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North Dakota State Board of Pharmacy News

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Drug Disposal Program Opportunity for North Dakota Licensed Pharmacies

The North Dakota State Board of Pharmacy has developed a partnership with the Yellow Jug Old Drugs program to provide an option for the safe disposal of a patient's prescription drug medications. The Board has generously decided to provide these systems and containers to any pharmacy eligible and willing to participate in the program. This will be free of charge and, depending upon the impact and scope of the program, the Board hopes to continue funding for future years.

The collection of unused controlled substances (CS) from the public is a new initiative based on a rule recently passed by Drug Enforcement Administration (DEA) that allows certain DEA registrants, such as pharmacies, to be eligible to register as a disposal location and provide that service to the public in the registrants' area.

Information on the procedures for registering with DEA as a disposal site was sent to pharmacies along with instructions on how and where they would need to place the secure container within the pharmacy so it is accessible to the public.

The goal of providing this program to our citizens in an accessible manner is to decrease the number of prescription drug medications left in medicine cabinets waiting to be discovered by an individual who will divert them for misuse. National data show 71% of people misusing prescriptions first obtained them from friends or relatives. This is why it is important for pharmacies to provide this service and to inform their patients of this program.

Pharmacies received forms to complete in order to participate in the program. Once a form is submitted to the Yellow Jug Old Drugs program, the pharmacy will receive a container as soon as one is available. Of course, participation is voluntary and a service you can choose to offer. The Board hopes that you will agree to provide this important service by becoming a disposal location for your patients and the public.

Findings of September CE Audit of Registered Technicians

- 37 technicians were randomly audited
- 17 technicians were compliant per CPE Monitor®
- 13 technicians were compliant with additional documentation
- Seven technicians did not have adequate continuing education (CE) hours

Those not in compliance received administrative fines and/or suspensions according to the North Dakota Administrative Code.

The Board will be looking to conduct random audits of pharmacists and pharmacy technicians in summer 2016.

North Dakota Health Information Network

The North Dakota Health Information Technology Advisory Committee (HITAC), in collaboration with the North Dakota Information Technology Department, is charged with expanding the secure exchange of health information in the state of North Dakota. HITAC is a public-private partnership made up of health care stakeholders. To meet this charge, HITAC has established the North Dakota Health Information Network (NDHIN).

The NDHIN connects providers to other providers through a secure, online network to share their patients' electronic health records. The NDHIN creates a roadmap of data for a more thorough understanding of patients' conditions, allowing for up-to-the-minute decisions and faster diagnoses. The NDHIN helps reduce patient intake time, minimize duplication of tests and paperwork, provide access to the most recent updates to health records, and cut costs while increasing mobility. The network ensures that your patients' data are protected and confidential. The goals of the NDHIN are to connect to a national network to accommodate patients everywhere, regardless of their home state, and to improve health care.

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FDA Issues Warning About Name Confusion for Brintellix and Brilinta

Due to similar brand names, there have been incidents where the antidepressant Brintellix® (vortioxetine) and the anti-blood clotting medication Brilinta® (ticagrelor) have been confused, resulting in prescribing and dispensing errors, warns Food and Drug Administration (FDA). The agency notes that no reports indicate that a patient has ingested the wrong medication; however, reports of prescribing and dispensing errors continue. FDA recommends that health care providers include the generic name of the medication in addition to the brand name, as well as the indication for use when prescribing these medications. Patients are advised to check their prescriptions to ensure that the correct medication was dispensed. More information is available in an FDA safety alert at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm456569.htm.*

Seven Persistent Safety Gaffes in Community/Ambulatory Settings That Need to Be Resolved!

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.*

This is part two of a three-part series on seven persistent safety gaffes of 2014.

3) Vaccine Errors: Repetitive Errors Reported in the Last Decade

How often do DTaP (diphtheria and tetanus toxoids, and acellular pertussis) and Tdap (tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis) vaccine mix-ups need to occur before regulatory action is taken to prevent confusion? Whatever the number, we can say that health care providers have probably met that threshold! Yet, vaccine errors like this continue to occur at an alarming rate (based on those reported to ISMP alone). Vaccine mix-ups occur often because of age-dependent formulations of the same vaccine, similar vaccine abbreviations, similar vaccine containers and labels, and storage near each other. Confusion between the diluent and vaccine has led to administration of the diluent alone or use of the wrong diluent. With an unfortunate rise in parents choosing not to vaccinate their children or themselves, health care providers cannot continue to make errors when vaccinating those who choose to be immunized; the impact on both individual and community immunity may be far-reaching.

4) Wrong Patient Errors: Not Opening the Bag at the Point of Sale

Community pharmacies are vulnerable to dispensing correctly filled prescriptions to the wrong patient at the point of sale, a risk that is well substantiated in the literature. This error is not influenced by the attributes of a specific medication; thus, dispensing any prescription medication to the wrong patient at the point of sale carries a similar level of risk. Based on an ISMP study, the error happens frequently at an estimated rate of 1.22 per 1,000 prescriptions. Among approximately 56,000 community pharmacies in the United States, this error rate suggests that 332,755 prescriptions will be dispensed to the wrong patient each month, or about six every month per pharmacy. One of the most effective ways to prevent this error is to open the bag of filled prescriptions at the point of sale to verify that the medications are for the correct patient. According to the ISMP study, this simple step reduces the risk of error by 56%, yet few pharmacies follow this practice.

5) Disrespectful Behavior: A History of Tolerance in Health Care

Bullying, incivility, and other forms of disrespectful behavior are still rampant in health care and allowed to exist. Health care providers tolerate the behavior, remain silent, or make excuses in an attempt to minimize the profound devastation that disrespectful behavior causes. An ISMP survey conducted in 2003 clearly demonstrated the scope of disrespectful behavior among many levels of interdisciplinary staff, and an ISMP survey conducted a decade later demonstrates little progress. Disrespect diminishes a person's ability to think clearly, make sound judgments, speak up regarding questions, or avoid at-risk behaviors. Disrespectful behaviors also underlie a resistance to collaborate with others, follow procedures that promote safe practices, or implement new safety practices. While a culture of disrespect is harmful on many levels, its effect on patient safety makes it a matter of national urgency.

FDA Advises Caution Against Codeine for Treating Colds in Young Patients

FDA is evaluating the safety of using medicines containing codeine to treat patients under 18 years old for coughs and colds because of the possibility of severe side effects. Codeine, an opioid, may cause slowed or difficult breathing in children, especially for those who already suffer from breathing problems, the agency notes. FDA recommends that health care providers use caution when prescribing or recommending codeine for patients under 18 years old, and that parents and caregivers be alert for signs of shallow or noisy breathing, confusion, or unusual sleepiness. FDA is also considering a European Medicines Agency recommendation made in April to not give children under 12 codeine for coughs and colds, and to not use codeine for patients 12 to 18 years old who have asthma or other chronic breathing problems. More information is provided in an FDA safety alert available at *www.fda.govSafety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm453379.htm.*

Daytrana Patch May Cause Permanent Skin Color Changes, FDA Warns

In June 2015, FDA warned health care providers and consumers that Daytrana®, a methylphenidate transdermal system prescribed for treating attention deficit hyperactivity disorder, may cause permanent loss of skin color in the affected area. FDA has added a new warning to the drug label to describe this skin condition, known as chemical leukoderma. Chemical leukoderma is a skin condition that causes the skin to lose color as a result of repeated exposure to specific chemical compounds, according to an FDA safety alert. The condition is not physically harmful, but it is disfiguring.

FDA advises patients and caregivers to watch for new areas of lighter skin, especially under the drug patch, and to immediately report any changes to their health care providers. Patients should not stop using the Daytrana patch without consulting a health care provider. FDA also recommends that providers for patients who experience these skin color changes consider alternative treatments. More details are included in the FDA safety alert available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm452595.htm.*

FDA Expands NSAID Warning Labels Regarding Risks of Heart Attack, Stroke

The labels of certain non-steroidal anti-inflammatory drugs (NSAIDs) will soon contain more detailed information about the risk that the drugs may contribute to heart attack and stroke, reports FDA. Such warnings have been on prescription and over-the-counter NSAIDs since 2005, but the new requirements take into account new data showing that the risk of heart attack and stroke occurs even during the first few weeks of taking an NSAID. People who have cardiovascular and other heart problems are at even greater risk of adverse effects. An FDA alert available at *www.fda.gov/ForConsumers/ConsumerUpdates/ucm453610.htm* provides more details.

Baxter International, Inc, Recalls Three Lots of IV Solutions Due to Particulate Matter

In July 2015, Baxter International, Inc, voluntarily recalled two lots of intravenous (IV) solutions distributed to hospitals and other health offices because of the presence of particulate matter identified as an insect. The problem was identified before patient administration and no adverse health effects have been reported. The recall affects 0.9% sodium chloride injection, USP 50 mL and 100 mL, lot numbers P319921 and P327635, which were distributed to US customers between October 7, 2014, and July 14, 2015. Additional information is available in an FDA press release at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm455421.htm.*

Baxter also voluntarily recalled one lot of IV solution to the hospital/user level because of the potential for leaking containers, particulate matter, and missing port protectors. This recall affects 0.9% sodium chloride injection, USP (AUTO-C) with lot number C964601 (National Drug Code 0338-0049-03; expiration date: April 30, 2016). This recalled lot was distributed to customers and distributors nationwide between January 22, 2015, and February 12, 2015. Leaking containers, particulate matter, and missing port protectors could result in contamination of the solution and, if not detected, could lead to a bloodstream infection or other serious adverse health consequences, explains FDA. The agency notes further that "injecting a product containing particulate matter, in the absence of in-line filtration, may result in blockage of blood vessels, which can result in stroke, heart attack or damage to other organs such as the kidney or liver. There is also the possibility of allergic reactions, local irritation and inflammation in tissues and organs." More information about this recall is available in an FDA safety alert at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm456793.htm.*

FDA Warns Against Unapproved Prescription Ear Drops

FDA has ordered the manufacturers of certain prescription ear drops to stop making and distributing the products because they are not FDA-approved. The product labels do not disclose that they lack FDA approval, and health care providers may not be aware of the unapproved status, notes FDA. The agency took action against unapproved prescription otic drug products containing these ingredients:

- benzocaine;
- benzocaine and antipyrine;
- benzocaine, antipyrine, and zinc acetate;
- benzocaine, chloroxylenol, and hydrocortisone;
- chloroxylenol and pramoxine; and
- chloroxylenol, pramoxine, and hydrocortisone.

These drugs are frequently given to relieve ear swelling and pain in young children, and FDA took this action to protect patients from the risks of taking unapproved drugs with no proven safety or effectiveness information. Further, such drugs may be contaminated or manufactured incorrectly, notes the agency. More information is provided in an FDA news release available at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm453348.htm.*

Acino Products in New Jersey Ordered to Stop Selling Rectacort-HC and GRx HiCort 25

Under the direction of FDA, a federal judge for the District of New Jersey has ordered Acino Products, LLC, of Hamilton, NJ, to stop selling and destroy certain unapproved and misbranded prescription drugs in its possession.

According to FDA, Acino has marketed unapproved hydrocortisone acetate 25 mg suppositories, under the brand names Rectacort-HC and GRx HiCort 25, for treatment of medical conditions including inflamed hemorrhoids, chronic ulcerative colitis, and other inflammatory conditions. The drugs have not been FDA-approved and also fail to carry adequate directions for use on their labels. Acino continued to market and sell the products despite several warnings from FDA investigators. The FDA news release is available at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm453466.htm.*

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Current functionality of the NDHIN includes direct secure messaging, known as NDHIN Communicate, and query-based services. NDHIN Communicate, which utilizes a web-based software and XDR messaging services, allows a provider to send information to another provider through a secure electronic system. It allows providers to exchange unstructured documents, structured files, images, pictures, or anything else that can be attached to an email with other providers through a secure email service. Using NDHIN Communicate essentially pushes protected health information to another provider securely.

The Clinical Portal, which is a more robust exchange of health information also known as query technology, includes the capability to find information on a patient needed to provide good-quality health care. Information that may be obtained includes, but is not limited to, patient demographics, encounter history, allergies, diagnoses, lab results, procedures, imaging studies with links to the actual image, and other clinical documents. Essentially, the query technology is a tool that a provider can use to pull information from other providers as he or she is providing medical services to the patient. (See "How NDHIN Works" diagram at right.)

To minimize the number of places that a provider needs to go to obtain information, a Clinical Portal user can query the North Dakota Immunization Information System (NDIIS), and the immunization and forecast received from the NDIIS will be displayed. A user can also query the prescription drug monitoring program and receive a CS report.

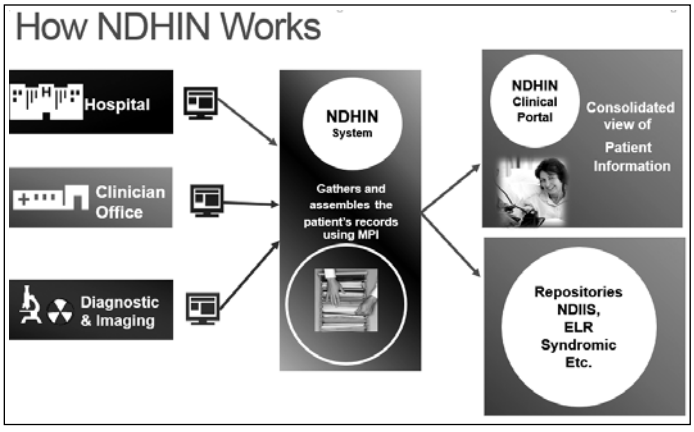
Other functionalities currently available or in the works include subscription and notification services. This allows providers who have a treating relationship with a patient an option to "subscribe" to a patient and receive notifications when an event is triggered. Event triggers include inpatient admission, inpatient discharge, abnormal lab result, panic results, new final radiology result, or if the patient is admitted to an emergency room.

Future enhancements include adding medication information to the Clinical Portal, expanding the image exchange to include more providers in the state, creating a process to access patient information from other states and federal agencies, and expanding the information received from other providers, such as long-term care and behavioral health providers.

The NDHIN is a statewide system that was initially funded with state and federal funds; future funding will be through a public-private partnership of statewide stakeholders.

Join today by visiting *www.ndhin.org/services/ndhin-enrollment.* Once your application has been submitted, an NDHIN staff member will contact you to set up training and provide access information.

For more information, visit *www.ndhin.org.*



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