Report of the Committee on Law Enforcement/Legislation

Members Present:
Jeenu Philip (FL), *chair*; Paul Brand (MT); Kevin Dang (AZ); Laura Forbes (VI); Kari Shanard-Koenders (SD); Kim Tanzer (MA); Linda Witzal (NJ); Jenny Downing Yoakum (TX).

Others Present:
Nicole Chopski, *Executive Committee liaison*; Carmen A. Catizone, Melissa Madigan, Eileen Lewalski, Maureen Schanck, Romy Schafer, *NABP staff*.

Introduction:
The Committee on Law Enforcement/Legislation met January 23-24, 2019, at NABP Headquarters, Mount Prospect, IL.

Review of the Committee Charge
Committee members reviewed their charge and accepted it as follows:

1. Review and comment on existing legislation and rules for the practice of pharmacy, legal distribution of drugs, and related areas within pharmacy.
2. Develop model regulations for pharmacy as assigned by the Executive Committee, or from resolutions adopted by the members of the Association, or from reports of the other committees of the Association.
3. Recommend to the Executive Committee areas where model regulations are needed in pharmacy for improving the protection of the public health.

LE/L Recommendation 1: The Committee Recommends Approving the Amendments to the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* Suggested by the Suspicious Orders Work Group, With Revisions.

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

National Association of Boards of Pharmacy
Model State Pharmacy Act

Article I

Title, Purpose, and Definitions

…

Section 105. Definitions.

…

"~~Potential~~ Diversion Activity" means activity where evidence exists that controlled substances or Drugs of Concern are ~~likely~~ being diverted ~~or have the potential for diversion~~ from legitimate channels.

…

"Drug of Concern" means any prescription or over-the-counter medication that demonstrates a potential for abuse, particularly ~~controlled substances and~~ those identified by Boards of Pharmacy, law enforcement, and addiction treatment professionals. ~~legislative or regulatory enactments.~~

…

"Suspicious Order" includes, but is not limited to, an unsubstantiated order with the following characteristic(s):

(1) ~~Orders~~ unusual size or frequency; or

(2) ~~Orders~~ deviating substantially from a normal pattern.~~;~~

~~(3) Orders of unusual frequency.~~

National Association of Boards of Pharmacy Model State Pharmacy Act

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, Repackagers, Third-Party Logistics Providers, 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 verify compliance with federal requirements and 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 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, Repackager, Third-Party Logistics Provider, 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, Manufacturer, Repackager, Third-Party Logistics Provider, Wholesale Distributor, Pharmacy, or Pharmacy Benefits Manager on any of the following grounds:[1]

(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) ~~the furnishing of~~ willfully and knowingly submitting false or fraudulent information or omitting information on due diligence questionnaires and/or attestation documents regarding the purchase or receipt of Drugs from Manufacturers, Repackagers, Third-Party Logistics Providers, and Wholesale Distributors.

…

Model Rules for the Practice of Pharmacy

…

Section 3. 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:[2]

(A) Policies and procedures addressing the following:

[1] 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.

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

(-a-) the provision of Pharmacy services;[3]

(-b-) the procurement, storage, security, and disposition of Drugs and Devices, particularly controlled substances and drugs of concern ~~and the accurate completion and submission of due diligence questionnaires and attestation documents regarding the purchase or receipt of Drugs from Manufacturers, Repackagers, Third-Party Logistics Providers, and Wholesale Distributors~~;

(-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

...

Section 16. 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

[3] 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 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**.

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 Services, absent a clear benefit to the patient, solely in response to promotion or marketing activities.

(l) willfully and knowingly completing and submitting inaccurate due diligence questionnaires and attestation documents regarding the purchase or receipt of Drugs from Manufacturers, Repackagers, Third-Party Logistics Providers, and Wholesale Distributors.

Model Rules for the Licensure of Manufacturers, Repackagers, Third-Party Logistics Providers, and Wholesale Distributors

…

Section 7. Operations/Reporting Requirements.

(a) Manufacturers, Repackagers, Third-Party Logistics Providers, and Wholesale Distributors must comply with all reporting requirements and exchange Transaction History, Transaction Information, and Transaction Statements with authorized Trading Partners as outlined in Federal law.

(b) Manufacturers, Repackagers, Third-Party Logistics Providers, and Wholesale Distributors shall design and operate a system to identify and report Suspicious Orders of controlled substances and Drugs of Concern to a program approved by the Board ~~for Suspicious Orders or Drugs of Concern by customers and potential customers~~.

(1) Suspicious Orders shall be submitted electronically to an approved program ~~the NABP Suspicious Orders System~~ within five days of the order being identified as suspicious by the Manufacturer, Repackager, Third-Party Logistics Provider, and Wholesale Distributor, and must include, but not be limited to:

(i) Customer name;
(ii) NABP e-Profile ID;
(iii) Customer address;
(iv) Customer DEA registration number;
(v) State license number(s);
(vi) Transaction date;
(vii) Drug name;
(viii) NDC number;
(ix) Quantity ordered; and
(x) Indication of whether the drug was shipped, and if not, the factual basis for the refusal to supply.

(2) Zero reports shall be submitted if no suspicious orders have been identified in a calendar month, and such reports shall be submitted within 15 days of the end of the calendar month.

(3) Manufacturers, Repackagers, Third-Party Logistics Providers, and Wholesale Distributors may apply to the Board for an exemption from the reporting requirements if they do not distribute controlled substances or Drugs of Concern.

(c) Except as described in paragraph 7(d), a Manufacturer, Repackager, Third-Party Logistic Provider, or Wholesale Distributor shall exercise due diligence to identify customers ordering or seeking to order controlled substances or Drugs of Concern and establish the normal and expected transactions conducted by those customers, as well as to identify and prevent the sale of controlled substances or Drugs of Concern that are likely to be diverted from legitimate channels. Such due diligence measures shall include, but are not limited to the following, which shall be conducted prior to an initial sale and on a~~n annual~~ regular basis, as necessary:

(1) Questionnaires and affirmative steps by the Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale Distributor to confirm the accuracy and validity of the information provided;

(2) For a customer who is a prescriber, confirmation of prescriber type, specialty practice area, and if the prescriber personally furnishes controlled substances or Drugs of Concern, ~~and~~ the quantity furnished;

(3) Review of drug utilization reports; and

(4) Obtaining and conducting a review of the following:

(i) Methods of payment accepted and in what ratios;

(ii) The ratio of controlled versus non-controlled Drug orders and overall sales;

(iii) Orders for controlled substances or Drugs of Concern from other Manufacturers, Repackagers, Third-Party Logistics Providers, or Wholesale Distributors made available by US DEA's Automation of Reports and Consolidated Orders System; and

(iv) The ratio of out-of-state patients served compared to in-state patients.

(d) A Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale Distributor receiving a request for an initial sale of a controlled substance or Drug of Concern may conduct the sale ~~without~~ before complying with paragraph 7(c) if all the following apply:

(1) The sale is to a new customer;

(2) The Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale Distributor documents that the order is to meet an emergent need; ~~and~~

(3) The Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale Distributor completes the requirements of 7(c) no later than 60 days from the date of sale.

(e) A Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale Distributor receiving a request from an existing customer to purchase a controlled substance or Drug of Concern, the size/quantity of which exceeds the established algorithm limitations or quota restrictions for such customer, may sell the Drug of Concern or controlled substance provided that the customer submits documentation of an emergent need for a specific patient.

(~~e~~f) Any customer that is believed to ~~likely~~ be engaged in ~~P~~potential Diversion Activities, including those to whom a Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale

Distributor refuses to sell, shall be electronically reported ~~by a Wholesale Distributor~~ to a program approved by the Board. Such reports shall include:

(1) Customer name;
(2) NABP e-Profile ID;
(3) Customer address;
(4) DEA number;
(5) State license number(s); and
(6) A detailed explanation of why the Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale Distributor identified the customer as a possible diversion risk.

Such reports shall be submitted within ~~five~~ 30 days of refusal, cessation, or identification by the Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale Distributor.

(~~f~~g) Within 90 days of the effective date of this rule, a Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale Distributor shall provide to a program approved by the Board, information on all customers in the state where the Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale Distributor has refused to sell or has stopped selling within the past year because the Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale Distributor has identified the customer(s) as engaging in ~~possible~~ potential Diversion Activity that may cause reported Drugs to be diverted from legitimate channels.

(~~g~~h) All licensed Manufacturers, Repackagers, Third-Party Logistics Providers, and Wholesale Distributors shall submit all reports to a ~~the NABP Suspicious Orders System~~ Board-approved program in a DEA Automation of Reports and Consolidated Orders System format.

…

Section 10. Policies and Procedures.

Manufacturers, Repackagers, Third-Party Logistics Providers, and 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 inventories. Manufacturers, Repackagers, Third-Party Logistics Providers, and Wholesale Distributors shall include in their written policies and procedures the following:[4]

(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 Manufacturers, Repackagers, Third-Party Logistics Providers, and Wholesale Distributors prepare for, protect against, and handle any crisis that affects

[4] 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.

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.

(d) A procedure for the destruction of outdated Prescription Drugs in accordance with federal and state laws.

(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 as required to FDA, 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) as required to the Board, FDA, and, if applicable, DEA.

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

(i) Procedures addressing:

(1) The design and operation of the Suspicious Order monitoring and reporting system;

(2) Mandatory annual training for staff responsible for identifying and reporting Suspicious Orders and potential ~~d~~Diversion ~~a~~Activities. Such training must include the following:

(i) The Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale Distributor's Suspicious Order monitoring system

(ii) The process to collect all relevant information on customers in accordance with paragraph 7(c);

(iii) The requirement and process for submission of Suspicious Orders and information on customers who ~~may likely~~ engage in ~~P~~potential Diversion Activities.

(j) A procedure for timely responding to customers who submit purchase orders for patients with emergent needs.

…

Background:

The committee members were advised that after the Suspicious Orders Work Group met to develop recommendations, the United States Congress passed the SUPPORT for Patients and Communities Act, which addressed many of the reporting requirements recommended by the work group and charged the US Attorney General, in collaboration with US Drug Enforcement Administration (DEA), to develop a suspicious order reporting system. Nevertheless, the committee members agreed that it was imperative that NABP have model language available should DEA or other federal agencies seek NABP's input in this matter.

After thoughtful review and consideration, the committee members recommended the following amendments. First, "manufacturer, repackager, and third-party logistics provider"

should be added wherever “wholesale distributor” appears, if applicable, to be consistent with the Drug Supply Chain Security Act.

Committee members also agreed that it is imperative to require the truthful reporting regarding orders to prescription drug suppliers when asked. Consequently, the committee further recommended that the submission of truthful information be required and that the responsibility to provide truthful information be shared by the pharmacist-in-charge and the pharmacy permittee/owner. Also, with this in mind, members recommended that willful misreporting of purchase order information be added to the unprofessional conduct section of the Model Rules for the Practice of Pharmacy.

The committee reviewed the definitions recommended by the Suspicious Orders Work Group and determined that controlled substances should be removed from the definition of “drug of concern,” since in most states “drugs of concern” are defined separately from “controlled substances.” Members also recommended that the definition of “suspicious order” include the word “unsubstantiated” when referring to orders of unusual size or frequency and deviating from typical patterns. After some spirited discussion, the committee felt that it made more sense to define the term “diversion activity” and to modify it with the word “potential” when referring to possible diversion activity, rather than define the narrower term “potential diversion activity.”

The committee recommended that the term “NABP Suspicious Orders System” not be included in the *Model Act* in light of the new federal reporting requirements outlined in the SUPPORT for Patients and Communities Act. Consequently, it was deleted and changed to a “board-approved program” to give deference to a federal reporting system that may, in the future, be established. There was also discussion about the need for manufacturers, repackagers, third-party logistics providers, and wholesale distributors to be able to apply for an exemption if they do not distribute controlled substances or drugs of concern. Thus, the committee recommended that the operations/reporting requirements section include a statement about such an exemption.

The committee members stressed the importance of limiting barriers to the dispensing of needed medication by pharmacies in a timely manner, especially in cases of an emergency. Mindful of their mission to protect the public, members recommended that the operations/reporting requirements section include a provision for existing customers of wholesale distributors to purchase a controlled substance or drug of concern outside of its normal ordering pattern, provided that the customer submits documentation of an emergent need for a specific patient. Furthermore, the committee recommended that the policies and procedures section for manufacturers, repackagers, third-party logistics providers, and wholesale distributors include procedures for timely responding to customers who submit purchase orders for patients with emergent needs.

LE/L Recommendation 2: The Committee Recommends Approving the Amendments to the *Model Act* Pursuant to the Recommendation of the Task Force to Develop Regulations Based on Standards of Care, With Revisions.

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

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.[5] 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.

[5] 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.

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 Certified Pharmacy Technicians and Certified Pharmacy Technician Candidates; the licensure, control, and 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.[6]

Section 104. Practice of Pharmacy.

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

Section 105. Definitions.

…

(a3) "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

[6] 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.

stop-loss insurance and excess of loss insurance),[7] 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.[8]

…

(b4) "Medication Therapy Management" is a distinct Pharmacist Care 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] 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 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.

[8] 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.

(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.

(c4) "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.

(d4) "Pharmacist Care Services" is the provision by a Pharmacist of patient care activities within this State or into this State, 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, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process.[9]

…

(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.

…

(d6) <u>"Standard of Care" means the degree of care a prudent and reasonable licensee or registrant with similar education, training, and experience will exercise under similar circumstances.</u>

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. Inclusion of or authorization for specific activities, such as the Administration of medications, is purposely not delineated in the definition in order to be empowering and not proscriptive. To assist states in the interpretation of the revised definition of the "Practice of Pharmacy," the *Model Act* includes the definition of "Pharmacist Care Services" and Model Rules for the Provision of Pharmacist Care Services for those states that need to include specific lists of activities or authorizations due to legislative and/or administrative policies and procedures.

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

[9] Objectives of Pharmacist Care Services 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 Services should be provided by all Pharmacists <u>within the Standard of Care</u> to the extent of their abilities regardless of the practice setting.

Background:
The committee members reviewed several suggested definitions for "standard of care" pursuant to the Task Force to Develop Regulations Based on Standards of Care's recommendation to develop a definition for inclusion in the *Model Act*. Members noted that it is important to include a definition that is not pharmacist-specific, so it can have broader applicability for other licensees, such as pharmacy technicians, as well. In addition to a new definition, the members agreed to amend the footnote regarding objectives of pharmacist care services to include a reference to standard of care.

LE/L Recommendation 3: The Committee Recommends Approving the Amendments to the *Model Act* Pursuant to the Recommendation of the PMP Steering Committee Report, With Revisions.

The recommended revisions by the PMP Steering Committee are denoted by underlines. The recommended revisions by the LE/L Committee are denoted by double underlines.

Appendix F

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) "Electronic Health Information Systems" means an electronic data intermediary, gateway, or hub that facilitates secure delivery of electronic health information to Practitioners or Dispensers, including:

(1) health information exchanges;
(2) health information networks;
(3) pharmacy software systems;
(4) electronic medical (health) record software applications; or
(5) electronic prescribing software applications.

(d) "Interoperability" means the sharing of Prescription Monitoring Program Information with another PMP, or the integration of Prescription Monitoring Program Information into the Electronic Health Information Systems.

(e) "Prescription Monitoring Program Information" means information submitted to and maintained by the Prescription Monitoring Program.[10]

(f) "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.

(c) The Board of Pharmacy shall promulgate rules or establish policy to include the following:
(1) using the PMP to improve patient care and to facilitate the goal of reducing misuse, abuse, overdose, addiction to and diversion of controlled substances and drugs of concern;
(2) implementing security and safeguards necessary to ensure information is released only to authorized individuals;
(3) developing criteria for referring Prescription Monitoring Program information to a law enforcement agency
(4) developing criteria for referring Prescription Monitoring Program Information to a licensing boards, or other state or federal agency charged with the regulation of prescribing, dispensing, or administering a controlled substance or drug of concern;
(5) designing and implementing training, education, and/or instruction in the appropriate access to and use of the PMP;
(6) adopting the most recent version of the American Society for Automation in Pharmacy (ASAP) technical standards for electronic reporting of Prescription Monitoring Program Information; and
(7) incorporating technological improvement to facilitate the interoperability of the PMP with other state PMPs and Electronic Health Information Systems and to facilitate Prescribers' and Dispensers' access to and use of the PMP.

Section 6. Reporting Of Prescription Monitoring Program Information.

(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, within 24 hours, information specified by the Board of Pharmacy, including:

[10] 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.

(1) identification Number of Dispenser;
(2) identification number of the Prescriber;[11]
(3) patient name, address, and telephone number[12];
(4) patient gender;
(5) patient date of birth;
(6) identification of the drug by a national drug code number;
(7) quantity dispensed;
(8) number of days supplied;
(9) number of refills ordered;
(10) whether drug was dispensed as a refill or as a new prescription;
(11) date prescription was dispensed;[13]
(12) if a refill, date of the original dispensing;
(13) prescription number;
(14) date the prescription was issued by the Prescriber;
(15) method of payment for the prescription; and
(16) such other information as may be required by State law.

(b) Each Dispenser shall ensure that information reported to the PMP is correct and shall submit corrections when necessary.

(c) Each Dispenser shall reverse information for any prescription that was not dispensed.

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 professional or occupational standards) may have occurred, the Board shall notify the appropriate law enforcement, or professional or occupational licensing, certification, or regulatory agency or entity, and provide Prescription Monitoring Program Information required for an investigation.[14]

(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 (or agents thereof) 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, or verifying PMP information for prescriptions issued by practitioners;

[11] It is recommended that Boards of Pharmacy consider using practitioner's NPI number for identification purposes when applicable. Consider using state license numbers for veterinarians.

[12] For veterinary prescriptions, use the pet owner's name, address, telephone number, gender, and date of birth.

[13] It is recommended that the date prescription was dispensed be clarified to mean the date of delivery to the patient.

[14] 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 for the purpose of 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) entities that serve as sources of data impacting the identification and reporting of prescription drug injuries and deaths, such as, but not limited to, coroners' offices, to help address the prescription drug epidemic and improve patient care;
(6) other appropriate entities[15]; and
(7) 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. Interoperability.

(a) The Board of Pharmacy shall execute a memorandum of understanding to participate in a single national hub capable of facilitating interoperability among Prescription Monitoring Programs and between Prescription Monitoring Programs and Electronic Health Information Systems.

(b) The Board of Pharmacy shall ensure that access to Prescription Monitoring Program Information by other state Prescription Monitoring Programs is limited to persons described in Section 7(d).

(c) The Board of Pharmacy shall establish the technological connectivity and infrastructure to facilitate the secure delivery of Prescription Monitoring Program Information to authorized users of Prescription Monitoring Programs through other states' Prescription Monitoring Programs or Electronic Health Information Systems.

(d) Any such gateway, hub, or any Electronic Health Information System that facilitates the integration of Prescription Monitoring Program Information into a patient's medical record shall:
(1) verify the identity of the individual requesting the Information;
(2) verify the credential of the individual requesting the Information;
(3) provide the Board of Pharmacy with an audit trail for each request; and
(4) maintain the security and confidentiality of such information.

[15] It is recommended that other appropriate entities include drug courts, district attorneys' offices, addiction treatment professionals, 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 9. 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 10. 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).

Section 11. Rules And Regulations.

The Board of Pharmacy shall promulgate rules and regulations necessary to implement the provisions of this Act.

Section 12. 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 13. Effective Date.

This Act shall be effective on (insert specific date or reference to normal State method of determination of the effective date).

Background:

The committee discussed the disturbing trend whereby drug seekers are harming pets to obtain controlled substances and the subsequent increase in states requiring veterinary prescriptions to be reported to the state's PMP. Included in the discussion was that veterinarians are not required to obtain DEA registrations to prescribe drugs of concern, such as legend drugs that are deemed controlled substances only by the state. Moreover, it was noted that because veterinarians are not eligible for national provider numbers, prescriber identification has been a source of inconsistency for PMP reporting. In addition to inconsistencies with prescriber

identification numbers, it was also mentioned that there has been confusion about whose information to use for PMP reporting purposes: the patient's, which would be the animal's information, or the pet owner's.

After some thoughtful exchange, members agreed with proposed *Model Act* amendments that reflect the recommendations of the PMP Steering Committee report. For one, the LE/L Committee supported the addition of a footnote in Appendix F, Model Prescription Monitoring Program Act, which specifies that the veterinarian's state license number should be used for prescriber identification purposes. Secondly, the LE/L Committee also recommended, by means of a footnote, that the pet owner's name, address, telephone number, and gender should be reported to the PMP, along with his or her date of birth.

LE/L Recommendation 4: The Committee Recommends Approving the Amendments to the *Model Act* Pursuant to FDA's Rules for Biological Products, With Revisions.

The recommended revisions pursuant to FDA's rules are denoted by underlines. The recommended revisions by the committee are denoted by double underlines.

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 Services, the following rules are essential.

…

Section 4. Prescription Drug Order Processing.

…

(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: [16]

(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.[17] Critical information text should never be truncated and shall include:

(A) patient name

[16] 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.

[17] Alternative-access methods may be utilized to address visual impairment in patients or caregivers.

(-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[18]; and

(-b-) language should be simplified, avoiding unfamiliar words and medical jargon; when applicable, use numeric instead of alphabetic characters.[19]

(C) drug name

(-a-) if written for a brand name and a generic drug is dispensed, include phrase "Generic for [brand name]" or similar wording;[20] and

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

(D) drug strength, expressed in the metric system whenever possible

(E) "use by" date

(-a-) date after which Drug should not be used; not expiration date of Drug or expiration date of prescription[21]; 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: [22]

(A) pharmacy name or dispensing practitioner's entity name[23];

(B) pharmacy telephone number[24];

(C) prescriber name;

(-a-) format as – "Prescriber: [prescriber name]."

(D) "fill date"[25];

---

[18] 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.

[19] Consider adhering to the universal medication schedule (UMS). The UMS shifts medication-taking into four standardized time periods (morning, noon, evening, bedtime) and uses simplified language and formatting to promote understanding (eg, "take 1 tablet in the morning and 1 tablet at bedtime").

[20] If an interchangeable biologic is dispensed, include the phrase, "interchangeable for [reference product]".

[21] Boards of Pharmacy may determine that this "use by" date does not apply to all Drugs (for example epinephrine auto-injectors) and may allow the Manufacturer's expiration date to be used if the Drug is kept in the Manufacturer's original, unopened packaging, provided that the Pharmacist uses professional judgement to assess the continued need for the Drug and counsels the patient on proper storage.

[22] 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.

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

[24] 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.

[25] "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.

(-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[26];

(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. [27]

Background:

The committee reviewed the FDA definitions related to biological products and also reviewed what is currently in the *Model Act* related to generic drug substitution. First, the committee decided to add a clarification that similar wording is appropriate for prescription drug labeling in regard to generic substitution and the phrase "generic for [brand name]." The members then agreed that the addition of a footnote in the prescription labeling section of the *Model Act*, which references interchangeable product for a reference product, is sufficient to align the *Model Act* with FDA regulations at this time.

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

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