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North Dakota State Board of Pharmacy News

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Important Counseling Points for Patients Receiving Controlled Substance Prescriptions

We are all aware of the increased problems with prescription drug abuse. The North Dakota State Board of Pharmacy has been participating in discussions specifically related to this increased abuse within our youth population and the correlating trend leading to the increased use of street drugs like heroin.

Reports from treatment specialists show that often an individual will start by abusing opiate-based prescription drugs and when financial constraints develop they will switch to drugs like heroin, as they are cheaper. A common theme among young people starting their addiction is obtaining unused prescription drugs from their family's or friend's medicine cabinet.

While counseling our patients on drugs that have a potential for abuse, our conversations should also include educating our patients on the importance of securing and destroying any medications not needed or discontinued. If you have law enforcement centers that have a drug take-back program, it would be helpful to distribute that information directly to the patient upon receiving his or her prescriptions.

The National Association of Boards of Pharmacy® (NABP®) has created a great resource for pharmacies to utilize called the AWAR$_X$E® program. Their site provides timely medication safety and pharmacy regulatory resources that will assist you in protecting your patients. The Web site is *www.AWARERX.ORG*.

We as a profession need to be as proactive as we can with tackling this growing epidemic. Use of the Prescription Drug Monitoring Program continues to be an essential tool in our practices. If you have questions or are looking for resources for your practice, feel free to contact the Board office for more information.

Board Looking to Implement a Controlled Substance Registration

Currently, NDCC 19-03.1-17 gives the authority to the North Dakota State Board of Pharmacy to put in place a controlled substance registration. Although the Board has not felt the need to enforce this in the past, they now wish to implement this due to the increased problems the Board has witnessed with controlled medication coupled with the need for a funding mechanism to maintain the Prescription Drug Monitoring Program. It is the Board's intention to bring the matter to the North Dakota Legislature to ask for language to clarify a few points of the current legislation and also to add a fee.

Registration would be needed for any individuals or businesses that handle, sell, or distribute controlled substances. This includes but is not limited to pharmacies, practitioners, medical facilities, veterinarians, dog trainers, and research facilities.

Update on Buprenorphine Drug Products

Currently, there are four different buprenorphine drug delivery systems available in the United States. However, unlike most other groups of drug products that contain the same drug substance, there are significant differences in the indications for these individual products and, based on federal statute and regulation, restrictions on who can lawfully prescribe some of them for certain indications.

The buprenorphine drug products that are currently approved for clinical use by Food and Drug Administration (FDA), along with their corresponding indications are listed below. They are all classified by the Drug Enforcement Administration (DEA) in Schedule III under the federal Controlled Substances Act.

Formulation Type	Brand (proprietary) Name	FDA-Approved Indication
Parenteral	Buprenex®, and generics	Relief of moderate to severe pain
Sublingual Tablets	Suboxone® Subutex®, and generics	Treatment of opioid dependence
Sublingual Film	Suboxone	Maintenance treatment of opioid dependence
Transdermal Delivery System	Butrans®	Management of moderate to severe chronic pain in patients requiring a continuous, around-the-clock opioid analgesic for an extended period of time

The Drug Addiction Treatment Act of 2000 (DATA) codified at 21 U.S.C. 823(g), limits the use of certain buprenorphine-containing drug products for the **maintenance or detoxification treatment** of opioid dependence (ie, opioid addiction) to **physicians** who (a) meet certain qualifying requirements and (b) have notified the Secretary of Health and Human Services (HHS) of their intent to prescribe the products for the management of opioid dependence. HHS processes the notification and contacts DEA. Once the waiver is approved, HHS notifies the physician that he or she has a waiver under DATA and informs the physician of his or her modified DEA registration number (the so-called "X" number). At present, the only products that meet the criteria in DATA are the sublingual tablets and film (rows 2 and 3 in the above table). It is important to note that for the prescription of these sublingual products, the federal Substance

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FDA Recommends Use of Sterile Needle and Syringe for Administration of Inactivated Influenza Vaccines

Food and Drug Administration (FDA) recommends that health care providers use a sterile needle and syringe to administer inactivated influenza vaccines. The recommendation was released in response to questions regarding the use of jet injector devices to administer inactivated influenza vaccines. FDA advises that "inactivated influenza vaccines that are approved by FDA have information in their labeling stating how the vaccines should be administered, such as, by intramuscular (IM) or intradermal (ID) administration." Further, FDA clarifies its October 21, 2011 communication "to inform the public that inactivated influenza vaccines labeled for IM injection are intended for administration using a sterile needle and syringe. There is one inactivated influenza vaccine labeled for ID administration, this vaccine is supplied in its own pre-filled syringe. The live attenuated influenza vaccine is given through the nose as a spray; the sprayer is not a jet injector." FDA also notes the following:

- Currently, there is only one vaccine, Measles, Mumps, and Rubella (MMR), that is approved and specifically labeled for administration by jet injector.
- Safety and effectiveness information that would support labeling inactivated influenza vaccines for delivery by jet injector have not been submitted to FDA.
- At this time, there are no inactivated influenza vaccines that are approved and specifically labeled by FDA for administration by jet injector.

FDA recommends that all approved vaccines, including influenza, be administered in accordance with their approved labeling, and FDA advises that if a vaccine has been approved for administration with a jet injector, information specifically addressing vaccine use with a jet injector will appear in the vaccine labeling. Additional background information is available in the communication posted on the FDA Web site at *www.fda.gov/BiologicsBloodVaccines/Vaccines/QuestionsaboutVaccines/ucm276773.htm.*

The Centers for Disease Control and Prevention continues to encourage people to get vaccinated throughout the flu season, which can begin as early as October and last as late as May. For information about the flu vaccine visit *www.cdc.gov/flu.*

'Tell Back' Works Best to Confirm Patient Understanding

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.*

In the past few years, multiple studies have demonstrated that patients often leave medical encounters with a poor understanding of their health conditions and recommended treatment. One recent study on this subject demonstrates the low level of understanding patients have about follow-up care and medication therapy upon discharge from the emergency department (Engel KG et al. Patient Comprehension of Emergency Department Care and Instructions: Are Patients Aware of When They Do Not Understand? Ann Emerg Med. Available on the journal Web site).

Given the importance of patient understanding of medical information, there are surprisingly few studies that point out how to approach this task. However, a study published in 2008 offers some insight into what approach to assessing understanding of medical information patients most prefer and perceive to be the most effective (Kemp EC, et al. Patients Prefer the Method of "Tell Back-Collaborative Inquiry" to Assess Understanding of Medical Information. J Am Board Fam Med 2008;21(1):24-30). Researchers tested three types of inquiry about the patient's understanding:

- Yes-No
- Tell Back-Directive
- Tell Back-Collaborative

The Yes-No approach asked closed-ended questions to assess patient understanding. (Example: "I've given you a lot of information. Do you understand?") The Tell Back-Directive method used open-ended questions that were physician-centered and paternalistic in that it was clear authority and control still remained with the physician. (Example: "It's really important that you do this exactly the way I explained. What do you understand?") The Tell Back-Collaborative approach used open-ended questions that were patient centered, making it clear that power and responsibility were shared between the health care provider and patient. (Example: I imagine you are really worried about your blood pressure. I've given you a lot of information. It would be helpful to me to hear your understanding about your clot and its treatment.)

Patients showed a significant preference for the Tell Back-Collaborative inquiry over other tested approaches. Because of the potential for embarrassment if patient misunderstandings are exposed, one might anticipate health care providers' reluctance to put patients "on the spot" with open-ended questions. But a collaborative approach to Tell Back allows the patient to save face for misunderstandings by acknowledging the large amount of information being provided. Patients might also view the request for Tell Back as evidence of the health care provider's care and concern for them personally, or evidence of the provider's attention to detail and competence. So, when counseling patients about their medications, instead of asking "Do you have any questions?" or "Do you understand?" ask them to restate their understanding of the information you provided in their own words within a shame-free, blame-free environment.

DEA Clarifications on Certification Process for Audits of EPCS Software

Drug Enforcement Administration (DEA) emphasizes that third-party audits of software applications for Electronic Prescriptions for Controlled Substances (EPCS) must encompass all applicable requirements in DEA regulations, including security, and must address "processing integrity" as set forth in the regulations. Further, DEA recommends that where questions or gaps may arise in reviewing a particular applica-

tion, federal guidelines set forth in National Institute of Standards and Technology Special Publication 800 – 53A should be consulted. DEA has also announced the first DEA-approved certification process for EPCS. Certifying organizations with a certification process approved by DEA pursuant to the regulations are posted on DEA's Web site at *www.deadiversion.usdoj.gov/ecomm/e_rx/thirdparty.htm#approved*. Detailed background information is provided in the Federal Register Notice, available for download at *www.gpo.gov/fdsys/pkg/FR-2011-10-19/pdf/2011-26738.pdf*.

'Script Your Future' Provides Tools and Outreach to Encourage Medication Adherence

United States Surgeon General Regina Benjamin called upon pharmacists, physicians, nurses, and other health care providers to talk with their patients about the importance of taking medications as directed to help prevent serious health complications at the recent launch of the national campaign, "Script Your Future." Benjamin also "encouraged patients with chronic conditions to speak with their health care professionals about their medication" as noted in a press release. A survey released by the National Consumer League, the organization that developed Script Your Future, indicates that "patients who do not always take their medication as directed are less likely to have received a full explanation of the consequences of their condition, and are less convinced of the importance of adherence." The Script Your Future campaign is targeting six regional areas with outreach activities and advertising, and more information is available at *www.ScriptYourFuture.org*. The campaign brings together "stakeholders in health care, business, and government to offer practical tools for patients to help them better adhere to their medication, and to help health care professionals better communicate with patients." More information about the campaign is available in a press release at *www.prnewswire.com/news-releases/us-surgeon-general-joins-baltimore-launch-of-the-national-script-your-future-campaign-to-highlight-importance-of-taking-medication-as-directed-133077423.html*.

FDA Releases 'Use Medicines Wisely' Video

FDA Office of Women's Health has released a new public service announcement (PSA) video titled, "Use Medicines Wisely," to help raise awareness about safe medication use. As stated in an FDA news release, "Millions of people benefit from FDA approved medications and are living longer productive lives. However, when medications are used incorrectly, they can cause serious injuries, even death. Many of these injuries can be prevented."

The video shows simple steps women can take to use medications wisely. Viewers are reminded to:

- Make a list of the medications they take
- Keep their medication list with them at all times
- Know the name of each medication, why they are taking it, how much to take, and when to take it
- Talk with their doctor, nurse, or pharmacist to find out how to safely use their medications

In addition to the video, a medications record-keeper, fact sheets, and other safe medication use resources are available on the FDA Web site.

Training Video Provides Tips on Preventing Pharmacy Robbery

Rx Pattern Analysis Tracking Robberies and Other Losses (RxPATROL) has released a training video discussing pharmacy robbery and how to prevent it. The video features a pharmacist and law enforcement liaison as they tour a pharmacy, evaluating security measures and discussing additional steps that can be taken to prevent robbery. RxPATROL is an initiative designed to collect, collate, analyze, and disseminate pharmacy theft intelligence to law enforcement throughout the nation. RxPATROL is designed to gather and disseminate critical information to help protect pharmacists, guard against potential robberies, and assist law enforcement in their efforts to successfully apprehend and prosecute those involved in controlled substance pharmacy crime. The training video can be accessed on the RxPATROL Web site at *http://rxpatrol.org/TrainingVideos.aspx*.

Nearly 20 Products Marketed as Natural Supplements Contain Sibutramine, FDA Warns

FDA has posted public warnings regarding 19 products, frequently marketed as natural supplements, and found to contain sibutramine, a controlled substance that was removed from the US market in October 2010 for safety reasons. These products pose a threat to consumers because sibutramine is known to substantially increase blood pressure and/or pulse rate in some patients and may present a significant risk for patients with a history of coronary artery disease, congestive heart failure, arrhythmias, or stroke. These products may also interact in life threatening ways with other medications a consumer may be taking. FDA warnings included products marketed as "Slender Slim 11," "Dream Body Slimming Capsule," "Acai Berry Soft Gel ABC," and 16 other product names. The products included in the warnings are being sold on Web sites and in some retail stores. FDA advises consumers not to purchase or use the products listed in the warnings. Consumers who have purchased any of these products should stop use immediately. And if consumers have experienced any negative side effects from using these products, they should consult a health care provider as soon as possible. The complete list of warnings is available on the FDA Web site at *www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm234592.htm*.

2012 Survey of Pharmacy Law Now Available

Serving as a convenient reference source for individuals seeking an overview of the state laws and regulations that govern pharmacy practice, the updated 2012 *Survey of Pharmacy Law* is now available and can be purchased online for $195 by visiting the NABP Web site at *www.nabp.net/publications*.

The *Survey,* produced in a CD format, consists of four sections including a state-by-state overview of organizational law, licensing law, drug law, and census data. Newly added this year, a question in Section 17, Wholesale Distributor Licensure Requirements, asks which state agency has regulatory authority over medical device distributors. In addition, a newly added question in Section 22, Electronic Transmission of Prescriptions: Computer-to-Computer, asks whether the state allows electronic prescribing of controlled substances.

Updates for the 2012 *Survey* were graciously provided by the state boards of pharmacy. In addition to the boards' support, NABP requested data from relevant health care associations for the *Survey's* prescribing authority and dispensing authority laws in Sections 24 and 25, and laws pertaining to the possession of non-controlled legend drugs and possession of controlled substances in Sections 26 and 27.

All final-year pharmacy students receive the *Survey* free of charge through the generous grant of Purdue Pharma L.P.

For more information on the *Survey,* please contact Customer Service via phone at 847/391-4406 or via e-mail at custserv@nabp.net.

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Abuse and Mental Health Services Administration interprets the word **physicians** literally, precluding the prescription of these products by any other type of health care professional **for the management of opioid dependence.** The federal law and regulations do not address the off-label use of these products (eg, prescribing sublingual tablets for the management of pain).

The other buprenorphine products (injectable and transdermal formulations) are approved for analgesic use **only** and are **not** approved by FDA for maintenance or treatment of opioid dependence, so the provisions of DATA **do not affect their legal status or use.** Thus, a physician or a non-physician health care professional, who does not have a DATA waiver, but has both federal and state authority to prescribe Schedule III products, can prescribe either of these analgesic formulations containing buprenorphine, for pain.

Veterinary Retail Facilities and Veterinary Dispensing Technicians

During the last legislative session, legislation (NDCC 43-15.4-01) was passed to allow a legal method for facilities that handle and sell non-controlled legend drugs specifically for equidae, food-animals, and nontraditional livestock to consumers pursuant to a valid prescription. The businesses are licensed by the North Dakota State Board of Pharmacy as Veterinary Retail Facilities and the individuals handling the drugs are registered as Veterinary Dispensing Technicians (VDT).

Each VDT must go through an educational program that teaches them the proper method for handling prescription drugs and how to prepare the products for the consumer. Also, each VDT will be informed of the limitations on what he or she may perform and what he or she may legally do.

The Board has currently licensed two facilities and will need to seek out and educate others that are currently engaged in the prescription veterinary drug business of this new legislation and requirement.

Prescription Drug Repository Program

As a reminder, the Board continues to operate the Prescription Drug Repository Program for its pharmacies. The program allows the transfer of unused and unopened legend drugs, devices, and supplies from pharmacies to patients for a small handling fee to the patient. The program has been tremendously successful since its inception. It has provided a method for many patients to obtain medications for free.

If your pharmacy is signed up, please continue to keep your inventory list accurate including removing any expired medications. If the pharmacy you are employed at is not signed up, please refer to the Board's Web site at *www.nodakpharmacy.com* for more information. This is a prime example of North Dakota pharmacies working together to benefit the patient.

Pain Management Program Available

The pain management program is intended for community, hospital, and consultant pharmacists. It is also appropriate for pharmacy technicians, physicians, mid-level practitioners, and nurses with an interest in the subject area.

This pain management program will provide pharmacists with necessary tools to help patients manage pain associated with injuries and illnesses. It contains valuable information that is of benefit to any health care practice setting.

As a reminder, the pain management program is available for free for all practitioners, pharmacists, and nurses with prescribing privileges. Any interested nurse (without prescribing privileges) may also participate in the program and receive continuing education credits for $100.

The program is now administered by the North Dakota State University Distance and Continuing Education department. More information may be found at *www.ndsu.edu/dce/* or by calling 1-800/726-1724. Please pass this information along to any practitioner that would benefit from this information.

Pharmacy *Newsletters* are also available online at the Board's Web site at *www.nodakpharmacy.com.* Feel free to print it off and pass it along to any other individuals that would benefit from the information the Board sends out.

Please visit the Board's Web site at *www.nodakpharmacy.com.* There are many helpful guidance documents, potential rule changes, and links to various sources of information that could be beneficial to your practice.

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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