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Iowa Board of Pharmacy News

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Clarification on Compounded Preparations

Iowa Board of Pharmacy Subrule 657 IAC 20.3(1) allows the compounding of a commercially available product only if it is necessary to meet the unique medical need of a patient. The complete text of that subrule is provided below. Pursuant to 657 IAC 20.2, all compounding, regardless of the type of product, is to be done pursuant to a prescription and the prescription must be based on a valid pharmacist/patient/prescriber relationship. Subrule 657 IAC 20.3(4) allows for the preparation of non-patient-specific products for "office use" if the product is administered to an individual patient by the prescribing practitioner in a professional practice setting. Subrule 657 IAC 20.3(4) also allows a pharmacy to prepare and sell to a hospital pharmacy a compounded drug product prepared pursuant to a prescriber's authorization for administration to a specific patient. Iowa law and rules have never allowed a pharmacy to prepare and sell to a hospital pharmacy compounded preparations in the absence of a prescription. Such activity is considered manufacturing. This would include the preparation of sterile products such as outsourced compounded solutions, IVs, or injectables.

657 Iowa Administrative Code – 20.3(1) *Compounding commercially available product.* Based on the existence of a pharmacist/patient/prescriber relationship and the presentation of a valid prescription, pharmacists may compound, for an individual patient, drug products that are commercially available in the marketplace, if the compounded product is changed to produce for that patient a significant difference, as authorized by the prescriber, between the compounded drug and the comparable commercially available drug product, or if use of the compounded product is in the best interest of the patient. "Significant difference" would include the removal of a dye for a medical reason such as an allergic reaction. When a compounded product is to be dispensed in place of a commercially available product, the prescriber and patient shall be informed that the product will be compounded.

Compounding Survey

The Board has requested that all Iowa pharmacies respond to the following survey. Responses may be sent via e-mail to **terry.witkowski@iowa.gov.** Please respond by July 1, 2013.

1. Are you compounding prescription or over-the-counter (OTC) drugs at your pharmacy?
2. If you are engaged in compounding, what type of compounding is being done (eg, sterile, nonsterile, OTC)?
3. Does your pharmacy ship compounded products to other states?
4. Are your pharmacists, technicians, or the pharmacy itself accredited?
5. If accredited, what is the name of the accrediting body?
6. Are all compounds dispensed pursuant to a patient-specific prescription?
7. If compounds are distributed for "office use," what is the percentage of total compounded prescription volume?
8. Does your pharmacy have a separate compounding area within the prescription department? If so, please describe.
9. Are you compounding any commercially available products? If so, what products are being produced and in what quantities?
10. Does your pharmacy document and track adverse drug events associated with compounded drug products?

Board Members Retire

DeeAnn Wedemeyer-Oleson

Margaret Boyle Whitworth

Pharmacist **DeeAnn Wedemeyer-Oleson** of Adair, IA, and public member **Margaret (Peggy) Boyle Whitworth** of Cedar Rapids, IA, retired from the Board on April 30, 2013. They served six years on the Board, beginning on May 1, 2007. While on the Board, DeeAnn also served on the Board's Rules Committee, the Patient Safety Task Force, and as vice chairperson of the Board. The Board extends its sincere thanks to DeeAnn and Peggy for their many contributions and their dedicated public service.

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 or 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/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.*

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/NCPDPAcetaminophenInfoBulletin_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/159035/congress-retains-low-honesty-rating.aspx*.

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New Board Members Appointed

Congratulations to pharmacist **Sharon Meyer** of Urbandale, IA, and public member **Judy Trumpy** of Ames, IA, on their appointment to three-year terms on the Iowa Board of Pharmacy by Governor Terry Branstad effective May 1, 2013.

Sharon Meyer

Sharon Meyer is a graduate of Creighton University with a doctor of pharmacy degree and she completed a fellowship in family practice at Creighton University. She also has a master's in health services management from Clarkson College. She is employed by Cardinal Health Pharmacy Solutions. Her current position is a shared position working as a pharmacy analyst with UnityPoint Health IT and working as a senior project manager with UnityPoint Health – Des Moines. Prior to this position, she was the executive director of pharmacy for Iowa Health – Des Moines (now known as UnityPoint Health – Des Moines) for 10 years.

Judy Trumpy

Judy Trumpy is a native Iowan and a graduate of Iowa State University (ISU) in food and nutrition – dietetics. Judy has over 44 years of experience practicing in hospitals, long-term care settings, and lastly, 20 years with ISU Dining as an assistant manager and a nutrition counselor at the Thielen Student Health Center. Judy completed her dietetic internship with the US Army Medical Department and served an additional year as chief of diet therapy at the US Army Hospital in Ft Carson, CO. She recently joined the American Legion in Ames, Post 37, and is a member of the honor guard.

Election of Board Officers

The Board has elected **Ed Maier** of Mapleton, IA, as Board chairperson for a one-year term beginning May 1, 2013. **Jim Miller** of Dubuque, IA, was elected vice chairperson for the same term.

Board Web Site

Please visit the Board's Web site at *www.state.ia.us/ibpe/.*

Board Mission

The Iowa Board of Pharmacy promotes, preserves, and protects the public health, safety, and welfare through the effective regulation of the practice of pharmacy and the licensing of pharmacies, pharmacists, and others engaged in the sale, delivery, or distribution of prescription drugs and devices. Iowa Code §155A.2(1).

Iowa Board of Pharmacy
Pictured left to right: Pete Fay, LaDonna Gratias, Mark Oleson, Jim Miller, Brenda Halling, DeeAnn Wedemeyer-Oleson, Ed Maier, Susan Frey, Peggy Whitworth
Front Row: Katie Beth Oleson

The *Iowa Board of Pharmacy News* is published by the Iowa Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, 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 the Foundation or the Board unless expressly so stated.

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