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Suboxone, Subutex (Buprenorphine), Prescriber Choice, and Pregnancy

The West Virginia Board of Pharmacy has gotten some calls about whether the new requirement for sublingual film being required when dispensing Suboxone® (buprenorphine with naloxone) applies to Subutex® (just buprenorphine). At least two prescribers have called to discuss this issue, stating that they have patients who cannot afford Suboxone, and that the prescriber has chosen to treat them with buprenorphine, knowing that the alternative for the financially limited patient would likely be no treatment at all if limited to Suboxone. The reason for their call to the Board office was to determine how to discuss this further with the pharmacists who were questioning whether they could dispense buprenorphine because of the Suboxone sublingual film requirement if Suboxone is prescribed. Quite simply, the new statute only applies to the combination product, and does not apply to buprenorphine. Nothing in the law requires Suboxone over buprenorphine.

In addition, there have been some questions concerning whether dispensing of Subutex (buprenorphine) is appropriate for women who are pregnant, and if it is permitted for patients who are not pregnant, given that Suboxone sublingual film seems to be preferred at this time to prevent diversion. Obviously, with regard to pregnancy and treatment of addiction, all of the practitioners must exercise their learned professional judgment to treat the patient. Per Food and Drug Administration (FDA), both Suboxone and buprenorphine are pregnancy Category C drugs. What to do to treat a patient who is pregnant would be up to the practitioners involved, both the prescriber who establishes the treatment and the pharmacist who must exercise professional judgment in filling the prescription, to determine if this is clinically appropriate. Obviously, there may be indications and contraindications one way or the other, so the risks and benefits must be weighed. With regard to patients who are not pregnant, as indicated in the initial paragraph above, prescribers may have specific reasons for choosing buprenorphine to help a given patient. Again, nothing in the law requires Suboxone to be prescribed, only that if it is prescribed, that the sublingual film be dispensed unless contraindicated. Finally, when the pharmacist is exercising his or her professional judgment, Rule §15-1-19.3.1 clearly states that if the pharmacist believes there is any error, irregularity, or ambiguity with the prescription, then "[t]he pharmacist shall hold a conference with the prescriber before dispensing, if there is any doubt that the prescription order is not legal or correct or issued for a legitimate medical purpose." So, as always, as part of the patient's health care team, if the pharmacist has questions, then he or she should have a professional discussion with the prescriber.

Compounding Versus Manufacturing: Do You Have a Prescription?

In view of the relatively recent meningitis outbreak due to the unsanitary conditions at the New England Compounding Center (NECC), FDA, Congress, and states have been looking at the practice of compounding in the states to look for ways to prevent a future issue such as the one at NECC. Therefore, the Board felt that a review of the compounding rules may be helpful. As such, the Board looked at its position at the December 2012 Board meeting, and reaffirmed its support for current laws in this state covering compounding.

First, the Board fully supports compounding for prescriptions, and distinguishes it from manufacturing when done for that purpose. The current statutory definition in current West Virginia Code §30-5-1b(6) is:

> (6) "Compounding" means:
>
> (A) The preparation, mixing, assembling, packaging or labeling of a drug or device:
>
> (I) As the result of a practitioner's prescription drug order or initiative based on the practitioner/patient/pharmacist relationship in the course of professional practice for sale or dispensing; or
>
> (ii) For the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale or dispensing; and
>
> (B) The preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

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NIH Database Provides Information on Drugs Associated With Liver Injury

The National Institutes of Health (NIH) has launched a free searchable database with information on prescription and over-the-counter (OTC) drugs, herbals, and dietary supplements associated with liver injury. The LiverTox database, *www.livertox.nih.gov*, is a free resource for health care providers and researchers studying liver injury associated with these products. The database provides up-to-date, accurate, and easily accessed information on the diagnosis, cause, frequency, patterns, and management of liver injury attributable to prescription and nonprescription medications, herbals, and dietary supplements. The database currently contains information on 700 medications, and 300 more will be added.

Coalition Urges Consumers to 'Double Check, Don't Double Up' on Acetaminophen

With the start of cold and flu season in October 2012, the Acetaminophen Awareness Coalition began urging consumers to double check their medicine labels to make sure they do not double up on medicines containing acetaminophen. The coalition's "Double Check, Don't Double Up" message is aimed to reach the more than 50 million Americans who use acetaminophen every week, encouraging them to take three simple steps to avoid acetaminophen overdose: (1) know if your medicine contains acetaminophen; (2) never take two medicines with acetaminophen at the same time; and (3) always read your medicine label. The coalition also wants to educate consumers that taking more acetaminophen than directed is an overdose and can lead to liver damage. Health care providers can join the effort by educating patients about safe use of acetaminophen, and can refer patients to the *KnowYourDose.org* Web site for more information. The Acetaminophen Awareness Coalition is made up of a diverse group of organizations representing health care providers and consumers who have joined forces through the Know Your Dose campaign to inform consumers about safe acetaminophen use and preventing liver damage that can result from unintentional overdose.

Root Cause Analysis

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.*

To assist pharmacists in the process of minimizing the occurrence of medication errors, many state boards of pharmacy are contemplating or already requiring community pharmacies to have a continuous quality improvement program in place. Many of these state's regulations include the requirement of root cause analysis (RCA) in the case of sentinel events. The Joint Commission defines a sentinel event as an "unexpected occurrence involving death or serious physical or psychological injury or risk thereof," and recommends completing an RCA for all sentinel events for health care organizations in which they accredit. It is anticipated that RCA for sentinel events may be required as part of an accreditation program for community/ambulatory pharmacies.

RCA is a process for identifying the basic or causal factors that underlie variation in performance, including the occurrence or risk of occurrence of a sentinel event. RCA focuses primarily on systems and processes, not individual performance. Finding and identifying root causes during an investigation adds considerable value by pointing out significant, underlying, fundamental conditions that increase the risk of adverse consequences. These analyses can be of enormous value in capturing both the big-picture perspective and the details of the error. They facilitate system evaluation, analysis of need for corrective action, and tracking and trending.

The RCA process starts by creating a team, holding a meeting, and stating the problem. The team gathers documentation (prescriptions, labels, computer reports, etc) and interviews staff involved in the error to determine the sequence of events.

The RCA team will review the documentation and review the sequence of events and continue asking themselves "Why did this happen?" until they arrive at each root cause.

The team must assume that any problem is preventable and caused by weak or vulnerable systems rather than individual incompetence. Even in the case of a person making a mistake, the team must ask "Why do our systems allow these types of mistakes to happen so easily?" or "What factors set this person up to make this error?"

The heart of the process is the analysis itself. Table 1 lists basic questions that should be answered during RCA.

Table 1. Basic Questions to Answer During RCA
1. What happened?
2. What normally happens?
3. What do policies/procedures require?
4. Why did it happen?
5. How was the organization managing the risk before the event?

It is important to answer "What normally happens?"(Question 2, in the above table). The difference between "What normally happens?" and "What do the policies and procedures require?" (Question 3) helps determine the reliability of processes and how often staff cut corners to get the work done.

RCA also includes a method to measure the effectiveness of these strategies over time. Targeting corrective measures at the identified root causes is the best way to ensure that similar problems do not occur in the future.

USP Releases Universal Standards for Prescription Labels

New United States Pharmacopeial Convention (USP) standards for a universal approach to the format, appearance, content, and instructions for medicines in containers dispensed by pharmacists have been released. "Wide variability in prescription container labels exists today across individual prescriptions, pharmacies, retail chains and states. The USP standards provide specific direction on how to organize labels in a 'patient-centered' manner that best reflects how most patients seek out and understand medication instructions," as explained in a USP press release. Lack of universal standards for medication labeling can contribute to patients

misunderstanding dosage instructions and can lead to medication errors. Elements of the new USP standards, contained in General Chapter <17> Prescription Container Labeling, of the USP and the National Formulary, include:

- Emphasizing instructions and other information important to patients
- Improving readability
- Giving explicit instructions
- Including purpose for use
- Addressing limited English proficiency
- Addressing visual impairment

Descriptions of each standard including examples, as well as more information about the development of the standards, are provided in a USP press release, available at *http://us.vocuspr.com/Newsroom/ViewAttachment.aspx?SiteName=USPharm&Entity=PRAsset&AttachmentType=F&EntityID=109587&AttachmentID=5dc9eb96-5706-4e61-b0fa-ce9673fb3010*.

Enforcement of the standards will be the decision of individual state boards of pharmacy, which may choose to adopt it into their regulations, notes USP. The National Association of Boards of Pharmacy® (NABP®) member boards adopted Resolution 108-1-12 at the NABP 108th Annual Meeting stating that the Association should support state boards of pharmacy in efforts to require a standardized prescription label. NABP also convened a task force on this issue in December 2008. The resolution and the Report of the NABP Task Force on Uniform Prescription Labeling Requirements are available in the Members section of the NABP Web site.

New Law Increases Penalties on Medical Cargo Theft

New legislation signed into law by President Obama on October 5, 2012, increases penalties for medical product cargo theft, a significant problem that threatens patient safety when these stolen products are reintroduced into the legitimate supply chain. The Strengthening and Focusing Enforcement to Deter Organized Stealing and Enhance Safety Act of 2012 (SAFE DOSES Act) prohibits theft of medical products as well as trafficking, buying, selling, or distributing illegally obtained pre-retail medical products. The law "prescribes criminal and civil penalties for violations, including a civil penalty of up to the greater of 3 times the economic loss attributable to the violation or $1 million." According to the Coalition for Patient Safety and Medicine Integrity, "current federal criminal laws do not distinguish between stealing a load of insulin and stealing a truck full of paper clips." By increasing the penalties for medical theft, the SAFE DOSES Act should help deter such theft. The text of the new law is available for download from the Government Printing Office Web site at *www.gpo.gov/fdsys/pkg/BILLS-112hr4223enr/pdf/BILLS-112hr4223enr.pdf*.

NABP Implements Action Plan to Assist States in Regulating Compounding Pharmacies

Supporting state board of pharmacy efforts to enforce compounding regulations, NABP is implementing a four-part action plan centered around inspection of nonresident compounding pharmacies and creating an information-sharing network of regulatory details on such pharmacies. Focusing on inspections of nonresident compounding pharmacies and sharing this data among boards of pharmacy nationwide was determined by NABP and its member state boards of pharmacy to be key to preventing future tragedies like the current meningitis outbreak.

NABP developed the action plan at a November 2012 meeting of board of pharmacy executive directors where the attendees expressed a strong commitment to correcting system failures that allowed the meningitis outbreak to occur, and implementation began quickly thereafter. The Iowa Board of Pharmacy recently requested NABP to develop an inspection program for entities that are licensed by the state as nonresident pharmacies and dispensing compounded drugs in Iowa. Those in attendance expressed their support of this inspection initiative, which became a cornerstone of the four-part action plan.

In the first part of its action plan, NABP shared the list of nonresident compounding pharmacies provided by the Iowa Board with other NABP member boards of pharmacy and began coordinating the collection of information on these pharmacies. The boards' collaboration on this data helped NABP identify the initial pharmacies to inspect. NABP believes that the list provided by Iowa represents a significant number of nonresident pharmacies dispensing compounded drugs across the country.

Implementing the inspection program is the second part of the action plan and is currently underway. Initial results will reveal whether the selected pharmacies are compounding pursuant to a prescription in compliance with state regulations, or instead are engaging in manufacturing. Entities that refuse inspection may be subject to disciplinary action by the Iowa Board and such actions will be shared with all of NABP's member boards.

The third part of the action plan includes NABP collecting and maintaining data on the compounding pharmacies identified by the Iowa Board and by other boards of pharmacy. Initial data collected from the boards and the inspection reports will be stored in an NABP Pharmacy e-Profile, allowing the Association to disseminate pertinent public information among state boards. Ultimately, states will be able to submit inspection reports and other related information to NABP for inclusion in pharmacies' e-Profiles. The network will be made available at no cost to boards for use in making licensure and registration determinations for pharmacies, and may also help to identify pharmacies whose operations are more akin to manufacturing than compounding.

As the final part of the action plan, NABP plans to schedule immediate and ongoing training of board of pharmacy inspectors and compliance officers via Webinar and field training opportunities. NABP will also continue cooperative efforts with Food and Drug Administration and legislators to address the regulatory quagmire that exists when traditional compounding is exceeded and manufacturing may be occurring.

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Therefore, unless it is for a research, teaching, or other similar situation that is not for sale or dispensing, pharmacies may compound only for individual prescriptions, or in anticipation of their regular and routine prescription-dispensing needs.

Second, looking at the Massachusetts situation as an example, because of the quantities shipped by the NECC, it appears they were manufacturing and selling at wholesale, and not for individual prescriptions. This would be wholly illegal under West Virginia law unless the pharmacy gets the proper licensures. If a pharmacy manufactures, it is legal **only if** the pharmacy gets licensed as a manufacturer and follows all state and federal laws governing manufacturing of prescription drugs. Further, if a pharmacy were to sell its manufactured products, then it would need to be properly licensed as either a manufacturer or wholesaler/distributor in the jurisdictions into which it is sending its product (note, of course, this is different than the exception to wholesaling drugs where a pharmacy is simply making distributions that do not exceed 5% of their business, such that a wholesale license is not required).

Third, in order to protect the safety of the public, naturally, great scrutiny is put on manufacturers for good manufacturing practices and standards. Likewise, compounding must be done in a safe manner to protect the patient. Rule §15-1-18 sets minimal standards in West Virginia for sanitary regulations in the pharmacy. Further, Rule §15-1-16 governs compounding in this state, which, among other things, requires in Subsection 16.3 that ". . . [t]he environment shall facilitate controlled aseptic conditions and meet all standards of the United States Pharmacopeial Convention (USP). . ." That is why when inspecting a compounding pharmacy, the Board looks for USP Chapters 795 and 797 compliance (flow hoods, donning and doffing antechambers, sterility, etc).

In summary, if you do compounding, be sure you have a prescription for each shipment to a patient. Make sure you are doing it in a clean and safe environment, and are properly handling the materials and instruments used to serve your patients. Compounding is at the heart of the practice of pharmacy, and to keep it there, every person involved in the process must do his or her best to safeguard the art by keeping the safety of the patient first and foremost at all times.

Controlled Substances Monitoring Program Upgrades Rolling Forward

At the time of this writing, the West Virginia Controlled Substances Monitoring Program (CSMP) is in the final stages of upgrades and revamping to bring it to American Society for Automation in Pharmacy 4.2 reporting standards, allowing it to provide for collection and reporting of all the data required by the changes to West Virginia Code §60A-9-1, et seq., in Senate Bill 437 (2012), and to finally let the Board connect to the PMP InterConnect® hub operated by the National Association of Boards of Pharmacy® for interstate data sharing. The Board had hoped to be rolling it out for final testing and full implementation in March 2013, but, unfortunately, the purchase and delivery of the required servers was a bit delayed, taking about six weeks longer for the process than the Board had realized for them to be ordered, shipped, and installed. Nonetheless, the work has continued to go forward, and, if all has gone well between the time of this writing and it coming to you in print, the Board will be asking all users at this time to re-credential themselves in the new system platform with your user-profile data, and some other information to get the system off the ground. Thank you for your patience and feedback as the Board unveils the new CSMP platform. The Board is very excited about all of the things it will enable the Board to do on the administrative side, and hopes that it provides a more secure, user-friendly, and valuable tool to you as practitioners.

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West Virginia Board of Pharmacy

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