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North Dakota State Board of Pharmacy News

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Update to Board Contact Information

The North Dakota State Board of Pharmacy transitioned its working email to new addresses utilizing the .pharmacy domain. The email addresses containing btinet.net will be discontinued and no longer accessible in the near future. Please note the new contact emails below. The Board is also utilizing the website domain *www.ndboard.pharmacy,* which redirects to the Board's current website *www .nodakpharmacy.com.* Should you have any questions, feel free to use the new email addresses at any point or call the Board office at 701/328-9535.

- Mark Hardy: mhardy@ndboard.pharmacy
- Eileen Heidrich: ndboph2@ndboard.pharmacy
- Howard Anderson: ndboph@ndboard.pharmacy
- Kathy Zahn: pdmp@nd.gov or pdmp@ndboard .pharmacy

What Is a .Pharmacy Domain?

A .pharmacy domain (pronounced "dot pharmacy") is part of a website's address like ".com" or ".biz": *www.ndboard .pharmacy.* It enables people to identify an online pharmacy or pharmacy-related website as safe and legitimate. Since .pharmacy is a verified domain, websites are evaluated against a set of safety standards before being able to register the domain.

Why Is .Pharmacy Important?

Today, the vast majority of websites selling prescription drugs online are doing so illegally – many of them sell unapproved, substandard, and counterfeit medicine. The National Association of Boards of Pharmacy® (NABP®), the official registry of the .pharmacy domain, has found that 96% of the nearly 11,500 internet drug outlets it has reviewed are out of compliance with United States pharmacy laws and practice standards. Of the websites NABP has identified as Not Recommended, 88% appear to have affiliations with networks of rogue internet drug outlets and 89% do not require a valid prescription!

Transfer of Unfilled EPCS Between Pharmacies

The Board office has received questions on the ability and procedures for transferring an unfilled controlled substance (CS) prescription (ie, a prescription for a CS that a pharmacy received but has not filled) to another pharmacy.

The following is reprinted with permission from NABP. Drug Enforcement Administration (DEA) provided the information to NABP as part of a partnership through the Controlled Substances Stakeholder Coalition (emphasis added):

> The Controlled Substances Act and its implementing regulations outline what can take place regarding prescriptions for controlled substances. In Title 21, Code of Federal Regulations, Section 1306.25 the DEA made a specific exception so that a DEA registered pharmacy can, once it has filled an original prescription for a controlled substance in Schedules III-V, transfer the original prescription information to another DEA registered pharmacy for the purpose of allowing that second pharmacy to then dispense any remaining valid refills still permitted by law and the prescriber's authorization. With one exception, such an allowance currently does not exist for the forwarding of an unfilled prescription from one DEA registered retail pharmacy so that it may be filled at another DEA registered retail pharmacy.
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> Prescriptions can take the form of paper (including fax), call-in, or electronic prescription for controlled substances (EPCS). The DEA has addressed the forwarding of an EPCS prescription. The DEA published information in the preamble of the notice of proposed rulemaking (NPRM) on EPCS, 73 FR 36722, and the preamble of the interim final rule (IFR) on EPCS, 75 FR 16235. Note, because this was in the preamble and not in the EPCS regulations, it represents the DEA's policy. **As posted in the preambles of the NPRM and the IFR, an unfilled original EPCS prescription can be forwarded from one DEA registered retail pharmacy to another DEA registered retail pharmacy, and this includes Schedule II controlled substances.**
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> At the start of 2017, the DEA received inquiries from some pharmacists regarding this issue. The DEA was

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WHO Launches Global Patient Safety Challenge on Medication Safety

To reduce severe, avoidable medication-associated harm in all countries by 50% over the next five years, the World Health Organization (WHO) has launched a worldwide initiative, the Global Patient Safety Challenge on Medication Safety. Medication errors cause at least one death every day and injure approximately 1.3 million people every year in the United States. In addition, low- and middle-income countries are estimated to have similar rates of medication-related adverse events as high-income countries.

The Global Patient Safety Challenge on Medication Safety aims to make improvements in each stage of the medication use process including prescribing, dispensing, administering, monitoring, and use. WHO intends to provide guidance and develop strategies, in addition to plans and tools to ensure that the medication process has the safety of patients at its core in all health care facilities.

Previous WHO Global Safety Challenges have included the Clean Care is Safer Care challenge on hand hygiene in 2005 and the Safe Surgery Saves Lives challenge in 2008. Additional information is available in the WHO press release available at *http://who.int/mediacentre/news/releases/2017/medication-related-errors/en.*

Continuous Quality Improvement and Patient Safety Organizations

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 provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at* www.ismp.org. *Email: ismpinfo@ismp.org.*

Data from the ISMP Medication Errors Reporting Program reveals that medication-related problems are repetitive in nature. An incident of misuse in one setting is likely to repeat itself in another. Most importantly, the system changes that are necessary to prevent errors are similar, and a growing body of literature is available to guide these efforts. Tragically, too many organizations and individual providers do not believe similar incidents could happen to them. They fail to use information about errors occurring elsewhere as a roadmap for improvement in their own organization or practice. It is not until a serious error hits home that aggressive prevention efforts are implemented. With so much evidence-based information about error prevention at hand, there is little excuse for reacting to errors after they happen instead of preventing them.

The development and implementation of continuous quality improvement (CQI) efforts should be the highest priority in all pharmacies. Such efforts must be aimed specifically at preventing well-known and repetitive dispensing errors. Pharmacies should seek out medication safety information and use it proactively to prevent medication errors. At the same time, safety issues recognized internally and/or reported by patients should be documented and analyzed, with a process to determine the best strategies to prevent future problems and methods to ensure implementation. An annual survey to assess consumer perceptions of the quality of pharmaceutical products and professional services could supply additional information upon which to base improvement strategies. For more information on CQI programs, visit Section 7 of Model Rules for the Practice of Pharmacy in *The Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy.*

Informational tools like the *ISMP Medication Safety Alert!* publication, or ISMP's *Quarterly Action Agenda,* which is a readily available list of medication problems compiled from the nation's reporting programs, can be a backbone of any CQI effort. The very purpose of the ISMP Medication Errors Reporting Program – indeed the purpose of any type of safety reporting program and the expert recommendations that stem from it – is to guide the implementation of quality improvement initiatives by practitioners and organizations.

It is important that certain information from the CQI proceedings and records of review be protected from discovery. Patient safety organizations (PSO) are organizations that share the goal of improving the quality and safety of health care delivery. Patient Safety Work Product (PSWP) is the information protected by the privilege and confidentiality protections of the Patient Safety Act and Patient Safety Rule. PSOs serve as independent, external experts who can collect, analyze, and aggregate PSWP locally, regionally, and nationally to develop insights into the underlying causes of patient safety events, thus improving quality by identifying and reducing the risks and hazards associated with patient care. Communications with PSOs are protected to allay fears of increased risk of liability because of collection and analysis of patient safety events.

For more information on PSOs, visit *https://www.pso.ahrq.gov/faq.*

NCPDP Releases Guide to Ensure Patients Get Their Medications During a Disaster

The National Council for Prescription Drug Programs (NCPDP) released the *NCPDP Emergency Preparedness Information* guide to assist pharmacists and other health care providers during a declared emergency. Prepared by the NCPDP Emergency Preparedness Committee, the guide provides resource information for eligibility and claims processing affecting displaced individuals. The guide is available at *www.ncpdp.org/NCPDP/media/pdf/NCPDPEmergencyPreparednessInformation_v1_4.pdf.* Additional information for pharmacists about emergency preparedness is available on the NCPDP website at *www.ncpdp.org/Resources/Emergency-Preparedness.*

FDA Warns of Illnesses and Deaths in Pets Exposed to Fluorouracil

Food and Drug Administration (FDA) is alerting pharmacists that patients' pets are at risk of illness and death when exposed to the topical cancer medication fluorouracil cream USP 5% (5-FU) that is intended for use in people. Fluorouracil may also be marketed under the brand names Carac®, Efudex®, and

Fluoroplex®. Very small amounts could be dangerous to household pets; thus, patients should use care when applying and storing the medication. FDA has received reports of five dogs that became ill and died after accidentally ingesting the topical cream, notes a Center for Veterinary Medicine Update available at *www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm537434.htm.*

Although FDA has not received any reports involving cats to date, cats are also expected to be extremely sensitive to fluorouracil cream. For instance, if an owner applies fluorouracil cream to an afflicted area and touches his or her cat, the cat may accidentally ingest the medication when grooming itself and suffer adverse events.

FDA advises that pharmacists who fill these prescriptions should advise patients with pets to prevent exposing their pet to the medication. Adverse events may be reported to FDA using the Form FDA 1932a, which may be obtained at *www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm055305.htm.*

FDA Revises Final Guidance Documents on Bulk Drug Substances Used in Compounding

In January 2017, FDA issued revised versions of two final guidance documents regarding the use of bulk drug substances in compounding.

- Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act
- Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act

FDA clarified that the policies described in the guidances do not apply to inactive ingredients. Inactive ingredients are not included in the definition of a "bulk drug substance" and can be used in compounding without appearing on the bulk drug substances lists developed under sections 503A or 503B of the Federal Food, Drug, and Cosmetic Act, if all applicable conditions are met.

As indicated on its website at *www.fda.gov/Drugs/DrugSafety/ucm502075.htm,* FDA will also provide regular updates to the categories of bulk drug substances described in the guidances. FDA previously stated that it would not evaluate new nominations for placement in one of the three categories until after it completed its review of substances already nominated with adequate supporting information.

Now, the guidances state that FDA will determine after submissions are received whether new nominations, including renominations of substances with additional supporting information, have sufficient information for FDA to review them. After making that determination, FDA will place nominated substances in the appropriate category on FDA's website. FDA intends to update the categories with any new nominations the first business day of each month. This revised policy will further minimize unnecessary disruptions to patient treatment while FDA develops the lists of bulk drug substances for use in compounding.

The guidances are available online at *www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469120.pdf* and *www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469122.pdf.*

APhA Resource Guide Applies JCPP Pharmacists' Patient Care Process to Immunization Services

The American Pharmacists Association (APhA) published a resource guide that applies the Joint Commission of Pharmacy Practitioners (JCPP) Pharmacists' Patient Care Process to pharmacy-based immunization services. The components of the Pharmacists' Patient Care Process to collect, assess, plan, implement, and follow-up should be implemented as routine practice along with the National Vaccine Advisory Committee Standards for Adult Immunization Practice, as noted in the resource guide, *Applying the Pharmacists' Patient Care Process to Immunization Services.* "[P]harmacists and other vaccine providers need to strive to constantly improve collaboration, communication, and documentation," indicates the APhA guide. For more information, visit the APhA Immunization Center at *www.pharmacist.com/immunization-center.*

CPE Training on Older Adult Fall Prevention Available Online

Developed in collaboration with the Centers for Disease Control and Prevention (CDC) and the APhA, the Stopping Elderly Accidents, Deaths, and Injuries (STEADI) initiative is offering continuing pharmacy education (CPE) training for pharmacists to prevent falls in adults 65 and older. The training will provide strategies to help pharmacists screen older adults for fall risk, conduct medication review and management, and offer patient education. To participate in the free online training, "STEADI: The Pharmacist's Role in Older Adult Fall Prevention," visit the CDC website at *www.cdc.gov/steadi/training.html* for more information.

New FDA Drug Info Rounds Training Video Addresses the Combat Methamphetamine Epidemic Act

Drug Info Rounds, a series of online videos by FDA, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the latest Drug Info Rounds video, "Combat Methamphetamine Epidemic Act," pharmacists discuss the legal requirements for the sale of over-the-counter drug products that contain pseudoephedrine. Drug Info Rounds was developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research (CDER), Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.*

FDA Presents Series of CE Webinars for Students and Clinicians

FDA's Division of Drug Information in the CDER presents a series of continuing education (CE) webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Previous webinar topics have included an overview of FDA's role in medication error prevention and prescription drug labeling. The webinars and presentation slides can be accessed on FDA's website at *www.fda.gov/DDIWebinars.*

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advised that these pharmacists had received notice from their management that they could not forward original unfilled prescriptions for controlled substances as there was no exception in Federal regulation that expressly allowed this activity. The pharmacists were provided with the above information. Although the DEA received several inquiries regarding this issue earlier in the year, these have now ceased . . .

Loren T. Miller

Associate Section Chief

Liaison and Policy Section

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Drug Enforcement Administration

If you have any questions, please feel free to contact the Board office by phone at 701/328-9535 or by email at mhardy@ndboard.pharmacy.

Transition of the Board-Provided CS Disposal Program to Sharps MedSafe

The Board has made the decision to change providers of its drug disposal program, which the Board offers to participating North Dakota pharmacies. The Board will no longer utilize the Yellow Jug Old Drugs Program, which has discontinued business operations. The Board has decided to utilize Sharps Compliance, Inc's MedSafe drug disposal program as its vendor.

This program will continue to be provided by the Board, free of charge, to qualifying participating pharmacies that are committed to offering this service to their patients. The Board is dedicated to funding a long-term disposal program to ensure the maximum opportunity is provided for patients to properly destroy CS and further prevent diversion or abuse. With the opiate epidemic North Dakota is facing, it is important that the pharmacy profession is committed to providing an avenue for patients to safely dispose of their medications.

Please reach out to the Board office for more information if your pharmacy would like to participate in the disposal program. Nearly 90 locations across the state are providing this important public service to their communities.

Gabapentin Is Now a Reportable Drug to the PDMP

The Board has implemented and notified pharmacies of the law requiring gabapentin (Neurontin®) to be a reportable drug to the prescription drug monitoring program (PDMP). Effective August 1, dispensers are required to report gabapentin prescriptions to the PDMP. For pharmacies, make sure your software vendor has made the necessary adjustments for this and ensure you are compliant by checking your patients' profiles for your pharmacy's records.

The Board has heard increasing reports on the concerning activities around gabapentin. Although the rationale for abuse is unknown, reports describe abuse due to the effects of euphoria, improved sociability, a marijuana-like "high," relaxation, and a sense of calm. Concerning activities described include obtaining high doses and utilizing multiple practitioners and pharmacies. Please be aware of this increasing trend and, when available, monitor patients through the PDMP when appropriate.

Prescriptive Authority for Naloxone

In 2016, the Board promulgated rules (North Dakota Administrative Code (NDAC) 61-04-12) implementing the authority given by the state legislature, which granted prescriptive privileges for naloxone to pharmacists in North Dakota. This important measure will be one of the tools the profession of pharmacy can utilize to help save lives from the illicit and prescription drug abuse issues currently affecting so many.

The procedure for a pharmacist to prescribe naloxone is available on the Board's website along with information that can be provided to patients and their loved ones. The process is very straightforward and involves reviewing the context of the rule, completing one of the educational programs, and informing the Board of your intentions to prescribe this lifesaving drug. The Board will make the locations where pharmacists are prescribing naloxone available to the public for their information.

Please strongly consider providing this service in your pharmacy location!

Pharmacy Inspections

Board inspectors are currently out conducting their yearly inspections. By the time you receive this, some of you will have your pharmacy's inspection completed. The inspectors this year will be Howard Anderson, RPh; Rick Detwiller, RPh; Judy Swisher, RPh; and Bonnie Thom, RPh. The focus of this year's inspection will include:

- Compounding – NDAC 61-02-01-03
- Patient Counseling – North Dakota Century Code 43-15-31.2 Prescription Drug Information Required
- Continuous Quality Improvement – NDAC 61-02-01-19
- Individual Identification and License/Registration Posted to Public – NDAC 61-02-07.1 and 61-03-03.1

Please have your inspection form filled out and ensure that your staff know where it will be kept in the pharmacy. The Board wants staff to spend some quality time with the inspector while he or she is there and ask any questions that the pharmacy may have.

Newsletter Goes Electronic

Going forward, future Board *Newsletters* will mostly be provided as a downloadable pdf posted to the Board's web page on the NABP website at *www.nabp.pharmacy/boards-of-pharmacy.* Licensees will receive an email alert whenever a new issue of the electronic *Newsletter* becomes available. To ensure you receive these alerts, please keep your contact information up to date with the Board. The Board is undertaking this effort to deliver updates as timely as possible and make the information more easily accessible.

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® (NABPF®) 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 NABPF or the Board unless expressly so stated.

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