

September 2013

News



North Dakota State Board of Pharmacy

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Gary Dewhirst – NABP Executive Committee

Gary Dewhirst, RPh, was elected to serve a three-year member term, representing District 5, on the Executive Committee of the National Association of Boards of Pharmacy® (NABP®) during the Association's 109th Annual Meeting, held May 18-21, 2013, in St Louis, MO.

Gary has been a member of the North Dakota State Board of Pharmacy since 1999 and has served as the Board's president. In addition, he is a pharmacy manager for Thrifty White Drug in Hettinger, ND. Previously, he owned and was general manager of Hettinger Drug, LLC, in Hettinger for over 20 years. His pharmacy was recognized as an Independent Superstar Retail Pharmacy by Drug Topics in 1989.

As a member of NABP, Gary has made many contributions to the NABP District 5 meetings, including serving on the Resolutions Committee. Gary is also an active member of the North Dakota Pharmacists Association.

Further, Gary is active in health and education related organizations. He is a member of the Advisory Committee for Dickinson State University Department of Nursing. He has also served as a member of the West River Health Services Board since 1999. Active in community organizations, Gary received the Wyeth-Ayerst Bowl of Hygeia Award for outstanding community service in 1995. He was also recognized with the Al Doerr Service Award for community service in North Dakota in 1997.

Gary earned his bachelor of science degree in pharmacy from North Dakota State University. He also holds certifications in pain management, immunization, and medication therapy management.

The Board congratulates Gary on his election and appreciates his willingness to serve his profession.

Quality-Related Events – Errors and Continuous Quality Improvement

By Howard C. Anderson, Jr, RPh

The Board, at its July 18, 2013 meeting, voted to move ahead with a rule to require a continuous quality improvement (CQI) program in all North Dakota pharmacies.

The Board already has a requirement in all of its telepharmacies, central sites, its hospitals, and for sterile product preparation.

Many states have mandated reporting of errors that cause mortality or significant morbidity. The North Dakota Board feels this is too late in the process, as harm has already occurred.

It is the intent of the new requirement to focus on quality-related events (QREs), which are the precursors of errors (those that get out of the pharmacy's hands and put the patient at risk).

The rule will require recording of QREs and analysis of them to identify places where changes can be made to prevent errors from occurring. Errors are also reported and serious analysis (gap analysis) is conducted to determine why we have a gap between our expected outcome (a perfect prescription or more importantly, a good patient outcome) and what actually occurred (an error of some kind resulting in a poor patient outcome).

The rule will include discovery protection (a lawyer cannot ask for your CQI report so he or she can find potential clients or reveal that you had six near misses to bolster his or her case before the judge or jury).

The rule will include a reference to reporting to a patient safety organization (PSO) to provide federal protection under the 2005 Patient Safety and Quality Improvement Act.

The North Dakota Pharmacists Association has a co-marketing agreement with a PSO and an excellent online CQI program. The Board will also have manual QRE recording forms on its Web site should you not choose to utilize an online CQI program. The Board will ask you to analyze your internally recorded QREs in lieu of the computer-assisted analysis.

Look for the rule hearing announcement, and of course the proposed rule will be published.

Certificate to Administer Immunizations or Other Injectable Medications

The Board Web site now allows its pharmacists to obtain their immunization certification online. Pharmacists will be able to scan and upload the appropriate documents and view previously uploaded documents. Once completed and approved by the Board office, a certificate will be sent via e-mail.

The necessary documentation includes proof of your course certificate, current CPR certification, and documentation of six continuing education hours related to immunizations/injectables over the past two years. The certificate will still need to be re-

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Pharmacists Likely to Recommend OTC Medications, CHPA Reports

Patients most often seek a pharmacist's advice on treating coughs, headaches, migraines, and allergies, and 98% of pharmacists recommend or have no reservations recommending over-the-counter (OTC) products to treat such ailments, according to a recent survey. The Consumer Healthcare Products Association's (CHPA) report, "Understanding Trust in OTC Medicines: Consumers and Healthcare Provider Perspectives," presents the results of the survey, which was developed to better understand what drives consumer and health care provider trust in OTC products. The survey, developed and conducted by Nielsen and IMS, included over 1,100 consumer respondents, and over 500 health care provider respondents, composed of pharmacists, pediatricians, nurse practitioners, and primary care providers.

Pharmacists surveyed reported that they were more likely to recommend OTC products that demonstrated successful patient outcomes and consistent outcomes, and products known to be as efficacious as a prescription drug, and those containing ingredients known to be safe.

The survey also asked health care providers whether they recommended OTC products without, before, or in conjunction with recommending prescription drugs for certain symptoms. A majority of pharmacists surveyed, over 60%, recommend OTC medications to treat stomach symptoms and pain, without recommending a prescription treatment, and over 70% recommended OTC allergy, sinus, and flu medications without advising that a prescription drug is needed.

CHPA notes that with the expansion of patient self-care, OTC products will play an increasingly important role in health care. The potential for more prescription products to become OTC products in the new paradigm under consideration by Food and Drug Administration (FDA) could further impact this trend. As consumers are becoming more empowered in making health care decisions, they are also relying more on their pharmacist for medication advice. In fact, Nielsen and IMS findings show that multigenerational households, Hispanic households, and households who care for an adult outside of their home place a high value on pharmacist recommendations regarding selecting appropriate OTC medications, notes CHPA.

The full CHPA White Paper is available at www.yourhealthathand.org/images/uploads/OTC_Trust_Survey_White_Paper.pdf.

ISMP Study on Targeted Mandatory Patient Counseling

 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 a recent study funded by a grant from Agency for Healthcare Research and Quality, ISMP evaluated the use of a combined checklist and patient information leaflet used during mandatory counseling sessions for consumers who pick up a filled prescription for 11 targeted medications:

- ◆ Opioid-containing analgesics
 - ◇ fentanyl patches
 - ◇ hydrocodone with acetaminophen
 - ◇ oxycodone with acetaminophen
- ◆ Anticoagulants
 - ◇ warfarin
 - ◇ enoxaparin
- ◆ Antidiabetic drugs (insulin analogs)
 - ◇ Humalog® (insulin lispro)
 - ◇ NovoLog® (insulin aspart)
 - ◇ Levemir® (insulin detemir)
 - ◇ Lantus® (insulin glargine)
 - ◇ Apidra® (insulin glulisine)
- ◆ Antineoplastic drug (non-oncologic use)
 - ◇ methotrexate

All 11 medications are on ISMP's list of high-alert medications dispensed from community pharmacies. Errors with high-alert medications may not be more frequent than errors with other medications; however, the consequences of errors with high-alert medications are often harmful. These 11 medications are also among the top 200 drugs dispensed in the United States, and many are used to treat chronic conditions, thus increasing the potential impact on public safety.

The medications were flagged in some manner to identify mandatory counseling opportunities. When a patient or patient representative picked up a flagged prescription, a pharmacist conducted a short counseling session (one to three minutes) that included the exchange of several key points on the checklist. At the end of the counseling session, the pharmacist provided the leaflet to the patient, along with a survey to complete and send back to ISMP.

Counseling sessions for these drugs were conducted for a consecutive period of four weeks, during which time, one trained ISMP staff member observed the counseling sessions for one day (six hours) to collect information on factors that facilitate or inhibit the counseling sessions. At the end of the four-week period of mandatory counseling, pharmacists at participating pharmacies were asked to complete a short mail-in survey regarding their perceived value of the process.

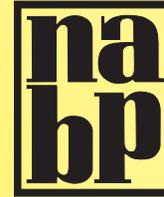
Results of the study showed that these consumer leaflets offer important safety tips for taking medication safely. Each leaflet begins with, "High-alert medicines have been proven to be safe and effective. But these medicines can cause serious injury if a mistake happens while taking them. This means that it is vitally important for you to know about this medicine and take it exactly as intended."

ISMP tested the readability, usability, and perceived value of the leaflets. Ninety-four percent of patients felt the leaflets provided great information or good information to know. Ninety-seven percent felt the information in the leaflets was provided in a way they could understand. Eighty-two percent of patients taking the drug for the first time and 48% of patients who had previously taken the medication reported learning something new. Overall, 85% of the patients felt they were less likely to make a mistake with the medication because they had read the leaflet.

The leaflets are available for download and can be reproduced for free distribution to consumers at www.ismp.org/AHRO/default.asp?link=ha.

Generic Drug Substitution Requires Pharmacist Attention to State Laws and Regulations

While 40 years ago, most states forbade prescription drug substitution, almost all states now have drug product selection laws that allow, encourage, or mandate pharmacists to substitute generics for brand-name



Compliance News to a particular state or jurisdiction should not be assumed as representing the law of such state or jurisdiction.)

drugs. These laws vary widely from state to state and pharmacists are therefore encouraged to review their state's substitution laws to ensure that they understand and comply with the state's requirements.

FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* publication, commonly known as the *Orange Book*, is generally considered the primary source for identifying suitable generic alternatives for a brand-name drug, and while not mandated by FDA regulations, the majority of states use the *Orange Book's* determinations of therapeutic equivalence to legally guide pharmacists in substituting generics.

State laws on generic substitution vary widely. A few states, such as Kentucky or Minnesota, follow a "negative formulary" approach, in which substitution is permitted for all drugs except those that appear on a particular list. Other states, including Massachusetts and Wisconsin, use a "positive formulary" approach, in which substitution is limited to the drugs on a particular list.

States also differ as to whether their substitution laws are permissive, thereby allowing a pharmacist to substitute a generic version of a brand-name drug, provided all prescription requirements are met, or mandatory, thereby requiring substitution. Prescription requirements may include such factors as the availability of a cheaper, therapeutically equivalent drug, the prescriber's specification that a brand-name drug be dispensed, or requiring the patient's or prescriber's consent. As reported in the 2013 NABP *Survey of Pharmacy Law*, 14 boards of pharmacy indicate that generic substitution falls into the "mandatory" category, while 38 boards indicate that their substitution laws are "permissive." Oklahoma law states that "[I]t is unlawful for a pharmacist to substitute without the authority of the prescriber or purchaser."

Other regulatory variations include states specifying the acceptable means for the prescriber to designate that substitution is not authorized, and states requiring patient consent prior to substitution.

The full article on this subject, which also reviews considerations regarding the accuracy of therapeutic equivalent determinations, is available in the June-July 2013 *NABP Newsletter*, which may be accessed in the Publications section of www.nabp.net.

NHF Provides Standards of Care for Pharmacies Serving Hemophilia Patients

For pharmacies that offer blood-clotting medications, organizations such as the National Hemophilia Foundation (NHF) emphasize the importance of being able to meet the specialized needs of their patients with bleeding disorders.

NHF's Medical and Scientific Advisory Council (MASAC) issued a standards-of-care recommendation in 2008 to assist pharmacies providing clotting factor concentrates for home use to patients with bleeding disorders. MASAC's guidelines are intended to be minimum standards of care and are divided into six areas:

As a brief overview of the MASAC guidelines, pharmacists wishing to meet the standards should:

1. Have a basic knowledge of bleeding disorders and experience with and knowledge of the full range of clotting factor concentrates, ancillary supplies, and hazardous waste disposal.

Pharmacies wishing to meet MASAC standards:

2. Should be able to provide a full range of available concentrates in all available assays and vial sizes, along with all necessary ancillary supplies, and hazardous waste disposal assistance as well as access to nursing services.

3. Should support reliable access to clotting factor for appropriate home treatment, by filling prescription orders within 48 hours, in the quantities prescribed, with expiration dates commensurate with the individual patient's needs.
4. Should be reliably open during regular business hours; provide 24-hour emergency access; and have an emergency action plan that allows patients to receive factor within 12 hours "in case of emergent need," with a goal of three hours "where logistically possible."
5. Should deliver products to the patient's desired location, meeting federal medication shipping standards, and providing an emergency number for patients to call in case of a problem with a delivery.
6. Should maintain patients' treatment prescription information along with maintaining records in compliance with state and federal requirements and be able to track the clotting factor products from manufacturer to patient, and participate in a recall information system.

The full article on this topic is available in the June-July 2013 *NABP Newsletter*; accessible in the Publications section of www.nabp.net. NABP notes that each state needs to review the standards recommended by MASAC to determine whether they coincide with existing state board of pharmacy requirements. NABP recognizes the unique patient needs of hemophiliacs, but also the responsibility of state boards of pharmacy to set required standards for medication dispensing and use. NABP is working with NHF to help the boards of pharmacy gain a better understanding of the medication needs of patients to help achieve uniformity in related regulations.

NABPLAW Online Now Includes Guam, Puerto Rico, and the Virgin Islands

The complete pharmacy acts and regulations of Guam, Puerto Rico, and the Virgin Islands are now included in **NABPLAW**[®] Online, the comprehensive national data bank of state pharmacy laws and regulations provided by NABP. **NABPLAW** Online's powerful search capabilities allow users to research subjects one state at a time or across all 50 states and included jurisdictions. More information about **NABPLAW** Online and a link to the online subscription order form are available in the Programs section of the NABP Web site at www.nabp.net/programs/member-services/nabplaw/.



Pharmacists & Technicians:
Don't Miss Out on Valuable CPE Credit.
Set Up Your NABP e-Profile and Register for CPE Monitor Today!

Continuing pharmacy education (CPE) providers who are accredited by the Accreditation Council for Pharmacy Education (ACPE) have integrated CPE Monitor[®] into their systems and are requiring pharmacists and pharmacy technicians to provide an NABP e-Profile ID number and date of birth (MMDD) in order to process ACPE-accredited CPE credit.

Visit www.MyCPEmonitor.net to set up your NABP e-Profile and register for CPE Monitor and avoid possible delays in your CPE reporting.

CPE Monitor is a national collaborative service from NABP, ACPE, and ACPE providers that will allow licensees to track their completed CPE credit electronically.

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newed every two years. Obtaining this certificate will continue to be free when completed online.

As a reminder, the North Dakota Legislature approved legislation related to pharmacist administered immunizations and vaccinations. It removed the 18 or older age restriction for pharmacists in providing immunizations. This legislation lowers the age restrictions to at least 11 years of age for all immunizations and vaccinations. It also provides for the administration of influenza vaccination by injection or by “live” vaccine for an individual who is at least five years of age.

Our legislature clearly indicated that improving the immunization rate is a goal for North Dakota, and pharmacists are at the forefront of providing this service across the state. The Board believes it is essential for its pharmacists to capitalize on this opportunity and show what a crucial part of the health care team we are.

Visit www.nodakpharmacy.com/immunization/ to complete immunization certification online.

Technician-in-Training Registration Procedure Changes

The Board is looking to change its procedures for the registration of technicians-in-training. The Board has been experiencing an increasing number of requests for extensions in the two-year time period that is granted to finish the education and certification requirement for a pharmacy technician.

The Board will be changing its procedures on renewing the technician-in-training registration to ensure that progress is being made in the educational requirements. If no or very little progress is being made, the Board will expect the preceptor pharmacist to work with his or her technician-in-training to plan for completion in the two-year period.

Helpful Hints for Using Your PDMP Direct Access Account

The automatic setting for looking up your patient is on “Fastest: Last Name = and First Name Begins,” which means you will enter the full last name and the first few letters of the first name. The Board wants you to select “Begins with” and enter the first few letters of the last name and the first few letters of the first

name. Enter in the date of birth, then select the “Within” drop-down box and change it from “Exact Match” to “1 Year.” Skip straight down to the “Dispensed time frame” from and to fields. By entering in the zip code and other information, you may be limiting your search to pull back only the accounts that fall within the parameter of information you are selecting.

	Name Selection
Recipient	Begins with
	Sounds like
	Fastest: Name = and First Name Begins
*Last Name	
*First Name	

Why should you do this? If you have a patient that goes by the name of David or Dave McRuggles and you enter in “D-a-v-i-d” instead of “D-a-v” you are only going to get the accounts back under the name David and not Dave. Occasionally, the Board will find the rare misspelling of a last name, and by entering in “m-c” instead of “McRuggles,” you can catch an error where someone entering the script may have entered a space in between the “c” and “r” or left out a “g.” The Board chooses the “within one year” parameter to catch any typos for the date of birth, which generally would only be off by one number. If you find a misspelling of an account, want patient accounts linked together, or find a patient with several last names or nicknames, please contact Kathy at 701/328-9537 with any information about accounts that should be linked together. Or, if you find another type of error, please contact Kathy so that the Board can correct it for future health care professionals also using the system.