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Vermont Board of Pharmacy News

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New Board Members

Governor Peter Shumlin has appointed two new members to the Vermont Board of Pharmacy. King Milne, RPh, replaces Earl Pease, RPh, as a pharmacist member of the Board. Mr Pease's term on the Board was over and he was not eligible for reappointment. James Arisman replaces Conrad Boucher as a public member of the Board. Mr Boucher resigned for personal reasons. Both Mr Milne and Mr Arisman will serve a term of five years ending on December 31, 2017.

Mr Milne is a resident of Charlotte, VT. From 1983 until his retirement in 2011, Mr Milne served as director of pharmacy at Porter Hospital in Middlebury, VT, providing pharmacy services to a critical access hospital. As pharmacy director, he trained and assisted nursing staff in pharmacology and administration of newly approved drugs, was a member of the pharmacy and therapeutics committee, provided patient education regarding medication therapy, coordinated the adverse drug reaction database, and taught nursing students from nearby colleges. In addition, Mr Milne served as preceptor and instructor for pharmacy school students on rotation at Porter Hospital.

Mr Milne is a graduate of the Albany College of Pharmacy and received his bachelor of science in pharmacy in 1967. He is a currently licensed Vermont pharmacist, and a member of the Vermont Society of Health-System Pharmacists.

Mr Arisman is a resident of Marshfield, VT. He has been an attorney in private practice since 2009. From 1995 to 2009, Mr Arisman was an assistant attorney general in the Office of the Attorney General of Vermont, serving from 1998 to 2009 as the lead prosecutor for the Vermont Board of Medical Practice. He also served the office as trial counsel in federal civil rights matters.

Prior to his service in Vermont, Mr Arisman was assistant United States attorney for the District of Columbia, and a law clerk for the United States Attorney Office for the District of Columbia.

Mr Arisman is a graduate of the Catholic University School of Law, having received his juris doctor degree in 1989. He also received a bachelor of science degree from The Ohio State University.

Incident Reporting

Pharmacist managers are reminded of their duties as listed in the Board Rules, Part 6. All pharmacist managers should review this list of duties and be familiar with them. Of particular note is the pharmacist manager requirement to report any disciplinary action taken by a pharmacy against any pharmacist, pharmacist intern, or pharmacy technician.

Pharmacist managers must also immediately notify the Board of any theft or significant loss of prescription drugs by telephone, e-mail, or fax. There have been a number of incidents of drug diversion or loss of prescription drugs in which the pharmacy has only notified the Board after being contacted by the Board asking for the report. Failure to submit the required report in a timely manner may result in disciplinary action against the pharmacy and/or pharmacy manager.

For your convenience, the relevant portions of the Administrative Rules of the Vermont Board of Pharmacy are reprinted below. Please pay particular attention to (h) and (I)(1) as they relate to discipline and drug loss.

6.3 Duties Included. The current or proposed pharmacist-manager shall:

(a) be responsible for proper closing of the drug outlet; or if a foreclosure or bankruptcy, the official in charge shall obtain the services of a pharmacist to serve as acting pharmacy-manager.

(b) be responsible for required record keeping of drugs and devices that are destroyed, surrendered to the Board, or returned to the wholesaler or manufacturer for disposal.

(c) be responsible for enforcing security standards for the prescription area.

(d) ensure that all policies and procedures are in computerized form or if written shall be collected in a format such as a three-ring binder that can be easily accessed, updated and revised as necessary.

(e) assure that the automated pharmacy dispensing system is in good working order. and. accurately.

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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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dispenses the correct strength, dosage. form, and. quantity of the drug prescribed while maintaining appropriate record keeping and security safeguards.

(f) implement an ongoing quality assurance program that monitors performance of the automated pharmacy dispensing system, which is evidenced by written policies and procedures adopted by the pharmacy.

(g) assure that all pharmacists employed at the pharmacy are properly licensed, all pharmacy technicians are properly registered, and that all pharmacy interns employed at the pharmacy are properly registered with the Board of Pharmacy.

(h) report to the Board within 10 days, along with.. supporting information and evidence, any disciplinary action taken by it or its staff, after an initial investigation, or hearing in which a pharmacist, pharmacist intern, or pharmacy technician has been afforded the opportunity to participate, which limits or suspends, conditions, or terminates that person's employment for drug diversion or violations of the rules and statutes governing pharmacy practice. If the pharmacy manager is disciplined, the pharmacy owner shall report the action to the board.

(I) Notify the Board of Pharmacy immediately of any of the following changes on forms provided by the Board:

(1) Any theft or significant loss of prescription drugs shall be reported to the Board immediately by telephone, email or fax. Within three days, a written report shall be made on forms available from the Board and on line for this purpose;

(2) Change of ownership of the pharmacy, including the filing of a new application for licensure by the owner, corporate officer of partner;

(3) Change of address of the pharmacy, or if change of location, including the filing of a new application;

(4) In the event of bankruptcy or foreclosure, the official in charge shall obtain the services of a pharmacist to serve as acting pharmacist-manager;

(5) Permanent closing of the pharmacy; and

(6) Disasters, accidents and emergencies which may affect the strength, purity or labeling of drugs, medications, devices or other materials used in the diagnosis or the treatment of injury, illness and disease shall be immediately reported to the Board;

(j) Make or file any reports required by state or federal laws and rules;

(k) Respond to the Board of Pharmacy regarding any violations brought to his or her attention;

(l) Establish policies and procedures for maintaining the integrity and confidentiality of prescription information and patient health care information, or verifying the existence thereof and ensuring that all employees of the pharmacy read, sign, and comply with the established policies and procedures;

(m) Provide the Board with prior written notice of the installation or removal of automated pharmacy systems. The notice must include, but is not limited to:

(1) The name and address of the pharmacy;

(2) The name and location of the automated equipment; and

(3) The identification of the responsible pharmacist.

The *Vermont Board of Pharmacy News* is published by the Vermont 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.

Ronald J. Klein, RPh - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
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