



# North Dakota State Board of Pharmacy

*Published to promote compliance of pharmacy and drug law*

1906 E Broadway Ave • Bismarck, ND 58501-4700 • Phone: 701/328-9535  
Fax: 701/328-9536 • [www.nodakpharmacy.com](http://www.nodakpharmacy.com)

## **Howard C. Anderson, Jr Retires from Board**

Howard C. Anderson, Jr has decided to retire from his position as executive director of the North Dakota State Board of Pharmacy. Howard has been an icon for the profession of pharmacy, not only in the state of North Dakota, but also in the country. Howard received the 2014 Lester E. Hosto Distinguished Service Award at the National Association of Boards of Pharmacy® (NABP®) Annual Meeting in May. This award is the highest award bestowed by NABP. It is a well-deserved honor for Howard, and the Board appreciates his time and efforts for the profession during his distinguished career. Howard will not just be fishing in his retirement, as he has agreed to assist the Board and be a consultant and inspector when the Board needs him. The Board wishes Howard the best in his retirement!

The Board has appointed Mark J. Hardy to replace Howard as the executive director of the Board. Mark has worked as the assistant executive director of the Board for the past three years.

## **PDMP Software Changes**

On April 2, 2014, the North Dakota Prescription Drug Monitoring Program (PDMP) changed its database to PMP AWARD<sub>x</sub>E™, which is hosted by Apriss, Inc. The Board appreciates each pharmacy's assistance in making this transition smooth and efficient. With change often comes questions. Here are a few things to keep in mind about the new system.

- ◆ It can now be accessed on Mac systems, tablets, and even phones.
- ◆ Notarized forms are only required to be uploaded for those who are brand new to the program. Past account holders can bypass this step.
- ◆ There is now a 24-hour hotline available for support at 855/563-4767. They can assist you with the system functionality, retrieving your password, and reporting to the database.
- ◆ Since the data is new to this system, the system may ask you to send information to the administrator, which will be reviewed and sent back in as timely a manner as possible. If this happens, an e-mail notification will be sent to you once it is completed and ready to view. As the Board continues to use the system, this will happen less and less.
- ◆ The new system will load the pharmacy records immediately after receiving them instead of waiting for a scheduled time twice a day only on weekdays. This means the information will be more readily available to you and your staff, especially on the weekends.

- ◆ The Board has access to more states than ever before as it is connected directly to the national NABP PMP InterConnect® hub through NABP.
- ◆ Approving and modifying the delegates who are authorized to look up reports under a pharmacist's authority is quickly done online on the PMP AWARD<sub>x</sub>E site.

The Board highly encourages pharmacists to get an online account so they can access patients' controlled substance histories. The Board also encourages pharmacy technicians to sign up for an account as a delegate to run reports under their pharmacist's authority. The PDMP can be accessed via the Board's website, [www.nodakpharmacy.com](http://www.nodakpharmacy.com). If you have any questions on the PMP AWARD<sub>x</sub>E site, you may contact Apriss support at 855/563-4767 or Kathy Zahn, PDMP administrator, at 701/328-9535 or [ndbphpdmp@btinet.net](mailto:ndbphpdmp@btinet.net).

## **Rule Hearing Held at the NDPhA Convention**

During the North Dakota Pharmacists Association (NDPhA) Annual Convention in April, the Board held a rule hearing for six separate proposed rules. Comments were received from many pharmacists and technicians who were present. The Board was able to answer questions and respond to comments during the hearing. The rules that are moving forward include:

- ◆ 61-02-01-01 Pharmacy Permits, to add a Class L
- ◆ 61-02-01-19, to add a policy and procedure requirement
- ◆ 61-11, to list the fees required by Senate Bill 2342, adopted in the 2013 legislative session
- ◆ 61-04-02 Physician Exemption Revision, to expand the exemption
- ◆ 61-04-08 Limited Prescriptive Practices, to clarify the signature requirements and form
- ◆ 61-08-01 Inspection Rule for Out-Of-State Pharmacies
- ◆ 61-12-01 Prescription Drug Monitoring Program, to designate the submission standard and require accessing the program in certain circumstances by pharmacies

The content of each of the rules is available on the Board's website, [www.nodakpharmacy.com](http://www.nodakpharmacy.com).

## **Licenses and Registrations Should Be Posted in Pharmacies**

Now that yearly pharmacist and technician renewals are completed, please take the time to review the licenses/registrations displayed in the pharmacy to ensure all are current. Also ensure all technician-in-training registrations are also current.

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## New USP Webpage Answers Common Questions About USP Chapters <795> and <797>

In response to questions concerning United States Pharmacopeia-National Formulary (USP-NF) General Chapters <795> and <797>, USP has created a new frequently asked questions (FAQs) page on its website. The FAQs answer questions related to the Revision Bulletin for Chapter <795> that was issued on November 22, 2013, and became official on January 1, 2014. Among other topics, the FAQs address common questions regarding beyond-use dating and the differences between testing stability with strength (potency) or stability-inducing methods. The FAQs can be accessed at [www.usp.org/support-home/frequently-asked-questions/compounding](http://www.usp.org/support-home/frequently-asked-questions/compounding). Question four on the page includes a link to a USP article, "Strength and Stability Testing for Compounded Preparations."

## Only You Can Prevent Look-Alike Sound-Alike Drug Names

 *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](http://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 Error Reporting Program. Report online at [www.ismp.org](http://www.ismp.org). E-mail: [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org).*

**VESicare/Vesanoid Mix-Up.** A prescriber's office sent an electronic prescription to the patient's pharmacy; the prescriber intended to prescribe **VESicare**® (solifenacin succinate) for overactive bladder but inadvertently selected **Vesanoid**® (tretinoin), which is used to induce remission of acute promyelocytic leukemia. The pharmacy technician entered the prescription for generic tretinoin; however, the pharmacy was unable to dispense the medication as the patient's pharmacy benefit manager required a prior authorization. The technician faxed a request and the prescriber's office replied back that VESicare was intended. Both of these products are available in 10 mg solid oral dosage forms, increasing the risk of confusion. Investigate strategies (eg, tall man letters) to differentiate these products on computer screens. Prescribers should include the indication for the drug with the prescription. As always, providing patient education, especially for new prescriptions, is a good strategy to intercept errors before they impact the patient.

**Benazepril Confused With Benadryl.** A pharmacist reported a mix-up between benazepril (**Lotensin**®) and **Benadryl**® (diphenhydramine). A patient faxed a request to the pharmacy to ask for her "benazpryl." The pharmacist who received the fax interpreted

it as Benadryl and placed a bottle of diphenhydramine in the bag for pick-up. Around this same time, the pharmacy went through a change in wholesaler and many manufacturers of generic products were changed. A few days later, a coworker of the patient picked up the medication (along with several others). The technician at the point-of-sale told the coworker that many of the manufacturers had changed recently and that some of the pills may look different. The patient received the diphenhydramine, filled her medication box with the capsules, and took diphenhydramine daily for three weeks before noticing she was unusually tired. When she brought the bottle back to the pharmacy, the error was recognized.

ISMP continues to receive reports of confused drug name pairs being involved in errors. ISMP wants to inform its readers of these drug name confusions so they may continue evaluating what measures they have in place to protect against these possible confusions.

**Your Help Is Needed With Product Safety Testing.** If you are a pharmacist, nurse, pharmacy technician, or other health care practitioner who is interested in furthering medication safety and error prevention, you can make a difference! Med-ERRS (a subsidiary of ISMP) is looking for assistance to help evaluate medication labels, drug packaging, and proposed drug names prior to submission by pharmaceutical and biotech companies for approval by Food and Drug Administration (FDA). The process is fun, simple, and easy. A small honorarium is paid. For more information or to sign up, visit [www.med-errs.com](http://www.med-errs.com) and click on "Become a Reviewer."

## FDA Issues Alert on Acetaminophen Products

In light of all the recent news alerts and warnings about the use of acetaminophen and acetaminophen-containing products, FDA issued a recommendation of importance to pharmacists, prescribers, and patients.

FDA recommends that health care providers consider prescribing combination drug products that contain 325 mg or less of acetaminophen. FDA also recommends that when a pharmacist receives a prescription for a combination product with more than 325 mg of acetaminophen per dosage unit that he or she contacts the prescriber to discuss a product with a lower dose of acetaminophen. A two-tablet or two-capsule dose may still be prescribed, if appropriate. In that case, the total dose of acetaminophen would be 650 mg (the amount in two 325 mg dosage units). When making individual dosing determinations, health care providers should always consider the amounts of both the acetaminophen and the opioid components in the prescription combination drug product.

FDA, in its MedWatch Safety Alert, reports that, "There are no available data to show that taking more than 325 mg of acetaminophen per dosage unit provides additional benefit that outweighs the added risks for liver injury. Further, limiting the amount of acetaminophen per dosage unit will reduce the risk of severe liver injury from inadvertent acetaminophen overdose, which can lead to liver failure, liver transplant, and death."

In January 2011, FDA asked manufacturers of prescription combination drug products containing acetaminophen to limit the amount of acetaminophen to no more than 325 mg in each tablet or capsule by January 14, 2014. FDA requested this action to protect consumers from the risk of severe liver damage that

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can result from taking too much acetaminophen. More than half of manufacturers have voluntarily complied with FDA's request. However, some prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit remain available. In the near future, FDA intends to institute proceedings to withdraw approval of prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit that remain on the market.

Boards of pharmacy have received inquiries from pharmacists about remaining stock of the higher dose acetaminophen and what procedures should be followed. The FDA recommendation notes that pharmacists are advised to contact prescribers and request a change in the prescription. If the prescriber is not willing to make the change in the prescription, unfortunately, there is no clear cut recommendation at this point as to whether to dispense the higher dose acetaminophen product. It would appear that the higher dose acetaminophen-containing products will be regarded by FDA as unapproved and delisted from FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book." Until this occurs, pharmacists must make a judgment regarding continuing to dispense the higher dose acetaminophen containing products in light of the FDA recommendation and concern for patient safety.

## Some Rohto Eye Drops Products Recalled

The Mentholatum Company of Orchard Park, NY, has issued a voluntary recall of some Rohto® eye drop products due to a manufacturing review at the production facility in Vietnam involving sterility controls. The recall has been issued at the retail level and includes Rohto Arctic, Rohto Ice, Rohto Hydra, Rohto Relief, and Rohto Cool eye drops that were manufactured in Vietnam. Products made in other facilities are not affected by the recall. To date, there has been no evidence indicating the recalled products do not meet specifications, according to a press release.

The recalled products are sold over the counter at pharmacies and retail stores throughout the United States, and can be identified by the words "Made in Vietnam" on the side carton panel under the company name and address information as well as on the back label of the bottle. Lot numbers for the recalled products contain the letter "V." Distributors and retailers are being notified by letter to stop distributing the products and to follow the recall instructions provided by the company. Questions about the recall can be directed to The Mentholatum Company at 877/636-2677, Monday through Friday, 9 AM to 5 PM Eastern Time. FDA urges consumers and health care providers to report any adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information and Adverse Event Reporting Program. More information is available at [www.fda.gov/Safety/Recalls/ucm382076.htm](http://www.fda.gov/Safety/Recalls/ucm382076.htm).

## FDA Provides Compounding Law Implementation Information

FDA has provided implementation information on Title I of the recently passed Drug Quality and Security Act – known as the Compounding Quality Act – through its website.

Of note, FDA specifies that compounding entities may register as an outsourcing facility, which, under certain conditions, may be exempt from the Federal Food, Drug, and Cosmetic Act's (FD&C Act) approval and labeling requirements. Drugs produced by compounders that are not registered as outsourcing facilities must meet the conditions of Section 503A of the FD&C Act, which was amended by the new law, to qualify for certain exemptions.

The document adds, "If a compounded drug does not qualify for exemptions under either section 503A or 503B of the [FD&C Act], the compounded drug would be subject to all of the requirements of the [FD&C Act] that are applicable to drugs made by conventional manufacturers, including the new drug approval and adequate directions for use requirements." FDA also notes it will provide additional information about how the agency will interpret certain provisions of Section 503A at a later date.

The implementation information may be viewed at [www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm375804.htm](http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm375804.htm).

## New e-LTP Fees Effective July 1, 2014

Supporting ongoing efforts to protect the integrity of its licensure transfer programs and to support the expansion of new technologies that are being implemented to enhance the program, the National Association of Boards of Pharmacy® (NABP®) is adjusting the fees for the Electronic Licensure Transfer Program® (e-LTP™).

Beginning July 1, 2014, the e-LTP fees will be adjusted as follows:

- ◆ The preliminary application and first state transfer fee will increase from \$350 to \$375
- ◆ Each additional state transfer will increase from \$50 to \$75
- ◆ Change of states will increase from \$50 to \$75
- ◆ Time extensions will increase from \$50 to \$75

The fees for e-LTP were last adjusted in 2010. More information about e-LTP is available in the Programs section of the NABP website at [www.nabp.net](http://www.nabp.net). Additional questions about the fee adjustment may be directed to Neal Watson, licensure programs manager, at 847/391-4406, or at [nwatson@nabp.net](mailto:nwatson@nabp.net).



**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](http://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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If you need to reprint your license, you can do that right on the Board website using the “Reprint License” feature. Also, please keep your address current and, if you are a certified technician, your Pharmacy Technician Certification Board number and expiration date current by choosing the “Change Address” feature on the Board’s website.

The Board has had discussion as to whether it needs to be more punitive in the near future, with the use of fines, on anyone who does not keep his or her license/registration information current and posted.

**Certificate to Administer Immunizations or Other Injectable Medications**

The Board website 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 renewed every two years. Obtaining this certificate will continue to be free when completed online.

Visit [www.nodakpharmacy.com/immunization/](http://www.nodakpharmacy.com/immunization/) to complete the certification online.

**Statistics**

Current Statistical Data		
2013		2014
<b>Pharmacists</b>		
995	Active pharmacists	1,037
58	Inactive pharmacists	56
1,032	Out-of-state pharmacists	996
120	Lifetime – 50-year pharmacists	128

	Delinquent – yet to renew – pharmacists	220
<b>Technicians</b>		
665	Active pharmacy technicians	675
44	Inactive pharmacy technicians	49
217	Technicians-in-training	238
<b>Interns</b>		
360	North Dakota State University PharmD student interns	345
128	Pre-pharmacy or other PharmD students	163
<b>Pharmacies</b>		
253	North Dakota pharmacies	257
420	Out-of-state pharmacies	493
<b>Wholesale Licenses</b>		
976	Wholesale licenses issued	1,047