



North Carolina Board of Pharmacy

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Item 2269 – General Assembly Grants Pharmacists Broader Vaccination Authority

On July 3, Governor Pat McCrory signed S.L. 2013-246, An Act to Protect the Public's Health by Increasing Access to Immunizations and Vaccines through the Expanded Role of Immunizing Pharmacists. The text of the statute may be found here, and pharmacists are strongly encouraged to read the new statute: www.ncleg.net/Sessions/2013/Bills/House/PDF/H832v6.pdf. Pharmacists are, understandably, asking a number of questions about implementation. The following seem to be the most common.

- 1. When does the law take effect?** The law's effective date is October 1, 2013. But there are implementation issues (discussed below) that could delay the date on which pharmacists may begin exercising this broader authority, at least in some circumstances.
- 2. What does the law allow?** "Immunizing pharmacists" who meet the requirements in the statute may administer any Centers for Disease Control and Prevention-recommended vaccination to any patient at least 18 years of age pursuant to a specific prescription order. Immunizing pharmacists may administer pneumococcal, zoster, hepatitis B, meningococcal, tetanus, tetanus-diphtheria, and Tdap vaccines to patients at least 18 years of age pursuant to written protocols as defined in existing vaccination rules (found at 21 NCAC 46.2507). Pharmacists may continue to administer the influenza vaccine to patients age 14 and over as specified in current rules.
- 3. What notifications will be required?** The immunizing pharmacist must notify the patient's identified primary care provider within 72 hours of administering any vaccine. If the patient does

not identify a primary care provider, the pharmacist will be required to "direct the patient to information describing the benefits to a patient of having a primary care provider." This information may be prepared by the North Carolina Medical Board, North Carolina Academy of Family Physicians, North Carolina Medical Society, or Community Care of North Carolina. As these organizations develop these materials, Board staff will endeavor to provide links to them. Except for flu vaccines, a pharmacist must, within 72 hours, report administration of any vaccine to the North Carolina Immunization Registry (NCIR), if "operable."

- 4. How do I get access to the NCIR?** Various stakeholders are working with Immunization Branch officials on training and access issues. At the time of this writing, access to the NCIR appears to be the implementation issue most likely to delay pharmacists' ability to exercise the new authority. More information will follow as it becomes available.
- 5. I am already an immunizing pharmacist. Should I begin revising my supervising physician protocols?** North Carolina Board of Pharmacy staff recommend that immunizing pharmacists discuss the expanded authority with their supervising physicians and begin preparing appropriate changes to protocols. The statute requires representatives from the North Carolina Academy of Family Physicians, North Carolina Medical Society, North Carolina Pediatric Society, North Carolina Association of Community Pharmacists, North Carolina Association of Pharmacists, and North Carolina Retail Merchants Association to cooperatively create "a minimum standard screening questionnaire and safety procedures" for vaccines to be administered pursuant to protocol (ie, nonprescription-based vaccinations). These organizations have done so and, at the time of this writing, it is anticipated that the

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Enteric-Coated Aspirin Recalled for Potential Acetaminophen Mix-Up

In June 2013, Advance Pharmaceutical Inc initiated a voluntary recall of Rugby Laboratories label enteric-coated aspirin tablets, 81 mg (Lot 13A026; expiration date: January 2015) due to a complaint that a bottle labeled with this product name actually contained acetaminophen 500 mg tablets. This over-the-counter (OTC) product is packaged in bottles of 120 tablets with National Drug Code 0536-3086-41 and Universal Product Code 3 0536-3086-41 9. The affected lot was distributed nationwide by Rugby Laboratories to wholesalers and retailers. The manufacturer warns that inadvertently taking acetaminophen, 500 mg, instead of enteric coated aspirin, 81 mg, according to the directions on the label, can lead to an acetaminophen overdose and potential severe liver damage. The manufacturer indicates that consumers who take the dosage as indicated on the defective product labeling may be ingesting up to 24,000 mg of acetaminophen, which is about six times the maximum recommended daily dose of acetaminophen (4,000 mg).

Consumers who have bottles from the affected lot should stop using the product and return it to the pharmacy or store where it was purchased and should contact a health care provider if they are experiencing any problems that may be related to using the product. Food and Drug Administration (FDA) notes that any adverse reactions related to the use of the product should be reported to FDA's MedWatch Program. More information about this recall is available on the FDA Web site at www.fda.gov/Safety/Recalls/ucm357909.

Barcoding Technology for Community Pharmacy

 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.

Barcoding technology is well-established in industries outside of the health care sector and is now being used within health care to enhance efficiency and safety, and in pharmaceutical wholesale operations to improve supply chain inventory and efficiency. Numerous studies prove the effectiveness and cost benefits of using barcoding technology during the drug dispensing process. About 75% of wrong drug or wrong dose errors are captured and corrected using barcode technology¹ and there is sufficient evidence that barcode scanning is becoming the standard of practice in pharmacies.

Although barcoding technology is mature with abundant evidence regarding its effectiveness, a 2006² study showed that only half (53.5%) of United States community pharmacies utilize a barcode scanner for verification/identification of medications. The study also

revealed significantly lower adoption in independent pharmacies (11.5%) compared to chain pharmacies (62.6%).

According to a survey conducted by ISMP in 2009, the most frequently reported reasons for implementing barcode scanning for product verification included a desire to improve the accuracy and safety of the dispensing process, the ease with which the technology fits with pharmacy workflow, improvement of staff efficiency and inventory control, and a belief that the technology was necessary to stay in business. The most common reasons for **not** implementing barcode scanning for product verification, other than cost, included uncertainty regarding the "right" vendor product, satisfaction with the current system (without barcode product verification), and perceptions that the technology would reduce staff efficiency.

ISMP has developed a tool, Assessing Barcode Verification System Readiness in Community Pharmacies, to help address the reasons why barcode scanning has not been implemented and to facilitate the adoption of this technology in an estimated 27,327 community pharmacies that do not currently utilize it for product verification.

Given the resource commitment to purchase barcoding systems and the potential for technology to have a profound effect upon the work environment, this tool will help community pharmacy managers and owners better understand the issues related to barcode product verification systems. It will also help managers assess the pharmacy's readiness for the technology, prepare for the selection of a system, and implement the technology effectively.

Barcode scanning to verify prescription products prior to dispensing improves the safety and quality of pharmacy care provided to patients and increases efficiency during the provision of pharmacy services. Although technology should not be seen as a panacea, it can be a useful tool when used appropriately and combined with other patient safety strategies.³ Does your pharmacy use barcode technology for product verification? If not, please access this free tool, at www.ismp.org/AHRQ/Default.asp?link=sa.

¹Cochran GL, Jones KJ, Brockman J, Skinner A, et al. "Errors prevented by and associated with barcode medication systems." *Joint Comm J Qual Pt Safety*. 2007;33(5):293-301.

²Ukens C. "New study sheds light on medication errors." *Drug Topics*. 2002;146(21):33.

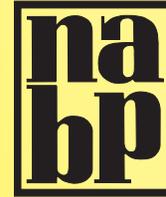
³Skrepnek GH, Armstrong EP, Malone DC, Abarca J, et al. "Workload and availability of technology in metropolitan community pharmacies." *J Amer Pharm Assoc*. 2006; 46(2):154-160.

⁴American Hospital Association, Health Research and Educational Trust, Institute for Safe Medication Practices. "Pathways for medication safety: assessing bedside bar-coding readiness." 2002. Accessed on October 15, 2010 at: www.ismp.org/selfassessments/PathwaySection3.pdf.

ISMP Launches Medication Safety Alert! Newsletter Tailored for LTCFs

ISMP has launched a new *ISMP Medication Safety Alert!* publication, *Long-Term Care Advise-ERR*, as a means to provide medication error prevention information tailored to assist staff and providers in long-term care facilities (LTCFs).

With *ISMP Medication Safety Alert!* publications making a significant impact on preventing medication errors, ISMP is now providing this new resource tailored to LTCFs. ISMP notes that medication errors reported to ISMP Medication Errors Reporting Program include reports from LTCFs. More information and a link to subscribe to this new publication are available in the Newsletters section of the ISMP Web site at www.ismp.org/newsletters/longtermcare.



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FDA Warns of Rare Skin Reactions in Patients Taking Acetaminophen

FDA has issued a consumer update that warns of rare but serious skin reactions that may occur in patients taking acetaminophen. These complications include three serious skin reactions: Stevens-Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN), and acute generalized exanthematous pustulosis (AGEP). SJS and TEN can both be fatal, and usually require hospitalization. Patients suffering from AGEP commonly recover within a few weeks after they stop taking the medication that caused the reaction.

Symptoms of these conditions include skin rashes, blisters, and widespread damage to the surface of the skin. Patients taking acetaminophen or other compounds that contain acetaminophen should be advised to stop taking the medication if they experience such symptoms and should consult their health care providers or seek an emergency department immediately.

FDA emphasizes that this information should be viewed within the context of millions of patients who, over generations, have used and benefited from acetaminophen and stresses that severe allergic skin reactions are an extremely rare condition. Further, the agency notes that many medications can cause allergic reactions, and skin allergy warnings have already been added to the drug labels of other categories of OTC analgesics including ibuprofen and naproxen. "This new information is not intended to worry consumers or health care professionals, nor is it meant to encourage them to use other medications," said Sharon Hertz, MD, deputy director of FDA's Division of Anesthesia, Analgesia, and Addiction Products. "However, it is extremely important that people recognize and react quickly to the initial symptoms of these rare but serious side effects, which are potentially fatal." The full consumer update is available on the FDA Web site at www.fda.gov/ForConsumers/ConsumerUpdates/ucm363010.htm.

Reminder to Purchase Drugs Only from Licensed Wholesalers, Including VAWD-Accredited Wholesale Distributors

To ensure that patients are receiving safe, FDA-approved medications, pharmacists and other health care providers should purchase prescription drugs either directly from the manufacturer or from wholesale drug distributors licensed in the US as advised by FDA. The agency provides a list of state agencies for assistance in verifying licensure at www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm.

Another way that pharmacies can be assured of the legitimacy of a wholesale distributor is to look for the National Association of Boards of Pharmacy® (NABP®) Verified-Accredited Wholesale Distributors® (VAWD®) Seal. Those wholesale distributors that achieve VAWD accreditation are in compliance with state and federal laws and NABP's VAWD criteria. NABP has recently revised the VAWD criteria to allow virtual manufacturers and virtual wholesale distributors – a growing segment of the pharmaceutical wholesale industry – to qualify for VAWD, as well as to implement other changes aimed to help to ensure that the drug supply chain remains secure.

The revised VAWD criteria responds to changing business models and helps safeguard drugs in distribution at a time when there is an increased risk of counterfeit and substandard drugs entering the legitimate US drug supply chain. In particular, the criteria have been revised

to provide stronger assurance that drugs diverted from pharmacies and unlawful sources are prevented from entering into the supply chain.

For a listing of VAWD-accredited facilities, please visit www.nabp.net/programs/accreditation/vawd.

Voluntary Recall of Unexpired Sterile Products After Reports of Adverse Events

FDA has announced a voluntary recall of all lots of unexpired sterile products produced by Specialty Compounding, LLC, in Cedar Park, TX. FDA received reports of 15 adverse events at two hospitals (Corpus Christi Medical Center Doctors Regional and Corpus Christi Medical Center Bay Area) potentially related to the use of these sterile products. Affected patients received an intravenous infusion of calcium gluconate supplied by the company.

Patients who were administered the injectable drug products are at risk of life-threatening infections. The recall applies to all unexpired sterile compounded medications dispensed by the company, including all strengths and dosage forms. Recalled products were distributed directly to hospitals and physicians' offices in Texas, and to patients located nationwide (with the exception of North Carolina). No calcium gluconate was shipped outside the state of Texas. Health care providers and patients should stop using all recalled products and return them to Specialty Compounding.

Veterinarians Not Eligible for NPIs, CMS Clarifies

Centers for Medicare and Medicaid Services (CMS) has become aware of cases in which veterinarians are told, incorrectly, that they must provide a National Provider Identifier (NPI) number for prescriptions they have written to be dispensed. The agency has issued a clarification, stressing that veterinarians do not meet the regulatory definition of "health care provider," and thus may not obtain NPI numbers. The clarification also states that "Any entity that insists veterinarians obtain an NPI [is] attempting to require veterinarians to obtain NPIs fraudulently." CMS also notes that "if a veterinarian fulfills the definition of 'health care provider' in a profession other than furnishing veterinary services," such as if they are also a nurse practitioner, "the veterinarian would be eligible for an NPI but would select a Nurse Practitioner code (not a Veterinarian code) from the Healthcare Provider Taxonomy Code Set when applying for an NPI."



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 a National Association of Boards of Pharmacy® (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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nursing, medical, and pharmacy boards will have received and accepted the recommendations by October 1.

- 6. May immunizing pharmacists continue to administer flu, pneumococcal, and zoster vaccines under existing law?** Yes. The new statute specifically provides that “pharmacists who were qualified to administer influenza, pneumococcal, and zoster vaccines prior to the effective date of this act may continue to administer these vaccines in accordance with [current rules] until June 30, 2014.” By June 30, 2014, immunizing pharmacists must have updated their supervising physician agreements and protocols to comport with the new statute.

Pharmacists should continue to monitor the Board’s Web site for updates on this fast-moving topic.

Item 2270 – Schedule II Prescriptions Now Carry a Six-Month Expiration Date Under North Carolina Law

The General Assembly passed, and Governor McCrory signed into law, S.L. 2013-79, the text of which may be found here: www.ncleg.net/Sessions/2013/Bills/House/PDF/H675v6.pdf. The statute makes several alterations to law governing the practice of pharmacy. Among them, “No Schedule II substance shall be dispensed pursuant to a written prescription more than six months after the date it was prescribed.” The new six-month limitation applies to all prescriptions issued on or after October 1, 2013.

Item 2271 – Certified Pharmacy Technicians May Obtain and Maintain Registration With the Board Independent of Active Employment as a Technician

S.L. 2013-79 also makes changes to the pharmacy technician registration process for **certified** technicians. As pharmacists know, the statute governing pharmacy technicians (NCGS 90-85.15A) has to date made registration as a pharmacy technician contingent upon active employment as a pharmacy technician.

Effective October 1, 2013, however, a **certified** pharmacy technician may apply for registration (and may renew registration) even if the certified technician is not actively employed in that role. A certified technician is required to notify the Board within 10 days of beginning employment as a pharmacy technician. The technician’s certification is deemed to satisfy the pharmacy technician training program requirements listed in the statute.

The Board recognizes the Pharmacy Technician Certification Board credential.

Item 2272 – General Assembly Passes Revisions to the Controlled Substances Reporting System

The General Assembly passed, and Governor McCrory signed into law, S.L. 2013-152, the text of which may be found here: www.ncleg.net/Sessions/2013/Bills/Senate/PDF/S222v4.pdf. This statute makes several amendments to the North Carolina Controlled Substances Reporting System (CSRS) Act. Chief among them:

- ◆ Elimination of the reporting exception for dispensing physicians. Dispensing physicians must now report into the CSRS just as a pharmacy.
- ◆ Dispensers must now report required information to the CSRS “no later than three business days after the day when the prescription was delivered.” Dispensers are “encouraged to report the information no later than 24 hours after the prescription was delivered.”
- ◆ Dispensers must now report the “method of payment for the prescription.”

These changes become effective January 1, 2014. The Board will work with the Department of Health and Human Services (DHHS) Drug Control Unit to communicate implementation information.

Item 2273 – Pharmacists May Apply for CSRS Registration Electronically Through a Board Portal

Working with staff at the DHHS Drug Control Unit, Board staff implemented an electronic application for access to the CSRS. All North Carolina-licensed pharmacists may readily complete and transmit an application for CSRS registration by logging on to their individual account at the Board Web site (www.ncbop.org). On the left-hand side of the menu, select “Helpful Links,” then click on the “North Carolina Controlled Substances Reporting System” hyperlink, which went live in May 2013. Clicking on that link takes the pharmacist through the application process.

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