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Nevada State Board of Pharmacy News

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Chris Shea Honored With Bowl of Hygeia

The Bowl of Hygeia Committee is pleased to announce the 2014 recipient of this most prestigious award, namely, Christopher J. Shea, PharmD, of Reno, NV. Chris is a graduate of Idaho State University (1999) and received his certification in geriatric pharmacy in 2002, from the Commission for Certification in Geriatric Pharmacy. Licensed in Nevada, Arizona, and Idaho, Chris is the founder and president of IntegriCare RX (operating a dispensing pharmacy servicing skilled nursing/step-down rehabilitation facilities, merging the dispensing and clinical aspects of pharmacy to maximize safety, efficacy, outcomes, and cost) and IntegriCare Clinical Associates (implementing pharmaceutical care plans; clinical pharmacy consulting and educational services; and cost containment). He is an adjunct professor for Idaho State University, and sits as a governor's appointee on both the Nevada Medicaid Drug Utilization Review Board and the Nevada Pharmacy and Therapeutics Committee. Chris has been involved with the University of Nevada School of Medicine both in a teaching role and at the Sanford Center for Aging on its Medication Therapy Management Program Committee.

The Bowl of Hygeia was first presented in 1958, prompted by the A.H. Robins Company, and currently recognizes one pharmacist from each state in the United States, the District of Columbia, Puerto Rico, and from each province in Canada who has compiled an outstanding record of community service, which reflects well upon our profession in addition to his or her professional accomplishments. Chris provides an extensive range of community service through varied presentations and seminars, demonstrating his passion for and dedication to improving the quality of life for our seniors.

The formal presentation of the Bowl of Hygeia to Chris took place the morning of December 3 at the December Nevada State Board of Pharmacy meeting in Reno. Congratulations, Chris!

Drug Disposal

On October 9, 2014, the Drug Enforcement Administration (DEA) final rule on drug disposal took effect. The rule creates pathways by which drugs that have been dispensed to the ultimate user may be securely submitted to authorized collectors for disposal. DEA registrants eligible to voluntarily participate may modify their current DEA registration to become an "authorized collector," and include retail pharmacies, hospitals, narcotic treatment facilities, and clinics with an on-site pharmacy. Pharmacies may operate a collection receptacle in a long-term care facility as well. The rules are many and detailed, and need to be carefully considered before changing your registration. Also of note, registrants may **not** use approved collection receptacles to dispose of unwanted or outdated stock.

Currently, Nevada law **prohibits** retail pharmacies, hospitals, and clinics from accepting drugs from an ultimate user. The Board, in upcoming meetings, will consider regulatory changes to allow participation.

Inspector's Corner

- A pharmaceutical technician-in-training must complete his or her 1,500 hours of training within **two years** of the granting of his or her technician-in-training registration. If those hours are not accomplished within this time frame, the technician-in-training must start all over by filing a new application and beginning another 1,500-hour quest!
- Many pharmacies are not compliant with the law when using mechanical devices (Pyxis, Yuyuma, ScripPro, Baker Cells, and the like) to count or dispense drugs. NAC 639.715-720 requires a review of the drugs placed into the mechanical device by the pharmacist, as well as documentation of that review, which must be kept for two years. The Board has had at least two recent cases where the wrong drug was dispensed to the patient (with harm, by the way) simply because the wrong drug was put in the cell by the technician and not verified by the pharmacist.
- Do not forget to post your current proof of licensure at your primary site of practice, and when working in another pharmacy, carry a copy of that proof of licensure. This goes for both pharmacists and pharmaceutical technicians. The pocket identification provided by the Board is not acceptable as proof of licensure, and it clearly states that it

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DEA Finalizes Rule on CS Prescription Drug Disposal

In September 2014, Drug Enforcement Administration (DEA) published its final rule, titled the Disposal of Controlled Substances, that allows some DEA registrants to modify their registration to become authorized collectors. Under the new rule, some DEA registrants, including retail pharmacies, hospitals/clinics with an on-site pharmacy, manufacturers, distributors, reverse distributors, and narcotic treatment programs, may modify their registration with DEA to become authorized collectors. The final rule implements the Secure and Responsible Drug Disposal Act of 2010, which authorized DEA to develop and implement regulations that would allow authorized entities other than law enforcement to collect unused and unwanted prescription drugs, including controlled substances (CS), for disposal purposes. Proper disposal of unused prescription medication is a key method of preventing and reducing prescription drug abuse. The final rule took effect on October 9, 2014.

The full rule is available on the *Federal Register* website at *www.federalregister.gov/articles/2014/09/09/2014-20926/disposal-of-controlled-substances.*

System-Based Causes of Vaccine Errors

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization 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 provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at* www.ismp.org. *Email: ismpinfo@ismp.org.*

Immunizations are widely recognized as one of the most successful and cost-effective health interventions ever introduced worldwide. However, errors with vaccines can result in an unintended and unrecognized source of vulnerability. While the immediate impact of a vaccine-related error on a patient may not be serious, such errors may render the vaccine ineffective or reduce its effectiveness, leaving patients unprotected against serious diseases such as hepatitis A, hepatitis B, diphtheria, tetanus, measles, cervical cancer, and many others. In September 2012, ISMP (in cooperation with the California Department of Public Health) established the ISMP National Vaccine Errors Reporting Program (VERP) to collect data about the type of vaccine errors occurring and the reasons they occur. In ISMP's November 28, 2013 newsletter *(www.ismp.org/sc?id=307),* ISMP provided a summary analysis of error reports submitted to the ISMP VERP during its first year. The vaccinations that are most frequently associated with errors included *Haemophilus influenzae* type b conjugate (Hib); diphtheria and tetanus toxoids, acellular pertussis adsorbed, and inactivated poliovirus (DTaP-IPV); tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis adsorbed (Tdap); diphtheria, tetanus toxoid, and acellular pertussis adsorbed (DTaP); hepatitis A (HepA); hepatitis B (HepB); human papillomavirus quadrivalent (types 6, 11, 16, and 18), recombinant (HPV4); zoster; and measles, mumps, rubella, and varicella (MMRV). The most common contributing factors associated with the reported vaccine errors included mistakes in choosing age-dependent formulations of vaccines intended to prevent the same diseases; unfamiliarity with the vaccine, particularly its dose, dosing schedule, age specifications, route of administration, and the vaccine's various components (eg, combination vaccines, diluents, and powder); failure to check or verify the patient's age, health record, or state registry; similar vaccine names and abbreviations; similar and confusing vaccine labeling and packaging; unsafe storage conditions (eg, stored near other similar vaccines or unwanted temperature fluctuations); and expiration dates not noticed or misunderstood.

Practice Recommendations. Involve the patient or parent(s)/caregiver(s) in a vaccine verification process by:

1) Documenting the vaccine name, formulation (pediatric or adult, if applicable), lot number, and expiration date on the patient's vaccine record **prior** to preparation/administration of the vaccine,
2) Bringing the vial and syringe or the prefilled syringe along with the immunization record into the exam room,
3) Asking the patient or parent/caregiver to simultaneously verify the information on the immunization record while a health care provider reads the information on the label aloud,
4) Asking the patient or parent/caregiver if the verified vaccine is what he or she expected to be administered (based on an immunization schedule provided to the patient or parent/caregiver previously),
5) Preparing and administering the vaccine immediately after verification, and
6) Documenting the vaccine on the patient's medical record.

FDA Warns of Growing Network of Rogue Wholesale Drug Distributors

Through a new educational program called Know Your Source, Food and Drug Administration (FDA) is warning pharmacists and other health care providers to watch for counterfeit and unapproved drugs. Aimed at protecting patients from unsafe and ineffective drugs, the program advises providers to only purchase drugs from wholesale drug distributors licensed in their state. Further, FDA offers tips to providers to protect patients, including being wary of offers too good to be true, and ensuring that all drugs received are FDA-approved medications.

Another way that pharmacies can be assured of the legitimacy of a wholesale distributor is to look for the National Association of Boards of Pharmacy® (NABP®) Verified-Accredited Wholesale Distributors® (VAWD®) Seal. Those wholesale distributors that achieve VAWD accreditation are in compliance with state and federal laws, as well as NABP's VAWD criteria. Wholesale distributors that display the VAWD Seal as part of their accreditation have undergone a criteria compliance review, including a rigorous

review of their operating policies and procedures, licensure verification, survey of facility and operations, background checks, and screening through the NABP Clearinghouse. Accredited facilities are reviewed annually and undergo a site survey every three years. Created in 2004, the accreditation program plays a pivotal role in preventing counterfeit drugs from entering the United States drug supply.

Additional information about the VAWD program is available in the Programs section of the NABP website. Know Your Source is available at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm389121.htm*.

PTCB Implements Changes to CE Requirements

In 2015, the Pharmacy Technician Certification Board (PTCB) will implement two changes in recertification requirements for certified pharmacy technicians (CPhTs) in accordance with its certification program changes announced in 2013. First, any continuing education (CE) hours earned by a CPhT will need to be pharmacy technician-specific in order to qualify toward recertification. Second, PTCB will reduce the number of allowable "in-service" CE hours from 10 to five. PTCB's certification program changes are intended to support and advance improved patient care and safety throughout pharmacy practice, a PTCB press release indicates. The changes are the result of a PTCB initiative that began with a 2011 summit on future directions for pharmacy technicians.

Additional information can be accessed on the PTCB website at *www.ptcb.org*.

Security Guidelines Available as Rate of Pharmacy Robberies Still a Concern

Nationally, pharmacy robberies dipped slightly from 745 in 2012, to 713 in 2013, according to a report compiled by *Drug Topics* using DEA statistics. The 10 states that had the most robberies are in stark contrast to other states that had no robberies (South Dakota, North Dakota, and Alaska) or as few as one or two (such as Montana and Illinois), reports *Drug Topics*. However, fueled by the prescription drug abuse epidemic, pharmacy robberies still pose a threat to the safety of personnel and customers. The report lists the top 10 states that had the most pharmacy thefts in 2013. Arizona experienced the most pharmacy robberies in 2013 with 77 incidents, and Indiana took second place with 71 robberies. The report, titled "Top 10 states for pharmacy robberies," may be found at *http://drugtopics.modernmedicine.com/drug-topics/content/tags/arizona/top-10-states-pharmacy-robberies?page=full.*

NABP partnered with DEA to create an educational pamphlet identifying key strategies pharmacists can take to secure their stores against robberies, which can be downloaded at *www.deadiversion.usdoj.gov/pubs/brochures/pharmtheft.pdf*. In addition, some boards of pharmacy have identified best practices for preventing pharmacy theft, and have supported these practices through regulations or recommendations for their licensees. For example, the New Jersey State Board of Pharmacy's *Pharmacy Security Best Practices* document recommends that all Schedule II and III CS be stored in a "safe or substantially constructed steel cabinet that is locked at all times," with only licensed pharmacists having access. Additional recommendations include annual pharmacist-in-charge self-assessments and interfacing with prescribers and customers, among others. The best practices document can be downloaded from the New Jersey Consumer Affairs website at *www.njconsumeraffairs.gov/press/05012013.pdf.*

Private organizations have also developed resources to assist pharmacies in improving security. One such resource is the RxPATROL program, which works with law enforcement, the pharmacy community, and security professionals to maintain a database containing detailed information about pharmacy robberies and other losses. In addition, the RxPATROL website, *www.rxpatrol.com*, provides training videos and a pharmacy security checklist.

Further, NABP members directed the Association to convene a task force to review strategies that states have taken to prevent theft and drug diversion. The Task Force to Examine Strategies for Preventing and Reacting to Pharmacy Robberies and Thefts met on October 22-23, 2014, to discuss these issues.

Assured Brand Naproxen Tablets Recalled Due to Packaging Error

In October 2014, Contract Packaging Resources of Greensboro, NC, a drug repackaging company, issued a voluntary recall of nearly 12,000 boxes of Assured brand naproxen sodium tablets because some cartons contain bottles of 200 mg ibuprofen softgels instead, a press release posted to the FDA website indicates. The packaging error affected boxes of Assured brand naproxen sodium tablets 220 mg, 15 count (Lot Number FH4102A), which were distributed to and sold at Dollar Tree stores and on the Dollar Tree website. Contract Packaging Resources is contacting customers to arrange for replacement of all recalled products. Adverse reactions or quality problems experienced with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting Program.

More information is available on the FDA website at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm419769.htm.*

Martin Avenue Pharmacy Issues Voluntary Recall for All Sterile Compounded Preparations

Martin Avenue Pharmacy, Inc, of Naperville, IL, issued a voluntary recall for all in-date compounded sterile preparations due to a lack of sterility assurance in August 2014. Following a recent FDA inspection that revealed "quality control procedures that present a risk to sterility assurance," the company issued the recall out of an abundance of caution, indicates a news release posted to the FDA website. Martin Avenue Pharmacy supplied compounded sterile preparations to offices of licensed medical professionals and individuals in multiple states including Illinois, Wisconsin, Ohio, Michigan, Florida, Alabama, and Texas until August 20, 2014. A full list of recalled products is available on the Martin Avenue Pharmacy website (registration required). FDA urges consumers and health care providers to report adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information Adverse Event Reporting Program.

More information is available on the FDA website at *www.fda.gov/Safety/Recalls/ucm412431.htm*.

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is not for posting purposes. A pharmacist must post his or her original certificate of registration at the primary place of practice, and an 8" x 11" copy of that original at any other location of practice.

- DEA promulgated a rule in 2010 (and Nevada followed suit in 2012) to allow the prescribing of all schedules of controlled substances (CS) electronically. Also required in that rule is a certification of any system utilized for the transmission or receipt of electronic prescriptions for CS. This certification is by either DEA itself or a DEA-authorized entity, so please ensure that your system is certified!

Inspectors Despise Cold Seats and Unprepared Pharmacies

The Board's inspectors complain more than usual lately. They are unhappy that the Board's vehicles do not have heated seats. They also grumble that, with greater frequency, pharmacies are not prepared for inspection when that exciting day arrives. The Board office takes both issues seriously. It is committed to resolving at least one of them.

The Board regulates the practice of pharmacy "for the protection of the public." To that end, Board staff must "inspect each licensed pharmacy annually" (NAC 639.501(2)). Likewise, each licensee gave consent to inspection by accepting a license from the Board (NRS 639.234(1)). The "refusal [of a licensee] to permit their inspection is a ground for suspension of and disciplinary action" against his or her license (NRS 639.234(4)). That last provision puzzles the Board, as regulatory inspections are known to be fun. Oddly, the law is silent regarding seat warmers in state vehicles.

To promote uniform and efficient annual inspections, the Board first sends a pre-inspection notice and self-assessment form (NAC 639.501(3)). The self-assessment form includes a compliance questionnaire and a workplace assessment form. The notice also directs the pharmacy to make ready for inspection its prior-year inspection form, current biannual inventory, DEA Form 222(s), and in-service records. (Tip: It is good to review the notes on the prior-year inspection form. Do make appropriate corrections before the inspector arrives.) While these forms are enjoyable to read, and the temptation to set them aside for future entertainment is understandable, the managing pharmacist or the designee of the owner shall complete the self-assessment form **before** each annual inspection (NAC 639.501(4); NAC 639.5016(1)).

When the inspector arrives, he or she will join in your merriment. He or she will "review [the] self-assessment form . . . with the managing pharmacist . . . or a pharmacist on duty in the pharmacy at the time of the inspection" (NAC 639.5016(1)). The inspector will note any discrepancies between the self-assessment form and the actual condition of the pharmacy (NAC 639.5016(2)). The pharmacy will correct noted items within a reasonable time (NAC 639.5016(3)). While it may be reasonable to own vehicles without seat warmers – particularly in southern Nevada – it is not reasonable (or wise) for a pharmacy to ignore deficiencies noted on its inspection form.

Incredibly, some pharmacies do not share the Board's passion for the inspection process. Inspectors often arrive to find that the pharmacy is unprepared. Paperwork is incomplete. Documents are missing. The pharmacy is not clean. When this happens, the inspection **may** still occur, but at a snail's pace while the pharmacist locates information and completes paperwork. More often, the inspector will leave a stern warning. He or she will return, but less excited after making a second – or even a third – trip without the calming comfort a heated seat can provide.

The Board is confident that Board staff can ease at least one of its inspectors' concerns. The first might be resolved with **outside** help from a local car dealership (inspectors, you probably should not count on it). The second issue, on the other hand, the Board can resolve without outside support. Consider yourself encouraged (or perhaps warned) to more adequately prepare for your annual inspection. If needed, the Board office stands ready to further assist by issuing personalized invitations to appear before the Board. Its members, the Board suspects, would provide additional help and inspiration.

The *Nevada State Board of Pharmacy News* is published by the Nevada State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation™ (NABPF™) 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 NABPF or the Board unless expressly so stated.

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