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Board Sets Deadline for Out-of-State Mail-Order Pharmacy PIC Licensure

As mentioned in the last issue, the legislature passed "The Larry W. Border Pharmacy Practice Act," House Bill 2577, on April 13, 2013, setting an effective date of July 1, 2013. As it was going through toward passage, some noticed that the language would require every pharmacist practicing "pharmacist care" in West Virginia to have a West Virginia pharmacist license. This is not a surprising concept, of course; that is, until people noticed that the language would require all out-of-state pharmacists dispensing from mail-order pharmacies into West Virginia to be licensed in this state, which would be a new burden if implemented. There are approximately 360 active mail-order permits issued by the West Virginia Board of Pharmacy, with the vast majority of those being out-of-state permits. So, the act was amended to provide that only the pharmacist-in-charge (PIC) of the out-of-state mail-order pharmacy would have to be licensed as a West Virginia pharmacist; the other pharmacists working under the PIC would simply need a valid pharmacist license in the state where the pharmacy is located. The Board noted that the PICs around the country would need some time to reciprocate their licenses to West Virginia. So, the Board voted to allow until July 1, 2014, for the out-of-state mail-order pharmacies and their PICs to become compliant. If you are one of those PICs, the Board looks forward to working with you through the licensing and reciprocation process in the coming weeks.

The Controlled Substances Monitoring Program Off and Running on New Platform

The new version of the West Virginia Controlled Substances Monitoring Program (CSMP) is up and running at *https://www.csapp.wv.gov.* It was turned on at the beginning of July for users to get their registrations in place, begin reporting dispensings into it, and use it to run patient profile reports. Notice from the Board's CSMP vendor, Mahantech Corporation (the old RxDataTrack and new West Virginia Controlled Substance Automated Prescription Program developer), of this changeover started going out to all of the pharmacy reporting systems about six months prior to the July start date. In addition, the Board's vendor put up a notice on the old CSMP Web site telling them, every time they logged in to upload data, of the impending improvements. So, the old system was unceremoniously shut down on August 2, 2013. Unfortunately, for those who had not yet gotten set up for the new version, this left them in a position where they had no access to the records, and, if a dispenser, no way to upload his or her ongoing dispensing data (which must now be in the American Society for Automation in Pharmacy (ASAP) 4.2 reporting format). If you need to register, visit the new Web site at *https://www.csapp.wv.gov* to begin the process. If you are having issues with running reports, or general questions about obtaining access to the database, please contact the CSMP staff at 304/558-8411. For technical questions involving access, or for reporting data, you can contact Mahantech support at 304/720-2246.

With a new system comes glitches and bugs to work out. One of them has to do with the reporting requirements in the law and what the system can accept in ASAP 4.2 format for reporting information on a person picking up a prescription on behalf of a patient. West Virginia Code §60A-9-4(a)(8) requires a dispenser of Schedule II through IV controlled substances (CS) to report the full legal name, address, and date of birth as set forth on a government-issued photo identification (ID) of any person picking up the prescription on behalf of the patient. However, the new database ASAP 4.2 format can only accept the person's first and last name, ID number, and what authority issued that ID (eg, state driver's license, military ID, passport). So, the Board voted to amend its rule to state that reporting in compliance with the ASAP 4.2 standard would comply with the statutory mandate, since an investigator can use the name and ID information to get the rest of the information when needed. However, this rule change must go through the legislative process; until then, the Board will use discretion in enforcement, and consider the ASAP 4.2 reporting as compliant with West Virginia Code §60A-9-4(a)(8).

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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Experiential Education Hours to Count for Internship

For many years, Rule §15-1-4, setting the general requirements for obtaining 1,500 hours of internship needed for licensure as a pharmacist, has stated that only 800 of those hours can be obtained through experiential education that is part of the curriculum at a school of pharmacy. Over the years, of course, the experiential education requirements grew as the schools of pharmacy moved to the PharmD programs that are in place now. Accreditation Council for Pharmacy Education (ACPE)-accredited school of pharmacy programs must have in place hands-on, practical experiential education programs governed by pharmacist-preceptors who oversee the experience. By graduation, these programs exceed 1,500 experiential hours in the practice sites. Recognizing this, the Board voted to change the rule to allow pharmacy interns to receive credit for all 1,500 internship hours through their ACPE-accredited school of pharmacy experiential education. Of course, outside intern hours can still be accepted. The Board staff is implementing this by policy immediately, pending the formal rule changes. Thank you to all of the pharmacists who act as preceptors to help educate the interns through the practical, hands-on experience needed to enter the profession.

New CPE Requirement on Drug Diversion and CS Prescribing

In 2012, the legislature passed a new requirement that all prescribers and dispensers of CS must, as a condition of their professional licensure, have continuing education on the subject of "drug diversion training and best practice prescribing of controlled substances" (West Virginia Code §30-1-7a). Following the lead of the other practitioner licensing boards, the Continuing Pharmacy Education Committee drafted proposed rules that would require three hours per renewal period in this category, starting with the July 1, 2014 renewal period. The Board approved, and the rules were filed as an emergency rule in July 2013, to allow time for notice. Continuing pharmacy education (CPE) providers have been offering compliant courses since the legislation was first passed in 2012, so many pharmacists already have their hours for their renewals next year.

Related to this, when adding this new requirement, the legislature deleted the language requiring the one-time end-of-life care education. The deletion takes into account that drug end-of-life care will be dealt with as a component of the new requirement. Further, the law requires that new licensees get this drug diversion and best practice prescribing CPE within their first year of licensure. So, new licensees no longer have to do any CPE specific to end-of-life care; rather, they will have to show that they obtained three hours of CPE on drug diversion training and best practice prescribing of CS in the first year of their first licensing period.

State Pseudoephedrine Sales and Methamphetamine Lab Incidents Data

The National Precursor Log Exchange (NPLEx) system for real-time reporting of pseudoephedrine (PSE) over-the-counter transactions was implemented January 1, 2013. NPLEx reported that as of the end of June 2013, West Virginia has 459 pharmacies enabled to use NPLEx, and 438 actively reporting sales transactions (Pharmacies that do not sell any PSE products have a waiver from reporting.). For the first six months of the year, NPLEx reports that West Virginia had 231,635 purchases of a total of 236,033 boxes of PSE products, and the system blocked the sale of 9,965 boxes by blocking 9,251 attempted purchases.

Before NPLEx was implemented in West Virginia, all PSE sales from January 1, 2007 through December 31, 2012, were reported monthly to the Board's RxDataTrack PSE sales tracking database. It indicates that 419,919 purchases of PSE products were made in 2011, and 517,202 purchases in 2012. Per West Virginia State Police data, through the end of June 2013, 301 meth lab incidents have been reported ("meth lab incident" refers to a law enforcement response to a lab, dump site, etc). For 2011, 229 incidents were reported, and 288 in 2012.

The *West Virginia Board of Pharmacy News* is published by the West Virginia 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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