No. 1135 Clarification of Pharmacy Compounding Standards

The Washington State Board of Pharmacy discussed pharmacy compounding standards at the February 21, 2013 business meeting, specifically WAC 246-878-020(4). The Board has always read Section (4) in conjunction with other subsections that specifically require a prescription for a compounded drug. However, it agreed that Section (4), read independently, could allow a pharmacy to provide compounded products for a practitioner to give out to individual patients without a prescription for a specific patient. Because this has clearly been the belief of some compounding pharmacies in Washington, the Board decided it will honor this interpretation of the rule.

On January 10, 2013, the Board authorized rulemaking regarding compounding practices to ensure appropriate standards are in place to protect the health and safety of the people of Washington. The Board will invite stakeholders to participate after filing the “Intent to Initiate Rulemaking” (CR101).

No. 1136 Five Percent Rule for Pharmacy Transfer of Prescription Drugs

In rule, “wholesale distribution” means distributing prescription drugs to people other than consumers or patients. It does not include selling, buying, or trading a drug or an offer to sell, buy, or trade a drug for emergency medical reasons. “Emergency medical reasons” include transfer of prescription drugs by a pharmacy to another pharmacy or practitioner to ease a temporary shortage. No emergency medical reason is in Drug Enforcement Administration (DEA) regulations.

The rule restricts the transferring or receiving pharmacy to no more than 5% of its total revenue of prescription drug sales during any 12 consecutive months. DEA regulations restrict sales of more than 5% of the total number of dosage units of all controlled substances (CS) the practitioner distributes and dispenses during the same calendar year.

The Board’s rule prevents a pharmacy from buying shortage drugs from one source (wholesaler or pharmacy) to resell to another (wholesaler or pharmacy) with no emergency medical reason.

The Board has found that “gray market” wholesalers and pharmacy representatives try to convince Washington pharmacies to buy shortage drugs for immediate resale (after a 10% to 20% markup) to gray market firms. They, in turn, resell the drugs (WAC 246-879-010(10) (e) and 21 CFR1307.11).

No. 1137 Faxing of Schedule II CS Prescriptions

The Board gets many questions about faxing Schedule II prescriptions in long-term care and hospice settings. Here is a summary of state laws and rules and federal regulations that apply.

Federal regulation 21 CFR 1306.05(a) and (d) define the requirements for a Schedule II prescription. One is that the prescriber must manually sign faxed prescriptions.

Section (a) states that all prescriptions for CS shall be dated as of, and signed on, the day issued. They shall bear the patient’s full name and address, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address, and registration number of the practitioner.

Section (d) states that a practitioner may sign a paper prescription in the same way he or she would sign a check or legal document (eg, J.H. Smith or John H. Smith). Where an oral order is not permitted, paper prescriptions shall be written with ink or indelible pencil, typewriter, or printed on a computer printer. The practitioner shall manually sign the paper. The prescriber must manually sign a printed hard copy of a computer-generated prescription given to the patient to deliver to the pharmacy or faxed by the practitioner.

Federal regulation 21 CFR 1306.11(5)(f) and (g) describe the instances in which faxed prescriptions may be used as the original prescription.

Section (f) states that the practitioner or the practitioner’s agent may transmit by facsimile to the dispensing pharmacy a prescription prepared in accordance with 21 CFR 1306.05
FDA Issues New Guidelines for Sleep Aids Containing Zolpidem

Food and Drug Administration (FDA) has issued new dosing recommendations for sleep aids containing zolpidem. The new recommendations are based upon new data that shows that when taken at night, blood levels of zolpidem remain high enough in the morning to impair activities that require alertness, such as driving. The new guidelines halve the dosage for women because the new data showed that their bodies take longer to eliminate the drug.

FDA urges drug manufacturers and health care providers to follow the new dosing instructions, which apply to brand name and generic drugs containing zolpidem:

- Ambien™, Edluar™, and Zolpimist™: 5 mg for women, 5 mg to 10 mg for men
- Ambien CR™: 6.25 mg for women, 6.25 mg or 12.5 mg for men

Additionally, manufacturers of these drugs have been instructed to follow the new guidelines and print new patient information drug labels containing the new recommendations.

The recommended doses of Intermezzo™, a lower dose zolpidem product approved for middle-of-the-night awakenings, are not changing. At the time of Intermezzo’s approval in November 2011, the label already recommended a lower dosage for women than for men. Additional details are available in an FDA Drug Safety Communication, available at www.fda.gov/Drugs/DrugSafety/ucm334033.htm.

What is the National Medication Error Rate? What Standards Are Available for Benchmarking?

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/F AIL-SAFE (1-800/324-5233) 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.

A national or other regional medication error rate does not exist. It is not possible to establish a national medication error rate or set a benchmark for medication error rates. Each pharmacy organization is different. The rates that are tracked are a measure of the number of reports at a given organization, not the actual number of events or the quality of the care given. Most systems for measuring medication errors rely on voluntary reporting of errors and near-miss events. Studies have shown that even in good systems, voluntary reporting only captures the “tip of the iceberg.” For this reason, counting reported errors yields limited information about how safe a pharmacy actually is. It is very possible that a pharmacy organization with a good reporting system, and thus what appears to be a high error “rate,” may have a safer system.

The National Coordinating Council for Medication Error Reporting and Prevention published a statement refuting the use of medication error rates. The statement, which is posted on the council’s Web site (www.nccmerp.org), states the “Use of medication error rates to compare health care organizations is of no value.” The council has taken this position for the following reasons:

- Differences in culture among health care organizations can lead to significant differences in the level of reporting of medication errors.
- Differences in the definition of a medication error among health care organizations can lead to significant differences in the reporting and classification of medication errors.
- Differences in the patient populations served by various health care organizations can lead to significant differences in the number and severity of medication errors occurring among organizations.
- Differences in the type(s) of reporting and detection systems for medication errors among health care organizations can lead to significant differences in the number of medication errors recorded.

According to the statement, the council believes that there are no acceptable incidence rates for medication errors. The goal of every health care organization should be to continually improve systems to prevent harm to patients due to medication errors. Pharmacies should monitor actual and potential medication errors that occur within their organization, and investigate the root cause of errors with the goal of identifying ways to improve the medication-use system to prevent future errors and potential patient harm. The value of medication error reporting and other data gathering strategies is to provide the information that allows an organization to identify weaknesses in its medication-use system and to apply lessons learned to improve the system. The sheer number of error reports is less important than the quality of the information collected in the reports, the organization’s analysis of the information, and its actions to improve the system to prevent harm to patients.

It is more important to create the open environment that encourages the reporting of errors and near errors than to develop less meaningful comparative error rates.

ISMP Launches Program to Track Vaccine Errors

ISMP has launched a National Vaccine Error Reporting Program (VERP) that allows health care providers to confidentially report vaccine administration errors and near misses. Health care providers from all practice settings, including pharmacies and physicians’ offices, are encouraged to report all mistakes related to vaccines, regardless of whether any harm resulted from the incident. The program will help ISMP “better quantify the sources of errors and advocate for vaccine name, labeling, device, information, and other needed product changes to ensure patient safety,” stated Michael Cohen, ISMP president. The ISMP VERP was designed with the assistance of the California Department of Public Health and with input from experts in the field, indicates ISMP. Reports sent to the ISMP VERP will be shared with FDA and forwarded to the vaccine manufacturer when applicable. ISMP also plans to work with the Centers for Disease Control and Prevention on information received to address vaccine-related safety. VERP can be accessed at http://verp.ismp.org/.
Providers Should Ensure Only Diluted Forms of Acetic Acid Are Used, ISMP Warns

ISMP has issued a National Alert Network (NAN) notice advising that health care organizations should take immediate steps to ensure that only diluted acetic acid solutions are used in patient care. ISMP advises that the use and purchase of glacial acetic acid, the most concentrated form of acetic acid available, should be eliminated. Several cases of severe burns, scarring, and other permanent damage to skin or mucous membranes due to the inadvertent application of glacial acetic acid have been reported to the National Medication Errors Reporting Program operated by ISMP; ISMP provides the following steps for preventing further such events:

- Remove glacial acetic acid, which has no use in its current form in clinical medicine, from the pharmacy and replace with vinegar (5% solution) or commercially available diluted acetic acid 0.25% (for irrigation) or 2% (for otic use).
- Restrict purchasing so that pharmacy staff is purchasing acetic acid for all procedural areas.
- Restrict choices for purchasing so that glacial acetic acid is not selected by mistake.
- Ensure the correct strength is ordered.
- Educate staff about the differences between glacial acetic acid and diluted forms of acetic acid.
- Order 5% as “vinegar,” which reduces the potential for confusion with glacial acetic acid.
- Verify the product by requiring an independent double-check of acetic acid solutions before dispensing or applying the product.

Information on the cases reported and common reasons for the cases are included in the NAN alert, which is available on the ISMP Web site at www.ismp.org/NAN/files/20130121.pdf.

New FDA Training Video

FDA Drug Info Rounds, a series of online training videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better medication decisions. In the latest Drug Info Rounds video, pharmacists discuss how FDA Drug Safety Communications let health care providers, patients, and consumers know about newly observed potential risks of FDA-approved drugs. Drug Info Rounds videos are developed with contributions from pharmacists in FDA’s Center for Drug Evaluation and Research, Office of Communications, and Division of Drug Information and are available on the FDA Web site at www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.

Progress Made in Implementing Recommendations Intended to Prevent Acetaminophen Overdose

Compelling progress has been made by stakeholders seeking to address the public health issue of acetaminophen overdose, indicates a white paper published by the National Council for Prescription Drug Programs (NCPDP). In 2011, NCPDP made recommendations that the health care industry take actions to support the safe use of acetaminophen, including recommending that pharmacies produce prescription labels with the complete spelling of acetaminophen and eliminating use of abbreviations such as “acet” or “APAP.”

Previous to that, in July 2010, the National Association of Boards of Pharmacy® (NABP®) recommended that “state boards of pharmacy prohibit the use of the abbreviation ‘APAP’ on prescription labels, and require that ‘acetaminophen’ be spelled out to assist in preventing the well-recognized danger of acetaminophen induced hepatotoxicity.” The recommendation was based on established policy and a letter, sent by FDA to state boards of pharmacy, regarding the pharmacist’s role in educating patients about acetaminophen induced hepatotoxicity caused by unintentional overdose. The recommendation was also consistent with the report of the NABP Task Force on Uniform Prescription Labeling Requirements, which made recommendations to encourage use of prescription labels that are organized in a patient-centered manner. NCPDP reports that pharmacy retailers “estimated to collectively represent more than half of the prescriptions dispensed in 2011, have either implemented or committed to a phased implementation” of the recommendation to use the complete spelling of acetaminophen on prescription labels. “This update to our white paper provides additional guidance for those industry stakeholders who have not yet implemented the new pharmacy labeling practices for acetaminophen-containing medicines,” states Lee Ann Stember, president, NCPDP. The updated white paper is accompanied by a bulletin (PDF), available at www.ncpdp.org/pdf/wp/NCPDP_Acetaminophen_InfoBulletin_PharmacyStakeholders.pdf, developed for pharmacists that summarizes some of NCPDP’s key recommendations regarding acetaminophen. In addition, the white paper, available for download at www.ncpdp.org/ind_WP.aspx, includes a list of resources for pharmacists to use in educating staff and pharmacy staff to use in educating patients (see Appendix D of the white paper). More information is available in an NCPDP news release available at www.ncpdp.org/press/013113_NCPDP_Acetaminophen%20WP_FINAL.pdf.

Pharmacists Rated High for Honesty and Ethical Standards in Gallup’s 2012 Poll

Pharmacists ranked as the second most trusted profession in the 2012 Gallup Poll that asked consumers to rate 22 professions according to their honesty and ethical standards. Pharmacists were ranked as very high or high in this category by 75% of those surveyed, with nurses ranking first at 85%, and medical doctors third at 70%. Additional information on the results of the 2012 poll is available on the Gallup Web site at www.gallup.com/poll/139035/congress-retains-low-honesty-rating.aspx.
As a pharmacist in Washington State, your duty is, under WAC 246–869–220, Section (3), “for each patient, the pharmacist shall determine the amount of counseling that is reasonable and necessary under the circumstance to promote safe and effective administration of the medication and to facilitate an appropriate therapeutic outcome for that patient from the prescription.”

Pharmacists cannot delegate this duty to a technician or cashier in the pharmacy. The pharmacist must offer to counsel and, if needed, accept in person the patient’s refusal of such counsel. Pharmacists cannot “triage” this critical function of clinical pharmacy practice. If the pharmacy operation or business model does not permit the proper time to implement this WAC rule, contact your Board inspector or staff members on how to file a proper complaint.

No. 1140 Prescription Monitoring Program – Pharmacy License Renewals

The pharmacy license renewal date is approaching (May 31). Chris Baumgartner, prescription monitoring program (PMP) director, reminds pharmacies with a Certification of No Dispensing of Controlled Substances on file with the Department of Health that a new one is required.

The PMP has collected data from licensed pharmacies (resident and nonresident) since October 2011. Pharmacies report dispensing records for any CS to the department weekly to help promote public health and safety.

A pharmacy that does not dispense any CS may submit a yearly certification indicating that. That takes away the need for a weekly report.

To comply, you must send the PMP the Certification of No Dispensing of Controlled Substances form to the PMP each year at the time you renew your pharmacy license.

For answers about the program or the yearly certification for pharmacies that do not dispense CS, contact Chris Baumgartner at 360/236-4806 or prescriptionmonitoring@doh.wa.gov.

No. 1141 2013 Legislative Session Update

March 15, marked the last day to consider legislative bills in the house of origin. The Board reviewed bills including one for a medication return and reuse program, as well as proposed changes to the Legend Drug Act and Uniform Controlled Substances Act. Following are bills that are still alive but not yet passed into law. The regular legislative session ends April 28. The Board will update readers then, via listserv, on new laws. More details and bill language are on the Washington State Legislature’s Bill Information Web page.

♦ SHB 1182 – The bill adds pharmacists to the Legend Drug Act to specify that licensed pharmacists may prescribe legend drugs within the scope of their practice act/as authorized under a collaborative drug therapy agreement.

♦ SHB 1382 – Under the bill, practitioners, pharmacists, medical facilities, drug manufacturers, and drug wholesalers could give pharmacies prescription drugs and supplies to redistribute, without being paid, to people who meet certain criteria. Pharmacies, pharmacists, and prescribing practitioners that elect to dispense donated prescription drugs and supplies would give priority to uninsured people who are at or below 200% of the federal poverty level (SB 5148 – Allowing for redistribution of medications under certain conditions).

♦ HB 1609 – The bill changes the Washington State Board of Pharmacy’s name to the Pharmacy Quality Assurance Commission. It doubles the number of members to 10 pharmacists, four public members, and one pharmacist technician.

Continued from page 1

Continued on page 5
HB 1800 – The bill adds exceptions to term “manufacturing” for the (1) compounding of products in anticipation of an order of a practitioner to administer to patients under his or her direct supervision; (2) repackaging of commercially available medication in small, reasonable quantities for practitioners to use for office use; (3) distribution of compounded drugs to other entities under common ownership of the facility in which the compounding takes place; (4) delivery of compounded products that are dispensed pursuant to a valid prescription to alternate delivery locations when requested by the patient, the prescriber to administer to the patient, or another pharmacy to dispense to the patient; or (5) distribution of a compounded drug to other licensed persons or commercial entities for resale or distribution, without specific product item approval by the Board. Compounded products or products prepared for patient administration or distribution to a practitioner for patient use must meet the oral product and parenteral product standards of the United States Pharmacopeia.

EHB 1808 – The bill requires the store manager or employee in a retail store with a pharmacy license to notify law enforcement upon finding one ounce or less of marijuana mistakenly left in the store. The bill defines “proper disposal” and requires the Board to adopt rules in conjunction with law enforcement.

ESB 5104 – The bill places epinephrine autoinjectors in schools.

SB 5149 – The bill modifies standard sentencing provisions about a robbery of a pharmacy.

2S SB 5213 – Requires contracts with managed care plans to include a requirement that any patient with five or more prescriptions be placed in a comprehensive medication management process with the primary care provider or state-licensed pharmacist to verify all the prescriptions are medically appropriate and to review for drug interactions and opportunities to reduce the number of prescriptions.

S SB 5416 – The bill permits original prescriptions or prescription refills for CS (including Schedule II) to be electronically communicated between the authorized practitioner and a pharmacy. Companion bill: SHB 1155.

S SB 5459 – The bill permits pharmacists to dispense up to a 90-day supply of a drug, other than a CS, with a valid prescription that specifies the initial quantity of less than a 90-day supply followed by refills under specific conditions. Those include the patient having completed an initial 30-day supply of the drug, or having been previously dispensed the same medication in a 90-day supply.

No. 1142 Jim Doll Retires After Two Decades

Pharmacist Investigator Jim Doll retired at the end of February after more than 21 years of service to the Board and the Department of Health. Jim averaged more than 50 investigations every year, or about 1,100 during his career. At the same time, Jim averaged 170 inspections each year for about 3,600 overall. His career included working with the federal DEA-sponsored Tactical Diversion Squad, and the Department of Health emergency operations warehouse. Jim also represented the Board on the Washington Recovery Assistance Program for Pharmacy.

The Board wishes Jim Doll and his wife Nancy many happy travels in warm and leisurely locations.

No. 1143 What Will the Next 20 Years Bring?

Since 1991, the number of:

♦ Pharmacies licensed in Washington increased from 1,181 to 1,428;
♦ Nonresident pharmacies increased from 82 to 527, a 543% change;
♦ Nonresident wholesalers increased from 499 to 893;
♦ Pharmacists increased from 5,064 to 9,212, an 80% change. Note, 233 of the 260 pharmacists licensed in 2011 and 2012 lived out of state;
♦ Pharmacy technicians increased from 1,802 to 9,257, a 414% climb; and
♦ Pharmacy assistants, first credentialed in 2001, have increased from 1,232 to 8,364, a 579% rise.

Who can say what the next 20 years will bring?