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News

Delaware State Board of Pharmacy

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Pharmacy Issues

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Legislation Update

Dispensing Syringes and Needles Without a Prescription

On June 30, 2013, Governor Jack Markell signed Senate Bill 73 into law. The new law allows Delaware-licensed pharmacists (or pharmacy interns or students under a pharmacist's supervision) to dispense hypodermic syringes or needles without a prescription to persons who are at least 18 years old. This includes pen needles for the administration of prescription medications by injection. Before dispensing the syringes or needles, the pharmacist, intern, or student must require identification that establishes the person's age (16 Del. C. §4762).

Reporting Sales of Products Containing Nonprescription Pseudoephedrine and Ephedrine

House Bill 130 establishes new requirements related to sales of products containing nonprescription pseudoephedrine (PSE) or ephedrine. These requirements, which go into effect on January 1, 2014, add Delaware to the growing list of states that participate in the National Precursor Log Exchange (NPLEx) system, a multistate PSE sales blocking system. The purpose of NPLEx is to prevent meth criminals from exceeding legal limits and from illegally obtaining PSE by simply crossing state lines.

The new requirements appear in 16 Del. C. §4740, Sale of pseudoephedrine and ephedrine:

(a) Beginning January 1, 2014, before completing a sale of an over-the-counter material, compound, mixture, or preparation containing any detectable quantity of pseudoephedrine or ephedrine, its salts or optical isomers, or salts of optical isomers a pharmacy or retailer shall electronically submit the information required pursuant to subsection (b) of this section to the National Precursor Log Exchange system ("NPLEx") administered by the National Association of Drug Diversion Investigators; provided that the National Precursor Log Exchange is available to pharmacies or retailers in the State without a charge for accessing the system. The pharmacy or retailer shall not complete the sale if the NPLEx system generates a stop sale alert. The system shall contain an override function that may be used by an agent of a retail establishment who is dispensing the drug product and who has a reasonable fear of imminent bodily harm if the transaction is not completed. The system shall create a record of each use of the override mechanism.

(b) The pharmacy or retailer shall maintain a written or electronic log of required information for each sale of a nonprescription product containing pseudoephedrine or ephedrine, including:

(1) The date and time of any transaction;

(2) The name, address, and date of birth of the person purchasing or obtaining the substance;

(3) The type of government-issued identification provided by the person purchasing or obtaining the substance and identification number;

(4) The government agency issuing the identification used; and

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Pharmacists Likely to Recommend OTC Medications, CHPA Reports

Patients most often seek a pharmacist's advice on treating coughs, headaches, migraines, and allergies, and 98% of pharmacists recommend or have no reservations recommending over-the-counter (OTC) products to treat such ailments, according to a recent survey. The Consumer Healthcare Products Association's (CHPA) report, "Understanding Trust in OTC Medicines: Consumers and Healthcare Provider Perspectives," presents the results of the survey, which was developed to better understand what drives consumer and health care provider trust in OTC products. The survey, developed and conducted by Nielsen and IMS, included over 1,100 consumer respondents, and over 500 health care provider respondents, composed of pharmacists, pediatricians, nurse practitioners, and primary care providers.

Pharmacists surveyed reported that they were more likely to recommend OTC products that demonstrated successful patient outcomes and consistent outcomes, and products known to be as efficacious as a prescription drug, and those containing ingredients known to be safe.

The survey also asked health care providers whether they recommended OTC products without, before, or in conjunction with recommending prescription drugs for certain symptoms. A majority of pharmacists surveyed, over 60%, recommend OTC medications to treat stomach symptoms and pain, without recommending a prescription treatment, and over 70% recommended OTC allergy, sinus, and flu medications without advising that a prescription drug is needed.

CHPA notes that with the expansion of patient self-care, OTC products will play an increasingly important role in health care. The potential for more prescription products to become OTC products in the new paradigm under consideration by Food and Drug Administration (FDA) could further impact this trend. As consumers are becoming more empowered in making health care decisions, they are also relying more on their pharmacist for medication advice. In fact, Nielsen and IMS findings show that multigenerational households, Hispanic households, and households who care for an adult outside of their home place a high value on pharmacist recommendations regarding selecting appropriate OTC medications, notes CHPA.

The full CHPA White Paper is available at *www.yourhealthathand.org/images/uploads/OTC_Trust_Survey_White_Paper.pdf.*

ISMP Study on Targeted Mandatory Patient Counseling

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. *ISMP is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also an FDA MedWatch partner. Call 1-800/FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at* www.ismp.org. *ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

In a recent study funded by a grant from Agency for Healthcare Research and Quality, ISMP evaluated the use of a combined checklist and patient information leaflet used during mandatory counseling sessions for consumers who pick up a filled prescription for 11 targeted medications:

- Opioid-containing analgesics
  - fentanyl patches
  - hydrocodone with acetaminophen
  - oxycodone with acetaminophen
- Anticoagulants
  - warfarin
  - enoxaparin
- Antidiabetic drugs (insulin analogs)
  - Humalog® (insulin lispro)
  - NovoLog® (insulin aspart)
  - Levemir® (insulin detemir)
  - Lantus® (insulin glargine)
  - Apidra® (insulin glulisine)
- Antineoplastic drug (non-oncologic use)
  - methotrexate

All 11 medications are on ISMP's list of high-alert medications dispensed from community pharmacies. Errors with high-alert medications may not be more frequent than errors with other medications; however, the consequences of errors with high-alert medications are often harmful. These 11 medications are also among the top 200 drugs dispensed in the United States, and many are used to treat chronic conditions, thus increasing the potential impact on public safety.

The medications were flagged in some manner to identify mandatory counseling opportunities. When a patient or patient representative picked up a flagged prescription, a pharmacist conducted a short counseling session (one to three minutes) that included the exchange of several key points on the checklist. At the end of the counseling session, the pharmacist provided the leaflet to the patient, along with a survey to complete and send back to ISMP.

Counseling sessions for these drugs were conducted for a consecutive period of four weeks, during which time, one trained ISMP staff member observed the counseling sessions for one day (six hours) to collect information on factors that facilitate or inhibit the counseling sessions. At the end of the four-week period of mandatory counseling, pharmacists at participating pharmacies were asked to complete a short mail-in survey regarding their perceived value of the process.

Results of the study showed that these consumer leaflets offer important safety tips for taking medication safely. Each leaflet begins with, "High-alert medicines have been proven to be safe and effective. But these medicines can cause serious injury if a mistake happens while taking them. This means that it is vitally important for you to know about this medicine and take it exactly as intended."

ISMP tested the readability, usability, and perceived value of the leaflets. Ninety-four percent of patients felt the leaflets provided great information or good information to know. Ninety-seven percent felt the information in the leaflets was provided in a way they could understand. Eighty-two percent of patients taking the drug for the first time and 48% of patients who had previously taken the medication reported learning something new. Overall, 85% of the patients felt they were less likely to make a mistake with the medication because they had read the leaflet.

The leaflets are available for download and can be reproduced for free distribution to consumers at *www.ismp.org/AHRQ/default.asp?link=ha.*

Generic Drug Substitution Requires Pharmacist Attention to State Laws and Regulations

While 40 years ago, most states forbade prescription drug substitution, almost all states now have drug product selection laws that allow, encourage, or mandate pharmacists to substitute generics for brand-name

drugs. These laws vary widely from state to state and pharmacists are therefore encouraged to review their state's substitution laws to ensure that they understand and comply with the state's requirements.

FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* publication, commonly known as the *Orange Book,* is generally considered the primary source for identifying suitable generic alternatives for a brand-name drug, and while not mandated by FDA regulations, the majority of states use the *Orange Book's* determinations of therapeutic equivalence to legally guide pharmacists in substituting generics.

State laws on generic substitution vary widely. A few states, such as Kentucky or Minnesota, follow a "negative formulary" approach, in which substitution is permitted for all drugs except those that appear on a particular list. Other states, including Massachusetts and Wisconsin, use a "positive formulary" approach, in which substitution is limited to the drugs on a particular list.

States also differ as to whether their substitution laws are permissive, thereby allowing a pharmacist to substitute a generic version of a brand-name drug, provided all prescription requirements are met, or mandatory, thereby requiring substitution. Prescription requirements may include such factors as the availability of a cheaper, therapeutically equivalent drug, the prescriber's specification that a brand-name drug be dispensed, or requiring the patient's or prescriber's consent. As reported in the 2013 NABP *Survey of Pharmacy Law*, 14 boards of pharmacy indicate that generic substitution falls into the "mandatory" category, while 38 boards indicate that their substitution laws are "permissive." Oklahoma law states that "[I]t is unlawful for a pharmacist to substitute without the authority of the prescriber or purchaser."

Other regulatory variations include states specifying the acceptable means for the prescriber to designate that substitution is not authorized, and states requiring patient consent prior to substitution.

The full article on this subject, which also reviews considerations regarding the accuracy of therapeutic equivalent determinations, is available in the June-July 2013 *NABP Newsletter,* which may be accessed in the Publications section of *www.nabp.net.*

NHF Provides Standards of Care for Pharmacies Serving Hemophilia Patients

For pharmacies that offer blood-clotting medications, organizations such as the National Hemophilia Foundation (NHF) emphasize the importance of being able to meet the specialized needs of their patients with bleeding disorders.

NHF's Medical and Scientific Advisory Council (MASAC) issued a standards-of-care recommendation in 2008 to assist pharmacies providing clotting factor concentrates for home use to patients with bleeding disorders. MASAC's guidelines are intended to be minimum standards of care and are divided into six areas:

As a brief overview of the MASAC guidelines, pharmacists wishing to meet the standards should:

1. Have a basic knowledge of bleeding disorders and experience with and knowledge of the full range of clotting factor concentrates, ancillary supplies, and hazardous waste disposal.

Pharmacies wishing to meet MASAC standards:

2. Should be able to provide a full range of available concentrates in all available assays and vial sizes, along with all necessary ancillary supplies, and hazardous waste disposal assistance as well as access to nursing services.
3. Should support reliable access to clotting factor for appropriate home treatment, by filling prescription orders within 48 hours, in the quantities prescribed, with expiration dates commensurate with the individual patient's needs.
4. Should be reliably open during regular business hours; provide 24-hour emergency access; and have an emergency action plan that allows patients to receive factor within 12 hours "in case of emergent need," with a goal of three hours "where logistically possible."
5. Should deliver products to the patient's desired location, meeting federal medication shipping standards, and providing an emergency number for patients to call in case of a problem with a delivery.
6. Should maintain patients' treatment prescription information along with maintaining records in compliance with state and federal requirements and be able to track the clotting factor products from manufacturer to patient, and participate in a recall information system.

The full article on this topic is available in the June-July 2013 *NABP Newsletter,* accessible in the Publications section of *www.nabp.net.* NABP notes that each state needs to review the standards recommended by MASAC to determine whether they coincide with existing state board of pharmacy requirements. NABP recognizes the unique patient needs of hemophiliacs, but also the responsibility of state boards of pharmacy to set required standards for medication dispensing and use. NABP is working with NHF to help the boards of pharmacy gain a better understanding of the medication needs of patients to help achieve uniformity in related regulations.

NABPLAW Online Now Includes Guam, Puerto Rico, and the Virgin Islands

The complete pharmacy acts and regulations of Guam, Puerto Rico, and the Virgin Islands are now included in **NABP***LAW*® Online, the comprehensive national data bank of state pharmacy laws and regulations provided by NABP. **NABP***LAW* Online's powerful search capabilities allow users to research subjects one state at a time or across all 50 states and included jurisdictions. More information about **NABP***LAW* Online and a link to the online subscription order form are available in the Programs section of the NABP Web site at *www.nabp.net/programs/member-services/nabplaw/.*

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(5) The name of the compound, mixture, or preparation and the amount.

The pharmacy or retailer shall require every person purchasing or obtaining the substance to sign a written or electronic log attesting to the validity of the information.

(c) If a pharmacy or retailer selling an over-the-counter product containing the substance experiences mechanical or electronic failure of the electronic tracking system and is unable to comply with the electronic sales tracking requirement under this section, the pharmacy or retailer shall maintain a written log or an alternative electronic record keeping mechanism until such time as the pharmacy or retailer is able to comply with the electronic sales tracking requirement.

72-Hour Limit on Controlled Substance Dispensing

On July 3, 2013, the governor signed Senate Bill 119 into law. This bill prohibits practitioners from dispensing controlled substances (CS) beyond the amount deemed medically necessary for a 72-hour supply (16 Del. C. §4739A). Samples that practitioners provide are not included in the 72-hour limit. Further, the new law also requires practitioners who dispense a 72-hour supply to report it to the Delaware Prescription Monitoring Program.

Please note that the new restriction pertains only to the act of dispensing, not to prescribing and/or administering. Dispensing is defined as the "preparation and delivery of a drug to a patient or patient's agent in a suitable container appropriately labeled for subsequent administration to, or use by, a patient." This new law does not restrict the amount of CS that a registered practitioner prescribes or administers.

You are encouraged to read all new legislation in its entirety. If you have any questions about this alert, please contact David Dryden at david.dryden@state.de.us or 302/677-7313.

Pharmacist-in-Charge Self-Inspection Report

As a reminder, the Pharmacist-in-Charge Self-Inspection Report is available on the Board Web site at *http://dpr.delaware.gov/boards/pharmacy/forms.shtml*. Please be aware that new pharmacy regulations 3.1.2.7 and 3.1.2.7.1A require pharmacists-in-charge (PICs) to complete an annual PIC Self-Inspection Report by February 1, of each year. New PICs must complete a PIC Self-Inspection Report within 30 days of becoming a new PIC. The PIC Self-Inspection Report should be downloaded from the Board Web site above. **Please do not mail the completed form to the Board office. Keep the completed form on file in the pharmacy for review at the time of a pharmacy inspection.** The controlled drug audit for the year 2013 should be completed for two of the four medications listed below:

- Oxycodone 30 mg
- Alprazolam 1 mg
- Lorazepam 1 mg
- Suboxone 8 mg Sublingual Film.

If a discrepancy resulting from the audit is greater than 3%, PICs must report the discrepancy to the Board within 30 days with an explanation.

Should you have any questions regarding this information, please contact the office.

Newly Licensed Pharmacists

24 Issued from April 1, 2013 to June 30, 2013

Leslie D. Nkansah – A1-0004397; Sharon L. Fine – A1-0004398; Scott G. Cahayla – A1-0004399; Karli M. Sartorio – A1-0004400; Carl K. Engmann – A1-0004401; Carolina Han – A1-0004402; Charles M. Gachengo – A1-0004403; Aaron M. Snyder – A1-0004404; Lucas M. Saviello – A1-0004405; Sabahat S. Abdullah – A1-0004406; Hieu K. Nguyen – A1-0004407; Joanna M. Ghayad – A1-0004408; Rina K. Kelly – A1-0004409; Na'Teka Ikea Shelton – A1-0004410; Chad J. Fornish – A1-0004411; David Dinh – A1-0004412; Gary F. Sobocinski – A1-0004413; Keang Hang Huynh – A1-0004414; Lindsey G. Butta – A1-0004415; Rupesh C. Shah – A1-0004416; Sean P. Reilly – A1-0004417; Jessica Lynn Kaminski – A1-0004418; Blaire L. Upchurch – A1-0004419; Jennifer M. Lukaszewicz – A1-0004420.

Distributor Permits

16 Issued from April 1, 2013 to June 30, 2013

BioGen Idec US – A4-0001986; TheraCom, LLC – A4 - 0001987; Clint Pharmaceuticals Inc – A4-0001989; Air Gas USA LLC – A4-0001990; Air Gas USA LLC – A4-0001991; Blu Pharmaceuticals, LLC – A4-0001992; AnovoRx Distribution LLC – A4-0001993; Medline Industries, Inc – A4-0001994; J. Knipper and Company – A4-0001995; DPT Laboratories, Ltd – A4-0001996; Antigen Laboratories, Inc – A4-0001997; Actavis Pharma, Inc – A4-0001998; Grifols USA, LLC – A4-0001999; Matheson Tri-Gas, Inc – A4-0002000; Par Pharmaceutical, Inc – A4-0002001; Unit Dose Services – A4-0002002.

In-State Pharmacy Permits

Three Issued from April 1, 2013 to June 30, 2013

Genoa Healthcare of Delaware, LLC – A3-0000953; Delaware CVS Pharmacy, LLC – A3-0000954; CVS Pharmacy #6869 – A3-0000955.

The *Delaware State Board of Pharmacy News* is published by the Delaware State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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