No. 502: Can I See That in Writing?
By Kerri Ann Anderko, 2012 PharmD Candidate, Pacific University

It has come to the Oregon State Board of Pharmacy’s attention that some ambiguity exists for both pharmacists and prescribers regarding which prescriptions must be manually signed by the prescriber. To help clarify this confusion, the Board would like to call your attention to OAR 855-019-0210(7), which states:

The pharmacist must ensure that a written prescription that is hand-carried or mailed into the pharmacy contains an original manually-signed signature of the prescribing practitioner or practitioner’s agent.

For example, if you are handed a prescription at your counter, or mailed a hard copy of a prescription, regardless of whether that hard copy is written, typed, or in another style of formatted prescription, it must be manually signed by the prescriber or the prescriber’s agent in ink or indelible pencil (prescriber’s agent only applies if the prescription is for a legend drug and not for a controlled substance). In other words, the signature cannot be an electronically printed signature or be stamped on the prescription.

What also may have brought about some of the confusion around this rule is that it does not apply to controlled substances only. This rule applies to all prescriptions. For instance, even a prescription handed to you for prenatal vitamins must also contain a manual signature.

Furthermore, as previously indicated, a federal law to bear in mind is 21 CFR 1306.03 Persons entitled to issue prescriptions, which states:

(a) A prescription for a controlled substance may be issued only by an individual practitioner who is:
   (1) Authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession and
   (2) Either registered or exempted from registration pursuant to 1301.22(c) and 1301.23 of this chapter.

(b) A prescription issued by an individual practitioner may be communicated to a pharmacist by an employee or agent of the individual practitioner.

Likewise the Drug Enforcement Administration’s (DEA) Pharmacist’s Manual reminds us:

A prescription must be written in ink or indelible pencil or typewritten and must be manually signed by the practitioner on the date when issued. An individual (i.e., secretary or nurse) may be designated by the practitioner to prepare prescriptions for the practitioner’s signature. The practitioner is responsible for ensuring the prescription conforms to all requirements of the law and regulations, both federal and state.

To paraphrase, the practitioner is the only one who can prescribe and sign a prescription for a controlled substance. To simplify, a prescription that is handed in or mailed must be manually signed. If the prescription is for a controlled substance, it must contain the personally hand written signature of the authorized practitioner. If the prescription is for a legend drug, it must be manually signed by either the practitioner or practitioner’s agent.

No. 503: Prescription Fraud and Diversion Scams on the Rise in Oregon

Pharmacists have always been vigilant at the pharmacy counter for the occasional phony prescription that would be presented by an individual seeking controlled substances under false pretenses. Times have changed, and not for the better on this front. Over the past year, three significant scams have hit pharmacies in the Portland, OR, area.

The first major scam included a number of individuals from another state working together, flying into Portland on Friday evening when medical offices were closing and flying out Sunday night before the Monday workday began. This organized group of individuals brought laptops with printers to print fake IDs, gathered information on local physicians and patients, and spread out over the city to defraud pharmacists out of thousands of doses of oxycodone.

This is not like the old days of the occasional malingerer that the pharmacist might be able to recognize. These people were highly organized and very skillful at producing professional appearing prescriptions and identification documents. They plied their piracy over repeated weekends when prescribers were not available, with very convincing performances of pain and the need for opiates. Some Oregon pharmacists fell prey.

Next, a scam that was very interesting and creative. A woman posing as an auditor appeared at the pharmacy counter for the occasional phony prescription that would be presented by an individual seeking controlled substances under false pretenses. Times have changed, and not for the better on this front. Over the past year, three significant scams have hit pharmacies in the Portland, OR, area.

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DEA Provides Information Regarding Carisoprodol Prescriptions

A Drug Enforcement Administration (DEA) announcement provides information regarding the scheduling of carisoprodol, effective as of January 11, 2012. The DEA Final Rule making the drug a Schedule IV controlled substance was published December 12, 2011, and states that effective January 11, 2012, all prescriptions for drugs containing carisoprodol shall comply with DEA regulations. Specifically, a pharmacy may only fill or refill a prescription for a drug containing carisoprodol if all of the following requirements are met:

♦ the prescription was issued for a legitimate medical purpose by a DEA-registered practitioner acting in the usual course of professional practice (21 CFR §1306.04);
♦ the prescription contains all the information required by 21 CFR §1306.05; and
♦ the number of refills authorized by the prescribing practitioner is five or less (21 USC §829(b)).

The full text of the notice is available on the DEA Web site at www.deadiversion.usdoj.gov/drugs_concern/carisoprodol/index.html.

Pfizer Recalls Several Lots of Two Oral Contraceptive Products

Pfizer Inc recalled 14 lots of Lo/Ovral®-28 (norgestrel and ethinyl estradiol) tablets and 14 lots of norgestrel and ethinyl estradiol tablets (generic) due to potential for inexact count and out-of-sequence tablets. A Pfizer investigation found that some blister packs of the affected products may contain an inexact count of inert or active ingredient tablets and that the tablets may be out of sequence. As a result of this packaging error, the daily regimen for these oral contraceptives may be incorrect and could leave women without adequate contraception, and at risk for unintended pregnancy. Food and Drug Administration (FDA) advises that patients who have the affected product should notify their physician and return the product to the pharmacy. A Pfizer press release includes a list of the affected products with the National Drug Code (NDC) number, lot number, and expiration date for each, and is available at www.fda.gov/Safety/Recalls/ucm289770.htm.

Changes in Medication Appearance Should Prompt Investigation by Pharmacists and Patients

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/FALL-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.

As the numbers of generic products continue to increase, it seems that both patients and practitioners have become desensitized to changes in medication appearance. So much so that patients may not question a change or, when they do, practitioners may simply reassure them that it was due to a change in manufacturer without actively investigating the reason. It is not uncommon for ISMP to receive reports from both practitioners and consumers where a change in medication appearance was not fully investigated and subsequently contributed to an error.

In one case, a man shared an account of what his 86-year-old father experienced over the course of nine days after his prescription for minoxidil was mistakenly refilled with another medication. He had been taking minoxidil 2.5 mg for years at a dose of 5 mg (2 tablets) twice daily. Due to failing vision, he did not realize that his minoxidil tablets looked different. His daughter noticed the change, but was unconcerned since the tablets had previously changed appearance. The pharmacy was contacted about the change and a staff member explained that it was a different generic for minoxidil, and that the pills could be exchanged for those that he usually received. There was no mention of a mistake being made when the medication was exchanged. He was taken to the hospital the following day, when he could barely walk.

After this incident was explained to hospital staff, they contacted the pharmacy. It was then revealed that he was given methotrexate by mistake because the bottles were stored next to each other. By this time, the man had taken 36 methotrexate 2.5 mg tablets, his white blood cell and platelet counts were extremely low, and he was in critical condition. He later learned that he passed away during that hospital visit.

Your pharmacy may be providing an important patient safety tool on the prescription label that may be overlooked by patients and their caregivers: a description of the shape, color, and imprint code of the medication that should be inside. This information can help ensure accuracy since it’s based on the NDC number. Teach patients to look for this description and question any differences. In addition, the patient needs to know if the medication name on the pharmacy generated label is the medication he or she was expecting to receive. Even if the generic manufacturer is different each time the prescription is renewed, the description on the label should match the NDC number and thus the product inside.

FDA Reminder: Purchasing Unapproved Injectable Cancer Medications Threatens Patient Safety

FDA is reminding health care providers to obtain and use only FDA-approved injectable cancer medications purchased directly from the manufacturer or from wholesale distributors licensed in the United States. FDA explains that “current shortages of injectable cancer medications may present an opportunity for unscrupulous individuals to introduce non-FDA approved products into the drug supply, which could result in...”
Patients, Stresses CDC

Insulin Pens Should Not Be Used for Multiple Patients, Stresses CDC

Centers for Disease Control and Prevention (CDC) issued a notice, reminding health care providers that insulin pens are intended for use by a single patient, and should never be used on more than one patient. CDC indicates that the agency has become "increasingly aware of complaints about the same product, such as a new side effect or lack of therapeutic effect, these may signal a product quality issue.

FDA also notes that if a health care provider receives multiple complaints about the same product, such as a new side effect or lack of therapeutic effect, these may signal a product quality issue.

FDA reminds health care providers that in certain circumstances the agency may authorize limited importation of medications that are in short supply. Such medications are imported from approved international sources and distributed in the US through a controlled network, and would not be sold in direct-to-clinic solicitations. If FDA has arranged for limited importation of the foreign version of a medication, information on obtaining that medication will be available in the Drug Shortages section of the FDA Web site, www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm050792.htm.

Additional details are provided in an FDA Drug Safety Communication, available at www.fda.gov/downloads/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm, provides the online resource for each state for verifying that a wholesale distributor is appropriately licensed.

Obtain and use only FDA-approved injectable cancer medications purchased directly from the manufacturer or from wholesale distributors licensed in the US. An FDA Web page, www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm, provides the online resource for each state for verifying that a wholesale distributor is appropriately licensed.

Hospitals and other facilities should review their policies and educate their staff regarding safe use of insulin pens and similar devices.

♦ If reuse is identified, exposed persons should be promptly notified and offered appropriate follow-up including bloodborne pathogen testing. The notice may be downloaded from the CDC Web site at www.cdc.gov/injectionsafety/PDF/Clinical-Reminder-insulin-pen.pdf.

US Public Health Service Report Supports Maximizing the Scope of the Pharmacist as Part of Health Care Team

Presenting an evidence-based discussion of the comprehensive patient care services that pharmacists currently provide, a new government report calls for expanded support for such pharmacist-delivered patient care models. The report, Improving Patient and Health System Outcomes through Advanced Pharmacy Practice, prepared by the Office of the Chief Pharmacist, US Public Health Service (PHS), is organized into four focus points as follows:

♦ Focus point 1 discusses how pharmacists are integrated in many practice settings as health care providers, such as through collaborative practice agreements, and provides data showing interprofessional support for such models.

♦ Focus points 2 and 3 support recognition of pharmacists as health care providers and compensation models that will allow pharmacists to continue to improve patient and health care system outcomes.

♦ Focus point 4 presents a review of numerous peer-reviewed studies that demonstrate favorable outcomes from pharmacist-delivered care.

RADM Scott Giberson, chief professional officer, PHS Pharmacists, and the primary author of the report, stated that "one of the most evidence-based and cost-effective decisions we can make as a nation is to maximize the expertise and scope of pharmacists, and minimize expansion barriers to successful health care delivery models." The report may be downloaded from the US PHS Web site at www.usphs.gov/corpslinks/pharmacy/comm/pdf/2011AdvancedPharmacyPracticeReporttotheUSSG.pdf.

Pharmacists & Technicians: Don't Miss Out on Valuable CPE Credit. Set Up Your NABP e-Profile Today!

CPE Monitor integration is underway. Soon all Accreditation Council for Pharmacy Education (ACPE)-accredited providers will require you to submit your NABP e-Profile ID, assigned when you set up your NABP e-Profile, along with your date of birth (MMDD), in order to obtain continuing pharmacy education (CPE) credit for any ACPE-accredited activity. Many have already begun to do so.

Visit www.MyCPEmonitor.net to set up your e-Profile and avoid possible delays in your CPE reporting.

CPE Monitor is a national collaborative service from NABP, ACPE, and ACPE providers that will allow licensees to track their completed CPE credit electronically.
was contacted right away and an alert was sent out to pharmacists via the Board’s e-mail listerv. This individual was caught and busted within days of the alert.

Yet a third scam has surfaced recently around the Portland area. This is another very organized group that has acquired at least three physicians’ addresses and DEA numbers as well as patients’ insurance information, fake IDs, and tamper-resistant prescription forms. These perpetrators passed fraudulent prescriptions that are virtually impossible to detect on their face. In one instance, the person was so convincing that she was allowed to pay cash for the prescriptions after the insurance card was discovered by the pharmacist to have been expired.

The Board was contacted by an observant pharmacist about this con and again an alert was sent out via the Board’s listerv. Several individuals have been apprehended in the investigation and the level of organization and sophistication is staggering.

This third example has created a learning moment, and there is a lesson in the law. ORS 689.525 Out-of-State Prescriptions states:

1. A prescription written by a practitioner licensed in a state or territory of the United States, other than Oregon, may be filled only if the pharmacist called upon to fill such prescription determines, in the exercise of professional judgment: (a) That it was issued pursuant to a valid patient-practitioner relationship; and (b) That it is authentic.

2. However, if the practitioner writing the prescription is not known to the pharmacist, the pharmacist shall obtain proof to a reasonable certainty of the validity of the prescription

3. The provisions of ORS 689.515 authorizing generic substitution shall not apply to prescriptions described in this section unless authorized on the prescription.

The demand for pharmacists’ vigilance and professional judgment at the dispensing counter has never been higher. Take special care with any out-of-state prescription for a controlled substance. Carefully review the document for appropriateness. Observe the patient for unexpected or aberrant behavior. Pay close attention to the clues. Check with the prescriber or “on call” practitioner when you do not recognize names and faces. Use your professional judgment. And, take care of the patient with a legitimate prescription. You are not a cop. You are a pharmacist.

No. 504: CPT license Renewal

Reminder to all licensed Certified Oregon Pharmacy Technicians that the annual license renewal cycle is rapidly approaching. Renewal notices are scheduled to be issued during the first week in July, so you should receive your notice with plenty of time to complete the online renewal process well before the deadline. Remember, renewal is done online as it was last year and a delinquent fee applies to applications received on or after August 31, 2012. Make sure your address is updated and current with the Board if you moved since last year’s renewal.

No. 505: Sign up for Oregon’s PDMP

The Oregon Prescription Drug Monitoring Program (PDMP) went live September 1, 2011. As of March 1, 2011, 96% of pharmacies are reporting into the database. That is an extraordinary compliance rate for the first six months of the program and Oregon pharmacists are to be commended for their effort.

A large number of physicians have already signed up for authority to query the database and are doing so with increasing frequency. The number of queries is growing rapidly. Pharmacists, on the other hand, have not been signing up with the program at nearly the rate of the physicians. The Board encourages pharmacists to take a few moments and sign up for the program. It is easy, and the instructions for obtaining your account can be found on the PDMP Web site at www.orpdmp.com/health-care-provider/. Also, monthly and year to date reports on the program’s activities can be found on the Web site.

Do not just take your best guess and get caught off guard. Learn and know how the program works. Check the database when you do not know the patient or the prescriber, or if you have concerns about a controlled substance prescription. You have the most current statewide controlled substance dispensing data available at your fingertips. Do not be afraid to use it.