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News

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Finding Your Way

By John Ordiway, MS, LPC, LAT, clinical director, WPAP

Diabetes, hypertension, addiction, depression, and bipolar disorder; what do these conditions have in common? They are all chronic relapsing conditions. Generally, we do not have a problem seeking help if our body cannot function "normally;" however, when it comes to alcohol, drugs, and mental health, we too often avoid seeking help for fear of being seen as weak or "less than."

There are several reasons people in professional positions do not seek help for these conditions:

- Social stigma related to substance use and mental health
- Impact to professional reputation if condition becomes known to others
- Not recognizing the problem as serious compared to problems you see clients come in with
- Financial impact of attending treatment if needed
- Not knowing where to get help given the higher profile in the community
- Not ready to stop using substance or to start regulating mental health condition

No matter what, if your situation is mild depression, anxiety, stress, burnout, or addiction, resources are available to help you cope with the situation. If left untreated, these conditions can exasperate you over time and simply pull the joy out of your career and life. Research tells us that individuals in professional positions have significantly higher rates of suicide than the general public.

Let us take a look at some symptoms of various conditions that may indicate a need to reach out before things become overwhelming.

Substance Abuse	Depression	Anxiety
Neglecting responsibilities	Feeling helpless/ hopeless	Problems sleeping
Taking risks while under the influence (eg, driving)	Loss of interest in daily activities	Feeling fear/ uneasiness
Relationship problems	Sleep pattern changes	Excessive worry
Changed activities and friends	Anger or irritability	Irrational fears
Continued use despite knowing that it is hurting you	Loss of energy	Muscle tension
	Reckless behavior	

Burnout	Bipolar Disorder (Manic Phase)	Bipolar Disorder (Depressive Phase)
Negative attitude about work	Euphoria	Hopelessness
Feelings of stagnation	Racing thoughts	Fatigue
Feeling like you are never doing enough	Rapid speech	Guilt
Neglecting your own needs	Risky behaviors	Chronic pain
Lack of interest in social activities	Decreased need for sleep	Problems concentrating
Detached from people you care about	Easily distracted	Loss of interest in activities

What If I Have a Concern?

The first thing to do is to reach out and talk with someone. We all have different support systems; examples include a spouse, family member, friend, pastor, self-help program (eg, Wyoming Professional Assistance Program (WPAP), Alcoholics Anonymous, Narcotics Anonymous), or a treatment provider.

What Is Recovery?

Traditionally, when we think of recovery, it is related to a substance use problem. I propose an alternative thought: recovery is the process of improving your life. If you are taking medication to lower blood pressure, you are in recovery for better health outcomes. If you take medication for a mental health condition, you are in recovery from your symptoms and behaviors related to that condition. This concept can be applied to any change process you are going through, such as overspending, gambling, or lack of family time – truly, any behavior.

Contact WPAP for confidential assistance with any substance use or mental health concerns at 307/472-1222.

Compliance Corner

By Inspectors Richard Burton, RPh, and Hank York, RPh

The focus of inspections in 2015 will include the following: perpetual inventory reconciliation, demonstration of the ability to contact the Wyoming Online Prescription Database program, how the pharmacy reports immunizations to the Wyoming Immunization Registry database at the Wyoming Department of Health, written agreements between pharmacies and long-term care facilities, demonstration of sterile compounding (the compliance officer may garb and enter the cleanroom), documentation of quality assurance in sterile compounding, review of the master compounding record for nonsterile compounding, reconciliation of ingredients for any compounding, ability to access the Wyoming State Board of Pharmacy

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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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website for *Newsletters* and information, private space for immunizations, competency and training records for any compounding, how the pharmacist distributes Risk Evaluation and Mitigation Strategy information, canceling of controlled substance (CS) prescriptions, matching the sig code to the label, and any other issue identified during the previous inspection.

Duty to Report Violations, Wyoming Pharmacy Act, Rules, Chapter 2, Section 9(b)

> Responsibility as the [pharmacist-in-charge (PIC)] includes requiring that all federal and State pharmacy laws and regulations are complied with and enforced. It shall be the duty of the PIC to report all pharmacy violations within their facility to the Board, with the single exception that, whenever a PIC or staff pharmacist reports a pharmacist or pharmacy technician to the Wyoming Professional Assistance Program (WPAP) for suspected substance abuse, no further reporting to the Board regarding the name of the suspected substance abuse impaired pharmacist or pharmacy technician needs to be done. Any pharmacy technician-in-training or pharmacy intern suspected of substance abuse and reported to WPAP shall be reported to the Board.

EPCS

Effective July 1, 2011, the Wyoming Controlled Substances Act allowed for electronic prescriptions for controlled substances (EPCS) in Schedules II through V. In order to use computer-to-computer transmission, the prescribing software must undergo accreditation to ensure security, and the prescriber must use a two-factor authentication. The receiving pharmacy dispensing software must also be accredited. According to Surescripts, the number of prescriptions processed electronically for CS has grown in recent years and may reach 90% of all prescriptions by 2018. Providers can use one workflow for all electronic prescriptions, and legibility issues should decrease. The review of possible allergies and other adverse drug reactions takes place before the pharmacy does its review, which should decrease adverse events. Formulary issues can be resolved before the pharmacy receives a new prescription. The pharmacy may be able to reduce paper storage, and the number of forged prescriptions should decrease, whether by tampering with paper prescriptions or unauthorized telephone prescriptions. On the Surescripts website *(www.surescripts.com/epcs)* there is a listing of accredited prescribing and dispensing software systems, which may be accessed by clicking on the "State Readiness and Local Search Tool."

A pharmacy can contact its system vendor and ask about certification, then set up access controls and an electronic prescription audit process.

Recent Disciplinary Actions

K.T. Pharmacy Technician License #1789T: Letter of Admonition for dispensing a prescription drug product other than what was ordered by the practitioner. Additional continuing education (CE) required, plus must submit a personal plan to improve medication safety.

W.K. Pharmacist License #2769: Letter of Admonition for dispensing a prescription drug product other than what was ordered by the practitioner. Additional CE required, plus must submit a personal plan to improve medication safety.

C.B. Pharmacy Technician License #2071T: Revocation of license due to failure to comply with conditions placed on the license in 2013.

Theft or Loss of CS

Every month, the Board receives several Drug Enforcement Administration (DEA) Report of Theft or Loss of Controlled Substances forms (DEA Form 106). Many times, one of these forms reports the loss of a 100-count bottle of a Schedule II CS. Often, the reason cited is that the bottle was accidentally thrown out in the trash or swept into the garbage as the counter was cleaned. Other reasons include accidentally dispensing an extra 100 tablets when filling a prescription, and an inability to count the bottles of drugs on the shelf and add/subtract properly when doing the perpetual inventory.

The Board is very concerned about these losses and considers such losses to be unacceptable. The Board reminds PICs of their responsibility for all aspects of the pharmacy operation. This includes security and policies and procedures that prevent the loss of CS, as well as up-to-date maintenance of a perpetual Schedule II CS inventory. Reference Wyoming Controlled Substances Act, Rules and Regulations, Chapter 4, Section 1(c)(iv): "All retail and institutional pharmacies shall maintain a perpetual inventory for all schedule II controlled substances. This inventory shall be reconciled no less than once a quarter. Discrepancies discovered during reconciliation shall be reported to the board within 10 calendar days of discovery. Only those discrepancies, which are considered a significant loss or gain shall be reported. For the purpose of this section a significant loss or gain shall exist whenever the actual inventory differs from the recorded inventory by more than five percent (5%) for any drug product."

Goodbye to Randy Harrop

Randy Harrop, RPh, has completed two terms on the Board, including serving twice as president. He has worked to protect the citizens of Wyoming through various pharmacy issues such as immunizations by pharmacists, telepharmacy, wholesale distributor regulations, compounding, sterile compounding, and many other changes to the practice act and rules. His commitment and leadership over the past 12 years will be missed.

The *Wyoming State Board of Pharmacy News* is published by the Wyoming 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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