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North Dakota State Board of Pharmacy News

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Guidance on Disposal and Transfer of Controlled Substances

The Drug Disposal Log, available in the Applications/Forms section of the North Dakota State Board of Pharmacy's website, is for use in destruction of medications that have been dispensed to patients of a long-term care facility (LTCF) and now are not being used. These drugs cannot be part of any Drug Enforcement Administration (DEA) registrant's inventory.

The DEA Form 41, available online at DEA's website, is for the destruction of controlled substances (CS) that are still part of a registrant's inventory.

The North Dakota State Board of Pharmacy has an agreement with its local DEA diversion group supervisor to destroy these drugs in North Dakota when the Board makes its annual inspections or at others times, as needed. Please notify the Board if a clinic or practitioner contacts you for destruction of CS.

DEA can authorize the destruction of CS by the registrant after receiving the completed DEA Form 41, but usually refers him or her to the Board.

Keep in mind that all transfers of CS between registrants must be via invoice containing the address and DEA number of both registrants, or if transferring Schedule II CS, via the DEA Form 222. This would include the transfer of expired Schedule II CS to a reverse distributor for credit.

All CS, except patient-specific medications dispensed pursuant to a prescription, must be stored at a DEA-registered location or be the responsibility of a practitioner who holds a DEA registration at that location. The only exception is emergency boxes maintained according to rules of the Board of Pharmacy and counted as part of the pharmacy's inventory.

DEA Proposes Rule on Allowing Pharmacies to Take Back CS

DEA has proposed a rule that would allow retail pharmacies to register as approved drop-off locations for patients to dispose of unused narcotics. These receptacles located in a pharmacy will need to be kept secure, and there will be record-keeping requirements. The proposed rule would also allow pharmacies to have collection box locations at LTCFs.

This effort by DEA is being directed as a strategy to benefit the public by decreasing the supply of CS available for misuse, abuse, and accidental ingestion.

The rulemaking is still in process and thus is not effective at the time of writing this article. The Board has been discussing with disposal vendors on how they plan to service pharmacies with this new rule with the hope that this can be quickly incorporated by North Dakota pharmacies that would like to offer this service to the public.

Currently, the North Dakota Attorney General's office operates a take-back program for narcotics at many police stations in North Dakota. The Board recommends to check with your local police department to identify if it participates in the attorney general's program and to educate your patients on proper disposal options for narcotics. Further, drug disposal information can be found on the Board's website, *www.nodakpharmacy.com,* or the North Dakota Attorney General's website at *www.ag.state.nd.us.*

Pharmacy Technician Reminder on PTCB Certification

Pharmacy Technician Certification Board (PTCB) certification is required and must be obtained before registration for new pharmacy technicians who graduated from an American Society of Health-System Pharmacists-accredited program, and must be obtained and maintained by currently registered technicians. The only exception to this requirement will be for those technicians registered on or before August 1, 1995, who will continue to be grandfathered.

As a condition of registration, a pharmacy technician must obtain and keep current his or her PTCB certification. Certified pharmacy technicians (CPhTs) are required to recertify every two years to maintain certification. The purpose of recertification is to ensure that pharmacy technicians stay up to date in pharmacy practice through the completion of continuing education. Failure to recertify may result in having to retake the Pharmacy Technician Certification Exam (PTCE) along with jeopardizing your North Dakota registration.

Information about the PTCE, how to apply, and how to recertify can be found at *www.ptcb.org.*

Board Policy on What a Pharmacist May Change on a CS Prescription

Schedule III through V

- Pharmacist may add or change the patient's address, upon verification.

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Changes to Fentanyl Pain Patch Warnings Required by FDA

To reduce the risk of accidental exposure, Food and Drug Administration (FDA) has announced new requirements that change the appearance of fentanyl pain patch warnings to make them more visible. The change also requires new language in the warning that emphasizes the risk of death from accidental exposure, particularly in children. The announcement coincided with a Consumer Update that stressed the potential danger of improperly discarded fentanyl patches to children and pets. FDA reminded consumers of the agency's previous advice for securely storing unused patches and disposing of used fentanyl patches by folding the sticky sides together and then flushing them down the toilet. The agency also advises patients to cover in-use patches with an adhesive film to keep them from coming loose, and to regularly check patches to ensure they are securely in place. FDA offers additional information for health care providers on the "Fentanyl Transdermal System (marketed as Duragesic) Information" page, available at *www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm114961.htm*. Consumer information about safe drug disposal methods is also available on the AWAR$_X$E® Web site at *www.AWARERX.ORG*.

New: Free ISMP Medication Safety Alert! Newsletter for LTC Facilities

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization 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 July, ISMP began publishing *Long-Term Care Advise-ERR,* a new *ISMP Medication Safety Alert!* newsletter for nurses and administrators in long-term care (LTC) facilities. ISMP receives error reports that have occurred in LTC facilities. The newsletter is provided free to LTC facilities in the United States thanks in part to corporate sponsorship from Lilly and for a nominal subscription fee for pharmacies that service LTC facilities and others. Please visit ISMP's Web site at *www.ismp.org/Newsletters/longtermcare* for more information, and let your LTC facilities know about this free offer.

Here are a few excerpts from a recent issue.

Immediate Vs Extended Release Error

A physician called a LTC facility to change a resident's oxycodone order from an extended-release formulation to an immediate release formulation at the same dose and frequency. The nurse receiving the verbal order transcribed it as "Discontinue OxyContin 10 mg BID, Start OxyContin 10 mg IR BID," with "IR" meant to represent immediate release. Although Oxy**Contin**® is a brand of oxy**codone,** it is only available as an extended-release tablet. The pharmacy had previously been dispensing Oxy**Contin** for the resident, so the nurse thought she could communicate the prescriber's order by discontinuing the current Oxy**Contin** order and then ordering Oxy**Contin** as an immediate-release product. The pharmacy continued dispensing Oxy**Contin.** The differences between these products and formulations were brought to the attention of nursing staff via an in-service. To minimize the risk of confusion, do not attach modifiers such as "IR" for immediate-release or "RS" for regular strength unless it is part of the official drug name.

Errors Occur During Transitions of Care

A pharmacist reported the following hazardous situation that can occur during a hospital to LTC transfer. Residents are often admitted to a LTC facility with a list of medications printed from the hospital pharmacy computer. On these printouts, doses are expressed along with the number of tablets. For example, the printout may list hydrochlorothiazide 50 mg/2 tablets daily for an order in which the total dose was 50 mg because the hospital only stocks the 25 mg tablets. During hospitalization the patient required two tablets for each dose; however, the LTC nurse may misinterpret the order to mean two 50 mg tablets, making the total dose 100 mg, or two times more than prescribed. This issue arises every time the resident's total dose in the hospital requires more than one tablet or capsule. Discharge medication summaries and transfer orders should only list the total dose in mg or mcg and other directions for use (ie, frequency, route, drug name) to avoid misinterpretation.

2013 USP Chapter <797> Compliance Survey Shows Compliance Trends Unchanged From 2012

The 2013 United States Pharmacopoeia (USP) Chapter <797> Compliance Survey, the third annual report released since 2011, shows that the overall compliance rate of 77.2% remains nearly unchanged from the 2012 rate. Budgetary restrictions and physical plant limitations were among the top challenges to compliance by survey respondents. The report also details the

survey's findings on what types of facilities are participating in compounding, and compliance in specific domain areas such as environmental sampling and gloved fingertip sampling. Of the survey's 1,045 participants, 97% of the survey's respondents said that USP Chapter <797> "has had a positive influence on patient safety." The report notes National Association of Boards of Pharmacy® (NABP®) efforts to assist state boards of pharmacy in evaluating pharmacy compliance with USP Chapter <797> requirements for sterile compounding in their states. The report also noted that those who participated in the 2011 survey had a higher compliance score than those who did not. The survey's authors encouraged pharmacy owners with multiple areas of noncompliance to target one or two areas to improve. They also encouraged organizations that participated in the survey to make use of the free Action Plan – generated upon completion of the survey – and other free resources to "reshape" their sterile compounding practices. The full report on the survey's results is available in the October 2013 issue of *Pharmacy Purchasing & Products Magazine* and on the magazine's Web site at *www.pppmag.com/article/1403*.

FDA Recommends Schedule II Classification for Hydrocodone Combination Products

FDA planned to submit a formal recommendation to reclassify hydrocodone combination products as Schedule II controlled substances to the Department of Health and Human Services by early December 2013. FDA expects the National Institute on Drug Abuse to concur with the recommendation, indicates a statement on the FDA Web site. FDA also indicates that while "the value of and access to these drugs has been a consistent source of public debate," the agency has "been challenged with determining how to balance the need to ensure continued access to those patients who rely on continuous pain relief while addressing the ongoing concerns about abuse and misuse." Drug Enforcement Administration makes the final decision about the appropriate scheduling of these drugs. In January 2013, FDA's Drug Safety and Risk Management Advisory Committee made a recommendation that hydrocodone combination products be classified as Schedule II drugs following a 19-to-10 vote that concluded a two-day meeting during which members discussed the potential for abuse and misuse of the medications and the potential impact of rescheduling the drug products. FDA's statement on the recommendation is available at *www.fda.gov/Drugs/DrugSafety/ucm372089.htm*.

New FDA Drug Info Rounds Training Videos Available

FDA Drug Info Rounds, a series of online 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 two Drug Info Rounds videos, pharmacists discuss the review and approval of new drug names and the review of marketing and advertising materials for new drugs. The videos can be viewed at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm368620.htm* and *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm371785.htm,* respectively. Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, and Division of Drug Information.

CPPA Developing Specialty Pharmacy Accreditation Program

The Center for Pharmacy Practice Accreditation® (CPPA) has announced the development of a new accreditation program for specialty pharmacy practices. CPPA Executive Director Lynnae Mahaney, MBA, RPh, FASHP, VHA-CM, indicates that "CPPA will be able to develop the new specialty pharmacy standards quickly and efficiently with the existing standards development methodology, infrastructure, and network of specialty pharmacy expertise."

CPPA is a partnership between the American Pharmacists Association, the American Society of Health-System Pharmacists, and NABP. CPPA develops and implements comprehensive programs of pharmacy practice site accreditation, including the promotion, development, and maintenance of principles, policies, and standards. CPPA offers the general public and users of pharmacy services a means of identifying those pharmacies that satisfy the accreditation criteria and are focused on advancing patient care, safety, and quality.

More information may be found in the press release, available at *www.pharmacypracticeaccredit.org/news/2013/10/cppa-to-develop-specialty-pharmacy-accreditation-program*.

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- Pharmacist may add or change the dosage form, drug strength, drug quantity, directions for use, or issue date after consultation and agreement with the prescribing practitioner. Such consultation and corresponding changes should be noted by the pharmacist on the prescription.
- Pharmacist may add the practitioner's DEA number.

Schedule II

- Pharmacist may add or change the patient's address, upon verification.
- Pharmacist may add or change the dosage form, drug strength, drug quantity, directions for use, or issue date after consultation and agreement with the prescribing practitioner. Such consultation and corresponding changes should be noted by the pharmacist on the prescription.
- Pharmacist may add the practitioner's DEA number.

The pharmacist is not permitted to make changes to the patient's name, the CS prescribed (except for generic substitution), or the prescriber's signature.

The important tenets of any changes to a CS prescription should be to:

- take care of the patient;
- verify the identity of each patient receiving a CS; and
- verify that the prescriber's intentions for the care of his or her patient are being fulfilled.

Federal Drug Quality and Security Act Brings Changes to Pharmaceutical Compounding Practices

On November 27, 2013, President Barack Obama signed into law the Drug Quality and Security Act (DQSA). DQSA focuses on two broad issues: (1) further refinement of the state and federal roles in regulating compounding pharmacy practices and (2) creation and implementation of a national "track and trace" program intended to ensure integrity of the prescription drug supply chain.

Regarding the compounding of pharmaceuticals, the large change is the addition of a business class now referred to as "outsourcing facilities." The law defines an "outsourcing facility" as a facility at one geographic location or address that is engaged in the compounding of sterile drugs; has elected to register as an outsourcing facility; and complies with all of the requirements of the new law (Section 503B).

An outsourcing facility can qualify for exemptions from the Food and Drug Administration (FDA) approval requirements and the requirement to label products with adequate directions for use, but not the exemption from current Good Manufacturing Practices (cGMPs) requirements. Outsourcing facilities:

- must comply with cGMP requirements;
- will be inspected by FDA according to a risk-based schedule; and
- must meet certain other conditions, such as reporting adverse events and providing FDA with certain information about the products they compound.

For retail or hospital pharmacies that conduct compounding, the recently passed law will likely not cause much change in their processes. The requirement to compound based on a patient-specific prescription or order is still a basic tenet for pharmacies to follow. The only exception is compounding a product "for office use," which is defined as only use within the practitioner's office and prohibited from being dispensed to a patient.

Should you have any questions from your practice setting, please feel free to give the Board a call to discuss.

Common Question on Tramadol in LTCFs

Now that tramadol is a CS in North Dakota, can it still be returned for credit when packaged appropriately for a LTCF patient?

Since the prohibition for the transfer of CS between non-registrants or from non-registrants to registrants, eg, patient to pharmacy, is in the federal law and tramadol is not yet scheduled federally, the federal prohibition does not apply to tramadol. The Board does not have a CS registration in North Dakota and no specific prohibition for such a transfer, so you can take back tramadol and credit the patient.

The *North Dakota State Board of Pharmacy News* is published by the North Dakota 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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