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West Virginia Board of Pharmacy News

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New Practice Act Entitled 'The Larry W. Border Pharmacy Practice Act'

The West Virginia Pharmacy Practice Act received a make-over during the 2013 Regular Legislative Session. The legislature passed House Bill 2577 on April 13, 2013, setting an effective date of July 1, 2013. At the time of this writing, the bill was among the many pieces of legislation that passed that have to be painstakingly reviewed by the Governor's Office as he decides whether to sign them or not. The West Virginia Board of Pharmacy has been informed that Governor Earl Ray Tomblin plans to sign the bill, so it will become law, effective at the beginning of July. If for some reason the bill does get vetoed, then you can stop reading here . . . that is, unless you just love the *Newsletter* so much that you want to see what the Board would have had to say about it anyway.

As many of you are aware, Delegate Larry W. Border, a pharmacist in West Virginia, was a long-time delegate to the West Virginia Legislature who, sadly, passed away. He was very passionate about his chosen profession, and took his role in the legislature very seriously. Merging the two, he took great pride in teaming with Delegate Don Perdue, also a pharmacist and chair of the House Health and Human Resources Committee, to get this bill first introduced in the 2011 Regular Session. After his passing, Delegate Border's wife, Anna, was appointed to fulfill his term; she, too, supported the bill in the 2012 session, and again in 2013. This year, with the bill again in front of his committee, Chairman Perdue ushered through a committee change to rename the act after Delegate Larry Border, in homage to his service to the profession and to the legislature. The bill then moved forward through the rest of the legislative process in the House and then the Senate, with final passage of "The Larry W. Border Pharmacy Practice Act" being wrapped up on the very last day of the session. No bill is ever perfect, but a lot of work, negotiation, and, yes, compromise, went into the final product, which the Board is hopeful will help add further clarity to the practice of pharmacy in this state.

Here are some of the highlights of the changes. The act puts in term limits for Board members. It states that a Board member may only serve two consecutive full terms, after which, he or she must go off the Board for at least one year before being eligible for appointment again. This is standard language that is being placed into the practice acts of all of the various licensing boards created in Chapter 30 of the West Virginia Code. Next, looking at pharmacy technicians (PTs), the act will require all future PTs newly registered beginning July 1, 2014, to be nationally certified. Of course, all PTs already registered with the Board prior to that date will be grandfathered in.

With regard to collaborative practice, it is preserved almost entirely as it was in the prior version of the act, but fully recognizes that it is practiced in the community settings, and that it is something that can be agreed to between a physician or group of physicians and a pharmacist or pharmacists. That way, if written appropriately, a collaborative agreement for treatment of a patient can be written to cover a group of prescribers and all of the qualified pharmacists at a pharmacy that may serve that patient. On that note, the West Virginia Boards of Medicine, Osteopathic Medicine, and Pharmacy have all committed to working on the rules governing this area of practice to try to make them work smoothly for the practitioners and patients.

Another highlight is that medication therapy management is now defined and specifically mentioned in the pharmacist's scope of practice. While this is not in any way an expansion of the scope, and really is just a new moniker for the types of services a pharmacist provides when doing drug utilization reviews and other things that pharmacists long have done, it was important to many to include it in code to ensure that it can be covered as a reimbursable item under Medicaid and any other applicable federal laws.

The last item the Board will address here is a small but very important advancement for pharmacist immunizations. The various stakeholders involved in crafting this law all agreed that it would be appropriate that pharmacy students who are properly trained to provide immunizations to be permitted to give them as registered interns as part of their experiential education. Therefore, the act permits interns to administer immunizations as permitted by rules, so long as done under the

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FDA Issues New Guidelines for Sleep Aids Containing Zolpidem

Food and Drug Administration (FDA) has issued new dosing recommendations for sleep aids containing zolpidem. The new recommendations are based upon new data that shows that when taken at night, blood levels of zolpidem remain high enough in the morning to impair activities that require alertness, such as driving. The new guidelines halve the dosage for women because the new data showed that their bodies take longer to eliminate the drug.

FDA urges drug manufacturers and health care providers to follow the new dosing instructions, which apply to brand name and generic drugs containing zolpidem:

- Ambien®, Edluar™, and Zolpimist®: 5 mg for women, 5 mg or 10 mg for men
- Ambien CR®: 6.25 mg for women, 6.25 mg or 12.5 mg for men

Additionally, manufacturers of these drugs have been instructed to follow the new guidelines and print new patient information drug labels containing the new recommendations.

The recommended doses of Intermezzo®, a lower dose zolpidem product approved for middle-of-the-night awakenings, are not changing. At the time of Intermezzo's approval in November 2011, the label already recommended a lower dosage for women than for men. Additional details are available in an FDA Drug Safety Communication, available at *www.fda.gov/Drugs/DrugSafety/ucm334033.htm.*

What is the National Medication Error Rate? What Standards Are Available for Benchmarking?

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.*

A national or other regional medication error rate does not exist. It is not possible to establish a national medication error rate or set a benchmark for medication error rates. Each pharmacy organization is different. The rates that are tracked are a measure of the number of **reports** at a given organization, not the actual number of **events** or the quality of the care given. Most systems for measuring medication errors rely on voluntary reporting of errors and near-miss events. Studies have shown that even in good systems, voluntary reporting only captures the "tip of the iceberg." For this reason, counting **reported** errors yields limited information about how safe a pharmacy actually is. It is very possible that a pharmacy organization with a good reporting system, and thus what appears to be a high error "rate," may have a safer system.

The National Coordinating Council for Medication Error Reporting and Prevention published a statement refuting the use of medication error rates. The statement, which is posted on the council's Web site (*www.nccmerp.org*), states the "Use of medication error rates to compare health care organizations is of no value." The council has taken this position for the following reasons:

- Differences in **culture** among health care organizations can lead to significant differences in the level of reporting of medication errors.
- Differences in the **definition** of a medication error among health care organizations can lead to significant differences in the reporting and classification of medication errors.
- Differences in the **patient populations** served by various health care organizations can lead to significant differences in the number and severity of medication errors occurring among organizations.
- Differences in the **type(s) of reporting and detection systems** for medication errors among health care organizations can lead to significant differences in the number of medication errors recorded.

According to the statement, the council believes that there are no acceptable incidence rates for medication errors. The goal of every health care organization should be to continually improve systems to prevent harm to patients due to medication errors. Pharmacies should monitor actual and potential medication errors that occur within their organization, and investigate the root cause of errors with the goal of identifying ways to improve the medication-use system to prevent future errors and potential patient harm. The value of medication error reporting and other data gathering strategies is to provide the information that allows an organization to identify weaknesses in its medication-use system and to apply lessons learned to improve the system. The sheer number of error reports is less important than the quality of the information collected in the reports, the organization's analysis of the information, and its actions to improve the system to prevent harm to patients.

It is more important to create the open environment that encourages the reporting of errors and near errors than to develop less meaningful comparative error rates.

ISMP Launches Program to Track Vaccine Errors

ISMP has launched a National Vaccine Error Reporting Program (VERP) that allows health care providers to confidentially report vaccine administration errors and near misses. Health care providers from all practice settings, including pharmacies and physicians' offices, are encouraged to report all mistakes related to vaccines, regardless of whether any harm resulted from the incident. The program will help ISMP "better quantify the sources of errors and advocate for vaccine name, labeling, device, information, and other needed product changes to ensure patient safety," stated Michael Cohen, ISMP president. The ISMP VERP was designed with the assistance of the California Department of Public Health and with input from experts in the field, indicates ISMP. Reports sent to the ISMP VERP will be shared with FDA and forwarded to the vaccine manufacturer when applicable. ISMP also plans to work with the Centers for Disease Control and Prevention on information received to address vaccine-related safety. VERP can be accessed at *http://verp.ismp.org/.*

Providers Should Ensure Only Diluted Forms of Acetic Acid Are Used, ISMP Warns

ISMP has issued a National Alert Network (NAN) notice advising that health care organizations should take immediate steps to ensure that only diluted acetic acid solutions are used in patient care. ISMP advises that the use and purchase of glacial acetic acid, the most concentrated form of acetic acid available, should be eliminated. Several cases of severe burns, scarring, and other permanent damage to skin or mucous membranes due to the inadvertent application of glacial acetic acid have been reported to the National Medication Errors Reporting Program operated by ISMP. ISMP provides the following steps for preventing further such events:

- Remove glacial acetic acid, which has no use in its current form in clinical medicine, from the pharmacy and replace with vinegar (5% solution) or commercially available diluted acetic acid 0.25% (for irrigation) or 2% (for otic use).
- Restrict purchasing so that pharmacy staff is purchasing acetic acid for all procedural areas.
- Restrict choices for purchasing so that glacial acetic acid is not selected by mistake.
- Ensure the correct strength is ordered.
- Educate staff about the differences between glacial acetic acid and diluted forms of acetic acid.
- Order 5% as "vinegar," which reduces the potential for confusion with glacial acetic acid.
- Verify the product by requiring an independent double-check of acetic acid solutions before dispensing or applying the product.

Information on the cases reported and common reasons for the cases are included in the NAN alert, which is available on the ISMP Web site at *www.ismp.org/NAN/files/20130121.pdf.*

New FDA Training Video

FDA Drug Info Rounds, a series of online training videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better medication decisions. In the latest Drug Info Rounds video, pharmacists discuss how FDA Drug Safety Communications let health care providers, patients, and consumers know about newly observed potential risks of FDA-approved drugs. Drug Info Rounds videos are developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, and Division of Drug Information and are available on the FDA Web site at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.*

Progress Made in Implementing Recommendations Intended to Prevent Acetaminophen Overdose

Compelling progress has been made by stakeholders seeking to address the public health issue of acetaminophen overdose, indicates a white paper published by the National Council for Prescription Drug Programs (NCPDP). In 2011, NCPDP made recommendations that the health care industry take actions to support the safe use of acetaminophen, including recommending that pharmacies produce prescription labels with the complete spelling of acetaminophen and eliminating use of abbreviations such as "acet" or "APAP." Previous to that, in July 2010, the National Association of Boards of Pharmacy® (NABP®) recommended that "state boards of pharmacy prohibit the use of the abbreviation 'APAP' on prescription labels, and require that 'acetaminophen' be spelled out to assist in preventing the well-recognized danger of acetaminophen induced hepatotoxicity." The recommendation was based on established policy and a letter, sent by FDA to state boards of pharmacy, regarding the pharmacist's role in educating patients about acetaminophen induced hepatotoxicity caused by unintentional overdose. The recommendation was also consistent with the report of the NABP Task Force on Uniform Prescription Labeling Requirements, which made recommendations to encourage use of prescription labels that are organized in a patient-centered manner. NCPDP reports that pharmacy retailers "estimated to collectively represent more than half of the prescriptions dispensed in 2011, have either implemented or committed to a phased implementation" of the recommendation to use the complete spelling of acetaminophen on prescription labels. "This update to our white paper provides additional guidance for those industry stakeholders who have not yet implemented the new pharmacy labeling practices for acetaminophen-containing medicines," states Lee Ann Stember, president, NCPDP. The updated white paper is accompanied by a bulletin (PDF), available at *www.ncpdp.org/pdf/wp/NCPDPAcetaminophenInfoBulletin_PharmacyStakeholders.pdf,* developed for pharmacists that summarizes some of NCPDP's key recommendations regarding acetaminophen. In addition, the white paper, available for download at *www.ncpdp.org/ind_WP.aspx,* includes a list of resources for pharmacists to use in educating staff and pharmacy staff to use in educating patients (see Appendix D of the white paper). More information is available in an NCPDP news release available at *www.ncpdp.org/press/013113_NCPDP_Acetaminophen%20WP_FINAL.pdf.*

Pharmacists Rated High for Honesty and Ethical Standards in Gallup's 2012 Poll

Pharmacists ranked as the second most trusted profession in the 2012 Gallup Poll that asked consumers to rate 22 professions according to their honesty and ethical standards. Pharmacists were ranked as very high or high in this category by 75% of those surveyed, with nurses ranking first at 85%, and medical doctors third at 70%. Additional information on the results of the 2012 poll is available on the Gallup Web site at *www.gallup.com/poll/159035/congress-retains-low-honesty-rating.aspx*.

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supervision of a properly licensed immunizing pharmacist. Of course, the rules in Title 15, Series 12, governing pharmacist immunizers will need to be updated to include interns, and define how it will work. So, some work by the West Virginia Boards of Pharmacy, Medicine, and Osteopathic Medicine on the joint rule remains to be done, but having it in code is a step forward for the education process of tomorrow's pharmacists.

Compounding Versus Manufacturing: Compounding for Office Use

Last quarter, the Board discussed compounding pursuant to a prescriber's order (prescription) versus manufacturing. That article concluded, in part, " . . . unless it is for a research, teaching or other similar situation which is not for sale or dispensing, pharmacies may compound only for individual prescriptions, or in anticipation of their regular and routine prescription-dispensing needs." However, during the legislative session, representatives of ophthalmologists expressed concern about being able to get certain eye drops prepared for their office use with their patients during certain routine procedures. They indicated that the solutions are not available on the market and must be compounded, and that the current law would require them to write or call in prescriptions for the patient to pick up and bring with them to appointments. They suggested that this would be inconvenient and unnecessarily costly for the patients, often requiring patients to make a second visit because the doctor would not know until during the initial examination that the drops would be needed, requiring the exam to be postponed until the drops could be prescribed, prepared, and picked up by the patient. As a result, the Board discussed at the March Board meeting whether to permit limited compounding done "for office use," or whether a prescription is always required.

After some discussion, the Board determined that it is in the best interest of the patient to permit limited compounding for office use in West Virginia. Therefore, the Board decided that it would exercise discretion in enforcement with regard to compounding for that purpose. The motion passed by the Board stated that this would extend only to minimal amounts of compounding necessary to fill an order placed by a prescriber for use in his or her office in the immediate future. No bulk compounding is permitted under this exception. Further, in no event, whether for compounded drugs supplied for office use or any other transfer of prescription drug stock for office use, may this be documented as a prescription order. Because the transfer of the compounded product would be done for a prescriber to have in supply for general office use, the transaction must be properly documented by invoice the same as any other wholesale transaction. Finally, this very limited exception does not in any way change the analysis that all other compounding must be done for a prescription, or for a research, teaching, or other similar situation that is not for sale or dispensing, as required by law.

Controlled Substances Monitoring Program Update

As reported last quarter, the West Virginia Controlled Substances Monitoring Program (CSMP) is in the final stages of upgrades to bring it up to American Society for Automation in Pharmacy 4.2 reporting standards, and finally connect to the interstate PMP InterConnect® operated by the National Association of Boards of Pharmacy®. The new servers are in place and the system is being rolled out. If you have any general questions, please contact the CSMP staff at 304/558-8411; for technical questions, you can contact our vendor, Mahantech Corporation, at 304/720-2246.

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West Virginia Board of Pharmacy

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