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News

West Virginia Board of Pharmacy

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Accuracy of Records in the Controlled Substances Monitoring Program Database

In the September 2010 issue of this *Newsletter,* the West Virginia Board of Pharmacy ran an article under this same title. Since then, a rules revision became effective in July 2011, at West Virginia Code of State Rules Section 15-8-5 making it explicitly clear that accurate information must be transmitted to the West Virginia Controlled Substances Monitoring Program (CSMP) database. Unfortunately, the Board continues to experience problems with incorrect data being reported, and has to take time to correct the data, if and when the errors are found. In the words of the vendor that maintains the CSMP: "We continue to receive an avalanche of script reversal requests, ie, dispensed but not picked up. Due to the design of [the CSMP], each individual request takes 6-12 minutes to reverse. As you can imagine this is becoming an immense burden. Please help us mitigate this issue."

West Virginia Code Section 60A-9-4 says reporting to the CSMP must be done "[w]henever a medical services provider **dispenses** a controlled substance. . . ." (emphasis added). Rule 15-8-5 says the information reported must be accurate. That is a given. Rule 15-1-14.7.5 says all completed prescription orders must be bagged and kept in the pharmacy until they are delivered to the patient, the person picking up for the patient, or the person delivering it to the patient's residence or similar place. The definition of "dispense" in Rule 15-1-2.1.12 describes the process that is covered, and then ends with this sentence: "**Dispensing has not occurred until the drug is actually delivered to the patient or patient's representative**" (emphasis added). Deliver is also defined in 15-1-2.1.9 as transferring the drug from one person to another. In short, **if the prescription order is still sitting in will call, it has not been delivered or dispensed. Do not report it to the CSMP until it is actually dispensed.** To do otherwise is a clear violation.

In addition, human error is preventable, and is causing corrupted data that is being relied upon by prescribers, dispensers, licensing boards, law enforcement, and others who get access to the information. Dispensers are too often entering incorrect information for the patient names (not using their proper, official name so that all dispensers report the same way for that individual), selecting the wrong prescriber (in several instances causing a patient a problem with that prescriber who thinks the patient might be doctor shopping, or causing the prescriber a problem wherein he or she is being investigated and asked why he or she prescribed medication to someone he or she does not know and have never seen as a patient), and other simple data entry errors. Please save yourself time in reversing out orders that were returned to stock, or correcting data entry errors, which will in turn help the Board maintain the integrity of the information in the CSMP. This will help us all as we use this tool.

Rules Revisions and the Pharmacy Practice Act Pending Before the Legislature

The Pharmacy Practice Act revisions, which stalled in the legislature last year, have been introduced again this year. The sticking point last year was over how generic drugs would be priced for purposes of generic substitution. That issue remains this year, as some advocate keeping the current state of the law, and others advocate removing the language and replacing it with language that would let the free market control. In between, some are looking at whether the intent of the current language can be preserved with changes making it clearer. This is definitely something to keep informed of and to follow. Any changes will directly affect how you calculate your prices for generic substitutes to be in compliance with the statutory requirements.

Four series of the Board's rules are being considered by the legislature in the 2012 Regular Legislative Session: Title 15, Series 2, dealing with controlled substances, Series 3, concerning continuing pharmacy education, Series 5, on licensure of wholesale drug distributor, and joint rules in Series 12, with the Boards of Medicine and Osteopathy to expand the vaccines/immunizations that a properly certified pharmacist may give. At the time of this writing, they are each moving through the various committees in the House and the Senate. It appears

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FDA Recommends Use of Sterile Needle and Syringe for Administration of Inactivated Influenza Vaccines

Food and Drug Administration (FDA) recommends that health care providers use a sterile needle and syringe to administer inactivated influenza vaccines. The recommendation was released in response to questions regarding the use of jet injector devices to administer inactivated influenza vaccines. FDA advises that "inactivated influenza vaccines that are approved by FDA have information in their labeling stating how the vaccines should be administered, such as, by intramuscular (IM) or intradermal (ID) administration." Further, FDA clarifies its October 21, 2011 communication "to inform the public that inactivated influenza vaccines labeled for IM injection are intended for administration using a sterile needle and syringe. There is one inactivated influenza vaccine labeled for ID administration, this vaccine is supplied in its own pre-filled syringe. The live attenuated influenza vaccine is given through the nose as a spray; the sprayer is not a jet injector." FDA also notes the following:

- Currently, there is only one vaccine, Measles, Mumps, and Rubella (MMR), that is approved and specifically labeled for administration by jet injector.
- Safety and effectiveness information that would support labeling inactivated influenza vaccines for delivery by jet injector have not been submitted to FDA.
- At this time, there are no inactivated influenza vaccines that are approved and specifically labeled by FDA for administration by jet injector.

FDA recommends that all approved vaccines, including influenza, be administered in accordance with their approved labeling, and FDA advises that if a vaccine has been approved for administration with a jet injector, information specifically addressing vaccine use with a jet injector will appear in the vaccine labeling. Additional background information is available in the communication posted on the FDA Web site at *www.fda.gov/BiologicsBloodVaccines/Vaccines/QuestionsaboutVaccines/ucm276773.htm.*

The Centers for Disease Control and Prevention continues to encourage people to get vaccinated throughout the flu season, which can begin as early as October and last as late as May. For information about the flu vaccine visit *www.cdc.gov/flu.*

'Tell Back' Works Best to Confirm Patient Understanding

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 the past few years, multiple studies have demonstrated that patients often leave medical encounters with a poor understanding of their health conditions and recommended treatment. One recent study on this subject demonstrates the low level of understanding patients have about follow-up care and medication therapy upon discharge from the emergency department (Engel KG et al. Patient Comprehension of Emergency Department Care and Instructions: Are Patients Aware of When They Do Not Understand? Ann Emerg Med. Available on the journal Web site).

Given the importance of patient understanding of medical information, there are surprisingly few studies that point out how to approach this task. However, a study published in 2008 offers some insight into what approach to assessing understanding of medical information patients most prefer and perceive to be the most effective (Kemp EC, et al. Patients Prefer the Method of "Tell Back-Collaborative Inquiry" to Assess Understanding of Medical Information. J Am Board Fam Med 2008;21(1):24-30). Researchers tested three types of inquiry about the patient's understanding:

- Yes-No
- Tell Back-Directive
- Tell Back-Collaborative

The Yes-No approach asked closed-ended questions to assess patient understanding. (Example: "I've given you a lot of information. Do you understand?") The Tell Back-Directive method used open-ended questions that were physician-centered and paternalistic in that it was clear authority and control still remained with the physician. (Example: "It's really important that you do this exactly the way I explained. What do you understand?") The Tell Back-Collaborative approach used open-ended questions that were patient centered, making it clear that power and responsibility were shared between the health care provider and patient. (Example: I imagine you are really worried about your blood pressure. I've given you a lot of information. It would be helpful to me to hear your understanding about your clot and its treatment.)

Patients showed a significant preference for the Tell Back-Collaborative inquiry over other tested approaches. Because of the potential for embarrassment if patient misunderstandings are exposed, one might anticipate health care providers' reluctance to put patients "on the spot" with open-ended questions. But a collaborative approach to Tell Back allows the patient to save face for misunderstandings by acknowledging the large amount of information being provided. Patients might also view the request for Tell Back as evidence of the health care provider's care and concern for them personally, or evidence of the provider's attention to detail and competence. So, when counseling patients about their medications, instead of asking "Do you have any questions?" or "Do you understand?" ask them to restate their understanding of the information you provided in their own words within a shame-free, blame-free environment.

DEA Clarifications on Certification Process for Audits of EPCS Software

Drug Enforcement Administration (DEA) emphasizes that third-party audits of software applications for Electronic Prescriptions for Controlled Substances (EPCS) must encompass all applicable requirements in DEA regulations, including security, and must address "processing integrity" as set forth in the regulations. Further, DEA recommends that where questions or gaps may arise in reviewing a particular applica-

tion, federal guidelines set forth in National Institute of Standards and Technology Special Publication 800 – 53A should be consulted. DEA has also announced the first DEA-approved certification process for EPCS. Certifying organizations with a certification process approved by DEA pursuant to the regulations are posted on DEA's Web site at *www.deadiversion.usdoj.gov/ecomm/e_rx/thirdparty.htm#approved*. Detailed background information is provided in the Federal Register Notice, available for download at *www.gpo.gov/fdsys/pkg/FR-2011-10-19/pdf/2011-26738.pdf*.

'Script Your Future' Provides Tools and Outreach to Encourage Medication Adherence

United States Surgeon General Regina Benjamin called upon pharmacists, physicians, nurses, and other health care providers to talk with their patients about the importance of taking medications as directed to help prevent serious health complications at the recent launch of the national campaign, "Script Your Future." Benjamin also "encouraged patients with chronic conditions to speak with their health care professionals about their medication" as noted in a press release. A survey released by the National Consumer League, the organization that developed Script Your Future, indicates that "patients who do not always take their medication as directed are less likely to have received a full explanation of the consequences of their condition, and are less convinced of the importance of adherence." The Script Your Future campaign is targeting six regional areas with outreach activities and advertising, and more information is available at *www.ScriptYourFuture.org*. The campaign brings together "stakeholders in health care, business, and government to offer practical tools for patients to help them better adhere to their medication, and to help health care professionals better communicate with patients." More information about the campaign is available in a press release at *www.prnewswire.com/news-releases/us-surgeon-general-joins-baltimore-launch-of-the-national-script-your-future-campaign-to-highlight-importance-of-taking-medication-as-directed-133077423.html*.

FDA Releases 'Use Medicines Wisely' Video

FDA Office of Women's Health has released a new public service announcement (PSA) video titled, "Use Medicines Wisely," to help raise awareness about safe medication use. As stated in an FDA news release, "Millions of people benefit from FDA approved medications and are living longer productive lives. However, when medications are used incorrectly, they can cause serious injuries, even death. Many of these injuries can be prevented."

The video shows simple steps women can take to use medications wisely. Viewers are reminded to:

- Make a list of the medications they take
- Keep their medication list with them at all times
- Know the name of each medication, why they are taking it, how much to take, and when to take it
- Talk with their doctor, nurse, or pharmacist to find out how to safely use their medications

In addition to the video, a medications record-keeper, fact sheets, and other safe medication use resources are available on the FDA Web site.

Training Video Provides Tips on Preventing Pharmacy Robbery

Rx Pattern Analysis Tracking Robberies and Other Losses (RxPATROL) has released a training video discussing pharmacy robbery and how to prevent it. The video features a pharmacist and law enforcement liaison as they tour a pharmacy, evaluating security measures and discussing additional steps that can be taken to prevent robbery. RxPATROL is an initiative designed to collect, collate, analyze, and disseminate pharmacy theft intelligence to law enforcement throughout the nation. RxPATROL is designed to gather and disseminate critical information to help protect pharmacists, guard against potential robberies, and assist law enforcement in their efforts to successfully apprehend and prosecute those involved in controlled substance pharmacy crime. The training video can be accessed on the RxPATROL Web site at *http://rxpatrol.org/TrainingVideos.aspx*.

Nearly 20 Products Marketed as Natural Supplements Contain Sibutramine, FDA Warns

FDA has posted public warnings regarding 19 products, frequently marketed as natural supplements, and found to contain sibutramine, a controlled substance that was removed from the US market in October 2010 for safety reasons. These products pose a threat to consumers because sibutramine is known to substantially increase blood pressure and/or pulse rate in some patients and may present a significant risk for patients with a history of coronary artery disease, congestive heart failure, arrhythmias, or stroke. These products may also interact in life threatening ways with other medications a consumer may be taking. FDA warnings included products marketed as "Slender Slim 11," "Dream Body Slimming Capsule," "Acai Berry Soft Gel ABC," and 16 other product names. The products included in the warnings are being sold on Web sites and in some retail stores. FDA advises consumers not to purchase or use the products listed in the warnings. Consumers who have purchased any of these products should stop use immediately. And if consumers have experienced any negative side effects from using these products, they should consult a health care provider as soon as possible. The complete list of warnings is available on the FDA Web site at *www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm234592.htm*.

2012 Survey of Pharmacy Law Now Available

Serving as a convenient reference source for individuals seeking an overview of the state laws and regulations that govern pharmacy practice, the updated 2012 *Survey of Pharmacy Law* is now available and can be purchased online for $195 by visiting the NABP Web site at *www.nabp.net/publications*.

The *Survey,* produced in a CD format, consists of four sections including a state-by-state overview of organizational law, licensing law, drug law, and census data. Newly added this year, a question in Section 17, Wholesale Distributor Licensure Requirements, asks which state agency has regulatory authority over medical device distributors. In addition, a newly added question in Section 22, Electronic Transmission of Prescriptions: Computer-to-Computer, asks whether the state allows electronic prescribing of controlled substances.

Updates for the 2012 *Survey* were graciously provided by the state boards of pharmacy. In addition to the boards' support, NABP requested data from relevant health care associations for the *Survey's* prescribing authority and dispensing authority laws in Sections 24 and 25, and laws pertaining to the possession of non-controlled legend drugs and possession of controlled substances in Sections 26 and 27.

All final-year pharmacy students receive the *Survey* free of charge through the generous grant of Purdue Pharma L.P.

For more information on the *Survey,* please contact Customer Service via phone at 847/391-4406 or via e-mail at custserv@nabp.net.

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that each will be successful in passage, but are still subject to amendment or rejection.

Methadone Prescriptions For Neonatal Abstinence Syndrome

Previously, state and federal laws did not allow methadone to be prescribed to treat opiate withdrawal. There is an exception, however, for the treatment of infants suffering from Neonatal Abstinence Syndrome (NAS).

- Infants born with opiate dependency cannot stay in a hospital indefinitely.
- Narcotic treatment programs do not take infants.

In 2001, the Federal Interagency Narcotic Treatment Policy Review Board (INTPRB) decided that the use of opioids for neonatal infants and children suffering opioid withdrawal does not fall under the Narcotic Addict Treatment Act (NATA) and is not subject to the same rules and regulations affiliated with the act. The INTPRB found that an increasing number of hospitals were requesting authorization to discharge opiate-dependant infants with small quantities of methadone for administration to the infant by a responsible individual. The INTPRB stressed to practitioners that these infants are not considered narcotic addicts. Thus, the NATA does not apply. In addition, the INTPRB emphasized that a physician treating NAS was free to write prescriptions for any opioid, including methadone, which would be appropriate to treat NAS based on clinical judgment, existing standards of practice, and the patient's response to therapy.

In summary, a physician may write a prescription for methadone to treat the infant suffering from NAS, and a retail pharmacy may dispense it. The prescription should document the patient is an infant. There should be very specific and clear dosing instructions to prevent poisoning and overdose. If not, confer with the prescriber to get it. Then, just do what you always do to take care of the patient.

Internet Pharmacies: Legitimate Practitioner-Patient Relationship Required

The Board has encountered several situations where West Virginia mail-order pharmacies are receiving and filling prescriptions sent to them by an Internet-based business in which the business advertises certain drugs as available by prescription, the "patient" fills out an online questionnaire or patient profile, the business sends it to a prescriber it has contracted for review, the prescriber issues a purported "prescription" for the drug requested by the "patient," and the business then forwards the prescription on to the pharmacy. Usually, the patient lives in one state, the prescriber is in another several states away, and the pharmacy is in a third state, again states away. West Virginia Code Section 30-5-3(g) clearly states:

> No pharmacist may compound or dispense any prescription order when he or she has knowledge that the prescription was issued by a practitioner without establishing an ongoing practitioner-patient relationship. An online or telephonic evaluation by questionnaire is inadequate to establish an appropriate practitioner-patient relationship. . . .

Be very careful. How likely is it that the doctor actually ever saw the patient and established a relationship in these cases? Dispensing in this scenario may result in discipline, or possibly even prosecution in certain circumstances.

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West Virginia Board of Pharmacy

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