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# Oregon State Board of Pharmacy News

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## No. 525: Corresponding Responsibility for the Dispensing of Controlled Substances

According to Title 21 of the Code of Federal Regulations, Section 1306.04, pharmacists are required to ensure that prescriptions for controlled substances (CS) are issued for a legitimate medical purpose *(www.deadiversion.usdoj.gov/21cfr/cfr/1306/1306_04.htm)*.

> A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act **(21 U.S.C. 829)** and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

### Corresponding Responsibility

What does this mean? Well, it does not mean the pharmacist has to prove the prescriber is providing the right therapy. That is the prescriber's job. The pharmacist should not "second guess" the prescriber's therapeutic decision. However, it does mean that pharmacists must confirm the authenticity of prescriptions before dispensing in order to satisfy Drug Enforcement Administration (DEA) requirements. The pharmacist must confirm that the prescription has been issued "for a legitimate medical purpose by a licensed practitioner acting in the usual course of professional practice." Pharmacists must use their judgment in this effort.

Each prescription is individual and unique and must be reviewed in its current context. Has the prescriber's DEA registration number been verified? Does the diagnosis or indication for use of the medication appear on the prescription? Has the patient's relationship with the prescriber been confirmed? These are essential in determining authenticity and legitimacy.

Has the prescription drug monitoring program been checked? Is the patient or the prescriber known to the pharmacy staff? Is the prescriber or patient from a distant location? Is the prescription written for an unusual quantity or combination? Are multiple prescriptions being issued by the same prescriber in the same quantities and combinations? Is the patient's behavior suspicious? Is the prescriber's signature consistent with other prescriptions written by the same prescriber? Is the patient opting to pay cash? These are all examples of potential red flags that may require further review under the pharmacist's corresponding responsibility. The more red flags one discovers, the more one should strive to confirm the legitimacy of the prescription. A pharmacist may not lawfully fill a prescription he or she knows, **or should have known,** is not legitimate.

Documentation is important. If it is not documented, it did not happen. Pharmacists may obtain necessary information directly from the patient or may need to verify certain prescriptions by contacting the prescriber. Privacy laws allow prescribers to share this information with other health care professionals who are providing care to the patient, including pharmacists *(www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/index.html)*.

## No. 526: Prescription Scam Scenarios Shared

*By Eric Okasaki, PharmD Candidate, Pacific University*

In 2010, 2 million people in the United States reported using prescription painkillers non-medically for the first time within the last year – nearly 5,500 a day. In subsequent years, the increase in non-medical use of prescription drugs, combined with the decline in the use of many illegal drugs, is being interpreted as a sign that prescription drugs have become a more relevant part of the nation's drug problem. With statistics like these, and with diversion schemes becoming ever more inventive and complex, the pressure on pharmacists to recognize fraudulent prescriptions continues to mount.

Pharmacists may use the Voluntary Fraudulent Prescription Reporting Form found on the Oregon State Board of Pharmacy Web site *(www.oregon.gov/pharmacy/pages/Fraud_info.aspx)* to report such occurrences to their local law enforcement agency and to the Board. Local law enforcement agencies want the reports so they can track trends and follow up on repeated attempts or organized prescription scams. They also provide information to the Board on organized fraudulent prescription activity. These agencies do not, however, have resources to respond to a pharmacy every time a prescription scam is occurring. It is important that the form be filed with your local police agency to facilitate their enforcement responsibilities and collaboration with the Board.

The Board's Compliance Department, upon receipt of the form, attempts to confirm the activity with law enforcement and practitioners involved, and compiles the reported information into a database. This enables the tracking of trends and patterns of fraudulent prescriptions or scam scenarios throughout the state. Armed with a comprehensive overview of fraudulent activity in the state, the Board can generate "fraud alerts" to be sent out on the Board

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## Pharmacists Likely to Recommend OTC Medications, CHPA Reports

Patients most often seek a pharmacist's advice on treating coughs, headaches, migraines, and allergies, and 98% of pharmacists recommend or have no reservations recommending over-the-counter (OTC) products to treat such ailments, according to a recent survey. The Consumer Healthcare Products Association's (CHPA) report, "Understanding Trust in OTC Medicines: Consumers and Healthcare Provider Perspectives," presents the results of the survey, which was developed to better understand what drives consumer and health care provider trust in OTC products. The survey, developed and conducted by Nielsen and IMS, included over 1,100 consumer respondents, and over 500 health care provider respondents, composed of pharmacists, pediatricians, nurse practitioners, and primary care providers.

Pharmacists surveyed reported that they were more likely to recommend OTC products that demonstrated successful patient outcomes and consistent outcomes, and products known to be as efficacious as a prescription drug, and those containing ingredients known to be safe.

The survey also asked health care providers whether they recommended OTC products without, before, or in conjunction with recommending prescription drugs for certain symptoms. A majority of pharmacists surveyed, over 60%, recommend OTC medications to treat stomach symptoms and pain, without recommending a prescription treatment, and over 70% recommended OTC allergy, sinus, and flu medications without advising that a prescription drug is needed.

CHPA notes that with the expansion of patient self-care, OTC products will play an increasingly important role in health care. The potential for more prescription products to become OTC products in the new paradigm under consideration by Food and Drug Administration (FDA) could further impact this trend. As consumers are becoming more empowered in making health care decisions, they are also relying more on their pharmacist for medication advice. In fact, Nielsen and IMS findings show that multigenerational households, Hispanic households, and households who care for an adult outside of their home place a high value on pharmacist recommendations regarding selecting appropriate OTC medications, notes CHPA.

The full CHPA White Paper is available at *www.yourhealthathand.org/images/uploads/OTC_Trust_Survey_White_Paper.pdf.*

## ISMP Study on Targeted Mandatory Patient Counseling

*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 a recent study funded by a grant from Agency for Healthcare Research and Quality, ISMP evaluated the use of a combined checklist and patient information leaflet used during mandatory counseling sessions for consumers who pick up a filled prescription for 11 targeted medications:

- Opioid-containing analgesics
  - fentanyl patches
  - hydrocodone with acetaminophen
  - oxycodone with acetaminophen
- Anticoagulants
  - warfarin
  - enoxaparin
- Antidiabetic drugs (insulin analogs)
  - Humalog® (insulin lispro)
  - NovoLog® (insulin aspart)
  - Levemir® (insulin detemir)
  - Lantus® (insulin glargine)
  - Apidra® (insulin glulisine)
- Antineoplastic drug (non-oncologic use)
  - methotrexate

All 11 medications are on ISMP's list of high-alert medications dispensed from community pharmacies. Errors with high-alert medications may not be more frequent than errors with other medications; however, the consequences of errors with high-alert medications are often harmful. These 11 medications are also among the top 200 drugs dispensed in the United States, and many are used to treat chronic conditions, thus increasing the potential impact on public safety.

The medications were flagged in some manner to identify mandatory counseling opportunities. When a patient or patient representative picked up a flagged prescription, a pharmacist conducted a short counseling session (one to three minutes) that included the exchange of several key points on the checklist. At the end of the counseling session, the pharmacist provided the leaflet to the patient, along with a survey to complete and send back to ISMP.

Counseling sessions for these drugs were conducted for a consecutive period of four weeks, during which time, one trained ISMP staff member observed the counseling sessions for one day (six hours) to collect information on factors that facilitate or inhibit the counseling sessions. At the end of the four-week period of mandatory counseling, pharmacists at participating pharmacies were asked to complete a short mail-in survey regarding their perceived value of the process.

Results of the study showed that these consumer leaflets offer important safety tips for taking medication safely. Each leaflet begins with, "High-alert medicines have been proven to be safe and effective. But these medicines can cause serious injury if a mistake happens while taking them. This means that it is vitally important for you to know about this medicine and take it exactly as intended."

ISMP tested the readability, usability, and perceived value of the leaflets. Ninety-four percent of patients felt the leaflets provided great information or good information to know. Ninety-seven percent felt the information in the leaflets was provided in a way they could understand. Eighty-two percent of patients taking the drug for the first time and 48% of patients who had previously taken the medication reported learning something new. Overall, 85% of the patients felt they were less likely to make a mistake with the medication because they had read the leaflet.

The leaflets are available for download and can be reproduced for free distribution to consumers at *www.ismp.org/AHRQ/default.asp?link=ha.*

## Generic Drug Substitution Requires Pharmacist Attention to State Laws and Regulations

While 40 years ago, most states forbade prescription drug substitution, almost all states now have drug product selection laws that allow, encourage, or mandate pharmacists to substitute generics for brand-name

drugs. These laws vary widely from state to state and pharmacists are therefore encouraged to review their state's substitution laws to ensure that they understand and comply with the state's requirements.

FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* publication, commonly known as the *Orange Book,* is generally considered the primary source for identifying suitable generic alternatives for a brand-name drug, and while not mandated by FDA regulations, the majority of states use the *Orange Book's* determinations of therapeutic equivalence to legally guide pharmacists in substituting generics.

State laws on generic substitution vary widely. A few states, such as Kentucky or Minnesota, follow a "negative formulary" approach, in which substitution is permitted for all drugs except those that appear on a particular list. Other states, including Massachusetts and Wisconsin, use a "positive formulary" approach, in which substitution is limited to the drugs on a particular list.

States also differ as to whether their substitution laws are permissive, thereby allowing a pharmacist to substitute a generic version of a brand-name drug, provided all prescription requirements are met, or mandatory, thereby requiring substitution. Prescription requirements may include such factors as the availability of a cheaper, therapeutically equivalent drug, the prescriber's specification that a brand-name drug be dispensed, or requiring the patient's or prescriber's consent. As reported in the 2013 NABP *Survey of Pharmacy Law*, 14 boards of pharmacy indicate that generic substitution falls into the "mandatory" category, while 38 boards indicate that their substitution laws are "permissive." Oklahoma law states that "[I]t is unlawful for a pharmacist to substitute without the authority of the prescriber or purchaser."

Other regulatory variations include states specifying the acceptable means for the prescriber to designate that substitution is not authorized, and states requiring patient consent prior to substitution.

The full article on this subject, which also reviews considerations regarding the accuracy of therapeutic equivalent determinations, is available in the June-July 2013 *NABP Newsletter,* which may be accessed in the Publications section of *www.nabp.net.*

## NHF Provides Standards of Care for Pharmacies Serving Hemophilia Patients

For pharmacies that offer blood-clotting medications, organizations such as the National Hemophilia Foundation (NHF) emphasize the importance of being able to meet the specialized needs of their patients with bleeding disorders.

NHF's Medical and Scientific Advisory Council (MASAC) issued a standards-of-care recommendation in 2008 to assist pharmacies providing clotting factor concentrates for home use to patients with bleeding disorders. MASAC's guidelines are intended to be minimum standards of care and are divided into six areas:

As a brief overview of the MASAC guidelines, pharmacists wishing to meet the standards should:

1. Have a basic knowledge of bleeding disorders and experience with and knowledge of the full range of clotting factor concentrates, ancillary supplies, and hazardous waste disposal.

Pharmacies wishing to meet MASAC standards:

2. Should be able to provide a full range of available concentrates in all available assays and vial sizes, along with all necessary ancillary supplies, and hazardous waste disposal assistance as well as access to nursing services.
3. Should support reliable access to clotting factor for appropriate home treatment, by filling prescription orders within 48 hours, in the quantities prescribed, with expiration dates commensurate with the individual patient's needs.
4. Should be reliably open during regular business hours; provide 24-hour emergency access; and have an emergency action plan that allows patients to receive factor within 12 hours "in case of emergent need," with a goal of three hours "where logistically possible."
5. Should deliver products to the patient's desired location, meeting federal medication shipping standards, and providing an emergency number for patients to call in case of a problem with a delivery.
6. Should maintain patients' treatment prescription information along with maintaining records in compliance with state and federal requirements and be able to track the clotting factor products from manufacturer to patient, and participate in a recall information system.

The full article on this topic is available in the June-July 2013 *NABP Newsletter,* accessible in the Publications section of *www.nabp.net.* NABP notes that each state needs to review the standards recommended by MASAC to determine whether they coincide with existing state board of pharmacy requirements. NABP recognizes the unique patient needs of hemophiliacs, but also the responsibility of state boards of pharmacy to set required standards for medication dispensing and use. NABP is working with NHF to help the boards of pharmacy gain a better understanding of the medication needs of patients to help achieve uniformity in related regulations.

## NABPLAW Online Now Includes Guam, Puerto Rico, and the Virgin Islands

The complete pharmacy acts and regulations of Guam, Puerto Rico, and the Virgin Islands are now included in **NABP***LAW*® Online, the comprehensive national data bank of state pharmacy laws and regulations provided by NABP. **NABP***LAW* Online's powerful search capabilities allow users to research subjects one state at a time or across all 50 states and included jurisdictions. More information about **NABP***LAW* Online and a link to the online subscription order form are available in the Programs section of the NABP Web site at *www.nabp.net/programs/member-services/nabplaw/.*

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listserv directly to pharmacists-in-charge (PICs). It is expected that PICs disseminate the information to their staff. Reporting is encouraged as the overall intent is to collect, identify, and relay relevant information to pharmacists as they work to ensure that the right medication gets into the right hands. However, do not expect that every report will result in a fraud alert.

Driven by pharmacists working daily in Oregon communities, the Board's fraud alert system is a way for pharmacists to collaborate and together reduce the threat of prescription fraud within their scope of practice.

## No. 527: Updated Immunization Protocols

Pharmacists play an increasingly important role in immunizing Oregonians. People over the age of 11 years can be immunized by their pharmacists against diseases such as pertussis, pneumonia, shingles, and influenza.

Oregon's online ALERT Immunization Information System (ALERT IIS) is an important tool for all vaccine providers, especially community pharmacists who often do not have access to comprehensive patient records beyond individual pharmacy profiles. Most immunizations that are given in Oregon are stored in the ALERT IIS system. As a result, the system provides authorized users access to millions of patient vaccination histories.

Many pharmacists, however, do not take advantage of some very helpful ALERT IIS tools for looking up patient histories and forecasting needed vaccinations. A pharmacist can avoid immunizing patients unnecessarily with vaccines they have already received and also find out what vaccines patients need that day, and in the future, by using the ALERT IIS. Pharmacy technicians and other staff can also access these tools.

The Board and the Oregon Immunization Program (OIP) have worked together to include the use of these ALERT IIS functions in the Pharmacy Protocols for Immunization. The effective date for this protocol change is no later than January 1, 2014, although pharmacies are encouraged to begin using the ALERT IIS as soon as possible.

The new language that appears in each protocol is as follows:

> Effective no later than January 1, 2014, prior to administering vaccine, pharmacy personnel will look up each patient in the ALERT Immunization Information System (IIS) to determine the patient's vaccine history and to forecast vaccines needed.

Exceptions:

- This is not required when administering only influenza vaccines, but will continue to be recommended to help increase pneumococcal vaccine rates.
- This is not required when the pharmacy/pharmacist conducts a remote vaccine clinic, but will continue to be recommended when remote connectivity is available.

The revised protocols are available online at *http://public.health.oregon.gov/preventionwellness/vaccinesimmunization/immunizationproviderresources/pages/pharmpro.aspx.*

OIP's ALERT IIS staff has begun working with some pharmacy chains to get pharmacists and staff enrolled and trained to access ALERT IIS. One pharmacy chain is also pilot testing a bidirectional query interface between its electronic health record and ALERT IIS; this may be an additional option other pharmacies could explore for requesting and submitting immunization information.

For more information on how you and your staff can connect to ALERT IIS, please contact Jenne McKibben at jenne.mckibben@state.or.us.

## No. 528: Temporary Fee Reduction

It is not often pharmacists hear from the Board that their license fees have been reduced. This year however, pharmacists received that message along with their annual license renewal notice. The action was taken as a result of an unexpected increase in revenue and a reduction in spending by the Board compared to earlier projections. Effective July 1, 2013, additional fees are also being reduced temporarily. The temporary reductions are expected to affect fees for two to three years and are necessary to reduce the Board's revenue balance. The list of fees being reduced is available on the Board's Web site and includes pharmacists, retail and institutional pharmacies, and other miscellaneous categories including hospital drug room, home dialysis, family planning and county health clinic, correctional facility, CS registration, and reciprocity. Ample notice will be provided before the fees are increased.



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