsely swears or certifies that he or she has Authenticated any documents related to the Wholesale Distribution of Prescription Drugs, commits a felony of the third degree.
(g) A Person who engages in the Wholesale Distribution of Prescription Drug(s) and knowingly forges, Counterfeits, or falsely creates any Pedigree, who falsely represents any factual matter contained on any Pedigree, or who knowingly omits to record material information required to be recorded in a Pedigree, commits a felony of the third degree.
(h) A Person who engages in the Wholesale Distribution of Prescription Drug(s) or Device(s) and knowingly purchases or receives Prescription Drug(s) or Device(s) from a Person, not legally authorized to Wholesale Distribute Prescription Drug(s) or Device(s), in Wholesale Distribution commits a felony of the third degree.
(i) A Person who engages in the Wholesale Distribution of Prescription Drug(s) or Device(s) and knowingly sells, barters, brokers, or transfers Prescription Drug(s) or Device(s) to a Person not legally authorized to purchase Prescription Drug(s) or

[158] Boards should be advised that statutory amendments may be necessary in the State practice acts in order to properly integrate the prohibited and criminal acts. It is highly recommended that boards confer with Board Counsel before adopting the Model Rules to make certain that the appropriate statutory language exists in the state pharmacy practice act to support the Model Rules.

Device(s), under the jurisdiction in which the Person receives the Prescription Drug(s) or Device(s) in a Wholesale Distribution, commits a felony of the third degree.

(j) A Person who knowingly possesses, actually or constructively, any amount of a Contraband Drug(s) or Device(s), who knowingly sells or delivers, or who possesses with intent to sell or deliver any amount of a Contraband Drug(s) or Device(s) commits a felony of the third degree.

(k) A Person who knowingly forges, Counterfeits, or falsely creates any Label for a Prescription Drug(s) or Device(s) or who falsely represents any factual matter contained in any Label of a Prescription Drug(s) or Device(s) commits a felony of the third degree.

(l) A Person who knowingly Manufactures, purchases, sells, delivers, or brings into the State, or who is knowingly in actual or constructive possession of any amount of Contraband Drug(s) or Device(s), commits a felony of the third degree.

(m) A Person who knowingly Manufactures, purchases, sells, delivers, or brings into the State, or who is knowingly in actual or constructive possession of any amount of Contraband Drug(s) or Device(s), and whose acts result in the death of a Person, commits a felony in the first degree.

(n) 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 14. Salvaging and Reprocessing.

Wholesale Distributors shall be subject to the provisions of any applicable Federal, State, or local laws or rules that relate to Prescription Drug product salvaging or reprocessing, including Chapter 21, parts 207, 210, and 211k of the Code of Federal Regulations.

Section 15. Inspection and Accreditation by a Third Party.

(a) The Board shall have the authority to recognize a third party to inspect and accredit Wholesale Distributors.

(b) The Board may license by reciprocity, a Wholesale Distributor that is licensed under the laws of another state, if:

(1) the requirements of that State are deemed by the Board to be substantially equivalent; or

(2) the applicant is accredited by a third party recognized by the Board. An applicant that is accredited by a third party recognized and approved by the board, shall not be subject to duplicative requirements set by the Board. If an applicant is inspected, but not accredited by a third party, that applicant must comply with the requirements set by the Board through regulation.

(c) Any applicant that is denied accreditation described under paragraph (a), shall have the right of review of the accreditation body's decision, by:

(1) the accreditation body; and

(2) the Board.

(d) The Board recognized accreditation body shall ensure that the proprietary information obtained during the accreditation process remains confidential and privileged.

(e) The Board may waive requirements of this Chapter, by regulation, for Wholesale Distributors that have obtained and maintain a Board-approved accreditation.

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.[159]

(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 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.

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[159] 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.

(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 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:[160]

(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 (Record Keeping);

(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

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[160] 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.

(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) accreditation program.[161]

(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).

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[161] 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 the NABP Verified-Accredited Wholesale Distributors (VAWD) accreditation program as the inspection criteria is not applicable to Medical Gas or Medical Gas Equipment Related operations.

(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;[162]
  (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.

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[162] 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.

(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 record keeping requirements in Section 10 (Record Keeping) 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 record keeping requirements in Section 10 (Record Keeping) 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 record keeping requirements in Section 10 (Record Keeping) 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 (Record Keeping).

(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:[163]

(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. Record Keeping.

(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:[164]

(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.

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

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

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.

Model Rules for the

Privacy of Individually Identifiable Health Information

(a) Uses and Disclosures of Protected Health Information. A Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board may not use or disclose Protected Health Information, except as permitted or required by this Section.

(1) Permitted Uses and Disclosures. A Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board is permitted to use or disclose Protected Health Information as follows:

(i) to the patient;

(ii) for the treatment, payment, or health care operations as permitted or required by Paragraph (b) of this Section;

(iii) incident to a use or disclosure otherwise permitted or required by this Paragraph;

(iv) pursuant to and in compliance with a valid authorization under Paragraph (c) of this Section;

(v) pursuant to an agreement under, or as otherwise permitted by, Paragraph (d) of this Section;

(vi) as permitted by and in compliance with this Paragraph, Paragraph (e), or Paragraph (g).

(2) Required disclosures. A Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board is required to disclose Protected Health Information:

(i) to a patient, when requested under, and required by 45 CFR §164.524 or §164.528; and

(ii) when required to investigate or determine the Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board's compliance with this Section and Federal privacy regulations.

(See comment list.)

(b) Uses and Disclosures of Protected Health Information.

(1) Permitted Uses and Disclosures.

(i) Except with respect to uses or disclosures that require an authorization under Paragraph (c), a Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board may use or disclose Protected Health Information for treatment, payment, or health care operations.

(2) Treatment, Payment, or Health Care Operations

(i) A Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board may use or disclose Protected Health Information for their treatment, payment, or health care operations.

(ii) A Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board may disclose Protected Health Information for treatment activities of a health care provider.

(iii) A Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board may disclose Protected Health Information to a

covered entity defined by 45 CFR §160.103 for the payment activities of the entity that receives the information.[165]

(iv) A Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board may disclose Protected Health Information to a covered entity defined by 45 CFR §160.103 for health care operations activities of the entity that receives the information if each Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board has had a relationship with an individual who is the subject of the Protected Health Information being requested, the Protected Health Information pertains to such relationship, and the disclosure is:

(A) for a purpose listed in Paragraph (1) or (2) of the definition of "Health Care Operations"; or

(B) for the purpose of health care fraud and abuse detection or compliance.

(v) A Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board that participates in an organized health care arrangement may disclose Protected Health Information about a patient to a covered entity defined by 45 CFR §160.103 that participates in the organized health care arrangement for any health care operations activities of the organized health care arrangement.

(c) Uses and Disclosures for which an Authorization is Required.

(1) Authorization for Uses and Disclosures.

(i) Authorization required. General rule. Except as otherwise permitted or required by this section, a Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board may not use or disclose Protected Health Information without an authorization that is valid under this section. When a Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board obtains a valid authorization for its use and disclosure of Protected Health Information, such use or disclosure must be consistent with such authorization.

(ii) Authorization required. Marketing.

(A) A Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board must obtain authorization for any use or disclosure of Protected Health Information for marketing, except if the communication is in the form of:

(-a-) a face-to-face communication made by a Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board;

(-b-) a promotional gift of nominal value provided by the Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board.

(B) If the marketing involves direct or indirect remuneration to the Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board from a third party, the authorization must state that such remuneration is involved.

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[165] 45 CFR §160.103 defines "covered entity" as "(1) A health plan. (2) A health care clearinghouse. (3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter."

(iii) Valid authorizations. A valid authorization is a document that contains the elements listed in Paragraph (2) of this subsection.

(iv) Prohibition on conditioning of authorizations. A Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board may not condition the provision to a patient of treatment on the provision by a patient of an authorization, except:

(A) a Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board may condition the provision of research-related treatment on the provision of an authorization for the use or disclosure of Protected Health Information for such research; or

(B) a Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board may condition the provision of health care that is solely for the purpose of creating Protected Health Information for disclosure to a third party on provision of an authorization for the disclosure of the Protected Health Information to such third party.

(v) Revocation of authorizations. A patient may revoke an authorization at any time, provided that the revocation is in writing, except to the extent that the Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board has taken action in reliance thereon.

(vi) An authorization obtained by a Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board must be retained for a minimum of six years from the date of its creation or the date when it was last in effect, whichever is later.

(2) Authorization: Content Requirements.

(i) Core elements. A valid authorization must contain at least the following elements:

(A) a specific description of the information to be used or disclosed;

(B) the name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure;

(C) the name or other specific identification of the person(s), or class of persons, to whom the Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board may make the requested use or disclosure;

(D) the purpose for the requested use or disclosure. The statement "at the request of the individual" is sufficient when a patient initiates the authorization and does not, or elects not to, provide a statement of the purpose;

(E) an expiration date or an expiration event that relates to the patient or the purpose for the use or disclosure;

(F) signature of the patient and date. If the authorization is signed by a patient's agent, a description of such agent's authority to act for the patient must also be provided.

(ii) Required statements. In addition to the core elements, the authorization must contain statements adequate to place the patient on notice of all of the following:

(A) The patient's right to revoke the authorization in writing, and either:

(-a-) the exceptions to the right to revoke and a description of how the patient may revoke the authorization; or

(-b-) a reference to the notice of privacy practices of the Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board, that addresses the exceptions to the right to revoke and a description of how to revoke the authorization.

(B) The conditions under which the Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board may condition treatment or payment on the provision of an authorization or those conditions under which the Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board cannot condition treatment or payment on the provision of an authorization, and the consequences of a refusal to provide authorization.

(C) The potential for information disclosed pursuant to the authorization to be subject to redisclosure by the recipient and no longer be protected by these regulations.

(iii) Plain language requirement. The authorization must be written in plain language.

(iv) Copy to the patient. If a Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board seeks an authorization from a patient for a use or disclosure of Protected Health Information, the Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board must provide the patient with a copy of the signed authorization.

(d) Uses And Disclosures Requiring An Opportunity For The Patient To Agree Or To Object.

A Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board may use or disclose Protected Health Information provided that the patient is informed in advance of the use or disclosure and has the opportunity to agree to or prohibit or restrict the use or disclosure, in accordance with the applicable requirements of this subsection. The Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board may orally inform the patient of and obtain the patient's oral agreement or objection to a use or disclosure permitted by this subsection. Uses and disclosures permitted under this subsection are set out in 45 CFR §164.510 (a) and (b).

(See comment list.)

(e) Uses And Disclosures For Which An Authorization Or Opportunity To Object Is Not Required.

A Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board may use or disclose Protected Health Information without the written authorization of the patient or the opportunity for the patient to agree or object according to the standards set out in 45 CFR §164.512 (a) – (l). When the Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board is required by this subsection to inform the patient of, or when the patient may agree to, a use or disclosure permitted by this subsection, the Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board's information and the Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board's agreement may be given orally.

(See comment list.)

(f) Other Requirements Relating To Uses And Disclosures Of Protected Health Information.

(1) De-identification and Re-identification of Protected Health Information. The de-identification and re-identification of Protected Health Information must conform with the standards and specifications set out in 45 CFR §164.514 (a) – (c).

(2) Minimum Necessary. Uses and disclosures of Protected Health Information must meet the minimum necessary standards and specifications set out in 45 CFR §164.514 (d).

(3) Limited Data Set. A Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board may use or disclose a limited data set as indicated in 45 CFR §164.514(e).

(4) Verification. Uses and disclosures of Protected Health Information must meet the verification standards and specifications set out in 45 CFR §164.514 (h).

(See comment list.)

(g) Notice of Privacy Practices for Protected Health Information.
A Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board must provide each patient with a notice of privacy practices as indicated in 45 CFR §164.520.
(See comment list.)

(h) Right to Request Privacy Protection for Protected Health Information.
A Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board must permit a patient to request that the Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board restrict the use or disclosure of Protected Health Information as indicated in 45 CFR §164.522.

(See comment list.)

(i) Access of Patients to Protected Health Information.
A patient has a right of access to inspect and obtain a copy of Protected Health Information about the patient in a Designated Record Set, for as long as the Protected Health Information is maintained in the Designated Record Set, as indicated in 45 CFR §164.524.
(See comment list.)

(j) Amendment of Protected Health Information.
A patient has a right to have a Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board to amend Protected Health Information about the patient in a Designated Record Set, for as long as the Protected Health Information is maintained in the Designated Record Set, as indicated in 45 CFR §164.526.
(See comment list.)

(k) Accounting of Disclosures of Protected Health Information.

(1) A patient has a right to receive an accounting of disclosures of Protected Health Information made by a Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board in the six years prior to the date on which the accounting is requested, except for the following disclosures:

(i) to carry out treatment, payment, and health care operations, as provided in Paragraph (b) of this section;

(ii) to patients, of Protected Health Information about them;
(iii) incident to a use or disclosure otherwise permitted or required by this Paragraph, as provided in Paragraph (a);
(iv) pursuant to an authorization, as provided in Paragraph (c);
(v) for the facility's directory or to persons involved in the patient's care or other notification purposes as provided in Paragraph (d);
(vi) for national security or intelligence purposes as provided in 45 CFR §164.512(k)(2);
(vii) To correctional institutions or law enforcement officials as provided in 45 CFR §164.512(k)(5);
(viii) As part of a limited data set in accordance with 45 CFR §164.514(e); or
(ix) That occurred prior to the compliance date of April 14, 2003, for the Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board.
(See comment list.)

(2) (i) The Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board must temporarily suspend a patient's right to receive an accounting of disclosures to a health oversight agency or law enforcement official for the time specified by such agency or official, if such agency or official provides the covered entity with a written statement that such an accounting to the patient would be reasonably likely to impede the agency's activities and specifying the time for which the suspension is required.
(ii) If the agency or official statement in Paragraph (k)(2)(i) is made orally, the Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board must:
(A) Document the statement, including the identity of the agency or official making the statement;
(B) Temporarily suspend the patient's right to an accounting of disclosures subject to the statement; and
(C) Limit the temporary suspension to no longer than 30 days from the date of the oral statement, unless a written statement pursuant to Paragraph (k)(2)(i) is submitted during that time.
(3) A patient may request an accounting of disclosures for a period of time less than six years from the date of the request.
(4) The accounting of disclosures of Protected Health Information must conform to the requirements set out in 45 CFR §164.528 (b), (c), and (d).
(See comment list.)

Comments

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

45 CFR §164.524 reads:

§164.524 Access of individuals to protected health information.
(a) *Standard: Access to protected health information*—(1) *Right of access.* Except as otherwise provided in paragraph (a)(2) or (a)(3) of this section, an individual has a right of access to inspect and obtain a copy of protected health information about the individual in a designated record set, for as long as the protected health information is maintained in the designated record set, except for:
(i) Psychotherapy notes; and
(ii) Information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding.
(2) *Unreviewable grounds for denial.* A covered entity may deny an individual access without providing the individual an opportunity for review, in the following circumstances.
(i) The protected health information is excepted from the right of access by paragraph (a)(1) of this section.
(ii) A covered entity that is a correctional institution or a covered health care provider acting under the direction of the correctional institution may deny, in whole or in part, an inmate's request to obtain a copy of protected health information, if obtaining such copy would jeopardize the health, safety, security, custody, or rehabilitation of the individual or of other inmates, or the safety of any officer, employee, or other person at the correctional institution or responsible for the transporting of the inmate.
(iii) An individual's access to protected health information created or obtained by a covered health care provider in the course of research that includes treatment may be temporarily suspended for as long as the research is in progress, provided that the individual has agreed to the denial of access when consenting to participate in the research that includes treatment, and the covered health care provider has informed the individual that the right of access will be reinstated upon completion of the research.
(iv) An individual's access to protected health information that is contained in records that are subject to the Privacy Act, 5 U.S.C. 552a, may be denied, if the denial of access under the Privacy Act would meet the requirements of that law.
(v) An individual's access may be denied if the protected health information was obtained from someone other than a health care provider under a promise of confidentiality and the access requested would be reasonably likely to reveal the source of the information.
(3) *Reviewable grounds for denial.* A covered entity may deny an individual access, provided that the individual is given a right to have such denials reviewed, as required by paragraph (a)(4) of this section, in the following circumstances:
(i) A licensed health care professional has determined, in the exercise of professional judgment, that the access requested is reasonably likely to endanger the life or physical safety of the individual or another person;
(ii) The protected health information makes reference to another person (unless such other person is a health care provider) and a licensed health care professional has determined, in the exercise of professional judgment, that the access requested is reasonably likely to cause substantial harm to such other person; or
(iii) The request for access is made by the individual's personal representative and a licensed health care professional has determined, in the exercise of professional judgment, that the provision of access to such personal representative is reasonably likely to cause substantial harm to the individual or another person.
(4) *Review of a denial of access.* If access is denied on a ground permitted under paragraph (a)(3) of this section, the individual has the right to have the denial reviewed by a licensed health care professional who is designated by the covered entity to act as a reviewing official and who did not participate in the original decision to deny. The covered entity must provide or deny access in accordance with the determination of the reviewing official under paragraph (d)(4) of this section.
(b) *Implementation specifications: Requests for access and timely action*—(1) *Individual's request for access.* The covered entity must permit an individual to request access to inspect or to obtain a copy of the protected health information about the individual that is maintained in a designated record set. The covered

entity may require individuals to make requests for access in writing, provided that it informs individuals of such a requirement.
(2) *Timely action by the covered entity.* (i) Except as provided in paragraph (b)(2)(ii) of this section, the covered entity must act on a request for access no later than 30 days after receipt of the request as follows.
(A) If the covered entity grants the request, in whole or in part, it must inform the individual of the acceptance of the request and provide the access requested, in accordance with paragraph (c) of this section.
(B) If the covered entity denies the request, in whole or in part, it must provide the individual with a written denial, in accordance with paragraph (d) of this section.
(ii) If the covered entity is unable to take an action required by paragraph (b)(2)(i)(A) or (B) of this section within the time required by paragraph (b)(2)(i) of this section, as applicable, the covered entity may extend the time for such actions by no more than 30 days, provided that:
(A) The covered entity, within the time limit set by paragraph (b)(2)(i) of this section, as applicable, provides the individual with a written statement of the reasons for the delay and the date by which the covered entity will complete its action on the request; and
(B) The covered entity may have only one such extension of time for action on a request for access.
(c) *Implementation specifications: Provision of access.* If the covered entity provides an individual with access, in whole or in part, to protected health information, the covered entity must comply with the following requirements.
(1) *Providing the access requested.* The covered entity must provide the access requested by individuals, including inspection or obtaining a copy, or both, of the protected health information about them in designated record sets. If the same protected health information that is the subject of a request for access is maintained in more than one designated record set or at more than one location, the covered entity need only produce the protected health information once in response to a request for access.
(2) *Form of access requested.* (i) The covered entity must provide the individual with access to the protected health information in the form and format requested by the individual, if it is readily producible in such form and format; or, if not, in a readable hard copy form or such other form and format as agreed to by the covered entity and the individual.
(ii) Notwithstanding paragraph (c)(2)(i) of this section, if the protected health information that is the subject of a request for access is maintained in one or more designated record sets electronically and if the individual requests an electronic copy of such information, the covered entity must provide the individual with access to the protected health information in the electronic form and format requested by the individual, if it is readily producible in such form and format; or, if not, in a readable electronic form and format as agreed to by the covered entity and the individual.
(iii) The covered entity may provide the individual with a summary of the protected health information requested, in lieu of providing access to the protected health information or may provide an explanation of the protected health information to which access has been provided, if:
(A) The individual agrees in advance to such a summary or explanation; and
(B) The individual agrees in advance to the fees imposed, if any, by the covered entity for such summary or explanation.
(3) *Time and manner of access.* (i) The covered entity must provide the access as requested by the individual in a timely manner as required by paragraph (b)(2) of this section, including arranging with the individual for a convenient time and place to inspect or obtain a copy of the protected health information, or mailing the copy of the protected health information at the individual's request. The covered entity may discuss the scope, format, and other aspects of the request for access with the individual as necessary to facilitate the timely provision of access.
(ii) If an individual's request for access directs the covered entity to transmit the copy of protected health information directly to another person designated by the individual, the covered entity must provide the copy to the person designated by the individual. The individual's request must be in writing, signed by the individual, and clearly identify the designated person and where to send the copy of protected health information.
(4) *Fees.* If the individual requests a copy of the protected health information or agrees to a summary or explanation of such information, the covered entity may impose a reasonable, cost-based fee, provided that the fee includes only the cost of:
(i) Labor for copying the protected health information requested by the individual, whether in paper or electronic form;

(ii) Supplies for creating the paper copy or electronic media if the individual requests that the electronic copy be provided on portable media;
(iii) Postage, when the individual has requested the copy, or the summary or explanation, be mailed; and
(iv) Preparing an explanation or summary of the protected health information, if agreed to by the individual as required by paragraph (c)(2)(iii) of this section.
(d) *Implementation specifications: Denial of access.* If the covered entity denies access, in whole or in part, to protected health information, the covered entity must comply with the following requirements.
(1) *Making other information accessible.* The covered entity must, to the extent possible, give the individual access to any other protected health information requested, after excluding the protected health information as to which the covered entity has a ground to deny access.
(2) *Denial.* The covered entity must provide a timely, written denial to the individual, in accordance with paragraph (b)(2) of this section. The denial must be in plain language and contain:
(i) The basis for the denial;
(ii) If applicable, a statement of the individual's review rights under paragraph (a)(4) of this section, including a description of how the individual may exercise such review rights; and
(iii) A description of how the individual may complain to the covered entity pursuant to the complaint procedures in §164.530(d) or to the Secretary pursuant to the procedures in §160.306. The description must include the name, or title, and telephone number of the contact person or office designated in §164.530(a)(1)(ii).
(3) *Other responsibility.* If the covered entity does not maintain the protected health information that is the subject of the individual's request for access, and the covered entity knows where the requested information is maintained, the covered entity must inform the individual where to direct the request for access.
(4) *Review of denial requested.* If the individual has requested a review of a denial under paragraph (a)(4) of this section, the covered entity must designate a licensed health care professional, who was not directly involved in the denial to review the decision to deny access. The covered entity must promptly refer a request for review to such designated reviewing official. The designated reviewing official must determine, within a reasonable period of time, whether or not to deny the access requested based on the standards in paragraph (a)(3) of this section. The covered entity must promptly provide written notice to the individual of the determination of the designated reviewing official and take other action as required by this section to carry out the designated reviewing official's determination.
(e) *Implementation specification: Documentation.* A covered entity must document the following and retain the documentation as required by §164.530(j):
(1) The designated record sets that are subject to access by individuals; and
(2) The titles of the persons or offices responsible for receiving and processing requests for access by individuals.
[65 FR 82802, Dec. 28, 2000, as amended at 78 FR 5701, Jan. 25, 2013; 78 FR 34266, June 7, 2013; 79 FR 7316, Feb. 6, 2014]

§164.528 Accounting of disclosures of protected health information.
(a) *Standard: Right to an accounting of disclosures of protected health information.* (1) An individual has a right to receive an accounting of disclosures of protected health information made by a covered entity in the six years prior to the date on which the accounting is requested, except for disclosures:
(i) To carry out treatment, payment and health care operations as provided in §164.506;
(ii) To individuals of protected health information about them as provided in §164.502;
(iii) Incident to a use or disclosure otherwise permitted or required by this subpart, as provided in §164.502;
(iv) Pursuant to an authorization as provided in §164.508;
(v) For the facility's directory or to persons involved in the individual's care or other notification purposes as provided in §164.510;
(vi) For national security or intelligence purposes as provided in §164.512(k)(2);
(vii) To correctional institutions or law enforcement officials as provided in §164.512(k)(5);
(viii) As part of a limited data set in accordance with §164.514(e); or
(ix) That occurred prior to the compliance date for the covered entity.
(2)(i) The covered entity must temporarily suspend an individual's right to receive an accounting of disclosures to a health oversight agency or law enforcement official, as provided in §164.512(d) or (f),

respectively, for the time specified by such agency or official, if such agency or official provides the covered entity with a written statement that such an accounting to the individual would be reasonably likely to impede the agency's activities and specifying the time for which such a suspension is required.
(ii) If the agency or official statement in paragraph (a)(2)(i) of this section is made orally, the covered entity must:
(A) Document the statement, including the identity of the agency or official making the statement;
(B) Temporarily suspend the individual's right to an accounting of disclosures subject to the statement; and
(C) Limit the temporary suspension to no longer than 30 days from the date of the oral statement, unless a written statement pursuant to paragraph (a)(2)(i) of this section is submitted during that time.
(3) An individual may request an accounting of disclosures for a period of time less than six years from the date of the request.
(b) *Implementation specifications: Content of the accounting.* The covered entity must provide the individual with a written accounting that meets the following requirements.
(1) Except as otherwise provided by paragraph (a) of this section, the accounting must include disclosures of protected health information that occurred during the six years (or such shorter time period at the request of the individual as provided in paragraph (a)(3) of this section) prior to the date of the request for an accounting, including disclosures to or by business associates of the covered entity.
(2) Except as otherwise provided by paragraphs (b)(3) or (b)(4) of this section, the accounting must include for each disclosure:
(i) The date of the disclosure;
(ii) The name of the entity or person who received the protected health information and, if known, the address of such entity or person;
(iii) A brief description of the protected health information disclosed; and
(iv) A brief statement of the purpose of the disclosure that reasonably informs the individual of the basis for the disclosure or, in lieu of such statement, a copy of a written request for a disclosure under §§164.502(a)(2)(ii) or 164.512, if any.
(3) If, during the period covered by the accounting, the covered entity has made multiple disclosures of protected health information to the same person or entity for a single purpose under §§164.502(a)(2)(ii) or 164.512, the accounting may, with respect to such multiple disclosures, provide:
(i) The information required by paragraph (b)(2) of this section for the first disclosure during the accounting period;
(ii) The frequency, periodicity, or number of the disclosures made during the accounting period; and
(iii) The date of the last such disclosure during the accounting period.
(4)(i) If, during the period covered by the accounting, the covered entity has made disclosures of protected health information for a particular research purpose in accordance with §164.512(i) for 50 or more individuals, the accounting may, with respect to such disclosures for which the protected health information about the individual may have been included, provide:
(A) The name of the protocol or other research activity;
(B) A description, in plain language, of the research protocol or other research activity, including the purpose of the research and the criteria for selecting particular records;
(C) A brief description of the type of protected health information that was disclosed;
(D) The date or period of time during which such disclosures occurred, or may have occurred, including the date of the last such disclosure during the accounting period;
(E) The name, address, and telephone number of the entity that sponsored the research and of the researcher to whom the information was disclosed; and
(F) A statement that the protected health information of the individual may or may not have been disclosed for a particular protocol or other research activity.
(ii) If the covered entity provides an accounting for research disclosures, in accordance with paragraph (b)(4) of this section, and if it is reasonably likely that the protected health information of the individual was disclosed for such research protocol or activity, the covered entity shall, at the request of the individual, assist in contacting the entity that sponsored the research and the researcher.
(c) *Implementation specifications: Provision of the accounting.* (1) The covered entity must act on the individual's request for an accounting, no later than 60 days after receipt of such a request, as follows.
(i) The covered entity must provide the individual with the accounting requested; or

(ii) If the covered entity is unable to provide the accounting within the time required by paragraph (c)(1) of this section, the covered entity may extend the time to provide the accounting by no more than 30 days, provided that:
(A) The covered entity, within the time limit set by paragraph (c)(1) of this section, provides the individual with a written statement of the reasons for the delay and the date by which the covered entity will provide the accounting; and
(B) The covered entity may have only one such extension of time for action on a request for an accounting.
(2) The covered entity must provide the first accounting to an individual in any 12 month period without charge. The covered entity may impose a reasonable, cost-based fee for each subsequent request for an accounting by the same individual within the 12 month period, provided that the covered entity informs the individual in advance of the fee and provides the individual with an opportunity to withdraw or modify the request for a subsequent accounting in order to avoid or reduce the fee.
(d) *Implementation specification: Documentation.* A covered entity must document the following and retain the documentation as required by §164.530(j):
(1) The information required to be included in an accounting under paragraph (b) of this section for disclosures of protected health information that are subject to an accounting under paragraph (a) of this section;
(2) The written accounting that is provided to the individual under this section; and
(3) The titles of the persons or offices responsible for receiving and processing requests for an accounting by individuals

Section (d). Comment.

45 CFR §164.510(a) and (b) read:

> §164.510 Uses and disclosures requiring an opportunity for the individual to agree or to object.
> A covered entity may use or disclose protected health information, provided that the individual is informed in advance of the use or disclosure and has the opportunity to agree to or prohibit or restrict the use or disclosure, in accordance with the applicable requirements of this section. The covered entity may orally inform the individual of and obtain the individual's oral agreement or objection to a use or disclosure permitted by this section.
> (a) *Standard: Use and disclosure for facility directories*—(1) *Permitted uses and disclosure.* Except when an objection is expressed in accordance with paragraphs (a)(2) or (3) of this section, a covered health care provider may:
> (i) Use the following protected health information to maintain a directory of individuals in its facility:
> (A) The individual's name;
> (B) The individual's location in the covered health care provider's facility;
> (C) The individual's condition described in general terms that does not communicate specific medical information about the individual; and
> (D) The individual's religious affiliation; and
> (ii) Use or disclose for directory purposes such information:
> (A) To members of the clergy; or
> (B) Except for religious affiliation, to other persons who ask for the individual by name.
> (2) *Opportunity to object.* A covered health care provider must inform an individual of the protected health information that it may include in a directory and the persons to whom it may disclose such information (including disclosures to clergy of information regarding religious affiliation) and provide the individual with the opportunity to restrict or prohibit some or all of the uses or disclosures permitted by paragraph (a)(1) of this section.
> (3) *Emergency circumstances.* (i) If the opportunity to object to uses or disclosures required by paragraph (a)(2) of this section cannot practicably be provided because of the individual's incapacity or an emergency treatment circumstance, a covered health care provider may use or disclose some or all of the protected health information permitted by paragraph (a)(1) of this section for the facility's directory, if such disclosure is:
> (A) Consistent with a prior expressed preference of the individual, if any, that is known to the covered health care provider; and

(B) In the individual's best interest as determined by the covered health care provider, in the exercise of professional judgment.
(ii) The covered health care provider must inform the individual and provide an opportunity to object to uses or disclosures for directory purposes as required by paragraph (a)(2) of this section when it becomes practicable to do so.
(b) *Standard: Uses and disclosures for involvement in the individual's care and notification purposes*—(1) *Permitted uses and disclosures.* (i) A covered entity may, in accordance with paragraphs (b)(2), (b)(3), or (b)(5) of this section, disclose to a family member, other relative, or a close personal friend of the individual, or any other person identified by the individual, the protected health information directly relevant to such person's involvement with the individual's health care or payment related to the individual's health care.
(ii) A covered entity may use or disclose protected health information to notify, or assist in the notification of (including identifying or locating), a family member, a personal representative of the individual, or another person responsible for the care of the individual of the individual's location, general condition, or death. Any such use or disclosure of protected health information for such notification purposes must be in accordance with paragraphs (b)(2), (b)(3), (b)(4), or (b)(5) of this section, as applicable.
(2) *Uses and disclosures with the individual present.* If the individual is present for, or otherwise available prior to, a use or disclosure permitted by paragraph (b)(1) of this section and has the capacity to make health care decisions, the covered entity may use or disclose the protected health information if it:
(i) Obtains the individual's agreement;
(ii) Provides the individual with the opportunity to object to the disclosure, and the individual does not express an objection; or
(iii) Reasonably infers from the circumstances, based on the exercise of professional judgment, that the individual does not object to the disclosure.
(3) *Limited uses and disclosures when the individual is not present.* If the individual is not present, or the opportunity to agree or object to the use or disclosure cannot practicably be provided because of the individual's incapacity or an emergency circumstance, the covered entity may, in the exercise of professional judgment, determine whether the disclosure is in the best interests of the individual and, if so, disclose only the protected health information that is directly relevant to the person's involvement with the individual's care or payment related to the individual's health care or needed for notification purposes. A covered entity may use professional judgment and its experience with common practice to make reasonable inferences of the individual's best interest in allowing a person to act on behalf of the individual to pick up filled prescriptions, medical supplies, X-rays, or other similar forms of protected health information.
(4) *Uses and disclosures for disaster relief purposes.* A covered entity may use or disclose protected health information to a public or private entity authorized by law or by its charter to assist in disaster relief efforts, for the purpose of coordinating with such entities the uses or disclosures permitted by paragraph (b)(1)(ii) of this section. The requirements in paragraphs (b)(2), (b)(3), or (b)(5) of this section apply to such uses and disclosures to the extent that the covered entity, in the exercise of professional judgment, determines that the requirements do not interfere with the ability to respond to the emergency circumstances.
(5) *Uses and disclosures when the individual is deceased.* If the individual is deceased, a covered entity may disclose to a family member, or other persons identified in paragraph (b)(1) of this section who were involved in the individual's care or payment for health care prior to the individual's death, protected health information of the individual that is relevant to such person's involvement, unless doing so is inconsistent with any prior expressed preference of the individual that is known to the covered entity.

Section (e). Comment.

45 CFR §164.512(a) – (l) read:

§164.512 Uses and disclosures for which an authorization or opportunity to agree or object is not required.

A covered entity may use or disclose protected health information without the written authorization of the individual, as described in §164.508, or the opportunity for the individual to agree or object as described in §164.510, in the situations covered by this section, subject to the applicable requirements of this section. When the covered entity is required by this section to inform the individual of, or when the individual may agree to, a use or disclosure permitted by this section, the covered entity's information and the individual's agreement may be given orally.
(a) *Standard: Uses and disclosures required by law.* (1) A covered entity may use or disclose protected health information to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law.
(2) A covered entity must meet the requirements described in paragraph (c), (e), or (f) of this section for uses or disclosures required by law.
(b) *Standard: Uses and disclosures for public health activities.*—(1) *Permitted uses and disclosures.* A covered entity may use or disclose protected health information for the public health activities and purposes described in this paragraph to:
(i) A public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions; or, at the direction of a public health authority, to an official of a foreign government agency that is acting in collaboration with a public health authority;
(ii) A public health authority or other appropriate government authority authorized by law to receive reports of child abuse or neglect;
(iii) A person subject to the jurisdiction of the Food and Drug Administration (FDA) with respect to an FDA-regulated product or activity for which that person has responsibility, for the purpose of activities related to the quality, safety or effectiveness of such FDA-regulated product or activity. Such purposes include:
(A) To collect or report adverse events (or similar activities with respect to food or dietary supplements), product defects or problems (including problems with the use or labeling of a product), or biological product deviations;
(B) To track FDA-regulated products;
(C) To enable product recalls, repairs, or replacement, or lookback (including locating and notifying individuals who have received products that have been recalled, withdrawn, or are the subject of lookback); or
(D) To conduct post marketing surveillance;
(iv) A person who may have been exposed to a communicable disease or may otherwise be at risk of contracting or spreading a disease or condition, if the covered entity or public health authority is authorized by law to notify such person as necessary in the conduct of a public health intervention or investigation; or
(v) An employer, about an individual who is a member of the workforce of the employer, if:
(A) The covered entity is a covered health care provider who provides health care to the individual at the request of the employer:
(*1*) To conduct an evaluation relating to medical surveillance of the workplace; or
(*2*) To evaluate whether the individual has a work-related illness or injury;
(B) The protected health information that is disclosed consists of findings concerning a work-related illness or injury or a workplace-related medical surveillance;
(C) The employer needs such findings in order to comply with its obligations, under 29 CFR parts 1904 through 1928, 30 CFR parts 50 through 90, or under state law having a similar purpose, to record such illness or injury or to carry out responsibilities for workplace medical surveillance; and
(D) The covered health care provider provides written notice to the individual that protected health information relating to the medical surveillance of the workplace and work-related illnesses and injuries is disclosed to the employer:
(*1*) By giving a copy of the notice to the individual at the time the health care is provided; or
(*2*) If the health care is provided on the work site of the employer, by posting the notice in a prominent place at the location where the health care is provided.
(vi) A school, about an individual who is a student or prospective student of the school, if:
(A) The protected health information that is disclosed is limited to proof of immunization;

(B) The school is required by State or other law to have such proof of immunization prior to admitting the individual; and
(C) The covered entity obtains and documents the agreement to the disclosure from either:
(*1*) A parent, guardian, or other person acting *in loco parentis* of the individual, if the individual is an unemancipated minor; or
(*2*) The individual, if the individual is an adult or emancipated minor.
(2) *Permitted uses.* If the covered entity also is a public health authority, the covered entity is permitted to use protected health information in all cases in which it is permitted to disclose such information for public health activities under paragraph (b)(1) of this section.
(c) *Standard: Disclosures about victims of abuse, neglect or domestic violence*—(1) *Permitted disclosures.* Except for reports of child abuse or neglect permitted by paragraph (b)(1)(ii) of this section, a covered entity may disclose protected health information about an individual whom the covered entity reasonably believes to be a victim of abuse, neglect, or domestic violence to a government authority, including a social service or protective services agency, authorized by law to receive reports of such abuse, neglect, or domestic violence:
(i) To the extent the disclosure is required by law and the disclosure complies with and is limited to the relevant requirements of such law;
(ii) If the individual agrees to the disclosure; or
(iii) To the extent the disclosure is expressly authorized by statute or regulation and:
(A) The covered entity, in the exercise of professional judgment, believes the disclosure is necessary to prevent serious harm to the individual or other potential victims; or
(B) If the individual is unable to agree because of incapacity, a law enforcement or other public official authorized to receive the report represents that the protected health information for which disclosure is sought is not intended to be used against the individual and that an immediate enforcement activity that depends upon the disclosure would be materially and adversely affected by waiting until the individual is able to agree to the disclosure.
(2) *Informing the individual.* A covered entity that makes a disclosure permitted by paragraph (c)(1) of this section must promptly inform the individual that such a report has been or will be made, except if:
(i) The covered entity, in the exercise of professional judgment, believes informing the individual would place the individual at risk of serious harm; or
(ii) The covered entity would be informing a personal representative, and the covered entity reasonably believes the personal representative is responsible for the abuse, neglect, or other injury, and that informing such person would not be in the best interests of the individual as determined by the covered entity, in the exercise of professional judgment.
(d) *Standard: Uses and disclosures for health oversight activities*—(1) *Permitted disclosures.* A covered entity may disclose protected health information to a health oversight agency for oversight activities authorized by law, including audits; civil, administrative, or criminal investigations; inspections; licensure or disciplinary actions; civil, administrative, or criminal proceedings or actions; or other activities necessary for appropriate oversight of:
(i) The health care system;
(ii) Government benefit programs for which health information is relevant to beneficiary eligibility;
(iii) Entities subject to government regulatory programs for which health information is necessary for determining compliance with program standards; or
(iv) Entities subject to civil rights laws for which health information is necessary for determining compliance.
(2) *Exception to health oversight activities.* For the purpose of the disclosures permitted by paragraph (d)(1) of this section, a health oversight activity does not include an investigation or other activity in which the individual is the subject of the investigation or activity and such investigation or other activity does not arise out of and is not directly related to:
(i) The receipt of health care;
(ii) A claim for public benefits related to health; or
(iii) Qualification for, or receipt of, public benefits or services when a patient's health is integral to the claim for public benefits or services.
(3) *Joint activities or investigations.* Nothwithstanding paragraph (d)(2) of this section, if a health oversight activity or investigation is conducted in conjunction with an oversight activity or

investigation relating to a claim for public benefits not related to health, the joint activity or investigation is considered a health oversight activity for purposes of paragraph (d) of this section.
(4) *Permitted uses.* If a covered entity also is a health oversight agency, the covered entity may use protected health information for health oversight activities as permitted by paragraph (d) of this section.
(e) *Standard: Disclosures for judicial and administrative proceedings*—(1) *Permitted disclosures.* A covered entity may disclose protected health information in the course of any judicial or administrative proceeding:
(i) In response to an order of a court or administrative tribunal, provided that the covered entity discloses only the protected health information expressly authorized by such order; or
(ii) In response to a subpoena, discovery request, or other lawful process, that is not accompanied by an order of a court or administrative tribunal, if:
(A) The covered entity receives satisfactory assurance, as described in paragraph (e)(1)(iii) of this section, from the party seeking the information that reasonable efforts have been made by such party to ensure that the individual who is the subject of the protected health information that has been requested has been given notice of the request; or
(B) The covered entity receives satisfactory assurance, as described in paragraph (e)(1)(iv) of this section, from the party seeking the information that reasonable efforts have been made by such party to secure a qualified protective order that meets the requirements of paragraph (e)(1)(v) of this section.
(iii) For the purposes of paragraph (e)(1)(ii)(A) of this section, a covered entity receives satisfactory assurances from a party seeking protected health information if the covered entity receives from such party a written statement and accompanying documentation demonstrating that:
(A) The party requesting such information has made a good faith attempt to provide written notice to the individual (or, if the individual's location is unknown, to mail a notice to the individual's last known address);
(B) The notice included sufficient information about the litigation or proceeding in which the protected health information is requested to permit the individual to raise an objection to the court or administrative tribunal; and
(C) The time for the individual to raise objections to the court or administrative tribunal has elapsed, and:
(*1*) No objections were filed; or
(*2*) All objections filed by the individual have been resolved by the court or the administrative tribunal and the disclosures being sought are consistent with such resolution.
(iv) For the purposes of paragraph (e)(1)(ii)(B) of this section, a covered entity receives satisfactory assurances from a party seeking protected health information, if the covered entity receives from such party a written statement and accompanying documentation demonstrating that:
(A) The parties to the dispute giving rise to the request for information have agreed to a qualified protective order and have presented it to the court or administrative tribunal with jurisdiction over the dispute; or
(B) The party seeking the protected health information has requested a qualified protective order from such court or administrative tribunal.
(v) For purposes of paragraph (e)(1) of this section, a qualified protective order means, with respect to protected health information requested under paragraph (e)(1)(ii) of this section, an order of a court or of an administrative tribunal or a stipulation by the parties to the litigation or administrative proceeding that:
(A) Prohibits the parties from using or disclosing the protected health information for any purpose other than the litigation or proceeding for which such information was requested; and
(B) Requires the return to the covered entity or destruction of the protected health information (including all copies made) at the end of the litigation or proceeding.
(vi) Notwithstanding paragraph (e)(1)(ii) of this section, a covered entity may disclose protected health information in response to lawful process described in paragraph (e)(1)(ii) of this section without receiving satisfactory assurance under paragraph (e)(1)(ii)(A) or (B) of this section, if the covered entity makes reasonable efforts to provide notice to the individual sufficient to meet the requirements of paragraph (e)(1)(iii) of this section or to seek a qualified protective order sufficient to meet the requirements of paragraph (e)(1)(v) of this section.

(2) *Other uses and disclosures under this section.* The provisions of this paragraph do not supersede other provisions of this section that otherwise permit or restrict uses or disclosures of protected health information.
(f) *Standard: Disclosures for law enforcement purposes.* A covered entity may disclose protected health information for a law enforcement purpose to a law enforcement official if the conditions in paragraphs (f)(1) through (f)(6) of this section are met, as applicable.
(1) *Permitted disclosures: Pursuant to process and as otherwise required by law.* A covered entity may disclose protected health information:
(i) As required by law including laws that require the reporting of certain types of wounds or other physical injuries, except for laws subject to paragraph (b)(1)(ii) or (c)(1)(i) of this section; or
(ii) In compliance with and as limited by the relevant requirements of:
(A) A court order or court-ordered warrant, or a subpoena or summons issued by a judicial officer;
(B) A grand jury subpoena; or
(C) An administrative request, including an administrative subpoena or summons, a civil or an authorized investigative demand, or similar process authorized under law, provided that:
(*1*) The information sought is relevant and material to a legitimate law enforcement inquiry;
(*2*) The request is specific and limited in scope to the extent reasonably practicable in light of the purpose for which the information is sought; and
(*3*) De-identified information could not reasonably be used.
(2) *Permitted disclosures: Limited information for identification and location purposes.* Except for disclosures required by law as permitted by paragraph (f)(1) of this section, a covered entity may disclose protected health information in response to a law enforcement official's request for such information for the purpose of identifying or locating a suspect, fugitive, material witness, or missing person, provided that:
(i) The covered entity may disclose only the following information:
(A) Name and address;
(B) Date and place of birth;
(C) Social security number;
(D) ABO blood type and rh factor;
(E) Type of injury;
(F) Date and time of treatment;
(G) Date and time of death, if applicable; and
(H) A description of distinguishing physical characteristics, including height, weight, gender, race, hair and eye color, presence or absence of facial hair (beard or moustache), scars, and tattoos.
(ii) Except as permitted by paragraph (f)(2)(i) of this section, the covered entity may not disclose for the purposes of identification or location under paragraph (f)(2) of this section any protected health information related to the individual's DNA or DNA analysis, dental records, or typing, samples or analysis of body fluids or tissue.
(3) *Permitted disclosure: Victims of a crime.* Except for disclosures required by law as permitted by paragraph (f)(1) of this section, a covered entity may disclose protected health information in response to a law enforcement official's request for such information about an individual who is or is suspected to be a victim of a crime, other than disclosures that are subject to paragraph (b) or (c) of this section, if:
(i) The individual agrees to the disclosure; or
(ii) The covered entity is unable to obtain the individual's agreement because of incapacity or other emergency circumstance, provided that:
(A) The law enforcement official represents that such information is needed to determine whether a violation of law by a person other than the victim has occurred, and such information is not intended to be used against the victim;
(B) The law enforcement official represents that immediate law enforcement activity that depends upon the disclosure would be materially and adversely affected by waiting until the individual is able to agree to the disclosure; and
(C) The disclosure is in the best interests of the individual as determined by the covered entity, in the exercise of professional judgment.
(4) *Permitted disclosure: Decedents.* A covered entity may disclose protected health information about an individual who has died to a law enforcement official for the purpose of alerting law

enforcement of the death of the individual if the covered entity has a suspicion that such death may have resulted from criminal conduct.
(5) *Permitted disclosure: Crime on premises.* A covered entity may disclose to a law enforcement official protected health information that the covered entity believes in good faith constitutes evidence of criminal conduct that occurred on the premises of the covered entity.
(6) *Permitted disclosure: Reporting crime in emergencies.* (i) A covered health care provider providing emergency health care in response to a medical emergency, other than such emergency on the premises of the covered health care provider, may disclose protected health information to a law enforcement official if such disclosure appears necessary to alert law enforcement to:
(A) The commission and nature of a crime;
(B) The location of such crime or of the victim(s) of such crime; and
(C) The identity, description, and location of the perpetrator of such crime.
(ii) If a covered health care provider believes that the medical emergency described in paragraph (f)(6)(i) of this section is the result of abuse, neglect, or domestic violence of the individual in need of emergency health care, paragraph (f)(6)(i) of this section does not apply and any disclosure to a law enforcement official for law enforcement purposes is subject to paragraph (c) of this section.
(g) *Standard: Uses and disclosures about decedents*—(1) *Coroners and medical examiners.* A covered entity may disclose protected health information to a coroner or medical examiner for the purpose of identifying a deceased person, determining a cause of death, or other duties as authorized by law. A covered entity that also performs the duties of a coroner or medical examiner may use protected health information for the purposes described in this paragraph.
(2) *Funeral directors.* A covered entity may disclose protected health information to funeral directors, consistent with applicable law, as necessary to carry out their duties with respect to the decedent. If necessary for funeral directors to carry out their duties, the covered entity may disclose the protected health information prior to, and in reasonable anticipation of, the individual's death.
(h) *Standard: Uses and disclosures for cadaveric organ, eye or tissue donation purposes.* A covered entity may use or disclose protected health information to organ procurement organizations or other entities engaged in the procurement, banking, or transplantation of cadaveric organs, eyes, or tissue for the purpose of facilitating organ, eye or tissue donation and transplantation.
(i) *Standard: Uses and disclosures for research purposes*—(1) *Permitted uses and disclosures.* A covered entity may use or disclose protected health information for research, regardless of the source of funding of the research, provided that:
(i) *Board approval of a waiver of authorization.* The covered entity obtains documentation that an alteration to or waiver, in whole or in part, of the individual authorization required by §164.508 for use or disclosure of protected health information has been approved by either:
(A) An Institutional Review Board (IRB), established in accordance with 7 CFR lc.107, 10 CFR 745.107, 14 CFR 1230.107, 15 CFR 27.107, 16 CFR 1028.107, 21 CFR 56.107, 22 CFR 225.107, 24 CFR 60.107, 28 CFR 46.107, 32 CFR 219.107, 34 CFR 97.107, 38 CFR 16.107, 40 CFR 26.107, 45 CFR 46.107, 45 CFR 690.107, or 49 CFR 11.107; or
(B) A privacy board that:
(*1*) Has members with varying backgrounds and appropriate professional competency as necessary to review the effect of the research protocol on the individual's privacy rights and related interests;
(*2*) Includes at least one member who is not affiliated with the covered entity, not affiliated with any entity conducting or sponsoring the research, and not related to any person who is affiliated with any of such entities; and
(*3*) Does not have any member participating in a review of any project in which the member has a conflict of interest.
(ii) *Reviews preparatory to research.* The covered entity obtains from the researcher representations that:
(A) Use or disclosure is sought solely to review protected health information as necessary to prepare a research protocol or for similar purposes preparatory to research;
(B) No protected health information is to be removed from the covered entity by the researcher in the course of the review; and
(C) The protected health information for which use or access is sought is necessary for the research purposes.
(iii) *Research on decedent's information.* The covered entity obtains from the researcher:

(A) Representation that the use or disclosure sought is solely for research on the protected health information of decedents;
(B) Documentation, at the request of the covered entity, of the death of such individuals; and
(C) Representation that the protected health information for which use or disclosure is sought is necessary for the research purposes.
(2) *Documentation of waiver approval.* For a use or disclosure to be permitted based on documentation of approval of an alteration or waiver, under paragraph (i)(1)(i) of this section, the documentation must include all of the following:
(i) *Identification and date of action.* A statement identifying the IRB or privacy board and the date on which the alteration or waiver of authorization was approved;
(ii) *Waiver criteria.* A statement that the IRB or privacy board has determined that the alteration or waiver, in whole or in part, of authorization satisfies the following criteria:
(A) The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements;
(*1*) An adequate plan to protect the identifiers from improper use and disclosure;
(*2*) An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
(*3*) Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;
(B) The research could not practicably be conducted without the waiver or alteration; and
(C) The research could not practicably be conducted without access to and use of the protected health information.
(iii) *Protected health information needed.* A brief description of the protected health information for which use or access has been determined to be necessary by the institutional review board or privacy board, pursuant to paragraph (i)(2)(ii)(C) of this section;
(iv) *Review and approval procedures.* A statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures, as follows:
(A) An IRB must follow the requirements of the Common Rule, including the normal review procedures (7 CFR 1c.108(b), 10 CFR 745.108(b), 14 CFR 1230.108(b), 15 CFR 27.108(b), 16 CFR 1028.108(b), 21 CFR 56.108(b), 22 CFR 225.108(b), 24 CFR 60.108(b), 28 CFR 46.108(b), 32 CFR 219.108(b), 34 CFR 97.108(b), 38 CFR 16.108(b), 40 CFR 26.108(b), 45 CFR 46.108(b), 45 CFR 690.108(b), or 49 CFR 11.108(b)) or the expedited review procedures (7 CFR 1c.110, 10 CFR 745.110, 14 CFR 1230.110, 15 CFR 27.110, 16 CFR 1028.110, 21 CFR 56.110, 22 CFR 225.110, 24 CFR 60.110, 28 CFR 46.110, 32 CFR 219.110, 34 CFR 97.110, 38 CFR 16.110, 40 CFR 26.110, 45 CFR 46.110, 45 CFR 690.110, or 49 CFR 11.110);
(B) A privacy board must review the proposed research at convened meetings at which a majority of the privacy board members are present, including at least one member who satisfies the criterion stated in paragraph (i)(1)(i)(B)(2) of this section, and the alteration or waiver of authorization must be approved by the majority of the privacy board members present at the meeting, unless the privacy board elects to use an expedited review procedure in accordance with paragraph (i)(2)(iv)(C) of this section;
(C) A privacy board may use an expedited review procedure if the research involves no more than minimal risk to the privacy of the individuals who are the subject of the protected health information for which use or disclosure is being sought. If the privacy board elects to use an expedited review procedure, the review and approval of the alteration or waiver of authorization may be carried out by the chair of the privacy board, or by one or more members of the privacy board as designated by the chair; and
(v) *Required signature.* The documentation of the alteration or waiver of authorization must be signed by the chair or other member, as designated by the chair, of the IRB or the privacy board, as applicable.
(j) *Standard: Uses and disclosures to avert a serious threat to health or safety*—(1) *Permitted disclosures.* A covered entity may, consistent with applicable law and standards of ethical conduct,

use or disclose protected health information, if the covered entity, in good faith, believes the use or disclosure:
(i)(A) Is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public; and
(B) Is to a person or persons reasonably able to prevent or lessen the threat, including the target of the threat; or
(ii) Is necessary for law enforcement authorities to identify or apprehend an individual:
(A) Because of a statement by an individual admitting participation in a violent crime that the covered entity reasonably believes may have caused serious physical harm to the victim; or
(B) Where it appears from all the circumstances that the individual has escaped from a correctional institution or from lawful custody, as those terms are defined in §164.501.
(2) *Use or disclosure not permitted.* A use or disclosure pursuant to paragraph (j)(1)(ii)(A) of this section may not be made if the information described in paragraph (j)(1)(ii)(A) of this section is learned by the covered entity:
(i) In the course of treatment to affect the propensity to commit the criminal conduct that is the basis for the disclosure under paragraph (j)(1)(ii)(A) of this section, or counseling or therapy; or
(ii) Through a request by the individual to initiate or to be referred for the treatment, counseling, or therapy described in paragraph (j)(2)(i) of this section.
(3) *Limit on information that may be disclosed.* A disclosure made pursuant to paragraph (j)(1)(ii)(A) of this section shall contain only the statement described in paragraph (j)(1)(ii)(A) of this section and the protected health information described in paragraph (f)(2)(i) of this section.
(4) *Presumption of good faith belief.* A covered entity that uses or discloses protected health information pursuant to paragraph (j)(1) of this section is presumed to have acted in good faith with regard to a belief described in paragraph (j)(1)(i) or (ii) of this section, if the belief is based upon the covered entity's actual knowledge or in reliance on a credible representation by a person with apparent knowledge or authority.
(k) *Standard: Uses and disclosures for specialized government functions*—(1) *Military and veterans activities*—(i)*Armed Forces personnel.* A covered entity may use and disclose the protected health information of individuals who are Armed Forces personnel for activities deemed necessary by appropriate military command authorities to assure the proper execution of the military mission, if the appropriate military authority has published by notice in the Federal Register the following information:
(A) Appropriate military command authorities; and
(B) The purposes for which the protected health information may be used or disclosed.
(ii) *Separation or discharge from military service.* A covered entity that is a component of the Departments of Defense or Homeland Security may disclose to the Department of Veterans Affairs (DVA) the protected health information of an individual who is a member of the Armed Forces upon the separation or discharge of the individual from military service for the purpose of a determination by DVA of the individual's eligibility for or entitlement to benefits under laws administered by the Secretary of Veterans Affairs.
(iii) *Veterans.* A covered entity that is a component of the Department of Veterans Affairs may use and disclose protected health information to components of the Department that determine eligibility for or entitlement to, or that provide, benefits under the laws administered by the Secretary of Veterans Affairs.
(iv) *Foreign military personnel.* A covered entity may use and disclose the protected health information of individuals who are foreign military personnel to their appropriate foreign military authority for the same purposes for which uses and disclosures are permitted for Armed Forces personnel under the notice published in the Federal Register pursuant to paragraph (k)(1)(i) of this section.
(2) *National security and intelligence activities.* A covered entity may disclose protected health information to authorized federal officials for the conduct of lawful intelligence, counter-intelligence, and other national security activities authorized by the National Security Act (50 U.S.C. 401, *et seq.*) and implementing authority (*e.g.,* Executive Order 12333).
(3) *Protective services for the President and others.* A covered entity may disclose protected health information to authorized Federal officials for the provision of protective services to the President or

other persons authorized by 18 U.S.C. 3056 or to foreign heads of state or other persons authorized by 22 U.S.C. 2709(a)(3), or for the conduct of investigations authorized by 18 U.S.C. 871 and 879.
(4) *Medical suitability determinations.* A covered entity that is a component of the Department of State may use protected health information to make medical suitability determinations and may disclose whether or not the individual was determined to be medically suitable to the officials in the Department of State who need access to such information for the following purposes:
(i) For the purpose of a required security clearance conducted pursuant to Executive Orders 10450 and 12968;
(ii) As necessary to determine worldwide availability or availability for mandatory service abroad under sections 101(a)(4) and 504 of the Foreign Service Act; or
(iii) For a family to accompany a Foreign Service member abroad, consistent with section 101(b)(5) and 904 of the Foreign Service Act.
(5) *Correctional institutions and other law enforcement custodial situations.* (i) *Permitted disclosures.* A covered entity may disclose to a correctional institution or a law enforcement official having lawful custody of an inmate or other individual protected health information about such inmate or individual, if the correctional institution or such law enforcement official represents that such protected health information is necessary for:
(A) The provision of health care to such individuals;
(B) The health and safety of such individual or other inmates;
(C) The health and safety of the officers or employees of or others at the correctional institution;
(D) The health and safety of such individuals and officers or other persons responsible for the transporting of inmates or their transfer from one institution, facility, or setting to another;
(E) Law enforcement on the premises of the correctional institution; or
(F) The Administration and maintenance of the safety, security, and good order of the correctional institution.
(ii) *Permitted uses.* A covered entity that is a correctional institution may use protected health information of individuals who are inmates for any purpose for which such protected health information may be disclosed.
(iii) *No application after release.* For the purposes of this provision, an individual is no longer an inmate when released on parole, probation, supervised release, or otherwise is no longer in lawful custody.
(6) *Covered entities that are government programs providing public benefits.* (i) A health plan that is a government program providing public benefits may disclose protected health information relating to eligibility for or enrollment in the health plan to another agency administering a government program providing public benefits if the sharing of eligibility or enrollment information among such government agencies or the maintenance of such information in a single or combined data system accessible to all such government agencies is required or expressly authorized by statute or regulation.
(ii) A covered entity that is a government agency administering a government program providing public benefits may disclose protected health information relating to the program to another covered entity that is a government agency administering a government program providing public benefits if the programs serve the same or similar populations and the disclosure of protected health information is necessary to coordinate the covered functions of such programs or to improve Administration and management relating to the covered functions of such programs.
(l) *Standard: Disclosures for workers' compensation.* A covered entity may disclose protected health information as authorized by and to the extent necessary to comply with laws relating to workers' compensation or other similar programs, established by law, that provide benefits for work-related injuries or illness without regard to fault

Section (f). Comment.

45 CFR §164.514(a) - (c), (d), (e), and (h) read:

§164.514 Other requirements relating to uses and disclosures of protected health information.

(a) *Standard: De-identification of protected health information.* Health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual is not individually identifiable health information.
(b) *Implementation specifications: Requirements for de-identification of protected health information.* A covered entity may determine that health information is not individually identifiable health information only if:
(1) A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable:
(i) Applying such principles and methods, determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information; and
(ii) Documents the methods and results of the analysis that justify such determination; or
(2)(i) The following identifiers of the individual or of relatives, employers, or household members of the individual, are removed:
(A) Names;
(B) All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:
(*1*) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and
(*2*) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
(C) All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
(D) Telephone numbers;
(E) Fax numbers;
(F) Electronic mail addresses;
(G) Social security numbers;
(H) Medical record numbers;
(I) Health plan beneficiary numbers;
(J) Account numbers;
(K) Certificate/license numbers;
(L) Vehicle identifiers and serial numbers, including license plate numbers;
(M) Device identifiers and serial numbers;
(N) Web Universal Resource Locators (URLs);
(O) Internet Protocol (IP) address numbers;
(P) Biometric identifiers, including finger and voice prints;
(Q) Full face photographic images and any comparable images; and
(R) Any other unique identifying number, characteristic, or code, except as permitted by paragraph (c) of this section; and
(ii) The covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information.
(c) *Implementation specifications: Re-identification.* A covered entity may assign a code or other means of record identification to allow information de-identified under this section to be re-identified by the covered entity, provided that:
(1) *Derivation.* The code or other means of record identification is not derived from or related to information about the individual and is not otherwise capable of being translated so as to identify the individual; and
(2) *Security.* The covered entity does not use or disclose the code or other means of record identification for any other purpose, and does not disclose the mechanism for re-identification.
(d)(1) *Standard: minimum necessary requirements.* In order to comply with §164.502(b) and this section, a covered entity must meet the requirements of paragraphs (d)(2) through (d)(5) of this section with respect to a request for, or the use and disclosure of, protected health information.

(2) *Implementation specifications: Minimum necessary uses of protected health information.* (i) A covered entity must identify:
(A) Those persons or classes of persons, as appropriate, in its workforce who need access to protected health information to carry out their duties; and
(B) For each such person or class of persons, the category or categories of protected health information to which access is needed and any conditions appropriate to such access.
(ii) A covered entity must make reasonable efforts to limit the access of such persons or classes identified in paragraph (d)(2)(i)(A) of this section to protected health information consistent with paragraph (d)(2)(i)(B) of this section.
(3) *Implementation specification: Minimum necessary disclosures of protected health information.* (i) For any type of disclosure that it makes on a routine and recurring basis, a covered entity must implement policies and procedures (which may be standard protocols) that limit the protected health information disclosed to the amount reasonably necessary to achieve the purpose of the disclosure.
(ii) For all other disclosures, a covered entity must:
(A) Develop criteria designed to limit the protected health information disclosed to the information reasonably necessary to accomplish the purpose for which disclosure is sought; and
(B) Review requests for disclosure on an individual basis in accordance with such criteria.
(iii) A covered entity may rely, if such reliance is reasonable under the circumstances, on a requested disclosure as the minimum necessary for the stated purpose when:
(A) Making disclosures to public officials that are permitted under §164.512, if the public official represents that the information requested is the minimum necessary for the stated purpose(s);
(B) The information is requested by another covered entity;
(C) The information is requested by a professional who is a member of its workforce or is a business associate of the covered entity for the purpose of providing professional services to the covered entity, if the professional represents that the information requested is the minimum necessary for the stated purpose(s); or
(D) Documentation or representations that comply with the applicable requirements of §164.512(i) have been provided by a person requesting the information for research purposes.
(4) *Implementation specifications: Minimum necessary requests for protected health information.* (i) A covered entity must limit any request for protected health information to that which is reasonably necessary to accomplish the purpose for which the request is made, when requesting such information from other covered entities.
(ii) For a request that is made on a routine and recurring basis, a covered entity must implement policies and procedures (which may be standard protocols) that limit the protected health information requested to the amount reasonably necessary to accomplish the purpose for which the request is made.
(iii) For all other requests, a covered entity must:
(A) Develop criteria designed to limit the request for protected health information to the information reasonably necessary to accomplish the purpose for which the request is made; and
(B) Review requests for disclosure on an individual basis in accordance with such criteria.
(5) *Implementation specification: Other content requirement.* For all uses, disclosures, or requests to which the requirements in paragraph (d) of this section apply, a covered entity may not use, disclose or request an entire medical record, except when the entire medical record is specifically justified as the amount that is reasonably necessary to accomplish the purpose of the use, disclosure, or request.
(e)(1) *Standard: Limited data set.* A covered entity may use or disclose a limited data set that meets the requirements of paragraphs (e)(2) and (e)(3) of this section, if the covered entity enters into a data use agreement with the limited data set recipient, in accordance with paragraph (e)(4) of this section.
(2) *Implementation specification: Limited data set:* A limited data set is protected health information that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual:
(i) Names;
(ii) Postal address information, other than town or city, State, and zip code;
(iii) Telephone numbers;
(iv) Fax numbers;
(v) Electronic mail addresses;
(vi) Social security numbers;

(vii) Medical record numbers;
(viii) Health plan beneficiary numbers;
(ix) Account numbers;
(x) Certificate/license numbers;
(xi) Vehicle identifiers and serial numbers, including license plate numbers;
(xii) Device identifiers and serial numbers;
(xiii) Web Universal Resource Locators (URLs);
(xiv) Internet Protocol (IP) address numbers;
(xv) Biometric identifiers, including finger and voice prints; and
(xvi) Full face photographic images and any comparable images.
(3) *Implementation specification: Permitted purposes for uses and disclosures.* (i) A covered entity may use or disclose a limited data set under paragraph (e)(1) of this section only for the purposes of research, public health, or health care operations.
(ii) A covered entity may use protected health information to create a limited data set that meets the requirements of paragraph (e)(2) of this section, or disclose protected health information only to a business associate for such purpose, whether or not the limited data set is to be used by the covered entity.
(4) *Implementation specifications: Data use agreement*—(i) *Agreement required.* A covered entity may use or disclose a limited data set under paragraph (e)(1) of this section only if the covered entity obtains satisfactory assurance, in the form of a data use agreement that meets the requirements of this section, that the limited data set recipient will only use or disclose the protected health information for limited purposes.
(ii) *Contents.* A data use agreement between the covered entity and the limited data set recipient must:
(A) Establish the permitted uses and disclosures of such information by the limited data set recipient, consistent with paragraph (e)(3) of this section. The data use agreement may not authorize the limited data set recipient to use or further disclose the information in a manner that would violate the requirements of this subpart, if done by the covered entity;
(B) Establish who is permitted to use or receive the limited data set; and
(C) Provide that the limited data set recipient will:
(*1*) Not use or further disclose the information other than as permitted by the data use agreement or as otherwise required by law;
(*2*) Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by the data use agreement;
(*3*) Report to the covered entity any use or disclosure of the information not provided for by its data use agreement of which it becomes aware;
(*4*) Ensure that any agents to whom it provides the limited data set agree to the same restrictions and conditions that apply to the limited data set recipient with respect to such information; and
(*5*) Not identify the information or contact the individuals.
(iii) *Compliance.* (A) A covered entity is not in compliance with the standards in paragraph (e) of this section if the covered entity knew of a pattern of activity or practice of the limited data set recipient that constituted a material breach or violation of the data use agreement, unless the covered entity took reasonable steps to cure the breach or end the violation, as applicable, and, if such steps were unsuccessful:
(1) Discontinued disclosure of protected health information to the recipient; and
(2) Reported the problem to the Secretary.
(B) A covered entity that is a limited data set recipient and violates a data use agreement will be in noncompliance with the standards, implementation specifications, and requirements of paragraph (e) of this section.
. . .
(h)(1) *Standard: Verification requirements.* Prior to any disclosure permitted by this subpart, a covered entity must:
(i) Except with respect to disclosures under §164.510, verify the identity of a person requesting protected health information and the authority of any such person to have access to protected health information under this subpart, if the identity or any such authority of such person is not known to the covered entity; and

(ii) Obtain any documentation, statements, or representations, whether oral or written, from the person requesting the protected health information when such documentation, statement, or representation is a condition of the disclosure under this subpart.
(2) *Implementation specifications: Verification.* (i) *Conditions on disclosures.* If a disclosure is conditioned by this subpart on particular documentation, statements, or representations from the person requesting the protected health information, a covered entity may rely, if such reliance is reasonable under the circumstances, on documentation, statements, or representations that, on their face, meet the applicable requirements.
(A) The conditions in §164.512(f)(1)(ii)(C) may be satisfied by the administrative subpoena or similar process or by a separate written statement that, on its face, demonstrates that the applicable requirements have been met.
(B) The documentation required by §164.512(i)(2) may be satisfied by one or more written statements, provided that each is appropriately dated and signed in accordance with §164.512(i)(2)(i) and (v).
(ii) *Identity of public officials.* A covered entity may rely, if such reliance is reasonable under the circumstances, on any of the following to verify identity when the disclosure of protected health information is to a public official or a person acting on behalf of the public official:
(A) If the request is made in person, presentation of an agency identification badge, other official credentials, or other proof of government status;
(B) If the request is in writing, the request is on the appropriate government letterhead; or
(C) If the disclosure is to a person acting on behalf of a public official, a written statement on appropriate government letterhead that the person is acting under the government's authority or other evidence or documentation of agency, such as a contract for services, memorandum of understanding, or purchase order, that establishes that the person is acting on behalf of the public official.
(iii) *Authority of public officials.* A covered entity may rely, if such reliance is reasonable under the circumstances, on any of the following to verify authority when the disclosure of protected health information is to a public official or a person acting on behalf of the public official:
(A) A written statement of the legal authority under which the information is requested, or, if a written statement would be impracticable, an oral statement of such legal authority;
(B) If a request is made pursuant to legal process, warrant, subpoena, order, or other legal process issued by a grand jury or a judicial or administrative tribunal is presumed to constitute legal authority.
(iv) *Exercise of professional judgment.* The verification requirements of this paragraph are met if the covered entity relies on the exercise of professional judgment in making a use or disclosure in accordance with §164.510 or acts on a good faith belief in making a disclosure in accordance with §164.512(j).

Section (g). Comment.

45 CFR §164.520 reads:

§164.520 Notice of privacy practices for protected health information.
(a) *Standard: Notice of privacy practices*—(1) *Right to notice.* Except as provided by paragraph (a)(2) or (3) of this section, an individual has a right to adequate notice of the uses and disclosures of protected health information that may be made by the covered entity, and of the individual's rights and the covered entity's legal duties with respect to protected health information.
(2) *Exception for group health plans.* (i) An individual enrolled in a group health plan has a right to notice:
(A) From the group health plan, if, and to the extent that, such an individual does not receive health benefits under the group health plan through an insurance contract with a health insurance issuer or HMO; or
(B) From the health insurance issuer or HMO with respect to the group health plan through which such individuals receive their health benefits under the group health plan.
(ii) A group health plan that provides health benefits solely through an insurance contract with a health insurance issuer or HMO, and that creates or receives protected health information in addition to summary health information as defined in §164.504(a) or information on whether the individual is participating in the group health plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO offered by the plan, must:

(A) Maintain a notice under this section; and
(B) Provide such notice upon request to any person. The provisions of paragraph (c)(1) of this section do not apply to such group health plan.
(iii) A group health plan that provides health benefits solely through an insurance contract with a health insurance issuer or HMO, and does not create or receive protected health information other than summary health information as defined in §164.504(a) or information on whether an individual is participating in the group health plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO offered by the plan, is not required to maintain or provide a notice under this section.
(3) *Exception for inmates.* An inmate does not have a right to notice under this section, and the requirements of this section do not apply to a correctional institution that is a covered entity.
(b) *Implementation specifications: Content of notice*—(1) *Required elements.* The covered entity must provide a notice that is written in plain language and that contains the elements required by this paragraph.
(i) *Header.* The notice must contain the following statement as a header or otherwise prominently displayed:
"THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY."
(ii) *Uses and disclosures.* The notice must contain:
(A) A description, including at least one example, of the types of uses and disclosures that the covered entity is permitted by this subpart to make for each of the following purposes: treatment, payment, and health care operations.
(B) A description of each of the other purposes for which the covered entity is permitted or required by this subpart to use or disclose protected health information without the individual's written authorization.
(C) If a use or disclosure for any purpose described in paragraphs (b)(1)(ii)(A) or (B) of this section is prohibited or materially limited by other applicable law, the description of such use or disclosure must reflect the more stringent law as defined in §160.202 of this subchapter.
(D) For each purpose described in paragraph (b)(1)(ii)(A) or (B) of this section, the description must include sufficient detail to place the individual on notice of the uses and disclosures that are permitted or required by this subpart and other applicable law.
(E) A description of the types of uses and disclosures that require an authorization under §164.508(a)(2)-(a)(4), a statement that other uses and disclosures not described in the notice will be made only with the individual's written authorization, and a statement that the individual may revoke an authorization as provided by §164.508(b)(5).
(iii) *Separate statements for certain uses or disclosures.* If the covered entity intends to engage in any of the following activities, the description required by paragraph (b)(1)(ii)(A) of this section must include a separate statement informing the individual of such activities, as applicable:
(A) In accordance with §164.514(f)(1), the covered entity may contact the individual to raise funds for the covered entity and the individual has a right to opt out of receiving such communications; (B) In accordance with §164.504(f), the group health plan, or a health insurance issuer or HMO with respect to a group health plan, may disclose protected health information to the sponsor of the plan; or
(C) If a covered entity that is a health plan, excluding an issuer of a long-term care policy falling within paragraph (1)(viii) of the definition of *health plan,* intends to use or disclose protected health information for underwriting purposes, a statement that the covered entity is prohibited from using or disclosing protected health information that is genetic information of an individual for such purposes.
(iv) *Individual rights.* The notice must contain a statement of the individual's rights with respect to protected health information and a brief description of how the individual may exercise these rights, as follows:
(A) The right to request restrictions on certain uses and disclosures of protected health information as provided by §164.522(a), including a statement that the covered entity is not required to agree to a requested restriction, except in case of a disclosure restricted under §164.522(a)(1)
(B) The right to receive confidential communications of protected health information as provided by §164.522(b), as applicable;
(C) The right to inspect and copy protected health information as provided by §164.524;
(D) The right to amend protected health information as provided by §164.526;

(E) The right to receive an accounting of disclosures of protected health information as provided by §164.528; and
(F) The right of an individual, including an individual who has agreed to receive the notice electronically in accordance with paragraph (c)(3) of this section, to obtain a paper copy of the notice from the covered entity upon request.
(v) *Covered entity's duties.* The notice must contain:
(A) A statement that the covered entity is required by law to maintain the privacy of protected health information, to provide individuals with notice of its legal duties and privacy practices with respect to protected health information, and to notify affected individuals following a breach of unsecured protected health information;
(B) A statement that the covered entity is required to abide by the terms of the notice currently in effect; and
(C) For the covered entity to apply a change in a privacy practice that is described in the notice to protected health information that the covered entity created or received prior to issuing a revised notice, in accordance with §164.530(i)(2)(ii), a statement that it reserves the right to change the terms of its notice and to make the new notice provisions effective for all protected health information that it maintains. The statement must also describe how it will provide individuals with a revised notice.
(vi) *Complaints.* The notice must contain a statement that individuals may complain to the covered entity and to the Secretary if they believe their privacy rights have been violated, a brief description of how the individual may file a complaint with the covered entity, and a statement that the individual will not be retaliated against for filing a complaint.
(vii) *Contact.* The notice must contain the name, or title, and telephone number of a person or office to contact for further information as required by §164.530(a)(1)(ii).
(viii) *Effective date.* The notice must contain the date on which the notice is first in effect, which may not be earlier than the date on which the notice is printed or otherwise published.
(2) *Optional elements.* (i) In addition to the information required by paragraph (b)(1) of this section, if a covered entity elects to limit the uses or disclosures that it is permitted to make under this subpart, the covered entity may describe its more limited uses or disclosures in its notice, provided that the covered entity may not include in its notice a limitation affecting its right to make a use or disclosure that is required by law or permitted by §164.512(j)(1)(i).
(ii) For the covered entity to apply a change in its more limited uses and disclosures to protected health information created or received prior to issuing a revised notice, in accordance with §164.530(i)(2)(ii), the notice must include the statements required by paragraph (b)(1)(v)(C) of this section.
(3) *Revisions to the notice.* The covered entity must promptly revise and distribute its notice whenever there is a material change to the uses or disclosures, the individual's rights, the covered entity's legal duties, or other privacy practices stated in the notice. Except when required by law, a material change to any term of the notice may not be implemented prior to the effective date of the notice in which such material change is reflected.
(c) *Implementation specifications: Provision of notice.* A covered entity must make the notice required by this section available on request to any person and to individuals as specified in paragraphs (c)(1) through (c)(3) of this section, as applicable.
(1) *Specific requirements for health plans.* (i) A health plan must provide the notice:
(A) No later than the compliance date for the health plan, to individuals then covered by the plan;
(B) Thereafter, at the time of enrollment, to individuals who are new enrollees.
(ii) No less frequently than once every three years, the health plan must notify individuals then covered by the plan of the availability of the notice and how to obtain the notice.
(iii) The health plan satisfies the requirements of paragraph (c)(1) of this section if notice is provided to the named insured of a policy under which coverage is provided to the named insured and one or more dependents.
(iv) If a health plan has more than one notice, it satisfies the requirements of paragraph (c)(1) of this section by providing the notice that is relevant to the individual or other person requesting the notice.
(v) If there is a material change to the notice:
(A) A health plan that posts its notice on its web site in accordance with paragraph (c)(3)(i) of this section must prominently post the change or its revised notice on its web site by the effective date of the material change to the notice, and provide the revised notice, or information about the material

change and how to obtain the revised notice, in its next annual mailing to individuals then covered by the plan.
(B) A health plan that does not post its notice on a web site pursuant to paragraph (c)(3)(i) of this section must provide the revised notice, or information about the material change and how to obtain the revised notice, to individuals then covered by the plan within 60 days of the material revision to the notice.
(2) *Specific requirements for certain covered health care providers.* A covered health care provider that has a direct treatment relationship with an individual must:
(i) Provide the notice:
(A) No later than the date of the first service delivery, including service delivered electronically, to such individual after the compliance date for the covered health care provider; or
(B) In an emergency treatment situation, as soon as reasonably practicable after the emergency treatment situation.
(ii) Except in an emergency treatment situation, make a good faith effort to obtain a written acknowledgment of receipt of the notice provided in accordance with paragraph (c)(2)(i) of this section, and if not obtained, document its good faith efforts to obtain such acknowledgment and the reason why the acknowledgment was not obtained;
(iii) If the covered health care provider maintains a physical service delivery site:
(A) Have the notice available at the service delivery site for individuals to request to take with them; and
(B) Post the notice in a clear and prominent location where it is reasonable to expect individuals seeking service from the covered health care provider to be able to read the notice; and
(iv) Whenever the notice is revised, make the notice available upon request on or after the effective date of the revision and promptly comply with the requirements of paragraph (c)(2)(iii) of this section, if applicable.
(3) *Specific requirements for electronic notice.* (i) A covered entity that maintains a web site that provides information about the covered entity's customer services or benefits must prominently post its notice on the web site and make the notice available electronically through the web site.
(ii) A covered entity may provide the notice required by this section to an individual by e-mail, if the individual agrees to electronic notice and such agreement has not been withdrawn. If the covered entity knows that the e-mail transmission has failed, a paper copy of the notice must be provided to the individual. Provision of electronic notice by the covered entity will satisfy the provision requirements of paragraph (c) of this section when timely made in accordance with paragraph (c)(1) or (2) of this section.
(iii) For purposes of paragraph (c)(2)(i) of this section, if the first service delivery to an individual is delivered electronically, the covered health care provider must provide electronic notice automatically and contemporaneously in response to the individual's first request for service. The requirements in paragraph (c)(2)(ii) of this section apply to electronic notice.
(iv) The individual who is the recipient of electronic notice retains the right to obtain a paper copy of the notice from a covered entity upon request.
(d) *Implementation specifications: Joint notice by separate covered entities.* Covered entities that participate in organized health care arrangements may comply with this section by a joint notice, provided that:
(1) The covered entities participating in the organized health care arrangement agree to abide by the terms of the notice with respect to protected health information created or received by the covered entity as part of its participation in the organized health care arrangement;
(2) The joint notice meets the implementation specifications in paragraph (b) of this section, except that the statements required by this section may be altered to reflect the fact that the notice covers more than one covered entity; and
(i) Describes with reasonable specificity the covered entities, or class of entities, to which the joint notice applies;
(ii) Describes with reasonable specificity the service delivery sites, or classes of service delivery sites, to which the joint notice applies; and
(iii) If applicable, states that the covered entities participating in the organized health care arrangement will share protected health information with each other, as necessary to carry out treatment, payment, or health care operations relating to the organized health care arrangement.

(3) The covered entities included in the joint notice must provide the notice to individuals in accordance with the applicable implementation specifications of paragraph (c) of this section. Provision of the joint notice to an individual by any one of the covered entities included in the joint notice will satisfy the provision requirement of paragraph (c) of this section with respect to all others covered by the joint notice.
(e) *Implementation specifications: Documentation.* A covered entity must document compliance with the notice requirements, as required by §164.530(j), by retaining copies of the notices issued by the covered entity and, if applicable, any written acknowledgments of receipt of the notice or documentation of good faith efforts to obtain such written acknowledgment, in accordance with paragraph (c)(2)(ii) of this section.

Section (h). Comment.

45 CFR §164.522 reads:

§164.522 Rights to request privacy protection for protected health information.
(a)(1) *Standard: Right of an individual to request restriction of uses and disclosures.* (i) A covered entity must permit an individual to request that the covered entity restrict:
(A) Uses or disclosures of protected health information about the individual to carry out treatment, payment, or health care operations; and
(B) Disclosures permitted under §164.510(b).
(ii) Except as provided in paragraph (a)(1)(vi) of this section, a covered entity is not required to agree to a restriction.
(iii) A covered entity that agrees to a restriction under paragraph (a)(1)(i) of this section may not use or disclose protected health information in violation of such restriction, except that, if the individual who requested the restriction is in need of emergency treatment and the restricted protected health information is needed to provide the emergency treatment, the covered entity may use the restricted protected health information, or may disclose such information to a health care provider, to provide such treatment to the individual.
(iv) If restricted protected health information is disclosed to a health care provider for emergency treatment under paragraph (a)(1)(iii) of this section, the covered entity must request that such health care provider not further use or disclose the information.
(v) A restriction agreed to by a covered entity under paragraph (a) of this section, is not effective under this subpart to prevent uses or disclosures permitted or required under §§164.502(a)(2)(ii), 164.510(a) or 164.512.
(vi) A covered entity must agree to the request of an individual to restrict disclosure of protected health information about the individual to a health plan if:
(A) The disclosure is for the purpose of carrying out payment or health care operations and is not otherwise required by law; and
(B) The protected health information pertains solely to a health care item or service for which the individual, or person other than the health plan on behalf of the individual, has paid the covered entity in full.
(2) *Implementation specifications: Terminating a restriction.* A covered entity may terminate a restriction, if:
(i) The individual agrees to or requests the termination in writing;
(ii) The individual orally agrees to the termination and the oral agreement is documented; or
(iii) The covered entity informs the individual that it is terminating its agreement to a restriction, except that such termination is:
(A) Not effective for protected health information restricted under paragraph (a)(1)(vi) of this section; and
(B) Only effective with respect to protected health information created or received after it has so informed the individual.
(3) *Implementation specification: Documentation.* A covered entity must document a restriction in accordance with §160.530(j) of this subchapter.
(b)(1) *Standard: Confidential communications requirements.* (i) A covered health care provider must permit individuals to request and must accommodate reasonable requests by individuals to receive

communications of protected health information from the covered health care provider by alternative means or at alternative locations.
(ii) A health plan must permit individuals to request and must accommodate reasonable requests by individuals to receive communications of protected health information from the health plan by alternative means or at alternative locations, if the individual clearly states that the disclosure of all or part of that information could endanger the individual.
(2) *Implementation specifications: Conditions on providing confidential communications.* (i) A covered entity may require the individual to make a request for a confidential communication described in paragraph (b)(1) of this section in writing.
(ii) A covered entity may condition the provision of a reasonable accommodation on:
(A) When appropriate, information as to how payment, if any, will be handled; and
(B) Specification of an alternative address or other method of contact.
(iii) A covered health care provider may not require an explanation from the individual as to the basis for the request as a condition of providing communications on a confidential basis.
(iv) A health plan may require that a request contain a statement that disclosure of all or part of the information to which the request pertains could endanger the individual.

Section (i). Comment.

45 CFR §164.524 reads:

§164.524 Access of individuals to protected health information.
(a) *Standard: Access to protected health information*—(1) *Right of access.* Except as otherwise provided in paragraph (a)(2) or (a)(3) of this section, an individual has a right of access to inspect and obtain a copy of protected health information about the individual in a designated record set, for as long as the protected health information is maintained in the designated record set, except for:
(i) Psychotherapy notes; and
(ii) Information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding.
(2) *Unreviewable grounds for denial.* A covered entity may deny an individual access without providing the individual an opportunity for review, in the following circumstances.
(i) The protected health information is excepted from the right of access by paragraph (a)(1) of this section.
(ii) A covered entity that is a correctional institution or a covered health care provider acting under the direction of the correctional institution may deny, in whole or in part, an inmate's request to obtain a copy of protected health information, if obtaining such copy would jeopardize the health, safety, security, custody, or rehabilitation of the individual or of other inmates, or the safety of any officer, employee, or other person at the correctional institution or responsible for the transporting of the inmate.
(iii) An individual's access to protected health information created or obtained by a covered health care provider in the course of research that includes treatment may be temporarily suspended for as long as the research is in progress, provided that the individual has agreed to the denial of access when consenting to participate in the research that includes treatment, and the covered health care provider has informed the individual that the right of access will be reinstated upon completion of the research.
(iv) An individual's access to protected health information that is contained in records that are subject to the Privacy Act, 5 U.S.C. 552a, may be denied, if the denial of access under the Privacy Act would meet the requirements of that law.
(v) An individual's access may be denied if the protected health information was obtained from someone other than a health care provider under a promise of confidentiality and the access requested would be reasonably likely to reveal the source of the information.
(3) *Reviewable grounds for denial.* A covered entity may deny an individual access, provided that the individual is given a right to have such denials reviewed, as required by paragraph (a)(4) of this section, in the following circumstances:

(i) A licensed health care professional has determined, in the exercise of professional judgment, that the access requested is reasonably likely to endanger the life or physical safety of the individual or another person;
(ii) The protected health information makes reference to another person (unless such other person is a health care provider) and a licensed health care professional has determined, in the exercise of professional judgment, that the access requested is reasonably likely to cause substantial harm to such other person; or
(iii) The request for access is made by the individual's personal representative and a licensed health care professional has determined, in the exercise of professional judgment, that the provision of access to such personal representative is reasonably likely to cause substantial harm to the individual or another person.
(4) *Review of a denial of access.* If access is denied on a ground permitted under paragraph (a)(3) of this section, the individual has the right to have the denial reviewed by a licensed health care professional who is designated by the covered entity to act as a reviewing official and who did not participate in the original decision to deny. The covered entity must provide or deny access in accordance with the determination of the reviewing official under paragraph (d)(4) of this section.
(b) *Implementation specifications: Requests for access and timely action*—(1) *Individual's request for access.* The covered entity must permit an individual to request access to inspect or to obtain a copy of the protected health information about the individual that is maintained in a designated record set. The covered entity may require individuals to make requests for access in writing, provided that it informs individuals of such a requirement.
(2) *Timely action by the covered entity.* (i) Except as provided in paragraph (b)(2)(ii) of this section, the covered entity must act on a request for access no later than 30 days after receipt of the request as follows.
(A) If the covered entity grants the request, in whole or in part, it must inform the individual of the acceptance of the request and provide the access requested, in accordance with paragraph (c) of this section.
(B) If the covered entity denies the request, in whole or in part, it must provide the individual with a written denial, in accordance with paragraph (d) of this section.
(ii) If the covered entity is unable to take an action required by paragraph (b)(2)(i)(A) or (B) of this section within the time required by paragraph (b)(2)(i) of this section, as applicable, the covered entity may extend the time for such actions by no more than 30 days, provided that:
(A) The covered entity, within the time limit set by paragraph (b)(2)(i) of this section, as applicable, provides the individual with a written statement of the reasons for the delay and the date by which the covered entity will complete its action on the request; and
(B) The covered entity may have only one such extension of time for action on a request for access.
(c) *Implementation specifications: Provision of access.* If the covered entity provides an individual with access, in whole or in part, to protected health information, the covered entity must comply with the following requirements.
(1) *Providing the access requested.* The covered entity must provide the access requested by individuals, including inspection or obtaining a copy, or both, of the protected health information about them in designated record sets. If the same protected health information that is the subject of a request for access is maintained in more than one designated record set or at more than one location, the covered entity need only produce the protected health information once in response to a request for access.
(2) *Form of access requested.* (i) The covered entity must provide the individual with access to the protected health information in the form and format requested by the individual, if it is readily producible in such form and format; or, if not, in a readable hard copy form or such other form and format as agreed to by the covered entity and the individual.
(ii) Notwithstanding paragraph (c)(2)(i) of this section, if the protected health information that is the subject of a request for access is maintained in one or more designated record sets electronically and if the individual requests an electronic copy of such information, the covered entity must provide the individual with access to the protected health information in the electronic form and format requested by the individual, if it is readily producible in such form and format; or, if not, in a readable electronic form and format as agreed to by the covered entity and the individual.

(iii) The covered entity may provide the individual with a summary of the protected health information requested, in lieu of providing access to the protected health information or may provide an explanation of the protected health information to which access has been provided, if:
(A) The individual agrees in advance to such a summary or explanation; and
(B) The individual agrees in advance to the fees imposed, if any, by the covered entity for such summary or explanation.
(3) *Time and manner of access.* (i) The covered entity must provide the access as requested by the individual in a timely manner as required by paragraph (b)(2) of this section, including arranging with the individual for a convenient time and place to inspect or obtain a copy of the protected health information, or mailing the copy of the protected health information at the individual's request. The covered entity may discuss the scope, format, and other aspects of the request for access with the individual as necessary to facilitate the timely provision of access.
(ii) If an individual's request for access directs the covered entity to transmit the copy of protected health information directly to another person designated by the individual, the covered entity must provide the copy to the person designated by the individual. The individual's request must be in writing, signed by the individual, and clearly identify the designated person and where to send the copy of protected health information.
(4) *Fees.* If the individual requests a copy of the protected health information or agrees to a summary or explanation of such information, the covered entity may impose a reasonable, cost-based fee, provided that the fee includes only the cost of:
(i) Labor for copying the protected health information requested by the individual, whether in paper or electronic form;
(ii) Supplies for creating the paper copy or electronic media if the individual requests that the electronic copy be provided on portable media;
(iii) Postage, when the individual has requested the copy, or the summary or explanation, be mailed; and
(iv) Preparing an explanation or summary of the protected health information, if agreed to by the individual as required by paragraph (c)(2)(iii) of this section.
(d) *Implementation specifications: Denial of access.* If the covered entity denies access, in whole or in part, to protected health information, the covered entity must comply with the following requirements.
(1) *Making other information accessible.* The covered entity must, to the extent possible, give the individual access to any other protected health information requested, after excluding the protected health information as to which the covered entity has a ground to deny access.
(2) *Denial.* The covered entity must provide a timely, written denial to the individual, in accordance with paragraph (b)(2) of this section. The denial must be in plain language and contain:
(i) The basis for the denial;
(ii) If applicable, a statement of the individual's review rights under paragraph (a)(4) of this section, including a description of how the individual may exercise such review rights; and
(iii) A description of how the individual may complain to the covered entity pursuant to the complaint procedures in §164.530(d) or to the Secretary pursuant to the procedures in §160.306. The description must include the name, or title, and telephone number of the contact person or office designated in §164.530(a)(1)(ii).
(3) *Other responsibility.* If the covered entity does not maintain the protected health information that is the subject of the individual's request for access, and the covered entity knows where the requested information is maintained, the covered entity must inform the individual where to direct the request for access.
(4) *Review of denial requested.* If the individual has requested a review of a denial under paragraph (a)(4) of this section, the covered entity must designate a licensed health care professional, who was not directly involved in the denial to review the decision to deny access. The covered entity must promptly refer a request for review to such designated reviewing official. The designated reviewing official must determine, within a reasonable period of time, whether or not to deny the access requested based on the standards in paragraph (a)(3) of this section. The covered entity must promptly provide written notice to the individual of the determination of the designated reviewing official and take other action as required by this section to carry out the designated reviewing official's determination.

(e) *Implementation specification: Documentation.* A covered entity must document the following and retain the documentation as required by §164.530(j):
(1) The designated record sets that are subject to access by individuals; and
(2) The titles of the persons or offices responsible for receiving and processing requests for access by individuals.

Section (j). Comment.

45 CFR §164.526 reads:

§164.526 Amendment of protected health information.
(a) Standard: right to amend.
(1) Right to amend. An individual has the right to have a covered entity amend protected health information or a record about the individual in a designated record set for as long as the protected health information is maintained in the designated record set.
(2) Denial of amendment. A covered entity may deny an individual's request for amendment, if it determines that the protected health information or record that is the subject of the request:
(i) Was not created by the covered entity, unless the individual provides a reasonable basis to believe that the originator of protected health information is no longer available to act on the requested amendment;
(ii) Is not part of the designated record set;
(iii) Would not be available for inspection under §164.524; or
(iv) Is accurate and complete.
(b) Implementation specifications: requests for amendment and timely action.
(1) Individual's request for amendment. The covered entity must permit an individual to request that the covered entity amend the protected health information maintained in the designated record set. The covered entity may require individuals to make requests for amendment in writing and to provide a reason to support a requested amendment, provided that it informs individuals in advance of such requirements.
(2) Timely action by the covered entity. (i) The covered entity must act on the individual's request for an amendment no later than 60 days after receipt of such a request, as follows.
(A) If the covered entity grants the requested amendment, in whole or in part, it must take the actions required by paragraphs (c)(1) and (2) of this section.
(B) If the covered entity denies the requested amendment, in whole or in part, it must provide the individual with a written denial, in accordance with paragraph (d)(1) of this section.
(ii) If the covered entity is unable to act on the amendment within the time required by paragraph (b)(2)(i) of this section, the covered entity may extend the time for such action by no more than 30 days, provided that:
(A) The covered entity, within the time limit set by paragraph (b)(2)(i) of this section, provides the individual with a written statement of the reasons for the delay and the date by which the covered entity will complete its action on the request; and
(B) The covered entity may have only one such extension of time for action on a request for an amendment.
(c) Implementation specifications: accepting the amendment. If the covered entity accepts the requested amendment, in whole or in part, the covered entity must comply with the following requirements.
(1) Making the amendment. The covered entity must make the appropriate amendment to the protected health information or record that is the subject of the request for amendment by, at a minimum, identifying the records in the designated record set that are affected by the amendment and appending or otherwise providing a link to the location of the amendment.
(2) Informing the individual. In accordance with paragraph (b) of this section, the covered entity must timely inform the individual that the amendment is accepted and obtain the individual's identification of and agreement to have the covered entity notify the relevant persons with which the amendment needs to be shared in accordance with paragraph (c)(3) of this section.
(3) Informing others. The covered entity must make reasonable efforts to inform and provide the amendment within a reasonable time to:

(i) Persons identified by the individual as having received protected health information about the individual and needing the amendment; and
(ii) Persons, including business associates, that the covered entity knows have the protected health information that is the subject of the amendment and that may have relied, or could foreseeably rely, on such information to the detriment of the individual.
(d) Implementation specifications: denying the amendment. If the covered entity denies the requested amendment, in whole or in part, the covered entity must comply with the following requirements.
(1) Denial. The covered entity must provide the individual with a timely, written denial, in accordance with paragraph (b)(2) of this section. The denial must use plain language and contain:
(i) The basis for the denial, in accordance with paragraph (a)(2) of this section;
(ii) The individual's right to submit a written statement disagreeing with the denial and how the individual may file such a statement;
(iii) A statement that, if the individual does not submit a statement of disagreement, the individual may request that the covered entity provide the individual's request for amendment and the denial with any future disclosures of the protected health information that is the subject of the amendment; and
(iv) A description of how the individual may complain to the covered entity pursuant to the complaint procedures established in §164.530(d) or to the Secretary pursuant to the procedures established in §160.306. The description must include the name, or title, and telephone number of the contact person or office designated in §164.530(a)(1)(ii).
(2) Statement of disagreement. The covered entity must permit the individual to submit to the covered entity a written statement disagreeing with the denial of all or part of a requested amendment and the basis of such disagreement. The covered entity may reasonably limit the length of a statement of disagreement.
(3) Rebuttal statement. The covered entity may prepare a written rebuttal to the individual's statement of disagreement. Whenever such a rebuttal is prepared, the covered entity must provide a copy to the individual who submitted the statement of disagreement.
(4) Recordkeeping. The covered entity must, as appropriate, identify the record or protected health information in the designated record set that is the subject of the disputed amendment and append or otherwise link the individual's request for an amendment, the covered entity's denial of the request, the individual's statement of disagreement, if any, and the covered entity's rebuttal, if any, to the designated record set.
(5) Future disclosures. (i) If a statement of disagreement has been submitted by the individual, the covered entity must include the material appended in accordance with paragraph (d)(4) of this section, or, at the election of the covered entity, an accurate summary of any such information, with any subsequent disclosure of the protected health information to which the disagreement relates.
(ii) If the individual has not submitted a written statement of disagreement, the covered entity must include the individual's request for amendment and its denial, or an accurate summary of such information, with any subsequent disclosure of the protected health information only if the individual has requested such action in accordance with paragraph (d)(1)(iii) of this section.
(iii) When a subsequent disclosure described in paragraph (d)(5)(i) or (ii) of this section is made using a standard transaction under part 162 of this subchapter that does not permit the additional material to be included with the disclosure, the covered entity may separately transmit the material required by paragraph (d)(5)(i) or (ii) of this section, as applicable, to the recipient of the standard transaction.
(e) Implementation specification: actions on notices of amendment. A covered entity that is informed by another covered entity of an amendment to an individual's protected health information, in accordance with paragraph (c)(3) of this section, must amend the protected health information in designated record sets as provided by paragraph (c)(1) of this section.
(f) Implementation specification: documentation. A covered entity must document the titles of the persons or offices responsible for receiving and processing requests for amendments by individuals and retain the documentation as required by §164.530(j).

Section (k)(1)(vi) and (vii). Comment.

45 CFR §164.512(k)(2) and (5) read:

(k) Standard: uses and disclosures for specialized government functions.

. . .

(2) National security and intelligence activities. A covered entity may disclose protected health information to authorized federal officials for the conduct of lawful intelligence, counter-intelligence, and other national security activities authorized by the National Security Act (50 U.S.C. 401, et seq.) and implementing authority (e.g., Executive Order 12333).

. . .

(5) *Correctional institutions and other law enforcement custodial situations.* (i) *Permitted disclosures.* A covered entity may disclose to a correctional institution or a law enforcement official having lawful custody of an inmate or other individual protected health information about such inmate or individual, if the correctional institution or such law enforcement official represents that such protected health information is necessary for:

(A) The provision of health care to such individuals;

(B) The health and safety of such individual or other inmates;

(C) The health and safety of the officers or employees of or others at the correctional institution;

(D) The health and safety of such individuals and officers or other persons responsible for the transporting of inmates or their transfer from one institution, facility, or setting to another;

(E) Law enforcement on the premises of the correctional institution; or

(F) The Administration and maintenance of the safety, security, and good order of the correctional institution.

(ii) *Permitted uses.* A covered entity that is a correctional institution may use protected health information of individuals who are inmates for any purpose for which such protected health information may be disclosed.

(iii) *No application after release.* For the purposes of this provision, an individual is no longer an inmate when released on parole, probation, supervised release, or otherwise is no longer in lawful custody.

Section (k)(1)(viii). Comment.

45 CFR §164.514(e) reads:

§164.514 Other requirements relating to uses and disclosures of protected health information.

. . .

(e)(1) *Standard: Limited data set.* A covered entity may use or disclose a limited data set that meets the requirements of paragraphs (e)(2) and (e)(3) of this section, if the covered entity enters into a data use agreement with the limited data set recipient, in accordance with paragraph (e)(4) of this section.

(2) *Implementation specification: Limited data set:* A limited data set is protected health information that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual:

(i) Names;

(ii) Postal address information, other than town or city, State, and zip code;

(iii) Telephone numbers;

(iv) Fax numbers;

(v) Electronic mail addresses;

(vi) Social security numbers;

(vii) Medical record numbers;

(viii) Health plan beneficiary numbers;

(ix) Account numbers;

(x) Certificate/license numbers;

(xi) Vehicle identifiers and serial numbers, including license plate numbers;

(xii) Device identifiers and serial numbers;

(xiii) Web Universal Resource Locators (URLs);

(xiv) Internet Protocol (IP) address numbers;

(xv) Biometric identifiers, including finger and voice prints; and

(xvi) Full face photographic images and any comparable images.

(3) *Implementation specification: Permitted purposes for uses and disclosures.* (i) A covered entity may use or disclose a limited data set under paragraph (e)(1) of this section only for the purposes of research, public health, or health care operations.
(ii) A covered entity may use protected health information to create a limited data set that meets the requirements of paragraph (e)(2) of this section, or disclose protected health information only to a business associate for such purpose, whether or not the limited data set is to be used by the covered entity.
(4) *Implementation specifications: Data use agreement*—(i) *Agreement required.* A covered entity may use or disclose a limited data set under paragraph (e)(1) of this section only if the covered entity obtains satisfactory assurance, in the form of a data use agreement that meets the requirements of this section, that the limited data set recipient will only use or disclose the protected health information for limited purposes.
(ii) *Contents.* A data use agreement between the covered entity and the limited data set recipient must:
(A) Establish the permitted uses and disclosures of such information by the limited data set recipient, consistent with paragraph (e)(3) of this section. The data use agreement may not authorize the limited data set recipient to use or further disclose the information in a manner that would violate the requirements of this subpart, if done by the covered entity;
(B) Establish who is permitted to use or receive the limited data set; and
(C) Provide that the limited data set recipient will:
(*1*) Not use or further disclose the information other than as permitted by the data use agreement or as otherwise required by law;
(*2*) Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by the data use agreement;
(*3*) Report to the covered entity any use or disclosure of the information not provided for by its data use agreement of which it becomes aware;
(*4*) Ensure that any agents to whom it provides the limited data set agree to the same restrictions and conditions that apply to the limited data set recipient with respect to such information; and
(*5*) Not identify the information or contact the individuals.
(iii) *Compliance.* (A) A covered entity is not in compliance with the standards in paragraph (e) of this section if the covered entity knew of a pattern of activity or practice of the limited data set recipient that constituted a material breach or violation of the data use agreement, unless the covered entity took reasonable steps to cure the breach or end the violation, as applicable, and, if such steps were unsuccessful:
(1) Discontinued disclosure of protected health information to the recipient; and
(2) Reported the problem to the Secretary.
(B) A covered entity that is a limited data set recipient and violates a data use agreement will be in noncompliance with the standards, implementation specifications, and requirements of paragraph (e) of this section.
. . .

Section (k)(4). Comment.

45 CFR §164.528 reads:

§164.528 Accounting of disclosures of protected health information.
(a) Standard: right to an accounting of disclosures of protected health information.
(1) An individual has a right to receive an accounting of disclosures of protected health information made by a covered entity in the six years prior to the date on which the accounting is requested, except for disclosures:
(i) To carry out treatment, payment and health care operations as provided in §164.506;
(ii) To individuals of protected health information about them as provided in §164.502;
(iii) Incident to a use or disclosure otherwise permitted or required by this subpart, as provided in §164.502;
(iv) Pursuant to an authorization as provided in §164.508;
(v) For the facility's directory or to persons involved in the individual's care or other notification purposes as provided in §164.510;

(vi) For national security or intelligence purposes as provided in §164.512(k)(2);
(vii) To correctional institutions or law enforcement officials as provided in §164.512(k)(5);
(viii) As part of a limited data set in accordance with §164.514(e); or
(ix) That occurred prior to the compliance date for the covered entity.
(2)(i) The covered entity must temporarily suspend an individual's right to receive an accounting of disclosures to a health oversight agency or law enforcement official, as provided in §164.512(d) or (f), respectively, for the time specified by such agency or official, if such agency or official provides the covered entity with a written statement that such an accounting to the individual would be reasonably likely to impede the agency's activities and specifying the time for which such a suspension is required.
(ii) If the agency or official statement in paragraph (a)(2)(i) of this section is made orally, the covered entity must:
(A) Document the statement, including the identity of the agency or official making the statement;
(B) Temporarily suspend the individual's right to an accounting of disclosures subject to the statement; and
(C) Limit the temporary suspension to no longer than 30 days from the date of the oral statement, unless a written statement pursuant to paragraph (a)(2)(i) of this section is submitted during that time.
(3) An individual may request an accounting of disclosures for a period of time less than six years from the date of the request.
(b) Implementation specifications: content of the accounting. The covered entity must provide the individual with a written accounting that meets the following requirements.
(1) Except as otherwise provided by paragraph (a) of this section, the accounting must include disclosures of protected health information that occurred during the six years (or such shorter time period at the request of the individual as provided in paragraph (a)(3) of this section) prior to the date of the request for an accounting, including disclosures to or by business associates of the covered entity.
(2) Except as otherwise provided by paragraphs (b)(3) or (b)(4) of this section, the accounting must include for each disclosure:
(i) The date of the disclosure;
(ii) The name of the entity or person who received the protected health information and, if known, the address of such entity or person;
(iii) A brief description of the protected health information disclosed; and
(iv) A brief statement of the purpose of the disclosure that reasonably informs the individual of the basis for the disclosure or, in lieu of such statement, a copy of a written request for a disclosure under §§164.502(a)(2)(ii) or 164.512, if any.
(3) If, during the period covered by the accounting, the covered entity has made multiple disclosures of protected health information to the same person or entity for a single purpose under §§164.502(a)(2)(ii) or 164.512, the accounting may, with respect to such multiple disclosures, provide:
(i) The information required by paragraph (b)(2) of this section for the first disclosure during the accounting period;
(ii) The frequency, periodicity, or number of the disclosures made during the accounting period; and
(iii) The date of the last such disclosure during the accounting period.
(4)(i) If, during the period covered by the accounting, the covered entity has made disclosures of protected health information for a particular research purpose in accordance with §164.512(i) for 50 or more individuals, the accounting may, with respect to such disclosures for which the protected health information about the individual may have been included, provide:
(A) The name of the protocol or other research activity;
(B) A description, in plain language, of the research protocol or other research activity, including the purpose of the research and the criteria for selecting particular records;
(C) A brief description of the type of protected health information that was disclosed;
(D) The date or period of time during which such disclosures occurred, or may have occurred, including the date of the last such disclosure during the accounting period;
(E) The name, address, and telephone number of the entity that sponsored the research and of the researcher to whom the information was disclosed; and
(F) A statement that the protected health information of the individual may or may not have been disclosed for a particular protocol or other research activity.

(ii) If the covered entity provides an accounting for research disclosures, in accordance with paragraph (b)(4) of this section, and if it is reasonably likely that the protected health information of the individual was disclosed for such research protocol or activity, the covered entity shall, at the request of the individual, assist in contacting the entity that sponsored the research and the researcher.
(c) Implementation specifications: provision of the accounting.
(1) The covered entity must act on the individual's request for an accounting, no later than 60 days after receipt of such a request, as follows.
(i) The covered entity must provide the individual with the accounting requested; or
(ii) If the covered entity is unable to provide the accounting within the time required by paragraph (c)(1) of this section, the covered entity may extend the time to provide the accounting by no more than 30 days, provided that:
(A) The covered entity, within the time limit set by paragraph (c)(1) of this section, provides the individual with a written statement of the reasons for the delay and the date by which the covered entity will provide the accounting; and
(B) The covered entity may have only one such extension of time for action on a request for an accounting.
(2) The covered entity must provide the first accounting to an individual in any 12 month period without charge. The covered entity may impose a reasonable, cost-based fee for each subsequent request for an accounting by the same individual within the 12 month period, provided that the covered entity informs the individual in advance of the fee and provides the individual with an opportunity to withdraw or modify the request for a subsequent accounting in order to avoid or reduce the fee.
(d) Implementation specification: documentation. A covered entity must document the following and retain the documentation as required by §164.530(j):
(1) The information required to be included in an accounting under paragraph (b) of this section for disclosures of protected health information that are subject to an accounting under paragraph (a) of this section;
(2) The written accounting that is provided to the individual under this section; and
(3) The titles of the persons or offices responsible for receiving and processing requests for an accounting by individuals.

Appendix A

Model Inspection Form for Nuclear Pharmacies

I. General Information

Type of Inspection

Announced_____ Unannounced_____ Investigational_____

Date:_____ Time Inspection Started:_____

Time Inspection Completed:_____

A. Inspector's Name

Name_____

Position/Title_____

Address_____

City_____ State_____ Zip Code_____

Telephone_____ Ext_____

B. Nuclear Pharmacy

Pharmacy Name_____

Address_____

City_____ State_____ Zip Code_____

Telephone_____ Ext_____

C. Facility Hours

Time Open_____Time Closed_____

Days Open_____Total Hours_____

D. Prescription Department Hours

Time Open _____ Time Closed_____

Days Open _____ Total Hours_____

E. Is a nuclear pharmacist present in the facility at all times that the pharmacy is open for business?

Yes_____No_____

If no, give explanation in the space below:

F. Name of Facility

Facility Name_____

Manager_____

Pharmacy License/Permit Number_____

Expiration Date_____

Renewal of Pharmacy License/Permit Number Current: Yes____ No_____

Pharmacy License/Permit Number Posted: Yes_____ No_____

G. Facility Staff Information

Pharmacists:

Name	Title or Position	Certificate Number	Certificate Posted (Y or N)	Certificate Renewal Current (Y or N)
1.	_____	_____	_____	_____
	_____ ___	_	_	_
	_____	_	_	_
2.	_____	_____	_____	_____
	_____ ___	_	_	_
	_____	_	_	_
3.	_____	_____	_____	_____
	_____ ___	_	_	_
	_____	_	_	_
4.	_____	_____	_____	_____
	_____ ___	_	_	_
	_____	_	_	_

5.					
6.					
7.					
8.					
9.					
10.					

(Use additional sheets if necessary.)

Have all pharmacists notified the Board of Pharmacy of any changes in mailing address and place of employment?

Yes _____ No _____ If no, give explanation in the space below:

Pharmacists' Education and Training:

Name	Training BPS Board Certified (Yes or No)	Documentation Available (Yes or No)
1. _____	_____	_____
2. _____	_____	_____
3. _____	_____	_____
4. _____	_____	_____
5. _____	_____	_____
6. _____	_____	_____

(Use additional sheets if necessary.)

Qualifications of pharmacists are in accordance with State Board of Pharmacy standards for education and experience in the safe handling and use of radioactive pharmaceuticals and other related materials?

Yes _____ No _____ If no, give explanation in the space below:

Pharmacy Technicians/Supportive Personnel:

Name	Title or Position	Certificate Number	Certificate Posted (Y or N)	Certificate Renewal Current (Y or N)
1.	_____	_____	_____	_____
_____	___	_	_	_
_____		_	_	_
2.	_____	_____	_____	_____
_____	___	_	_	_
_____		_	_	_
3.	_____	_____	_____	_____
_____	___	_	_	_
_____		_	_	_
4.	_____	_____	_____	_____
_____	___	_	_	_
_____		_	_	_
5.	_____	_____	_____	_____

	_____	___	_	_	_
	_____		_	_	_
6.		_____	_____	_____	_____
	_____	___	_	_	_
	_____		_	_	_
7.		_____	_____	_____	_____
	_____	___	_	_	_
	_____		_	_	_
8.		_____	_____	_____	_____
	_____	___	_	_	_
	_____		_	_	_
9.		_____	_____	_____	_____
	_____	___	_	_	_
	_____		_	_	_
10.	_____	_____	_____	_____	_____
	___	___	_	_	_
			_	_	_

(Use additional sheets if necessary.)

Pharmacy Interns:

Name	Registration Number	Registration Renewal Current (Yes or No)	Registration Posted (Yes or No)
1._____	_____	_____	_____
2._____	_____	_____	_____
3._____	_____	_____	_____
4._____	_____	_____	_____
5._____	_____	_____	_____

(Use additional sheets if necessary.)

Are all pharmacy interns, Pharmacy Technicians, and/or supportive personnel performing tasks involving radioactive and associated non-radioactive Drugs under the supervision of a licensed pharmacist in accordance with State pharmacy laws?

Yes _____ No _____ If no, give explanation in the space below:

H. Compliance Posture of the Facility and Staff Personnel

1. Are there any current citations or other disciplinary actions against the facility's pharmacy license/permit?
   Yes _____ No _____ If yes, give explanation in the space below:

2. Are there any current citations or other disciplinary actions against any existing staff personnel at the facility? Yes _____ No _____ If yes, give explanation in the space below:

3. If there are any current citations or other disciplinary actions against either the facility or the staff personnel, are the communications regarding these events properly posted (eg, initial complaint letter along with written reply for corrective actions to be taken, etc)?
   Yes _____ No _____ If no, give explanation in the space below:

I. Radioactive materials (RAM) license for the facility:

RAM license: _____
Date of Issuance: _____ Expiration Date: _____
If there is no current RAM license for the facility, give explanation in the space below:

1. Are there any current citations or other disciplinary actions against the facility's RAM license?
   Yes _____ No _____ If yes, give explanation in the space below:

J. Does the facility store or use any controlled substances?

Yes _____ No _____ If no, give explanation in the space below:

1. If yes, is all necessary documentation and registration available?
   Yes _____ No _____ If no, give explanation in the space below:

2. If yes, is the DEA permit properly posted?
   Yes _____ No _____ If no, give explanation in the space below:

3. DEA Permit Number: _____ Permit Renewal Current: Yes ____ No ____
   Permit Expiration Date: _____
   If the permit is not current, give explanation in the space below:

4. Are authorized signatures and/or power of attorney documentation maintained and appropriate for the current DEA permit, and is this documentation available?
   Yes _____ No _____ If no, give explanation in the space below:

K. Are facility operational policies and procedures written, maintained, and followed for the purchase/receipt/storage/manipulation/Compounding/ distribution/quality assurance/disposal of radioactive and non-radioactive Drugs?

Yes _____ No _____ If no, give explanation in the space below:

L. Have any documented events of the following nature taken place since the last inspection?

1. MisAdministration of radioactive or non-radioactive Drugs?
   Yes _____ No _____ If yes, give explanation in the space below:

   a. Is documentation available describing corrective actions to be taken to prevent the reoccurrence of these events? Yes _____ No _____ If no, give explanation in the space below:

   b. Were any of these events reported to the State Board of Pharmacy and/or other appropriate State or Federal agencies? Yes _____ No _____ If no, give explanation in the space below:

2. Product mislabeling of radioactive or non-radioactive Drugs?
   Yes _____ No _____ If yes, give explanation in the space below:

3. Lost radioactive or non-radioactive Drugs?
   Yes _____ No _____ If yes, give explanation in the space below:

   a. Is documentation available describing corrective actions to be taken to prevent the reoccurrence of these events? Yes _____ No _____ If no, give explanation in the space below:

   b. Were any of these events reported to the State Board of Pharmacy and/or other appropriate State or Federal agencies? Yes _____ No _____ If no, give explanation in the space below:

M. Inspection History

1. Date of last State Board of Pharmacy inspection: _____
2. List of non-compliance item(s) noted during last inspection:

Non-Compliant Item	Corrective Action Taken
a.	a.
b.	b.
c.	c.
d.	d.
e.	e.
f.	f.
g.	g.
h.	h.

(Use additional sheets if necessary.)

Facility, Equipment, and Instrumentation

For the following sections, the key appearing below can be used as a guide for completing the "Source of Information" category as it appears for each statement. Items that do not apply to the operational perspectives of a given practice site can be indicated as such by writing "Not Applicable" or "N/A" in the space provided for that statement.

IO = Inspector's Observations

LS = Licensee Statement

RR = Records Review

WI = Worker Interview

A. Facility

		Yes	No	Source of Information	N/A or Comment Number
1.	Restricted areas are well defined and physically segregated by barriers from unrestricted areas.	_____	_____	_____	_____
2.	Access to restricted areas is secure from entry by unauthorized personnel.	_____	_____	_____	_____
3.	Access to the pharmacy is kept locked at all times when the pharmacist is not available.	_____	_____	_____	_____
4.	Pharmacy floor plans and layout design comply with all State Board of Pharmacy requirements.	_____	_____	_____	_____
5.	Shielding is present to prevent radiation exposure in unrestricted areas of the facility.	_____	_____	_____	_____
6.	Documentation that ventilation systems from fume hoods and biological cabinets are adequate to prevent the accidental release of airborne radioactive materials inside the facility.	_____	_____	_____	_____
7.	Pharmacy library contains current editions (as opposed	_____	_____	_____	_____

to "copies") of all reference texts and other documents, as stipulated by State Board of Pharmacy requirements.

	Yes	No	Source of Information	N/A or Comment Number
a. United States Pharmacopeia-National Formulary (with supplements).	_____	_____	_____	_____
b. United States Pharmacopeia Dispensing Information (USPDI)	_____	_____	_____	_____
c. Radiological Health Handbook (or equivalent).	_____	_____	_____	_____
d. State laws and regulations pertaining to Pharmacy practice.	_____	_____	_____	_____
e. State and/or federal laws and regulations pertaining to the safe handling, use, storage, Dispensing, transport, and disposal of radioactive and non-radioactive Drugs.	_____	_____	_____	_____
f. Other reference texts as required by State Pharmacy laws.	_____	_____	_____	_____

Equipment

	Yes	No	Source of Information	N/A or Comment Number
1. Equipment and supplies comply with applicable State and Federal laws/regulations governing the safe handling, use, storage, preparation, Dispensing, distribution, and disposal of radioactive and non-radioactive Drugs. Including but not limited to:	_____	_____	_____	_____
a. Laminar air flow hood	_____	_____		

and/or biological safety cabinet		
b. Fume hood	_____	_____
c. Dose calibrator	_____	_____
d. Analytical balance	_____	_____
e. Lead-shielded drawing station	_____	_____
f. Well scintillation counter	_____	_____
g. Assorted glassware	_____	_____
h. Microscope	_____	_____
i. Hemocytometer	_____	_____
j. Chromatographic apparatus	_____	_____
k. Thermometers	_____	_____
l. Refrigerator	_____	_____
m. Radiation monitoring equipment	_____	_____
n. Syringe and vial shields	_____	_____
o. Decontamination supplies	_____	_____
p. Transport containers/boxes	_____	_____
q. DOT shipping labels	_____	_____
r. Other supplies as necessary	_____	_____

B. Instruments

	Yes	No	Source of Information	N/A or Comment Number
1. Instruments (eg, Geiger-Mueller survey meters, area ratemeters, Cutie Pie survey meter, etc) comply with applicable State and Federal regulations governing radioactive and non-radioactive Drugs.	_____	_____	_____	_____
2. Instrument maintenance and repair logs are maintained and documentation is available.	_____	_____	_____	_____
3. Instruments are calibrated at intervals specified in the facility's radioactive materials license.	_____	_____	_____	_____

4. Dose calibrator	_____	_____	_____	_____
a. Constancy checks are performed in accordance with State and/or Federal regulations and documentation is available.	_____	_____	_____	_____
b. Accuracy checks are performed in accordance with State and/or Federal regulations and documentation is available.	_____	_____	_____	_____
c. Linearity checks are performed in accordance with State and/or Federal regulations and documentation is available.	_____	_____	_____	_____
d. Geometry checks are performed in accordance with State and/or Federal regulations and documentation is available.	_____	_____	_____	_____

Nuclear Pharmacy Procedure

A. Protective Clothing/Safety

	Yes	No	Source of Information	N/A or Comment Number
1. Safety principles and practices are adhered to as described in the facility's policy and procedure manual.	_____	_____	_____	_____
a. Disposable gloves are readily accessible and worn when handling radioactive and/or biohazard material.	_____	_____	_____	_____
b. Lab coats are readily accessible and worn by staff personnel when in restricted areas of the facility.	_____	_____	_____	_____

c. Used needles and other biohazardous materials are disposed of properly.	_____	_____	_____	_____
d. Facility employees have received training on infectious disease prevention. Documentation of such training is available.	_____	_____	_____	_____
e. Dosimetry Badges readily accessible and worn appropriately?	_____	_____	_____	_____

B. Posting and Labeling

	Yes	No	Source of Information	N/A or Comment Number
1. Radiation caution signs are properly used and posted throughout the restricted areas of the facility.	_____	_____	_____	_____
2. Biohazard caution signs are properly used and posted throughout the facility.	_____	_____	_____	_____
3. Appropriate notices to employees are posted.	_____	_____	_____	_____

C. Visitors

	Yes	No	Source of Information	N/A or Comment Number
1. Cleaning and maintenance personnel are escorted when entering and leaving the facility.	_____	_____	_____	_____
2. Custodial and maintenance personnel have been given training as to the proper procedures for entering and leaving the facility, and such training is documented.	_____	_____	_____	_____

D. Receipt of Incoming Shipments of Radioactive and Non-Radioactive Drugs

	Yes	No	Source of Information	N/A or Comment Number
1. Documentation is maintained for the receipt of Drugs (radioactive, non-radioactive, and controlled substances) in accordance with State and Federal regulations.	_____	_____	_____	_____
2. Procedures are established for the receipt of Drugs by the facility during times other than normal working hours.	_____	_____	_____	_____
3. Procedures are established for the handling of incoming shipments of radioactive and non-radioactive Drugs that are damaged, or for accidents (eg, spills) that occur while attempting delivery within the facility.	_____	_____	_____	_____
4. Both radioactive and non-radioactive Drugs are stored under appropriate conditions.	_____	_____	_____	_____

E. Traceability and Inventory of Radioactive and Non-radioactive Drugs

	Yes	No	Source of Information	N/A or Comment Number
1. Radioactive and non-radioactive Drugs and/or chemicals can be traced to Manufacturer's lot number.	_____	_____	_____	_____
2. Incoming shipment records for radioactive and non-radioactive Drugs and/or chemicals indicate date of	_____	_____	_____	_____

receipt, source or Manufacturer, lot number, amount or quantity, Drug expiration date, calibration (if applicable), and documentation is available.				
3. Outgoing shipment records for radioactive and non-radioactive Drugs contain all required information as specified by State pharmacy laws for legend Drugs.	_____	_____	_____	_____
4. Inventory for radioactive and non-radioactive Drugs (including controlled substances and chemicals) matches physical inventory, and documentation is available.	_____	_____	_____	_____
5. Receipt of expired radioactive Drugs and radioactive waste is documented and the records indicate the type, nature, and quantity of item(s), the date of placement into waste storage, the date of removal (disposal) from storage, and the method of disposal, along with other information as specified by State and Federal regulations.	_____	_____	_____	_____
6. Records of Drug destruction and/or return (including shipments to Manufacturers, DEA, etc) are maintained and documentation is available.	_____	_____	_____	_____
7. Outdated and deteriorated Drugs are removed from active inventory.	_____	_____	_____	_____
8. Outdated and deteriorated Drugs are disposed of in accordance with State and Federal regulations.	_____	_____	_____	_____

9. Drug product recalls.	_____	_____	_____	_____
a. Policies and procedures exist for responding to events involving Drug product recalls.	_____	_____	_____	_____
b. Events of Drug product recalls and action taken in response thereto is documented and available.	_____	_____	_____	_____

F. Dispensing

	Yes	No	Source of Information	N/A or Comment Number
1. Work area is neat and clean in appearance.	____	____	_____	_____
2. Proper aseptic technique is used in the preparation and Dispensing of all parenteral Drug products.	____	____	_____	_____
a. Adequate space and equipment is available for aseptic preparation and Dispensing of parenteral Drug products.	____	____	_____	_____
b. Personnel are adequately trained in aseptic technique and documentation of such training is available.	____	____	_____	_____
3. Syringe shields and other appropriate shielding are used during the preparation and Dispensing of radioactive Drugs.	____	____	_____	_____
4. Records are maintained for the Compounding, preparation, Dispensing, and distribution of both radioactive and non-radioactive Drugs in accordance with State and Federal regulations.	____	____	_____	_____
5. Radioactive and non-radioactive Drugs are dispensed upon a prescription order from a licensed (authorized user) medical Practitioner.	____	____	_____	_____

a. Radioactive and non-radioactive Drugs intended only for in vitro or animal research are dispensed to a non-medical Practitioner authorized by the Nuclear Regulatory Commission or an agreement State agency, or other regulatory agency, to possess such Drugs, and documentation recognizing such is available. _____ _____ _____ _____

6. A registered nuclear pharmacy, upon receiving an oral prescription for a radioactive or non-radioactive Drug, immediately reduces the prescription to writing in accordance with State pharmacy law. _____ _____ _____ _____

7. Each radiopharmaceutical dosage is assayed in the dose calibrator and dispensed within ±10% of the prescribed patient dose. _____ _____ _____ _____

8. Labeling for radioactive and non-radioactive Drugs is done prior to Dispensing in accordance with State and Federal regulations. _____ _____ _____ _____
   a. Accuracy of the information content on all product Labeling is verified by the licensed pharmacist on duty prior to Drug Dispensing. _____ _____ _____ _____

9. The outer container of each radioactive Drug dispensed has a label which contains the following information: _____ _____ _____ _____
   a. The standard radiation symbol _____ _____ _____ _____
   b. The words "Caution – Radioactive" _____ _____ _____ _____
   c. The radionuclide _____ _____ _____ _____
   d. The chemical form _____ _____ _____ _____
   e. The amount of radioactivity _____ _____ _____ _____
   f. The calibration date and time _____ _____ _____ _____
   g. The expiration date and time _____ _____ _____ _____
   h. If a liquid, the volume _____ _____ _____ _____
   i. If a solid, the number of dosage _____ _____ _____ _____

forms or weight				
j. If a gas, the number of vials or ampules	____	____	_____	_____
k. The Drug prescription or lot number	____	____	_____	_____
l. The name, address, and phone number of the pharmacy	____	____	_____	_____
m. If a Drug is to be used for diagnostic imaging and does not require a patient name, then the words "For Physician Use Only" appear on the prescription label (See Section III.G.7. for situations when a patient's name shall appear on the prescription label.)	____	____	_____	_____
10. The immediate inner container of each radioactive Drug dispensed has a label, which contains the following information:	____	____	_____	_____
a. The standard radiation symbol.	____	____	_____	_____
b. The words "Caution – Radioactive Materials."	____	____	_____	_____
c. The radiopharmaceutical name.	____	____	_____	_____
d. The Drug prescription or lot number.	____	____	_____	_____
e. The patient's name if the Drug is intended for therapy, involves a radio-labeled blood cell Component or monoclonal antibody or is investigational in nature.	____	____	_____	_____

G. Special Radiopharmaceutical Preparation and Labeling Procedures

	Yes	No	Source of Information	N/A or Comment Number
1. Procedures for the Radio Labeling of red blood cells are performed as stated in the facility's policy and procedures manual and/or Drug insert.	_____	_____	_____	_____
2. Procedures for the Radio Labeling of white blood cells are performed as stated in the facility's policy and procedures	_____	_____	_____	_____

manual and/or Drug insert.				
3. Procedures for the Radio Labeling of platelets (or other blood cell Components) are performed as stated in the facility's policy and procedures manual and/or Drug insert.	_____	_____	_____	_____
4. Procedures for the Radio Labeling of monoclonal antibodies are performed as stated in the facility's policy and procedure manual, Drug package insert or investigational new Drug (IND) protocol.	_____	_____	_____	_____
5. Procedures for the Radio Labeling and Dispensing of radiopharmaceuticals for patient therapy are performed as stated in the facility's policy and procedure manual and/or Drug package insert.	_____	_____	_____	_____
6. Procedures for the Compounding of Drugs labeled with positron-emitting radio-nuclides are performed as stated in the facility's policy and procedure manual.	_____	_____	_____	_____
7. The outer container Labeling for and radioactive Drug involving radio labeled blood cell Components, monoclonal antibodies, or whose use is intended for patient therapy, or is investigational in nature (under an IND protocol), shall list the patient's name.	_____	_____	_____	_____

H. Quality Control of Radiopharmaceuticals

	Yes	No	Source of Information	N/A or Comment Number
1. Sterility testing is	_____	_____	_____	_____

performed, when appropriate, as stated in the facility's policy and procedure manual and/or USP-NF, and documentation is available.				
2. Pyrogen testing is performed, when appropriate, as stated in the facility's policy and procedure manual or USP-NF, and documentation is available.	_____	_____	_____	_____
3. Breakthrough testing for the presence of the parent radionuclide in a generator eluate (eg, Molybdenum Mo99 from a Mo99/Tc99m generator) is performed, when appropriate, as stated in the facility's policy and procedure manual and/or Drug package insert, and documentation is available.	_____	_____	_____	_____
4. Breakthrough testing for the presence of column packing material in a generator eluate is performed, when appropriate, as stated in the facility's policy and procedure manual, or Drug package insert and/or USP-NF, and documentation is available.	_____	_____	_____	_____
5. Radionuclidic purity testing is performed, when appropriate, as stated in the facility's policy and procedure manual and/or USP-NF, and documentation is available.	_____	_____	_____	_____
6. Radiochemical purity testing is performed, when appropriate, as stated in the facility's policy and procedure manual and/or USP-NF, and documentation is available.	_____	_____	_____	_____
7. Microscopic inspection is performed, when appropriate, as stated in the	_____	_____	_____	_____

facility's policy and procedure manual and/or USP-NF, and documentation is available.				
8. pH testing is performed, when appropriate, as stated in the facility's policy, and procedure manual and/or USP-NF, and documentation is available.	_____	_____	_____	_____
9. Other types of quality control testing procedures are performed, when appropriate, as stated in the facility's policy and procedure manual and/or USP-NF, and documentation is available.	_____	_____	_____	_____
a. Chemical purity testing, and documentation is available.	_____	_____	_____	_____
b. Specific activity determinations, and documentation is available.	_____	_____	_____	_____
10. Facility employees have been properly trained to perform quality control testing procedures and documentation of such training is available.	_____	_____	_____	_____
11. Documentation available that leak testing of all sealed radioactive sources is performed, as stated in the facility's policy and procedure manual, and/or its radioactive materials license.	_____	_____	_____	_____

I. Pharmacy Law

	Yes	No	Source of Information	N/A or Comment Number
1. Phone prescriptions are received only by authorized personnel in accordance with State pharmacy law.	____	____	_____	_____
2. Phone prescriptions are	____	____	_____	_____

immediately reduced to writing and shall record information in accordance with State pharmacy law, including but not limited to:

a. The name of the Practitioner and the institution he or she represents _____ _____ _____ _____
b. The date of the prescription _____ _____ _____ _____
c. The name and dose of the radio-pharmaceutical or non-radioactive Drug _____ _____ _____ _____
d. The serial number assigned to the prescription by the Dispensing nuclear pharmacy _____ _____ _____ _____
e. The patient's name _____ _____ _____ _____
f. Any specific instructions, if required _____ _____ _____ _____

3. All prescriptions are reviewed by the pharmacist on duty and are initialed before Dispensing. _____ _____ _____ _____
4. Prescription orders and Dispensing records for radioactive Drugs contain all information stipulated by State and Federal regulations: _____ _____ _____ _____

a. Name and address of the pharmacy _____ _____ _____ _____
b. Drug prescription or lot number _____ _____ _____ _____
c. Date Drug is dispensed _____ _____ _____ _____
d. Name and address of the clinic, hospital, or office to which the Drug(s) is dispensed _____ _____ _____ _____
e. Name of the licensed medical Practitioner authorized to prescribe, receive, and use the Drug(s)[Note: See III.F.5a. pertaining to non-medical individuals who may also order, receive, and use the dispensed Drug(s)]. _____ _____ _____ _____
f. The name of the dispensed Drug _____ _____ _____ _____
g. Prescribed amount and/or activity of the dispensed Drug _____ _____ _____ _____
h. Drug concentration at the requested time/date of _____ _____ _____ _____

calibration				
i. Drug calibration date and time	_____	_____	_____	_____
j. Drug expiration date and time	_____	_____	_____	_____
k. Initials of the Dispensing pharmacist appear on all records pertaining to the Compounding, preparation, and Dispensing of the Drug	_____	_____	_____	_____
5. A copy of the clinic, hospital, or office's current radioactive material license, along with the names of individuals from these locals who can phone or transmit orders to the nuclear pharmacy, are kept on file and such documentation is available.	_____	_____	_____	_____
6. The facility's policy and procedure manual defines the roles and responsibilities of pharmacy interns and supportive personnel with respect to the acquisition, handling, use, preparation, Dispensing, quality assurance testing, distribution, inventory control, and disposal, etc, of radioactive and non-radioactive Drugs.	_____	_____	_____	_____
7. Transfer of Drug products are limited to unopened containers with Manufacturer's instructions attached (except in emergency situations).	_____	_____	_____	_____
8. Copies of any IND protocols, and patient consent forms, etc, for which the pharmacy may prepare and dispense the Drug are maintained on file, and such documentation is available.	_____	_____	_____	_____
a. Copy of the Institutional Review Board approval form (or letter).	_____	_____	_____	_____
b. Copy of the Radiation Safety Committee approval form (or letter).	_____	_____	_____	_____
c. Letter from the Manufacturer (sponsor) indicating that the physician requesting the IND Drug is a qualified investigator.	_____	_____	_____	_____

J. Regulatory (Miscellaneous)

	Yes	No	Source of Information	N/A or Comment Number
1. Documentation for any requests for facility remodeling (if appropriate) from either the city, county, or state is maintained.	____	____	_____	_____
2. Drugs and other materials are appropriately segregated and stored within the facility, such as:	____	____	_____	_____
a. Radioactive vs non-radioactive Drugs	____	____	_____	_____
b. Reagents/germicides/ disinfectants vs Drugs.	____	____	_____	_____
c. Irrigation and topical solutions vs injectable Drugs.	____	____	_____	_____
d. Flammable vs nonflammable Drugs.	____	____	_____	_____
e. Drugs vs food.	____	____	_____	_____
f. Drugs vs specimens.	____	____	_____	_____
g. Controlled substances.	____	____	_____	_____
3. DEA Schedule II Drugs are stored in a locked area, and keys are possessed only by authorized staff personnel.	____	____	_____	_____
4. Access to current copies of all applicable Department of Transportation (DOT), Nuclear Regulatory Commission (NRC), Food and Drug Administration (FDA), Environmental Protection Agency (EPA), Occupational Safety and Health Administration (OSHA), State Board of Pharmacy, and other local, State, or Federal regulations pertaining to	____	____	_____	_____

radioactive and non-radioactive Drugs are available.

5. All previous State Board of Pharmacy inspection reports and other related correspondence are available and readily retrievable. ____ ____ _____ _____

III. Comments Section

List all comments in the space below, referencing section/item number. Use additional sheets if necessary.

V. Evaluation

Provide in the space below a brief evaluation of the facility's compliance posture and program effectiveness overall. Use additional sheets if necessary.

VI. Follow-up Recommendations

Provide in the space below a brief statement of actions required in order to bring the facility's operation into full compliance. Use additional sheets if necessary.

Signature of Inspector_____

Printed Name of the Inspector_____

Date_____ Time_____

Signature of Pharmacy Manager_____

Printed Name of Pharmacy Manager _____

Date_____Time_____

Appendix B

Good Compounding Practices Applicable to State Licensed Pharmacies

The following Good Compounding Practices (GCPs) are meant to apply only to the Compounding of Drugs by State-licensed pharmacies.

Subpart A. General Provisions and Definitions

The procedures contained herein are considered to be the minimum current Good Compounding Practices for the preparation of Drug products by State-licensed Pharmacies for Dispensing and/or Administration to humans or animals. Compounding Pharmacists and Pharmacies shall practice in accordance with these Good Compounding Practices, the Board's Rules for Sterile Pharmaceuticals, and the current United States Pharmacopeia-National Formulary (USP-NF) chapters on Compounding and sterile product preparation.

The following definitions from the NABP Model State Pharmacy Act apply to these Good Compounding Practices. States may wish to insert their own definitions to comply with State Pharmacy Practice Acts.

(a) "Compounding" means the preparation of Components into a Drug product (1) as the result of a Practitioner's Prescription Drug Order based on the Practitioner/patient/Pharmacist relationship in the course of professional practice, or (2) for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or Dispensing. Compounding includes the preparation of limited amounts of Drugs or Devices in anticipation of receiving Prescription Drug Orders based on routine, regularly observed prescribing patterns.

(b) "Manufacturing" means the production, preparation, propagation, conversion, or processing of a Drug or Device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis. Manufacturing includes the packaging or repackaging of a Drug or Device or the Labeling or relabeling of the container of a Drug or Device for resale by pharmacies, Practitioners, or other Persons.

(c) "Active Ingredients" refer to chemicals, substances, or other Components of articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases in humans or animals or for use as nutritional supplements.

(d) "Added Substances" mean the ingredients necessary to prepare the Drug product but are not intended or expected to cause a human pharmacologic response if administered alone in the amount or concentration contained in a single doses of the Compounded Drug product. The term "added substances" is usually used synonymously with the terms "inactive ingredients," "excipients," and "pharmaceutic ingredients."

(e) "Component" means any Active Ingredient or Added Substance intended for use in the Compounding of a Drug product, including those that may not appear on the product Label.

Based on the existence of a Pharmacist/patient/Practitioner relationship and the presentation of a valid Prescription Drug Order or Medical Order, Pharmacists may Compound, in reasonable and justified quantities, Drug products that are commercially available in the marketplace when they

are different from the FDA-approved product and there is a specific, documented medical need for this variation for a particular patient.

Pharmacists shall receive, store, or use Drug substances for Compounding that are Components of FDA-approved drugs and that have been made in an FDA-registered facility. If this requirement cannot be met, Pharmacists shall procure a Certificate of Analysis for each lot purchased. Pharmacists shall also receive, store, or use Drug Components in Compounding prescriptions that meet official compendia requirements.

The Pharmacist shall notify patients if they may be affected by a product found to have a defect or an out-of-specification result.

Compounding includes the preparation of Drugs or Devices in anticipation of receiving Prescription Drug Orders or Medical Orders based on routine, regularly observed prescribing patterns. Pharmacists may Compound Drugs in limited quantities, prior to receiving a valid Prescription Drug Order or Medical Order based on a history of receiving valid Prescription Drug Orders or Medical Orders that have been generated solely within an established Pharmacist/patient/Practitioner relationship, and provided that they maintain the prescriptions on file for all such products Compounded at the Pharmacy (as required by State and Federal law). The Compounding of inordinate amounts of Drugs in anticipation of receiving prescriptions without any historical basis is considered Manufacturing.

A Pharmacist may not Compound a Drug that appears on the FDA List of Drugs Withdrawn or Removed from the Market for Safety Reasons or on the FDA List of Drug Products that Present Demonstrable Difficulties in Compounding unless approved by the Board.

Pharmacists shall not offer Compounded Drug products to other State-licensed persons or commercial entities for subsequent resale, except in the course of professional practice for a Practitioner to Administer to an individual patient, in limited quantities. Compounding pharmacies/Pharmacists may advertise or otherwise promote the fact that they provide prescription Compounding services, in accordance with State law, as well as applicable federal laws.

Pharmacists engaged in the Compounding of Drugs shall operate in conformance with applicable State law regulating the Practice of Pharmacy.

Subpart B. Organization and Personnel

As in the Dispensing of all prescriptions, the Pharmacist has the responsibility and authority to inspect and approve or reject all Components, Drug product containers, closures, in-process materials, Labeling, and the authority to prepare and review all Compounding records to ensure that no errors have occurred in the Compounding process. If errors have occurred, the Pharmacist is responsible for conducting a full investigation. A written record of the investigation shall be made and shall include conclusions and follow-up. The Pharmacist is also responsible for the proper maintenance, cleanliness, and use of all facilities and equipment used in prescription Compounding practice.

All Pharmacists who participate in the Compounding of Drugs, including other Compounding Pharmacy personnel who assist the Pharmacist in Compounding, shall be proficient in the art of Compounding and shall acquire the education, training, and/or experience to maintain that proficiency through participation in seminars, studying appropriate literature, and consulting colleagues, or by becoming certified by a Compounding certification program approved by the Board. Also, all Compounding Pharmacy personnel who participate in Drug Compounding must be aware of and familiar with all details of the Good Compounding Practices.

Training of Pharmacists and other Compounding Pharmacy personnel (eg, Pharmacy Technicians) shall be in the particular operations that are performed by that individual. Training shall be conducted by qualified individuals on a continuing basis and with sufficient frequency to ensure that Compounding Pharmacy personnel remain familiar with applicable operations.

Personnel engaged in the Compounding of Drugs shall wear clean clothing appropriate to the operation being performed. Protective apparel, such as a coat/jacket, apron, or hand or arm coverings, shall be worn as necessary to protect Drug products from contamination. For a sterile Compounding operation involving one or more aseptic manipulations, sterile gowning components are necessary. See the Model Rules for Sterile Pharmaceuticals.

Only personnel authorized by the responsible Pharmacist shall be in the immediate vicinity of the Drug Compounding operation. Any Person shown at any time (either by medical examination or Pharmacist determination) to have an apparent illness or open lesion(s) that may adversely affect the safety or quality of a Drug product being Compounded shall be excluded from direct contact with Components, Drug product containers, closures, in-process materials, and Drug products until the condition is corrected or determined by competent medical personnel not to jeopardize the safety or quality of the products(s) being Compounded. All personnel who normally assist the Pharmacist in Compounding procedures shall be instructed to report to the Pharmacist any health conditions that may have an adverse effect on Drug products.

Subpart C. Drug Compounding Facilities

Pharmacies engaging in Compounding shall have a specifically designated and adequate area (space) for the orderly placement of equipment and materials to be used to Compound medications and to prevent mix-ups or contamination between Components, containers, labels, in-process materials, and finished Drug products. The Drug Compounding area for sterile products shall be separate and distinct from the area used for the Compounding or Dispensing of nonsterile Drug products. The area(s) used for the Compounding of Drugs shall be maintained in a good state of repair and be of suitable construction and location to facilitate cleaning, maintenance, and proper operation. Adequate space and appropriate material flow shall be provided.

Bulk Drugs and other materials used in the Compounding of Drugs must be stored in adequately labeled containers in a clean, dry area or, if required, under proper refrigeration as specified on the label.

Adequate lighting, heating, ventilation, and air conditioning shall be provided in all Drug Compounding areas to prevent contamination or decomposition of Components. Potable water shall be supplied under continuous positive pressure in a plumbing system free of defects that could contribute contamination to any Compounded Drug product. Adequate washing facilities, easily accessible to the Compounding area(s) of the Pharmacy, shall be provided. These facilities shall include, but not be limited to, hot and cold water, soap or detergent, and air-driers or single-use towels.

The area(s) used for the Compounding of Drugs shall be maintained in a clean and sanitary condition. Sewage, trash, and other refuse in and from the Pharmacy and immediate Drug Compounding area(s) shall be held and disposed of in a safe, sanitary, and timely manner.

Sterile Products/Radiopharmaceuticals

If sterile (aseptic) products are being Compounded, conditions set forth in the NABP Model Rules for Sterile Pharmaceuticals must be followed.

If radiopharmaceuticals are being Compounded, conditions set forth in the NABP Model Rules for Nuclear/Radiologic Pharmacy must be followed.

Special Precaution Products

The Compounding area should be designed, arranged, used, and maintained to prevent cross-contamination. Equipment and Compounding areas should be thoroughly cleaned promptly after use, and special precautions should be taken to meticulously clean equipment and Compounding areas after Compounding Drug products that contain allergenic Components (eg, sulfonamides or penicillins).

Subpart D. Equipment

Equipment used in the Compounding of Drug products shall be of appropriate design, adequate size, and suitably located to facilitate operations for its intended use and for its cleaning and maintenance. The types and sizes of equipment will depend on the dosage forms and the quantities Compounded. Equipment used in the Compounding of Drug products shall be of suitable composition so that surfaces that contact Components, in-process materials, or Drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the Drug products beyond that which they purport or are represented to possess.

Equipment and utensils used for Compounding shall be cleaned and disinfected immediately prior to use to prevent contamination of the Drug product. In the case of equipment, utensils, and containers/closures used in the Compounding of sterile Drug products, cleaning, sterilization, and maintenance procedures as set forth in the NABP Model Rules for Sterile Pharmaceuticals must be followed.

Previously cleaned equipment and utensils used for Compounding Drugs must be protected from contamination prior to use. Immediately prior to the initiation of Compounding operations, they must be inspected by the Pharmacist and determined to be suitable for use.

Equipment shall be properly maintained to prevent malfunctions that would alter the drug product's safety, identity, strength, quality, or purity. Equipment shall be subject to maintenance and there shall be cleaning schedules and descriptions of the methods, equipment, and materials used in cleaning and maintenance operations. There shall be methods of reassembling equipment to ensure proper cleaning and maintenance.

Automatic, mechanical, or electronic equipment, or other types of equipment or related systems shall be routinely inspected, calibrated (if necessary), or checked to ensure proper performance, as per manufacturer instructions.

Subpart E. Control of Components and Drug Product Containers and Closures

Components, Drug product containers, and closures, used in the Compounding of Drugs shall be handled and stored in a manner to prevent contamination. Bagged or boxed Components of Drug product containers and closures used in the Compounding of Drugs shall be stored off the floor in such a manner as to permit cleaning and inspection.

Compounded Drug products should be packaged in containers meeting USP standards. The container used depends on the physical and chemical properties of the Compounded Drug

products. Drug product containers and closures shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the Compounded Drug beyond that which it purports or is represented to possess. Container-Drug interaction should be considered with substances such as phenolic Compounds and sorptive materials (eg, polypeptides and proteins).

Changes to these procedures shall be reviewed and approved by the appropriate organizational units and by a representative from the Continuous Quality Improvement Program.

Components, Drug product containers, and closures for use in the Compounding of Drug products shall be rotated so that the oldest stock is used first. Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the Compounded Drug product. Drug product containers and closures shall be clean and, where indicated by the intended use of the Drug, sterilized and processed to remove pyrogenic properties to ensure that they are suitable for their intended use.

Drug product containers and closures intended for the Compounding of sterile products must be handled, sterilized, stored, etc, in keeping with the NABP Model Rules for Sterile Pharmaceuticals. Methods of cleaning, sterilizing, and processing to remove pyrogenic properties shall be written and followed for Drug product containers and closures used in the preparation of sterile pharmaceuticals, if these processes are performed by the Pharmacist, or under the Pharmacist's supervision following the NABP Model Rules for Sterile Pharmaceuticals.

Components, Drug product containers, and closures shall not be used for Compounding operations for which they are unsuitable.

Subpart F. Drug Compounding Controls

There shall be written procedures for the Compounding of Drug products to ensure that the finished products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include a listing of the Components, their amounts (in weight or volume), the order of Component addition, and a description of the Compounding process. All equipment and utensils and the container/closure system, relevant to the sterility and stability of the intended use of the Drug, shall be listed. These written procedures shall be followed in the execution of the Drug Compounding procedure.

Components for Drug product Compounding shall be accurately weighed, measured, or subdivided as appropriate to ensure that the Compounded Drug product will be formulated with the intent to provide 100% of the Labeled or established amount of active ingredient. The Compounding Pharmacist should:

(a) check and recheck these operations at each stage of the process to ensure that each weight or measure is correct as stated in the written Compounding procedures,
(b) observe the finished Drug product to ensure that it appears as expected,
(c) record the various compounding steps completed at the time of performance, and
(d) investigate any discrepancies and take appropriate corrective action before the Drug product is dispensed to the patient.

If a Component is removed from the original container to another (eg, a powder is taken from the original container, weighed, placed in a container, and stored in another container) the new container shall be identified with the:

(a) Component name;
(b) weight or measure;
(c) lot number; and

(d) expiration date or Beyond-Use Date.

To ensure the reasonable uniformity and integrity of Compounded Drug products, written procedures shall be established and followed that describe the tests or examinations to be conducted on the product being Compounded (eg, Compounding of capsules). Such control procedures shall be established to monitor the output and to validate the performance of those Compounding processes that may be responsible for causing variability in the final Drug product. Such control procedures shall include, but are not limited to, the following (where appropriate):

(a) tablet or capsule weight variation;
(b) adequacy of mixing to assure uniformity and homogeneity; or
(c) clarity, completeness, or pH of solutions.

Rejected in-process and finished materials shall not be used for Compounding operations for which they are unsuitable.

Assurance of sterility in a Compounded sterile Drug product is mandatory. Appropriate written procedures designed to prevent microbiological contamination of Compounded Drug products shall be established and followed. Such procedures shall include validation of any sterilization process.

Subpart G. Continuous Quality Improvement Program

Each Compounding Pharmacy shall implement a Continuous Quality Improvement (CQI) Program intended to provide a mechanism for monitoring, evaluating, correcting, and improving the activities and processes described in this document. Emphasis on the CQI Program should be placed on maintaining and improving the quality of systems and the provision of patient care. The CQI Program should ensure that any plan aimed at correcting identified problems also includes appropriate follow-up to make certain that effective corrective actions are performed. The CQI Program should adhere to the provisions set out in the NABP Model Rules for the Practice of Pharmacy.

A CQI Program shall be documented through written policies and procedures and shall include the following:

(a) consideration of all aspects of the preparation and dispensing of products as described in the NABP Model Rules for Sterile Pharmaceuticals and the USP Chapter 797 "Pharmaceutical Compounding – Sterile Preparations;"
(b) description of specific monitoring and evaluation activities;
(c) specification of how results are to be reported and evaluated;
(d) collection of complaints, returns, or recalls that are the result of issues concerning the identity, strength, quality, and/or purity of Compounded Drug products;
(e) identification of appropriate follow-up mechanisms when action levels or thresholds are exceeded; and
(f) delineation of the individuals responsible for each aspect of the CQI Program.

In developing a specific plan, focus should be on establishing objective, measurable indicators for monitoring activities and processes that are deemed high risk, high volume, or problem prone, provided that Compounding of Drug products with these attributes are appropriate. Proper evaluation of environmental monitoring might include, for example, the trending of an indicator such as settling plate counts.

The selection of indicators and the effectiveness of the overall CQI Program plan should be reassessed as needed or on an annual basis.

Subpart H. Labeling Control of Excess Products

In the case where a limited quantity of a Compounded Drug product in excess of that to be initially Dispensed in accordance with Subpart A is prepared, the excess product shall be labeled or documentation referenced with the complete list of Components, the preparation date, and the assigned Beyond-Use-Date based upon appropriate testing, published data, and/or USP Guidelines. It shall also be stored and accounted for under conditions dictated by its composition and stability characteristics (eg, in a clean, dry place on a shelf or in the refrigerator) to ensure its strength, quality, and purity.

At the completion of the Drug finishing operation, the product shall be examined for correct Labeling.

Subpart I. Records and Reports

Compounding Pharmacies shall maintain a Formulation Record and a Compounding Record.

Formulation Record – A formulation record lists individually Compounded Drug products, and includes, but is not limited to, the following information:

(a) name, strength, and dosage form of the Drug product Compounded;
(b) all Components and an accurate statement of the weight or measure of each component;
(c) equipment needed to prepare the Drug product, when appropriate;
(d) mixing instructions, including:
    (1) mixing temperatures;
    (2) other environmental controls, such as the duration of mixing;
(e) other factors pertinent to the replication of the Drug product as Compounded;
(f) Beyond-use Date;
(g) container, closures, and packaging materials used in dispensing;
(h) storage requirements;
(i) Labels and Labeling with appropriate Beyond-use Date and instructions for storage and use; and
(j) quality control procedures to include identification of the Person(s) performing and directly supervising or checking each significant step in the Compounding operations.

Compounding Record – A Compounding record contains:

(a) documentation of the name and strength of the Compounded Drug product;
(b) the formulation record reference for the Drug product;
(c) the sources and lot numbers of the Components;
(d) the total number of dosage units Compounded;
(e) the name of the Person who prepared the Drug product;
(f) the name of the Pharmacist who approved the Drug product;
(g) the name of the Practitioner and the name of the patient who received the Compounded Drug product;
(h) the date of preparation;
(i) the prescription number or assigned internal identification number;
(j) the Dispensing or Distribution records to document who received the Compounded Prescriptions, if different than the Patient; and
(k) the results of quality control procedures (eg, weight range of filled capsules) as described within the pharmacy's CQI Program.

Records required under these Good Compounding Practices may be retained either as the original records or as true copies, such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records.

Any records required to be maintained in compliance with these Good Compounding Practices shall be retained for the same period of time as each State requires for the retention of prescription files. All records required to be retained under these Good Compounding Practices, or copies of such records, shall be readily available for authorized inspection during the retention period at the establishment where the activities described in such records occurred. These records or copies thereof shall be subject to photocopying or other means of reproduction as part of such inspection.

Comments

Subpart A. Comment.

Boards of Pharmacy should continually monitor compliance with these Good Compounding Practices to distinguish Compounding from Manufacturing, including consideration of the following factors:

(a) Compounded prescription volume;
(b) the existence of a Practitioner/patient/Pharmacist relationship;
(c) use of commercial scale equipment;
(d) availability of the product (commercially available);
(e) whether or not the pharmacy Compounds, in anticipation of receiving Prescription Drug Orders, an inordinate supply of product;
(f) whether the Pharmacy Compounds Drugs for third parties who resell to individual patients; or
(g) any such other indicators as may be necessary to monitor from time to time to determine compliance and distinguish Compounding from Manufacturing, such as Compounding Drugs that were withdrawn or removed from the market for safety reasons, or Compounding finished drugs from bulk active ingredients that are not components of FDA-approved Drugs.

Additionally, Boards of Pharmacy, in extreme situations as defined by the Board, may permit the Compounding of Products contained on the FDA List of Drugs Withdrawn or Removed from the Market for Safety Reasons or on the FDA List of Drug products that Present Demonstrable Difficulties in Compounding. For example, if a determination has been made and documented that other FDA-approved Drug Products have not been able to successfully treat the patient, the Pharmacist can Compound a product that appears on the FDA lists only if documentation of, for example, clinical assessments, benefit to risk analysis, etc, can be provided and the Patient and Practitioner are informed and aware of the benefits to risks.

Subpart D. Comment.

Boards of Pharmacy may consider referencing USP-NF Chapter 41 (Weights and Balances), Chapter 1176 (Prescription Balances and Volumetric Apparatus), and equipment manufacturers' instruction manuals.

Subpart E. Comment.

Boards of Pharmacy may consider referencing USP-NF Chapter 661(Containers) and Chapter 671(Containers-Permeation).

Subpart F. Comment.

Boards may consider referencing USP Chapter 797 "Pharmaceutical Compounding – Sterile Preparations" and requiring adherence by all Compounding Pharmacists to the Compounding and packaging of sterile product guidelines found within that chapter. The revised version of USP Chapter 797 went into effect June 1, 2008, after consideration of recommendations received from USP internal expert committees and the professional community.

Boards may consider referencing the following checklist, found in the USP Chapter 795 "Pharmaceutical Compounding – Nonsterile Preparations" and requiring its use by the Compounding Pharmacist to ensure the appropriate strength, quality, and purity of the Compounded product:

(a) Have the physical and chemical properties and medicinal, dietary, and pharmacological uses of the Drug products been reviewed?
(b) Is the quantity and quality of each Active Ingredient identifiable?
(c) Will the Active Ingredients be effectively absorbed, locally or systemically according to the prescribed purpose, from the Drug product and route of Administration?
(d) Are there Added Substances (confirmed or potentially present) from manufactured products that may be expected to cause an allergic reaction, irritation, toxicity, or undesirable organoleptic response from the patient? Are there Added Substances (confirmed or potentially present) that may be unfavorable (eg, unsuitable pH or inadequate solubility)?
(e) Were all calculations and measurements confirmed to ensure that the Drug product will be Compounded accurately?

Subpart I. Comment.

The objective of documentation is to allow another pharmacist to reproduce the identical prescription at a future date. The formulation record provides a consistent source document for preparing the Drug product (recipe), and the Compounding record documents the actual Components in the Drug product and the person responsible for the Compounding activity.

Normally, the patient's name and the name of the Practitioner Prescribing the Compounded Drug product are recorded in the Compounding Record at the time of compounding and dispensing. If, however, the Compounded Drug Product is prepared in anticipation of a Prescription Drug Order, a mechanism should be implemented that identifies to whom the previously Compounding Drug Products have been dispensed.

Appendix C

Sample Pharmacy Automation Policy and Procedure Outline

I. Access
- A. System Entry
- B. Access Codes
- C. System Access Privileges
- D. Changing Access Privileges
- E. Termination of User
- F. Temporary Access Codes
- G. Password Assignment

II. Controlled Substances
- A. Chain of Custody
- B. Discrepancy Resolution

III. Data
- A. Archiving
- B. Stored/Uploading to Database
- C. Backup

IV. Definitions

V. Dispensing/Distribution
- A. Removal of Medications and/or Pharmaceutical Supplies
- B. Medication Access

VI. Downtime Procedures (see Malfunction)

VII. Emergency Procedures

VIII. Information Security/Confidentiality
- A. Patient Information
- B. Medication Information
- C. Transaction Files
- D. Information Update Plan
- E. Patient Update Plan
- F. Information Access

IX. Inspection

X. Installation Requirements

XI. Maintenance
- A. Service and Repair Protocols

XII. Medication Administration
- A. Medication and Patient Validation

B. Administration Verification

XIII. Medication Security
- A. Security Management and Control
- B. Medication Loading and Storage
- C. Medication Loading Records
- D. Medication Containers
- E. Cross Contamination
- F. Lot Number Control
- G. Inventory
- H. Utilization Review
- I. Research

XIV. Malfunction
- A. Troubleshooting
- B. Power Failure

XV. Quality Assurance/Quality Improvement
- A. Documentation and Verification of Proper Loading and Refilling of Device
- B. Proof of Delivery
- C. Removal of Drugs for Administration, Return, or Waste
- D. Chain of Custody of Controlled Substances (Institutions)
- E. Recording, Resolving, and Reporting of Discrepancies
- F. Periodic Audits to Assure Compliance with Policies and Procedures

XVI. Reports
- A. System Maintenance
- B. Administrative Functions
- C. Inventory
- D. Error
- E. Discrepancies
- F. Activity
- G. Problem

XVII. Medication Inventory
- A. Management

XVIII. Staff Education and Training

XIX. System Setup

Appendix D

Guidelines for Disciplinary Sanctions

Improperly Obtaining or Attempting to Obtain a License

1. Fraud or Misrepresentation in applying for or procuring a pharmaceutical license or in connection with applying for or procuring periodic reregistration of a pharmaceutical license.
   Range of action: from Fine to Revocation or denial
2. Cheating on or attempting to subvert the Pharmacist licensure examination(s).
   Range of action: Revocation or denial

Misdemeanors/Felonies

3. The commission or conviction of a gross misdemeanor or a felony, whether or not related to the Practice of Pharmacy, or the entry of a guilty or nolo contendere plea to a gross misdemeanor or a felony charge.
   Range of action: from Probation to Revocation

Deception/Fraud/Misrepresentation

4. Conduct likely to deceive, defraud, or harm the public.
   Range of action: from Censure to Revocation
5. Making a false or misleading statement regarding one's skill of the efficacy or value of the medicine, treatment, or remedy Dispensed in the treatment of any disease or other condition of the body or mind.
   Range of action: from Probation to Revocation
6. The use of any false, fraudulent, or deceptive statement in any document connected with the Practice of Pharmacy.
   Range of action: from Warning to Revocation
7. Practicing Pharmacy under a false or assumed name.
   Range of action: from Probation to Revocation

Patient Confidentiality/Records

8. Improper management of Pharmacy patient records, including illegal use or disclosure of Protected Health Information.
   Range of action: from Warning to Suspension

Negligence/Incompetence/Disability/Malpractice

9. Negligence in the Practice of Pharmacy as determined by the Board.
   Range of action: from Warning to Revocation
10. Being found mentally incompetent or insane by any court of competent jurisdiction.
    Range of action: from Suspension to Revocation
11. Being physically or mentally unable to engage safely in the Practice of Pharmacy.
    Range of action: from Probation to Revocation
12. Demonstration of incapacity or incompetence to practice Pharmacy.
    Range of action: from Probation to Revocation

13. Any adverse judgment, award, or settlement against the licensee resulting from a professional malpractice claim related to conduct that would constitute grounds for action as defined in this section.
Range of action: from Censure to Revocation

Sexual Misconduct

14. Commission of any act of sexual abuse, misconduct, or exploitation related to a licensee's Practice of Pharmacy.
Range of action: from Probation to Revocation

Drug- and Alcohol-Related Offenses

15. Being dependent on or habituated to a Drug or intoxicant.
Range of action: from Probation to Revocation
16. Dispensing, prescribing, selling, Administering, Distributing, ordering, or giving any Drug legally classified as a controlled substance or recognized as an addictive or dangerous Drug for any purposes other than medically accepted as therapeutic.
Range of action: from Probation to Revocation
17. Except as otherwise permitted by law, Dispensing, prescribing, selling, Administering, Distributing, ordering, or giving to an habitué, addict, or any Person previously Drug dependent any Drug legally classified as a controlled substance or recognized as an addictive or dangerous Drug.
Range of action: from Probation to Revocation
18. Violating any State or Federal law or regulation relating to controlled substances.
Range of action: from Warning to Revocation

Misuse of License

19. Aiding or abetting the Practice of Pharmacy by an unlicensed, incompetent, or impaired Person.
Range of action: from Reprimand to Revocation
20. Allowing another Person or organization to use one's license to practice Pharmacy.
Range of action: from Reprimand to Revocation

Disciplinary Action by Other Jurisdictions

21. Disciplinary action of another state or jurisdiction against a license or other authorization to practice Pharmacy based upon conduct by the licensee similar to conduct that would constitute grounds for action as defined in this Section.
Range of action: same as for similar offense in this State

Failure to Report to and/or Cooperate with Board

22. Failure to report to the Board any adverse action taken by another licensing jurisdiction (United States or foreign), government agency, law enforcement agency, or court for conduct that would constitute grounds for action as defined in this Section.
Range of action: from Censure to Revocation
23. Failure to report to the Board one's surrender of a license or authorization to practice Pharmacy in another state or jurisdiction while under disciplinary investigation by any of those authorities or bodies for conduct that would constitute grounds for action as

defined in this section.
Range of action: from Censure to Revocation

24. Failure to report to the Board any adverse judgment, settlement, or award arising from a malpractice claim related to conduct that would constitute grounds for action as defined in this section.
Range of action: from Censure to Suspension

25. Failure to cooperate with a lawful investigation conducted by the Board.
Range of action: from Censure to Revocation

26. Failure to furnish to the Board, its investigators, or representatives any information legally requested by the Board.
Range of action: from Censure to Revocation

Other Violations

27. Violation of any provision(s) of the Pharmacy Practice Act, any rules and regulations of the Board, or any action, stipulation, or Agreement of the Board.
Range of action: corresponds to related actions above

Appendix E

Guidelines for the Appropriate Use and Disclosure of Protected Health Information in Medication Adherence Monitoring Services and Patient Intervention Programs

Section 1. Purpose.

The purpose of these Guidelines is to provide Pharmacists and patients with appropriate direction and information for the design, implementation, and participation in Medication Adherence Monitoring Services and Patient Intervention Programs. Such Guidelines are needed in the interest of public health to protect the confidentiality of patient health care information and prohibit inappropriate and potentially detrimental contact with the patient.

Medication Adherence Monitoring Services and Patient Intervention Programs are those that promote improved medication use behaviors, such as medication regimen adherence and appropriate self-monitoring and self-reporting, through such efforts as refill reminder programs and patient medication, disease state, and Drug therapy option education.

It shall be contrary to these Guidelines for any Person (including, but not limited to, health insurance carriers, health benefit management companies, and health care marketing enterprises) to attempt to or cause a switch of a patient's medication, or direct a patient away from a course of therapy, solely for economic or financial gains or incentives.

Nothing in these Guidelines supersedes existing State Drug product selection laws or procedures for Drug recalls, nor prevents access to Nonconfidential Health Care Information for research purposes.

The privacy standards found in the NABP's Model Rules for the Privacy of Individually Identifiable Patient Information should be carefully considered when conducting adherence and patient intervention programs.

Section 2. Definitions.

(a) "Affiliated Entity" means legally separate covered entities that are affiliated and that designate themselves as a single covered entity for the purposes of this section.

(b) "De-identified Health Information" means Health Information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual. De-identified health information must meet the specifications of the de-identified health information described in the Health Insurance Portability and Accountability Act (HIPAA) privacy rules (45 CFR §164.514(b)).

(c) "External Entities" means those organizations that exist outside of the pharmacist-patient relationship and that participate in the implementation of Patient Compliance and Patient Intervention Programs. External Entities include, but are not limited to, health insurance carriers, health benefit management companies, and health care marketing enterprises.[166]

[166] Depending on the activities conducted by External Entities, they may be construed as "business associates" as defined under HIPAA and its related privacy rules (45 CFR Part 160). If so, HIPAA and its privacy rules that apply to those External Entities acting as business associates shall take precedence over contrary state law. In addition, "business associate agreements," as defined under

(d) "Health Information" means any information, whether oral or recorded in any form or medium, that:
  (1) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse.
  (2) relates to the past, present, or future physical or mental health or condition of an individual; or the past, present, or future payment for the provision of health care to an individual.

(e) "HIPAA" is the federal Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191) and any amendments thereof.

(f) "Individually Identifiable Health Information" is information that is a subset of health information, including demographic information collected from an individual and
  (1) is created or received by a health care provider, health plan, employer, or health care clearinghouse; and
  (2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and
    (i) that identifies the individual; or
    (ii) with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

(g) "Medication Adherence Monitoring Service" is defined as any structured activity that complements or supplements the existing responsibilities regarding the Dispensing of prescriptions and associated Patient Counseling, and that uses Protected Health Information to contact the patient or caregiver via phone, print, electronic media, or other means of communication, in order to improve patient compliance with and adherence to prescribed medication therapy and that involves the collection and analysis of data related to patient medication use. Medication Adherence Monitoring Services may incorporate such efforts as refill reminder and patient education programs.

(h) "Patient Intervention Program" is defined as any structured activity that complements or supplements the existing responsibilities regarding the Dispensing of prescriptions and associated Patient Counseling, and that uses Protected Health Information to contact the patient or caregiver via phone, print, electronic media, or other means of communication, to discuss, inform, and/or affect patient therapy or choice of medications.

(i) "Protected Health Information" means individually identifiable health information:
  (1) Except as provided in paragraph (2) of this definition, that is
    (i) transmitted by electronic media;
    (ii) maintained in any medium described in the definition of electronic media at §162.103 of the HIPAA privacy rules (45 CFR Part 160);
    (iii) transmitted or maintained in any other form or medium.
  (2) Protected health information excludes individually identifiable health information in
    (i) education records covered by the Family Educational Right and Privacy Act, as amended 20 USC 1232(g);
    (ii) records described at 20 USC 1232(g)(4)(B)(iv); and
    (iii) employment records held by a licensee in its role as an employer.

HIPAA and its privacy rules, shall be required between a Pharmacist or Pharmacy and the External Entity acting as a business associate so as to prevent the unauthorized use or disclosure of Protected Health Information.

Section 3. Protection Against Illegal Use or Disclosure of Protected Health Information.

Medication Adherence Monitoring Services and Patient Intervention Programs shall be conducted in a manner to protect against the illegal use or disclosure of Protected Health Information. The illegal use or disclosure of Protected Health Information constitutes a violation of HIPAA and its related privacy rules (45 CFR Part 160) and may constitute a violation of state pharmacy practice acts or rules or other State laws or rules.

The following minimal safeguards shall be in place for Medication Adherence Monitoring Services and Patient Intervention Programs:

(a) Appropriate notice shall be given to patients regarding participation in Medication Adherence Monitoring Services and Patient Intervention Programs;

(b) Protected Health Information shall be maintained in a manner to protect against the illegal use or disclosure of such information;

(c) Protected Health Information shall be accessed only by the pharmacist or by individuals under the direct supervision of the pharmacist, or by an affiliated entity of that pharmacist and may be released or disclosed to an External Entity pursuant to the notice of privacy practices required by 45 CFR §164.520 and the Model Rules for the Privacy of Individually Identifiable Patient Information of this *Model Act*;

(d) Protected Health Information used to implement a Medication Adherence Monitoring Service or Patient Intervention Program shall not be released or disclosed to any External Entity other than the External Entity implementing the program with, or on behalf of, the pharmacy;

(e) All personnel with access to Protected Health Information shall sign and their employer shall retain on file current confidentiality and non-disclosure agreements;

(f) If the Medication Adherence Monitoring Service or Patient Intervention Program information is mailed, delivery systems that (1) ensure the information will be delivered to the designated patient or caregiver and will remain confidential; and (2) allow for the return of the information if not deliverable, shall be utilized. For example, if the contact is via the US Postal Service, the information should be mailed first class in a sealed security envelope;

(g) Methods to access, transmit, store, analyze, or purge Protected Health Information shall be implemented using procedures generally recognized as secure by experts qualified by training and experience;

(h) External Entities maintaining Protected Health Information outside the pharmacy's internal system shall adhere to the same security requirements adhered to by the pharmacy in regard to its internal system, including but not limited to, those requirements addressing information access, storage, auditability, and release;

(i) Procedures shall be in place to ensure that purged Protected Health Information cannot be misused or placed into active operation without appropriate authorization; and

(j) Internet connectivity or remote access tied directly to systems containing Protected Health Information must be secure.

Section 4. Patient Participation.

Medication Adherence Monitoring Services and Patient Intervention Programs shall be conducted in the best interest of the patient and shall inform patients about the program's purpose and use of Protected Health Information. The patient shall have the option to withdraw from any such program at any time. Patients shall be provided with a notice of privacy practices, which includes a description of the Medication Adherence Monitoring Service or Patient Intervention Program;

Programs designed to change a patient's medication or medication therapy solely for economic or financial gains or incentives without the consent of the patient and prescribing practitioner are contrary to these Guidelines and may violate state pharmacy practice acts and rules and/or other state and federal laws or regulations.

Nothing in these Guidelines supersedes existing State Drug product selection laws or procedures for Drug recalls, nor prevents access to De-identified Health Information for research purposes.

Section 5. Pharmacist Participation.

A pharmacist shall oversee and approve all Medication Adherence Monitoring Services and Patient Intervention Programs and shall be responsible for: (1) the accuracy of the list of participating patients; and (2) the accuracy and appropriateness of the information being presented to the patients during the life of the program. Pharmacists involved in Medication Adherence Monitoring Services and Patient Intervention Programs, whether through contact with patients or caregivers or through the design, implementation, management, and analysis of the programs, shall be educated about such programs and their objectives. Results of the programs shall be communicated to all participating pharmacists.

Section 6. Utilization of De-identified and Protected Health Information for Research Purposes.

Notwithstanding any other provision of law, nothing in these Guidelines shall be interpreted to prohibit the release of:

(a) Protected Health Information for research that is subject to the requirements of federal laws and regulations protecting the rights and welfare of research participants;
(b) De-identified Health Information; or
(c) A limited data set for purposes of research, public health, or health care operations.

Section 7. Measurement and Analysis of Program.

Medication Adherence Monitoring Services and Patient Intervention Programs may include methodologies to measure the outcomes of the program in relation to patient care and the performance of the pharmacy/pharmacist. The following minimum guidelines shall be observed when measuring and analyzing the program outcomes:

(a) Analysis and aggregate data reports shall not contain Protected Health Information;
(b) Study design, measurement, and analysis shall adhere to accepted research and study designs; and
(c) Reports prepared or published shall provide accurate and statistically correct information.

Comments

Section 2. Comment.

45 CFR §164.514(b) reads:

> (b) *Implementation specifications: Requirements for de-identification of protected health information.* A covered entity may determine that health information is not individually identifiable health information only if:
> (1) A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable:
> (i) Applying such principles and methods, determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information; and
> (ii) Documents the methods and results of the analysis that justify such determination; or
> (2)(i) The following identifiers of the individual or of relatives, employers, or household members of the individual, are removed:
> (A) Names;
> (B) All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:
> (*1*) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and
> (*2*) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
> (C) All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
> (D) Telephone numbers;
> (E) Fax numbers;
> (F) Electronic mail addresses;
> (G) Social security numbers;
> (H) Medical record numbers;
> (I) Health plan beneficiary numbers;
> (J) Account numbers;
> (K) Certificate/license numbers;
> (L) Vehicle identifiers and serial numbers, including license plate numbers;
> (M) Device identifiers and serial numbers;
> (N) Web Universal Resource Locators (URLs);
> (O) Internet Protocol (IP) address numbers;
> (P) Biometric identifiers, including finger and voice prints;
> (Q) Full face photographic images and any comparable images; and
> (R) Any other unique identifying number, characteristic, or code, except as permitted by paragraph (c) of this section; and
> (ii) The covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information.

20 USC 1232g reads:

Sec. 1232g. Family educational and privacy rights

(a) Conditions for availability of funds to educational agencies or institutions; inspection and review of education records; specific information to be made available; procedure for access to education records; reasonableness of time for such access; hearings; written explanations by parents; definitions

(1)(A) No funds shall be made available under any applicable program to any educational agency or institution which has a policy of denying, or which effectively prevents, the parents of students who are or have been in attendance at a school of such agency or at such institution, as the case may be, the right to inspect and review the education records of their children. If any material or document in the education record of a student includes information on more than one student, the parents of one of such students shall have the right to inspect and review only such part of such material or document as relates to such student or to be informed of the specific information contained in such part of such material. Each educational agency or institution shall establish appropriate procedures for the granting of a request by parents for access to the education records of their children within a reasonable period of time, but in no case more than forty-five days after the request has been made.

(B) No funds under any applicable program shall be made available to any State educational agency (whether or not that agency is an educational agency or institution under this section) that has a policy of denying, or effectively prevents, the parents of students the right to inspect and review the education records maintained by the State educational agency on their children who are or have been in attendance at any school of an educational agency or institution that is subject to the provisions of this section.

(C) The first sentence of subparagraph (A) shall not operate to make available to students in institutions of postsecondary education the following materials:

(i) financial records of the parents of the student or any information contained therein;

(ii) confidential letters and statements of recommendation, which were placed in the education records prior to January 1, 1975, if such letters or statements are not used for purposes other than those for which they were specifically intended;

(iii) if the student has signed a waiver of the student's right of access under this subsection in accordance with subparagraph (D), confidential recommendations—

(I) respecting admission to any educational agency or institution,

(II) respecting an application for employment, and

(III) respecting the receipt of an honor or honorary recognition.

(D) A student or a person applying for admission may waive his right of access to confidential statements described in clause (iii) of subparagraph (C), except that such waiver shall apply to recommendations only if (i) the student is, upon request, notified of the names of all persons making confidential recommendations and (ii) such recommendations are used solely for the purpose for which they were specifically intended. Such waivers may not be required as a condition for admission to, receipt of financial aid from, or receipt of any other services or benefits from such agency or institution.

(2) No funds shall be made available under any applicable program to any educational agency or institution unless the parents of students who are or have been in attendance at a school of such agency or at such institution are provided an opportunity for a hearing by such agency or institution, in accordance with regulations of the Secretary, to challenge the content of such student's education records, in order to insure that the records are not inaccurate, misleading, or otherwise in violation of the privacy rights of students, and to provide an opportunity for the correction or deletion of any such inaccurate, misleading or otherwise inappropriate data contained therein and to insert into such records a written explanation of the parents respecting the content of such records.

(3) For the purposes of this section the term "educational agency or institution" means any public or private agency or institution which is the recipient of funds under any applicable program.

(4)(A) For the purposes of this section, the term "education records" means, except as may be provided otherwise in subparagraph (B), those records, files, documents, and other materials which—

(i) contain information directly related to a student; and

(ii) are maintained by an educational agency or institution or by a person acting for such agency or institution.

(B) The term "education records" does not include—
(i) records of instructional, supervisory, and administrative personnel and educational personnel ancillary thereto which are in the sole possession of the maker thereof and which are not accessible or revealed to any other person except a substitute;
(ii) records maintained by a law enforcement unit of the educational agency or institution that were created by that law enforcement unit for the purpose of law enforcement;
(iii) in the case of persons who are employed by an educational agency or institution but who are not in attendance at such agency or institution, records made and maintained in the normal course of business which relate exclusively to such person in that person's capacity as an employee and are not available for use for any other purpose; or
(iv) records on a student who is eighteen years of age or older, or is attending an institution of postsecondary education, which are made or maintained by a physician, psychiatrist, psychologist, or other recognized professional or paraprofessional acting in his professional or paraprofessional capacity, or assisting in that capacity, and which are made, maintained, or used only in connection with the provision of treatment to the student, and are not available to anyone other than persons providing such treatment, except that such records can be personally reviewed by a physician or other appropriate professional of the student's choice.

(5)(A) For the purposes of this section the term "directory information" relating to a student includes the following: the student's name, address, telephone listing, date and place of birth, major field of study, participation in officially recognized activities and sports, weight and height of members of athletic teams, dates of attendance, degrees and awards received, and the most recent previous educational agency or institution attended by the student.
(B) Any educational agency or institution making public directory information shall give public notice of the categories of information which it has designated as such information with respect to each student attending the institution or agency and shall allow a reasonable period of time after such notice has been given for a parent to inform the institution or agency that any or all of the information designated should not be released without the parent's prior consent.
(6) For the purposes of this section, the term "student" includes any person with respect to whom an educational agency or institution maintains education records or personally identifiable information, but does not include a person who has not been in attendance at such agency or institution.
(b) Release of education records; parental consent requirement; exceptions; compliance with judicial orders and subpoenas; audit and evaluation of federally-supported education programs; recordkeeping
(1) No funds shall be made available under any applicable program to any educational agency or institution which has a policy or practice of permitting the release of education records (or personally identifiable information contained therein other than directory information, as defined in paragraph (5) of subsection (a) of this section) of students without the written consent of their parents to any individual, agency, or organization, other than to the following—
(A) other school officials, including teachers within the educational institution or local educational agency, who have been determined by such agency or institution to have legitimate educational interests, including the educational interests of the child for whom consent would otherwise be required;
(B) officials of other schools or school systems in which the student seeks or intends to enroll, upon condition that the student's parents be notified of the transfer, receive a copy of the record if desired, and have an opportunity for a hearing to challenge the content of the record;
(C)(i) authorized representatives of (I) the Comptroller General of the United States, (II) the Secretary, or (III) State educational authorities, under the conditions set forth in paragraph (3), or (ii) authorized representatives of the Attorney General for law enforcement purposes under the same conditions as apply to the Secretary under paragraph (3);
(D) in connection with a student's application for, or receipt of, financial aid;

(E) State and local officials or authorities to whom such information is specifically allowed to be reported or disclosed pursuant to State statute adopted—
(i) before November 19, 1974, if the allowed reporting or disclosure concerns the juvenile justice system and such system's ability to effectively serve the student whose records are released, or
(ii) after November 19, 1974, if—
(I) the allowed reporting or disclosure concerns the juvenile justice system and such system's ability to effectively serve, prior to adjudication, the student whose records are released; and
(II) the officials and authorities to whom such information is disclosed certify in writing to the educational agency or institution that the information will not be disclosed to any other party except as provided under State law without the prior written consent of the parent of the student.[1]

(F) organizations conducting studies for, or on behalf of, educational agencies or institutions for the purpose of developing, validating, or administering predictive tests, administering student aid programs, and improving instruction, if such studies are conducted in such a manner as will not permit the personal identification of students and their parents by persons other than representatives of such organizations and such information will be destroyed when no longer needed for the purpose for which it is conducted;
(G) accrediting organizations in order to carry out their accrediting functions;
(H) parents of a dependent student of such parents, as defined in section 152 of title 26;
(I) subject to regulations of the Secretary, in connection with an emergency, appropriate persons if the knowledge of such information is necessary to protect the health or safety of the student or other persons;
(J)(i) the entity or persons designated in a Federal grand jury subpoena, in which case the court shall order, for good cause shown, the educational agency or institution (and any officer, director, employee, agent, or attorney for such agency or institution) on which the subpoena is served, to not disclose to any person the existence or contents of the subpoena or any information furnished to the grand jury in response to the subpoena; and
(ii) the entity or persons designated in any other subpoena issued for a law enforcement purpose, in which case the court or other issuing agency may order, for good cause shown, the educational agency or institution (and any officer, director, employee, agent, or attorney for such agency or institution) on which the subpoena is served, to not disclose to any person the existence or contents of the subpoena or any information furnished in response to the subpoena;
(K) the Secretary of Agriculture, or authorized representative from the Food and Nutrition Service or contractors acting on behalf of the Food and Nutrition Service, for the purposes of conducting program monitoring, evaluations, and performance measurements of State and local educational and other agencies and institutions receiving funding or providing benefits of 1 or more programs authorized under the Richard B. Russell National School Lunch Act (42 U.S.C. 1751 et seq.) or the Child Nutrition Act of 1966 (42 U.S.C. 1771 et seq.) for which the results will be reported in an aggregate form that does not identify any individual, on the conditions that—
(i) any data collected under this subparagraph shall be protected in a manner that will not permit the personal identification of students and their parents by other than the authorized representatives of the Secretary; and
(ii) any personally identifiable data shall be destroyed when the data are no longer needed for program monitoring, evaluations, and performance measurements; and

(L) an agency caseworker or other representative of a State or local child welfare agency, or tribal organization (as defined in section 450b of title 25), who has the right to access a student's case plan, as defined and determined by the State or tribal organization, when such agency or organization is legally responsible, in accordance with State or tribal law, for the care and protection of the student, provided that the education records, or the personally identifiable information contained in such records, of the student will not be disclosed by such agency or organization, except to an individual or entity engaged in addressing the student's education needs and authorized by such agency or organization to receive such disclosure and such disclosure is consistent with the State or tribal laws applicable to protecting the confidentiality of a student's education records.

Nothing in subparagraph (E) of this paragraph shall prevent a State from further limiting the number or type of State or local officials who will continue to have access thereunder.
(2) No funds shall be made available under any applicable program to any educational agency or institution which has a policy or practice of releasing, or providing access to, any personally identifiable information in education records other than directory information, or as is permitted under paragraph (1) of this subsection, unless—
(A) there is written consent from the student's parents specifying records to be released, the reasons for such release, and to whom, and with a copy of the records to be released to the student's parents and the student if desired by the parents, or
(B) except as provided in paragraph (1)(J), such information is furnished in compliance with judicial order, or pursuant to any lawfully issued subpoena, upon condition that parents and the students are notified of all such orders or subpoenas in advance of the compliance therewith by the educational institution or agency, except when a parent is a party to a court proceeding involving child abuse and neglect (as defined in section 3 of the Child Abuse Prevention and Treatment Act (42 U.S.C. 5101 note)) or dependency matters, and the order is issued in the context of that proceeding, additional notice to the parent by the educational agency or institution is not required.

(3) Nothing contained in this section shall preclude authorized representatives of (A) the Comptroller General of the United States, (B) the Secretary, or (C) State educational authorities from having access to student or other records which may be necessary in connection with the audit and evaluation of Federally-supported education programs, or in connection with the enforcement of the Federal legal requirements which relate to such programs: *Provided*, That except when collection of personally identifiable information is specifically authorized by Federal law, any data collected by such officials shall be protected in a manner which will not permit the personal identification of students and their parents by other than those officials, and such personally identifiable data shall be destroyed when no longer needed for such audit, evaluation, and enforcement of Federal legal requirements.
(4)(A) Each educational agency or institution shall maintain a record, kept with the education records of each student, which will indicate all individuals (other than those specified in paragraph (1)(A) of this subsection), agencies, or organizations which have requested or obtained access to a student's education records maintained by such educational agency or institution, and which will indicate specifically the legitimate interest that each such person, agency, or organization has in obtaining this information. Such record of access shall be available only to parents, to the school official and his assistants who are responsible for the custody of such records, and to persons or organizations authorized in, and under the conditions of, clauses (A) and (C) of paragraph (1) as a means of auditing the operation of the system.
(B) With respect to this subsection, personal information shall only be transferred to a third party on the condition that such party will not permit any other party to have access to such information without the written consent of the parents of the student. If a third party outside the educational agency or institution permits access to information in violation of paragraph (2)(A), or fails to destroy information in violation of paragraph (1)(F), the educational agency or institution shall be prohibited from permitting access to information from education records to that third party for a period of not less than five years.
(5) Nothing in this section shall be construed to prohibit State and local educational officials from having access to student or other records which may be necessary in connection with the audit and evaluation of any federally or State supported education program or in connection with the enforcement of the Federal legal requirements which relate to any such program, subject to the conditions specified in the proviso in paragraph (3).
(6)(A) Nothing in this section shall be construed to prohibit an institution of postsecondary education from disclosing, to an alleged victim of any crime of violence (as that term is defined in section 16 of title 18), or a nonforcible sex offense, the final results of any disciplinary proceeding conducted by such institution against the alleged perpetrator of such crime or offense with respect to such crime or offense.

(B) Nothing in this section shall be construed to prohibit an institution of postsecondary education from disclosing the final results of any disciplinary proceeding conducted by such institution against a student who is an alleged perpetrator of any crime of violence (as that term is defined in section 16 of title 18), or a nonforcible sex offense, if the institution determines as a result of that disciplinary proceeding that the student committed a violation of the institution's rules or policies with respect to such crime or offense.
(C) For the purpose of this paragraph, the final results of any disciplinary proceeding—
(i) shall include only the name of the student, the violation committed, and any sanction imposed by the institution on that student; and
(ii) may include the name of any other student, such as a victim or witness, only with the written consent of that other student.

(7)(A) Nothing in this section may be construed to prohibit an educational institution from disclosing information provided to the institution under section 14071 [2] of title 42 concerning registered sex offenders who are required to register under such section.
(B) The Secretary shall take appropriate steps to notify educational institutions that disclosure of information described in subparagraph (A) is permitted.
(c) Surveys or data-gathering activities; regulations
Not later than 240 days after October 20, 1994, the Secretary shall adopt appropriate regulations or procedures, or identify existing regulations or procedures, which protect the rights of privacy of students and their families in connection with any surveys or data-gathering activities conducted, assisted, or authorized by the Secretary or an administrative head of an education agency. Regulations established under this subsection shall include provisions controlling the use, dissemination, and protection of such data. No survey or data-gathering activities shall be conducted by the Secretary, or an administrative head of an education agency under an applicable program, unless such activities are authorized by law.
(d) Students' rather than parents' permission or consent
For the purposes of this section, whenever a student has attained eighteen years of age, or is attending an institution of postsecondary education, the permission or consent required of and the rights accorded to the parents of the student shall thereafter only be required of and accorded to the student.
(e) Informing parents or students of rights under this section
No funds shall be made available under any applicable program to any educational agency or institution unless such agency or institution effectively informs the parents of students, or the students, if they are eighteen years of age or older, or are attending an institution of postsecondary education, of the rights accorded them by this section.
(f) Enforcement; termination of assistance
The Secretary shall take appropriate actions to enforce this section and to deal with violations of this section, in accordance with this chapter, except that action to terminate assistance may be taken only if the Secretary finds there has been a failure to comply with this section, and he has determined that compliance cannot be secured by voluntary means.
(g) Office and review board; creation; functions
The Secretary shall establish or designate an office and review board within the Department for the purpose of investigating, processing, reviewing, and adjudicating violations of this section and complaints which may be filed concerning alleged violations of this section. Except for the conduct of hearings, none of the functions of the Secretary under this section shall be carried out in any of the regional offices of such Department.
(h) Disciplinary records; disclosure
Nothing in this section shall prohibit an educational agency or institution from—
(1) including appropriate information in the education record of any student concerning disciplinary action taken against such student for conduct that posed a significant risk to the safety or well-being of that student, other students, or other members of the school community; or
(2) disclosing such information to teachers and school officials, including teachers and school officials in other schools, who have legitimate educational interests in the behavior of the student.
(i) Drug and alcohol violation disclosures
(1) In general

Nothing in this Act or the Higher Education Act of 1965 [20 U.S.C. 1001 et seq., 42 U.S.C. 2751 et seq.] shall be construed to prohibit an institution of higher education from disclosing, to a parent or legal guardian of a student, information regarding any violation of any Federal, State, or local law, or of any rule or policy of the institution, governing the use or possession of alcohol or a controlled substance, regardless of whether that information is contained in the student's education records, if—
(A) the student is under the age of 21; and
(B) the institution determines that the student has committed a disciplinary violation with respect to such use or possession.
(2) State law regarding disclosure
Nothing in paragraph (1) shall be construed to supersede any provision of State law that prohibits an institution of higher education from making the disclosure described in subsection (a) of this section.
(j) Investigation and prosecution of terrorism
(1) In general
Notwithstanding subsections (a) through (i) of this section or any provision of State law, the Attorney General (or any Federal officer or employee, in a position not lower than an Assistant Attorney General, designated by the Attorney General) may submit a written application to a court of competent jurisdiction for an ex parte order requiring an educational agency or institution to permit the Attorney General (or his designee) to—
(A) collect education records in the possession of the educational agency or institution that are relevant to an authorized investigation or prosecution of an offense listed in section 2332b(g)(5)(B) of title 18, or an act of domestic or international terrorism as defined in section 2331 of that title; and
(B) for official purposes related to the investigation or prosecution of an offense described in paragraph (1)(A), retain, disseminate, and use (including as evidence at trial or in other administrative or judicial proceedings) such records, consistent with such guidelines as the Attorney General, after consultation with the Secretary, shall issue to protect confidentiality.
(2) Application and approval
(A) In general.—An application under paragraph (1) shall certify that there are specific and articulable facts giving reason to believe that the education records are likely to contain information described in paragraph (1)(A).
(B) The court shall issue an order described in paragraph (1) if the court finds that the application for the order includes the certification described in subparagraph (A).
(3) Protection of educational agency or institution
An educational agency or institution that, in good faith, produces education records in accordance with an order issued under this subsection shall not be liable to any person for that production.
(4) Record-keeping
Subsection (b)(4) of this section does not apply to education records subject to a court order under this subsection.

Section 3. Comment.

45 CFR §164.520 reads:

§164.520 Notice of privacy practices for protected health information.
(a) *Standard: Notice of privacy practices*—(1) *Right to notice.* Except as provided by paragraph (a)(2) or (3) of this section, an individual has a right to adequate notice of the uses and disclosures of protected health information that may be made by the covered entity, and of the individual's rights and the covered entity's legal duties with respect to protected health information.
(2) *Exception for group health plans.* (i) An individual enrolled in a group health plan has a right to notice:
(A) From the group health plan, if, and to the extent that, such an individual does not receive health benefits under the group health plan through an insurance contract with a health insurance issuer or HMO; or
(B) From the health insurance issuer or HMO with respect to the group health plan through which such individuals receive their health benefits under the group health plan.
(ii) A group health plan that provides health benefits solely through an insurance contract with a health insurance issuer or HMO, and that creates or receives protected health information in addition

to summary health information as defined in §164.504(a) or information on whether the individual is participating in the group health plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO offered by the plan, must:
(A) Maintain a notice under this section; and
(B) Provide such notice upon request to any person. The provisions of paragraph (c)(1) of this section do not apply to such group health plan.
(iii) A group health plan that provides health benefits solely through an insurance contract with a health insurance issuer or HMO, and does not create or receive protected health information other than summary health information as defined in §164.504(a) or information on whether an individual is participating in the group health plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO offered by the plan, is not required to maintain or provide a notice under this section.
(3) *Exception for inmates.* An inmate does not have a right to notice under this section, and the requirements of this section do not apply to a correctional institution that is a covered entity.
(b) *Implementation specifications: Content of notice*—(1) *Required elements.* The covered entity must provide a notice that is written in plain language and that contains the elements required by this paragraph.
(i) *Header.* The notice must contain the following statement as a header or otherwise prominently displayed:
"THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY."
(ii) *Uses and disclosures.* The notice must contain:
(A) A description, including at least one example, of the types of uses and disclosures that the covered entity is permitted by this subpart to make for each of the following purposes: treatment, payment, and health care operations.
(B) A description of each of the other purposes for which the covered entity is permitted or required by this subpart to use or disclose protected health information without the individual's written authorization.
(C) If a use or disclosure for any purpose described in paragraphs (b)(1)(ii)(A) or (B) of this section is prohibited or materially limited by other applicable law, the description of such use or disclosure must reflect the more stringent law as defined in §160.202 of this subchapter.
(D) For each purpose described in paragraph (b)(1)(ii)(A) or (B) of this section, the description must include sufficient detail to place the individual on notice of the uses and disclosures that are permitted or required by this subpart and other applicable law.
(E) A description of the types of uses and disclosures that require an authorization under §164.508(a)(2)-(a)(4), a statement that other uses and disclosures not described in the notice will be made only with the individual's written authorization, and a statement that the individual may revoke an authorization as provided by §164.508(b)(5).
(iii) *Separate statements for certain uses or disclosures.* If the covered entity intends to engage in any of the following activities, the description required by paragraph (b)(1)(ii)(A) of this section must include a separate statement informing the individual of such activities, as applicable:
(A) In accordance with §164.514(f)(1), the covered entity may contact the individual to raise funds for the covered entity and the individual has a right to opt out of receiving such communications; (B) In accordance with §164.504(f), the group health plan, or a health insurance issuer or HMO with respect to a group health plan, may disclose protected health information to the sponsor of the plan; or
(C) If a covered entity that is a health plan, excluding an issuer of a long-term care policy falling within paragraph (1)(viii) of the definition of *health plan,* intends to use or disclose protected health information for underwriting purposes, a statement that the covered entity is prohibited from using or disclosing protected health information that is genetic information of an individual for such purposes.
(iv) *Individual rights.* The notice must contain a statement of the individual's rights with respect to protected health information and a brief description of how the individual may exercise these rights, as follows:
(A) The right to request restrictions on certain uses and disclosures of protected health information as provided by §164.522(a), including a statement that the covered entity is not required to agree to a requested restriction, except in case of a disclosure restricted under §164.522(a)(1)

(B) The right to receive confidential communications of protected health information as provided by §164.522(b), as applicable;
(C) The right to inspect and copy protected health information as provided by §164.524;
(D) The right to amend protected health information as provided by §164.526;
(E) The right to receive an accounting of disclosures of protected health information as provided by §164.528; and
(F) The right of an individual, including an individual who has agreed to receive the notice electronically in accordance with paragraph (c)(3) of this section, to obtain a paper copy of the notice from the covered entity upon request.
(v) *Covered entity's duties.* The notice must contain:
(A) A statement that the covered entity is required by law to maintain the privacy of protected health information, to provide individuals with notice of its legal duties and privacy practices with respect to protected health information, and to notify affected individuals following a breach of unsecured protected health information;
(B) A statement that the covered entity is required to abide by the terms of the notice currently in effect; and
(C) For the covered entity to apply a change in a privacy practice that is described in the notice to protected health information that the covered entity created or received prior to issuing a revised notice, in accordance with §164.530(i)(2)(ii), a statement that it reserves the right to change the terms of its notice and to make the new notice provisions effective for all protected health information that it maintains. The statement must also describe how it will provide individuals with a revised notice.
(vi) *Complaints.* The notice must contain a statement that individuals may complain to the covered entity and to the Secretary if they believe their privacy rights have been violated, a brief description of how the individual may file a complaint with the covered entity, and a statement that the individual will not be retaliated against for filing a complaint.
(vii) *Contact.* The notice must contain the name, or title, and telephone number of a person or office to contact for further information as required by §164.530(a)(1)(ii).
(viii) *Effective date.* The notice must contain the date on which the notice is first in effect, which may not be earlier than the date on which the notice is printed or otherwise published.
(2) *Optional elements.* (i) In addition to the information required by paragraph (b)(1) of this section, if a covered entity elects to limit the uses or disclosures that it is permitted to make under this subpart, the covered entity may describe its more limited uses or disclosures in its notice, provided that the covered entity may not include in its notice a limitation affecting its right to make a use or disclosure that is required by law or permitted by §164.512(j)(1)(i).
(ii) For the covered entity to apply a change in its more limited uses and disclosures to protected health information created or received prior to issuing a revised notice, in accordance with §164.530(i)(2)(ii), the notice must include the statements required by paragraph (b)(1)(v)(C) of this section.
(3) *Revisions to the notice.* The covered entity must promptly revise and distribute its notice whenever there is a material change to the uses or disclosures, the individual's rights, the covered entity's legal duties, or other privacy practices stated in the notice. Except when required by law, a material change to any term of the notice may not be implemented prior to the effective date of the notice in which such material change is reflected.
(c) *Implementation specifications: Provision of notice.* A covered entity must make the notice required by this section available on request to any person and to individuals as specified in paragraphs (c)(1) through (c)(3) of this section, as applicable.
(1) *Specific requirements for health plans.* (i) A health plan must provide the notice:
(A) No later than the compliance date for the health plan, to individuals then covered by the plan;
(B) Thereafter, at the time of enrollment, to individuals who are new enrollees.
(ii) No less frequently than once every three years, the health plan must notify individuals then covered by the plan of the availability of the notice and how to obtain the notice.
(iii) The health plan satisfies the requirements of paragraph (c)(1) of this section if notice is provided to the named insured of a policy under which coverage is provided to the named insured and one or more dependents.
(iv) If a health plan has more than one notice, it satisfies the requirements of paragraph (c)(1) of this section by providing the notice that is relevant to the individual or other person requesting the notice.

(v) If there is a material change to the notice:
(A) A health plan that posts its notice on its web site in accordance with paragraph (c)(3)(i) of this section must prominently post the change or its revised notice on its web site by the effective date of the material change to the notice, and provide the revised notice, or information about the material change and how to obtain the revised notice, in its next annual mailing to individuals then covered by the plan.
(B) A health plan that does not post its notice on a web site pursuant to paragraph (c)(3)(i) of this section must provide the revised notice, or information about the material change and how to obtain the revised notice, to individuals then covered by the plan within 60 days of the material revision to the notice.
(2) *Specific requirements for certain covered health care providers.* A covered health care provider that has a direct treatment relationship with an individual must:
(i) Provide the notice:
(A) No later than the date of the first service delivery, including service delivered electronically, to such individual after the compliance date for the covered health care provider; or
(B) In an emergency treatment situation, as soon as reasonably practicable after the emergency treatment situation.
(ii) Except in an emergency treatment situation, make a good faith effort to obtain a written acknowledgment of receipt of the notice provided in accordance with paragraph (c)(2)(i) of this section, and if not obtained, document its good faith efforts to obtain such acknowledgment and the reason why the acknowledgment was not obtained;
(iii) If the covered health care provider maintains a physical service delivery site:
(A) Have the notice available at the service delivery site for individuals to request to take with them; and
(B) Post the notice in a clear and prominent location where it is reasonable to expect individuals seeking service from the covered health care provider to be able to read the notice; and
(iv) Whenever the notice is revised, make the notice available upon request on or after the effective date of the revision and promptly comply with the requirements of paragraph (c)(2)(iii) of this section, if applicable.
(3) *Specific requirements for electronic notice.* (i) A covered entity that maintains a web site that provides information about the covered entity's customer services or benefits must prominently post its notice on the web site and make the notice available electronically through the web site.
(ii) A covered entity may provide the notice required by this section to an individual by e-mail, if the individual agrees to electronic notice and such agreement has not been withdrawn. If the covered entity knows that the e-mail transmission has failed, a paper copy of the notice must be provided to the individual. Provision of electronic notice by the covered entity will satisfy the provision requirements of paragraph (c) of this section when timely made in accordance with paragraph (c)(1) or (2) of this section.
(iii) For purposes of paragraph (c)(2)(i) of this section, if the first service delivery to an individual is delivered electronically, the covered health care provider must provide electronic notice automatically and contemporaneously in response to the individual's first request for service. The requirements in paragraph (c)(2)(ii) of this section apply to electronic notice.
(iv) The individual who is the recipient of electronic notice retains the right to obtain a paper copy of the notice from a covered entity upon request.
(d) *Implementation specifications: Joint notice by separate covered entities.* Covered entities that participate in organized health care arrangements may comply with this section by a joint notice, provided that:
(1) The covered entities participating in the organized health care arrangement agree to abide by the terms of the notice with respect to protected health information created or received by the covered entity as part of its participation in the organized health care arrangement;
(2) The joint notice meets the implementation specifications in paragraph (b) of this section, except that the statements required by this section may be altered to reflect the fact that the notice covers more than one covered entity; and
(i) Describes with reasonable specificity the covered entities, or class of entities, to which the joint notice applies;

(ii) Describes with reasonable specificity the service delivery sites, or classes of service delivery sites, to which the joint notice applies; and
(iii) If applicable, states that the covered entities participating in the organized health care arrangement will share protected health information with each other, as necessary to carry out treatment, payment, or health care operations relating to the organized health care arrangement.
(3) The covered entities included in the joint notice must provide the notice to individuals in accordance with the applicable implementation specifications of paragraph (c) of this section. Provision of the joint notice to an individual by any one of the covered entities included in the joint notice will satisfy the provision requirement of paragraph (c) of this section with respect to all others covered by the joint notice.
(e) *Implementation specifications: Documentation.* A covered entity must document compliance with the notice requirements, as required by §164.530(j), by retaining copies of the notices issued by the covered entity and, if applicable, any written acknowledgments of receipt of the notice or documentation of good faith efforts to obtain such written acknowledgment, in accordance with paragraph (c)(2)(ii) of this section.

Appendix F

Community Pharmacy Quality-Related Event (QRE) Data Collection Form

QRE Prescription Data			
Attach copy of: ❑ prescription ❑ label ❑ photo of vial (mark all available)			
Original Rx date: Refill date: Date/time reported:			
Drug Prescribed (name, strength, and dosage form): Directions: Medication indication:			
Prescription was received by the pharmacy via: ❑ telephone, by whom: ❑ written ❑ computer ❑ fax			

QRE Data	
QRE Type: (select all that apply)	B. A failure to identify and manage
A. Prescription processing error:	❑ Over/under-utilization (1)
❑ Incorrect drug (1)	❑ Therapeutic duplication (2)
❑ Incorrect strength (2)	❑ Drug-disease contraindications (3)
❑ Incorrect dosage form (3)	❑ Drug-drug interactions (4)
❑ Incorrect patient (4)	❑ Incorrect duration of treatment (5)
❑ Inaccurate or incorrect packaging, labeling, or directions (5)	❑ Incorrect dosage (6)
❑ Other (6):	❑ Drug-allergy interaction (7)
	❑ Clinical abuse/misuse (8)

QRE Contributing Factors
Day of the week and time of QRE:

No. of new prescriptions:	No. of refill prescriptions: RPh to tech ratio:
RPh staff status: ❑ regular staff ❑ part-time/substitute staff length of employment:	
No. of hours RPh on duty:	Average No. of prescriptions filled per hour:
No. of other RPhs on duty:	No. of support staff on duty:
Automation ❑ yes ❑ no	Type:
❑ Computer software (lighting/noise/distractions/workspace	❑ Environmental
❑ Equipment failure ❑ Failure to supervise	
❑ Legibility	❑ Increased Rx volume as compared to normal
❑ Shift change ❑ Policies and/or procedure not followed	
❑ Staff shortage ❑ Sound alike/look alike medication	
❑ Other, explain	
Describe factors checked above and/or other preliminary root contributors:	
Counseling was offered: ❑ yes ❑ no	Counseling was given: ❑ yes ❑ no
Documentation of offer: ❑ yes ❑ no	Documentation of counseling: ❑ yes ❑ no

Pharmacist Information
Name of verifying pharmacist:
Name(s) of other person(s) and title(s) involved in processing the prescription:
Describe remedial action taken:

If patient received medication, complete Patient and Prescriber Information Sections.

Patient Information
Patient's name: Prescription was dispensed to:
Address: Telephone No.:
Patient DOB: Sex: M or F If minor, name of parent(s)/guardian(s):
Who discovered the error/relationship to patient?:
Did patient ingest medication? ❑ yes ❑ no If yes, how many doses?:
❑ Not harmed ❑ Received treatment and or increased monitoring ❑ Seriously harmed, explain ❑ Did not survive, explain

Prescriber Information
Was the prescriber informed: ❑ yes ❑ no If yes, provide date:
Prescriber's name: Telephone No.:
Prescriber's instructions/comments:

Report Affirmation
Additional comments:
Name and title of preparer of this report:
Signature: Date:

Community Pharmacy Continuous Quality Improvement Program Inspection Form

General Information		
Pharmacy name:	License No.:	
Address:	Phone No.:	
Pharmacist-in-charge (PIC):		PIC License No.:
Date/time:	Date of previous inspection: Attach copy of previous inspection	
Purpose of inspection ❑ Complaint ❑ Routine ❑ Follow-up ❑ New pharmacy ❑ Change in owner ❑ Other Comment:		

Pharmacy Staff (Include pharmacist, intern, technician, cashier)			
Name	**Title**	**License No.**	**Present**

P=Present	A=Absent	N/A= Not applicable		
CQI Program		**P**	**A**	**N/A**
	Policy and procedures in place			
	Periodic CQI meetings held			
	Quality-Related Events (QRE) recorded			
	Sentinel Events			
	Workload compiled			
	Staffing needs analyzed/addressed			
	Outcome-based pharmacy technician training conducted			
	Technology utilized in current/updated			
	Pharmacist Care initiatives in place			
	Consumer survey policy in place			
	Professional performance evaluation policy in place			
Comments: **Recommendations:**				
Report Affirmation				
Additional comments:				
Pharmacist signature: Date:				
Surveyor signature: Date:				

Community Pharmacy Quality Self-Audit

Each pharmacy shall conduct a quality self-audit at least quarterly and upon change of pharmacist-in-charge. The goals of the quality self-audit are to monitor changes in the number of quality-related events (QRE) over time, to evaluate compliance with CQI procedures, and to develop a plan for improved adherence with the CQI Program.

General Information		
Date:	Quarterly ❑	Change of pharmacist-in-charge ❑
Pharmacy name:	Address:	
Telephone:	License No.:	
Pharmacist-in-charge:	Date of previous self-audit:	

Pharmacy Staff (Include pharmacist, intern, technician, cashier)			
Name	**Title**	**License No.**	**Start Date**

Staffing/Workload Date	
Staffing	**Yes/No/Answer**
Number of pharmacist hours allocated per week	
Number of pharmacy technician hours allocated per week	
Number of other pharmacy support staff hours allocated per week	
Number of certified technicians	
Number of noncertified technicians	
Technicians are encouraged to become certified	
Outcome-based pharmacy technician training program (If yes, check all applicable)	
❑ Cash register ❑ Prescription intake ❑ Prescription filling	
❑ Inventory ❑ Returning stock bottles to shelf ❑ Clean room	
❑ Computer data entry ❑ Pharmaceutical calculations ❑ Knowledge of practice settings	
❑ Identifying drugs, doses, routes of Administration, dosage forms, etc	
❑ Pharmaceutical and medical terminology ❑ Other	
Workload	**Yes/No/Answer**
Number of hours pharmacy department is open during the week	
Average number of prescriptions filled per week	
Usual ratio of pharmacist to technicians	
Policy is in place that requires increased staffing if workload increases	
Automation	**Yes/No/Answer**
Type	

CQI Program Data

General	Yes/No/Answer
Pharmacy has a CQI policy and procedure manual	
Employees must verify review of policy and procedure manual	
Periodic CQI Meetings	**Yes/No/Answer**
Pharmacy holds CQI meetings (if yes, indicate frequency)	
Average length of CQI meetings in minutes	
Staff attending CQI meetings ❑ Pharmacists ❑ Technicians ❑ Manager ❑ Pharmacy supervisor ❑ Owner ❑ Other	

Program Documentation Methods	Yes/No/Answer
QRE forms utilized	
Method used to document interaction in relation to CQI program ❑ Computer database ❑ On prescription ❑ Custom-made form ❑ Standard form ❑ Other	
Method used to verify drug product with prescription label ❑ Bar code ❑ NDC code ❑ Name of product ❑ Other	
First time refills are checked against hardcopy	
Consumer Surveys	**Yes/No/Answer**
Consumer survey policy in place, if yes, indicate frequency	
Other technique in place to evaluate performance, if yes, describe	
Method of conducting consumer survey ❑ Distributed at time of dispensing ❑ Mail ❑ Telephone ❑ Other	
Consumer survey feedback utilized to improve delivery of pharmacy services	
Outcome-Based Professional Performance Evaluation	

Frequency ❑ Annually ❑ Biannually ❑ Quarterly ❑ Other
Staff required to have outcome-based professional performance evaluations ❑ All employees ❑ Full-time pharmacists ❑ Part-time pharmacists ❑ Other
Self-audit includes:
❑ Number of overridden drug-drug interaction warnings
❑ Number of patients that received duplicative drug therapy
❑ Number of patients that received extensive counseling
❑ Number of QREs tracked over time. Indicate time period

QRE Incidents

Utilizing QRE Data Collection Sheets, compile the data below.

Date								
QRE type (eg, A(1) = incorrect drug dispensed)								
Drug name and strength								
Rx received via:								
New or refill								
Day of week/time								
RPh to tech ration								
RPh staff status								
No. of hrs RPh on duty								
No. of other pharmacists on duty								
No. of other support staff								
Average No. of prescriptions/hour								

Responsible pharmacist's name								
Patient received medication								
Prescriber notified								
Counseling offered								
Counseling accepted								

Appendix G

Model Prescription Monitoring Program Act

Section 1. Short Title.

This Act shall be known and may be cited as the Model Prescription Monitoring Program Act.

Section 2. Legislative Findings.

(Insert State-appropriate mission/purposes.)

Section 3. Purpose.

(Insert State-appropriate mission/purposes.)

Section 4. Definitions.

(a) "Dispenser" means a person authorized in this State to distribute to the ultimate user a substance monitored by the Prescription Monitoring Program, but does not include:
  (1) a licensed hospital or institutional facility Pharmacy that distributes such substances for the purposes of inpatient care;
  (2) a licensed nurse or medication aide who administers such a substance at the direction of a licensed physician;

(b) "Drug of Concern" means any prescription or over-the-counter medication that demonstrates a potential for abuse, particularly those identified by Boards of Pharmacy, law enforcement, and addiction treatment professionals.

(c) "Prescription Monitoring Program Information" means information submitted to and maintained by the Prescription Monitoring Program.[167]

(d) "Prescription Monitoring Program (PMP)" means a program established under Section 5 of this Act.

Section 5. Establishment Of A Prescription Monitoring Program.

(a) The Board of Pharmacy shall establish and maintain an electronic system for monitoring all controlled substances in Schedules II through V, all State-specified controlled substances in Schedules II through V, and State-specified Drugs of Concern dispensed to patients in this State.

(b) The Board of Pharmacy may contract with a vendor to establish and maintain the electronic monitoring system pursuant to guidelines, which the Board of Pharmacy shall promulgate.

Section 6. Reporting Of Prescription Monitoring Program Information.

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[167] This reporting exception also applies to situations where a patient, who has been dispensed controlled substance medications during a stay in an institutional facility, is allowed to retain any remaining medication upon discharge.

(a) Each Dispenser shall submit to the Board of Pharmacy, by electronic means, or other format specified in a waiver granted by the Board of Pharmacy, at a minimum of every seven days, information specified by the Board of Pharmacy, including:
(1) Drug Enforcement Administration Number of Dispenser;
(2) Drug Enforcement Administration Number and name of the practitioner who prescribed the drug;
(3) name, address, and telephone number of the ultimate user;
(4) identification of the drug by a national drug code number;
(5) quantity dispensed;
(6) number of days supplied;
(7) number of refills ordered;
(8) whether drug was dispensed as a refill or as a new prescription;
(9) date of dispensing;
(10) if a refill, date of the original dispensing; and
(11) such other information as may be required by State law.

(b) The Board of Pharmacy may grant a waiver of electronic submission to any Dispenser for good cause, including financial hardship, as determined by the Board of Pharmacy. The waiver shall State the format and frequency with which the Dispenser shall submit the required information.

Section 7. Access To Prescription Monitoring Program Information/Confidentiality.

(a) Except as indicated in paragraphs (b), (c), and (d) of this Section 7, Prescription Monitoring Program Information submitted to the Board of Pharmacy shall be considered Protected Health Information and not subject to public or open records laws.

(b) The Board of Pharmacy shall review the Prescription Monitoring Program Information. If there is reasonable cause to believe a violation of law (or breach of occupational standards) may have occurred, the Board shall notify the appropriate law enforcement and occupational licensing, certification, or regulatory agency or entity, and provide Prescription Monitoring Program Information required for an investigation.[168]

(c) The Board of Pharmacy may provide Prescription Monitoring Program Information for public research, policy or education purposes, to the extent all information has been De-identified.

(d) The following persons may access the Prescription Monitoring Program Information in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar Protected Health Information under federal and State law and regulation:
(1) Practitioners (or agents thereof) or Dispensers who certify, under the procedures determined by the State, that the requested information is for the purpose of providing medical or pharmaceutical treatment or evaluating the need for such treatment to a bona fide current patient;

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[168] This section is intended to allow boards of pharmacy to evaluate Prescription Monitoring Program information and determine appropriate information to provide to law enforcement entities. It is not intended to allow law enforcement officials open access to all data.

(2) Boards of Pharmacy or vendors/contractors establishing and maintaining the Prescription Monitoring Program;
(3) other state licensing, certification, or regulatory agencies that license, certify, or regulate health care professionals authorized to prescribe, administer, and dispense controlled substances, which certify, under the procedures determined by the State, that the requested information is related to an individual investigation or proceeding involving the unlawful diversion or misuse of a reportable substance, and such information will further the purpose of the investigation or assist in the proceeding;
(4) local, State, or Federal law enforcement, narcotics control, licensure, disciplinary, or program authorities, which certify, under the procedures determined by the State, that the requested information is related to an individual investigation or proceeding involving the unlawful diversion or misuse of a reportable substance, and such information will further the purpose of the investigation or assist in the proceeding;
(5) other appropriate entities as determined by the Board of Pharmacy[169]; and
(6) Patients who certify, under the procedures determined by the State, that the requested information is for the purpose of obtaining and reviewing their own records.

(e) The Board of Pharmacy shall be immune from civil liability arising from inaccuracy of any of the information submitted to the Board of Pharmacy pursuant to this Act.

Section 8. Unlawful Acts And Penalties.

(a) A Dispenser who knowingly fails to submit Prescription Monitoring Program Information to the Board of Pharmacy as required by this Act shall be subject to (insert appropriate administrative, civil, or criminal penalty).

(b) A person who knowingly accesses or uses Prescription Monitoring Program Information without authorization in violation of this Act shall be subject to (insert appropriate administrative, civil, or criminal penalty).

(c) A person authorized to have Prescription Monitoring Program Information pursuant to this Act who knowingly discloses such information in violation of this Act shall be subject to (insert appropriate administrative, civil, or criminal penalty).

(d) A person authorized to have Prescription Monitoring Program Information pursuant to this Act who uses such information in a manner or for a purpose in violation of this Act shall be subject to (insert appropriate administrative, civil, or criminal penalty).

Section 9. Evaluation, Data Analysis, And Reporting.

(a) The Board of Pharmacy shall design and implement an evaluation component to identify cost benefits of the Prescription Monitoring Program, and other information relevant to policy, research, and education involving substances monitored by the PMP.

(b) The Board of Pharmacy shall report to the (insert appropriate State decision makers, eg, legislature) on a periodic basis, no less than annually, about the cost-benefits and other information noted in paragraph (a).

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[169] It is recommended that appropriate entities include drug courts, district attorneys offices, or other similar entities, and only for the purpose of ensuring appropriate patient treatment, as opposed to efforts to search for information without knowledge of whether such information exists.

Section 10. Rules And Regulations.

The Board of Pharmacy shall promulgate rules and regulations necessary to implement the provisions of this Act.

Section 11. Severability.

If any provision of this Act or application thereof to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the Act which can be given effect without the invalid provisions or applications, and to this end the provisions of this Act are severable.

Section 12. Effective Date.

This Act shall be effective on (insert specific date or reference to normal State method of determination of the effective date).

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