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Delaware State Board of Pharmacy News

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Controlled Substance Regulation Amendment on Drive-Through Windows

Pursuant to 29 Del. C. §10118, the Secretary of State issued an order adopting amendments to the Delaware Controlled Substance Advisory Committee's Rules and Regulations. Effective May 11, 2013:

> 4.11.3 No filled prescription for any Schedule II controlled substance may be received at any drive through window unless the pharmacy is authorized to do so by the Office of Controlled Substances. Written prescriptions for Schedule II controlled substances may be initially presented at a drive through if the pharmacy has not obtained authorization, but the filled prescription must be picked up inside the pharmacy. Authorization to permit the receipt of filled Schedule II controlled substance prescriptions at a drive through window may be granted only if the pharmacy can demonstrate all of the following:
>
> 4.11.3.1 A security camera system that captures clear images of the driver's face and the license plate of the vehicle receiving any filled prescription; and
>
> 4.11.3.2 A written policy indicating that when picking up a Schedule II controlled substance at a drive through window, the driver must be recorded as the person picking up the prescription; and
>
> 4.11.3.3 A written policy requiring staff to review the identification of the driver, capture an image of the identification of the driver, and store that image in the pharmacy's records for at least three years for every filled Schedule II prescription picked up at the drive through window.

Drug Disposal Through a Pharmacy or Distributor

The Delaware State Board of Pharmacy office routinely receives calls related to patients or families of deceased patients wanting to give their unused controlled substances (CS) to a pharmacy or distributor for disposal. An "ultimate user" is a person who has lawfully obtained and who possesses a CS for his or her own use, for the use of a member of his or her household, or for an animal owned by him or her or by a member of his or her household. "Distribute" means to deliver (other than by administration or dispensing) a CS or a listed chemical. Ultimate users are not permitted to distribute CS without being separately registered. Due to registration requirements, at the present time and until further notice, it is unlawful for ultimate users to give their CS to pharmacies, reverse distributors, etc, for destruction. This issue may change in the future with new federal rules on disposal and future state law and authority.

Prescription Status When the Practitioner Retires, Passes Away, or Whose License is Suspended

The office sometimes receives pharmacist questions on how to handle prescriptions from practitioners who have prescribed a medication and then retires, passes away, or whose license is suspended. If the prescription was a valid prescription written by a licensed/registered practitioner at the time of the prescribing, then the prescription may be dispensed. Generally, the office would permit one dispensing of the medication and recommends that the dispensing pharmacist encourage the patient to find a new practitioner as soon as possible since the initial prescriber will no longer be treating the patient's condition.

Transfer of CS Between Pharmacies

In summary, 21 CFR 1306.25 states:

(a) The transfer of original prescription information for a CS listed in Schedules III, IV, or V for refill dispensing is permissible between pharmacies on a one-time basis only. Pharmacies electronically sharing a real-time, online database may transfer up to the maximum refills permitted by law and the prescriber's authorization.

(b) Transfers are subject to the following requirements:

(1) The transfer is communicated directly between two licensed pharmacists and the transferring pharmacists records the following information:

(i) Write the word "VOID" on the face of the invalidated prescription.

(ii) Record on the reverse of the invalidated prescription the name, address, and Drug

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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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Enforcement Administration (DEA) registration number of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information.

(iii) Record the date of the transfer and the name of the pharmacist transferring the information.

(3)(a) The receiving pharmacist shall reduce to writing the following:

(1) Write the word "transfer" on the face of the transferred prescription.

(2) Provide all information pursuant to 21 CFR 1306.05 and include:

(i) Date of issuance of original prescription.

(ii) Original number of refills authorized on original prescription.

(iii) Date of original dispensing.

(iv) Number of valid refills remaining and date(s) and locations of previous refill(s).

(v) Pharmacy's name, address, DEA registration number, and prescription number from which the prescription information was transferred.

(vi) Name of pharmacist who transferred the prescription.

(vii) Pharmacy's name, address, DEA registration number, and prescription number from which the prescription was originally filled.

(c) The original and transferred prescription(s) must be maintained for a period of two years from the date of last refill.

CS Registration Renewal

The biennial registration period for CS registrations will end June 30, 2013. Renewal forms were mailed in May. All CS registrants should be registered for the new biennial term of July 1, 2013 through June 30, 2015. If you have any questions regarding pharmacy registrations, please contact the Office of Controlled Substances at 302/744-4500.

Newly Licensed Pharmacists

21 Issued from January 1, 2013 to March 31, 2013

Amena Khan – A10004376; Jalaja Alisetty – A10004377; Ashwani Sheoran – A10004378; Cheri Briggs – A10004379; Gary Umland – A10004380; Venkat Lokula – A10004381; Michelle Mauroff – A10004382; Rochelle Kugler – A10004383; Terence Klar – A10004384; VenuGopal Ghanta Venkata – A10004385; Dorothy Hart – A10004386; Maureen McNally – A10004387; Odun Balogun – A10004388; Amira Elshendidi – A10004389; Kiran Gottipati – A10004390; Smita Kantak – A10004391; Shyam Mudigonda – A10004392; Dipen Patel – A10004393; Susan Oliveri – A10004394; Pullarao Jasti – A10004395; Stephanie Simpson – A10004396.

Distributor Permits

36 Issued from January 1, 2013 to March 31, 2013

Abbott Laboratories, Inc – A40001950; Reckitt Benckiser, LLC – A40001951; Reckitt Benckiser, LLC – A40001952; Exel, Inc – A40001953; Exel, Inc – A40001954; Exel, Inc – A40001955; Reckitt Benckiser, LLC – A40001956; Reckitt Benckiser, LLC – A40001957; Zo Skinhealth, Inc – A40001958; Harvard Third Party Logistics – A40001959; HarteHanks Direct Marketing – A40001960; Advance Trailer Systems, Inc – A40001961; Bonita Pharmaceuticals, LLC – A40001962; Lannett Company, Inc – A40001963; Amneal Agila, LLC – A40001964; Genzyme Corporation – A40001965; Positudes, Inc – A40001966; Lifeline Pharmaceuticals – A40001967; Blood Systems, Inc, dba Bio Care – A40001968; DPT Lakewood, LLC – A40001969; Sage Products, LLC – A40001970; AmeriPharm, Inc, dba MedVantx Pharmacy Services – A40001971; OPO, Inc – A40001972; Prolog Logistics, Inc – A40001973; Albertsons, LLC Distribution Center #8720 – A40001974; Allegis Pharmaceuticals, LLC – A40001975; Abraxis Bioscience, LLC – A40001976; Covidien Sales, LLC – A40001977; Hope Medical Enterprises, Inc – A40001978; CVS RX Services, Inc, dba Pharmacy Distribution Center – A40001979; Air Liquide Industrial U.S. LP – A40001980; Butler Animal Health Supply, LLC, dba Butler Schien Animal Health Supply – A40001981; RemedyRepack, Inc – A40001982; Penn Veterinary Supply, Inc – A40001983; Rock Tenn Converting Company – A40001984; Reckitt Benckiser, LLC – A40001985.

In-State Pharmacy Permits

Nine Issued from January 1, 2013 to March 31, 2013

Bayard Pharmacy – A30000944; Acme Markets, Inc, dba SavOn Pharmacy #7828 – A30000945; Acme Markets, Inc, dba SavOn Pharmacy #7806 – A30000946; Acme Markets, Inc, dba SavOn Pharmacy #7817 – A30000947; Acme Markets, Inc, dba SavOn Pharmacy #7816 – A30000948; Acme Markets, Inc, dba SavOn Pharmacy #7822 – A30000949; Acme Markets, Inc, dba SavOn Pharmacy #7836 – A30000950; Acme Markets, Inc, dba SavOn Pharmacy #7872 – A30000951; Rehoboth Pharmacy, Inc – A10000952.

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