Model Act Updates Address Veterinary Compounding, Long-Term Care Pharmacy Rules, and More

NABP recently amended the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act) to provide the state boards of pharmacy with model language that may be used for developing state laws or board rules for purposes of protecting the public health. Amendments to the Model Act were incorporated as a result of the NABP Executive Committee-approved recommendations suggested by the Task Force on Best Practices for Veterinary Compounding, the Task Force on Long-Term Care Pharmacy Rules, and the 2017-2018 Committee on Law Enforcement/Legislation. The following is a summary of the Model Act changes.

Veterinary Compounding Best Practices

The Committee on Law Enforcement/Legislation agreed with the Task Force on Best Practices for Veterinary Compounding that a new section addressing compounded drug preparations for veterinary use be added to the Model Rules for Compounded or Repackaged Pharmaceuticals. The new language was developed using existing California and North Dakota pharmacy regulations addressing veterinary compounding. The language will assist boards and licensees with identifying appropriate instances of compounding for office use by veterinarians as well as appropriate dispensing of such compounded products in emergency situations. Further, a definition for “veterinary dispensing” was added to recognize that the veterinary patient population is part of the practice of pharmacy.

In addition, the committee members agreed with the task force that the definition of “compounding” in Section 105 of the Model Act should clarify that reconstitution per Food and Drug Administration (FDA)-approved labeling is not compounding. Therefore, the definition in the Model Act was revised to define compounding as manipulation beyond “FDA-approved labeling.” In addition, a footnote was added stating, “Reconstitution of an FDA-approved drug according to labeling is not compounding.”

Long-Term Care Pharmacy Rules

The Committee on Law Enforcement/Legislation agreed with the Task Force on Long-Term Care Pharmacy Rules that the bidirectional transmission of chart orders between an institutional pharmacy and an institutional facility should be allowed, but recommended that the pharmacist-in-charge (PIC) maintain policies and procedures regarding this activity. Committee members also agreed with the task force that chart orders should be ongoing, unless discontinued by the prescriber or by means of an automatic stop order to decrease the chance of a patient’s drug therapy being unnecessarily interrupted. Further, the committee concurred with the task force that duplicate text found in the Model Rules for Institutional Pharmacy in the Definitions section should be removed.

The Committee on Law Enforcement/Legislation members also agreed with the task force’s recommendations regarding drug provisions in the absence of a pharmacist. The section title was changed to clarify that the rules are for pharmacies located within an institutional facility, and the rules were updated to include drug storage in the Automated Pharmacy section.

Regarding the use of emergency kits by institutional facilities, the committee agreed that a new section under Institutional Pharmacy should be devoted to emergency kits.

Virtual Manufacturers and Wholesale Distributors

The Committee on Law Enforcement/Legislation unanimously agreed that the definitions of “virtual manufacturer” and “virtual wholesale distributor” that have been added to the criteria for the Verified-Accredited Wholesale Distributors® program be added to the Model Act.

continued on page 16
Global Exchange Pharmacy Students

In response to Resolution 113-3-17, the Committee on Law Enforcement/Legislation recommended that a definition for “global exchange pharmacy student” be added to the Model Act and that a global exchange pharmacy student could participate, as an observer, in experiential activities as part of a formal educational exchange program without requiring board licensure as a pharmacy technician or pharmacy intern. However, if the global exchange pharmacy student is involved in clinical activities (ie, patient care), then the student must be qualified by the Accreditation Council for Pharmacy Education-accredited or board-approved school or college of pharmacy, as exists for introductory pharmacy practice experience and advanced pharmacy practice experience experiential rotations.

Concurrent Disciplinary Actions

After reviewing Resolution 113-5-17, Adjudication of Concurrent Disciplinary Actions, which concerns sister-state disciplinary actions, the Committee on Law Enforcement/Legislation agreed that the Model Act should be amended to clarify that jurisdictions should consider taking subsequent, concurrent disciplinary action if a licensee’s action “involves or may result in direct patient impact or harm in states other than that of the initiating Board.”

The updated Model Act will soon be available for free download in the Publications and Reports section of the NABP website at www.nabp.pharmacy.

NABP Joins Efforts to Raise Awareness of Counterfeit Drugs Made With Fentanyl

The Fentanyl Council – a joint project formed by NABP, National Association of Drug Diversion Investigators, and the Partnership for Safe Medicines (PSM) – is working to raise awareness of the danger illicit fentanyl poses to Americans. Specifically, the Council is working to develop federal and state solutions to the problem of illicitly manufactured fentanyl contaminating illicit and counterfeit medication, making them exponentially more deadly.

During PSM’s 2018 Interchange conference held June 7, 2018, the Council presented its initiatives, which include creating a guide to help local law enforcement agencies develop policies to protect officers from fentanyl exposure and a white paper about the regulation of the pill presses that make the production of oral fentanyl-laced drugs possible. At the conference, representatives from United States and Canadian federal enforcement agencies and academia discussed policy and law enforcement challenges related to foreign drug importation. Family members of victims also discussed the impacts of counterfeit drugs made with fentanyl.

More details about PSM’s conference can be found at www.safemedicines.org/2018-interchange. To learn more about the Council’s efforts, visit PSM’s web page at www.safemedicines.org/fentanyl-council.