

April 2012

News



North Carolina Board of Pharmacy

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Item 2234 – Further Updates Regarding S.L. 2011-349, Photo Identification Prior to Dispensing Certain Controlled Substances

As reported in the October 2011 and January 2012 *North Carolina Board of Pharmacy Newsletters*, the North Carolina General Assembly passed, and Governor Beverly Perdue signed into law S.L. 2011-349, which requires presentation of a photo identification prior to the dispensing of certain controlled substances. The statute became effective March 1, 2012.

Board staff continues to receive numerous questions about the statute. These questions have been pertinent and demonstrate how pharmacies are, in many respects, struggling to implement the statute for particular patient populations. Board staff continues to update the frequently asked questions (FAQs) document (which is found at the Board Web site, www.ncbop.org) and encourages pharmacists to check it regularly for updates. All updates to the FAQs are clearly marked as such so that pharmacists can readily identify new material in the document.

Board staff appreciates pharmacists who have taken time to raise questions about the statute. Your questions help ensure that the guidance document is meeting the needs of practitioners.

Item 2235 – Effective May 1, 2012, Board of Pharmacy Will No Longer Accept Checks

Effective May 1, 2012, the Board will no longer accept payment by check. The Board accepts payment via Visa, MasterCard, and Discover credit cards.

Item 2236 – Any License, Permit, or Registration Not Renewed or Reinstated for 2012 is Now Inactive

Under North Carolina law, any license, permit, or registration issued by the Board of Pharmacy expires on December 31, of the year of issuance. North Carolina builds in a so-called "grace period" allowing for renewal up to 60 days after December 31. The renewal period closed on March 1, 2012.

As of the date of this publication – April 1, 2012 – any license, permit, or registration not renewed or reinstated is now inactive. Any practitioner, pharmacy, or durable medical

equipment facility holding an inactive license, permit, or registration must cease activities unless and until such practitioner or facility files an application for, and is granted, a new license, permit, or registration. Continuing to practice without a valid license, permit, or registration will result in disciplinary action.

Item 2237 – Changes to Continuing Education Approval Began March 1, 2012

Beginning March 1, 2012, the Board of Pharmacy ceased approving requests for continuing education (CE) courses that are not accredited by Accreditation Council for Pharmacy Education (ACPE) or the North Carolina Association of Pharmacists (NCAP). The reasons for the policy are two-fold: (1) the volume of such requests has increased substantially in the past two years, hindering Board staff's ability to focus on the Board's core functions; and (2) relatedly, Board staff was concerned about its ability to assess these requests for substantive acceptability as CE courses.

CE programs approved by Board staff on or before February 29, 2012, will remain available on the Board CE page and may be used for 2013 license renewal.

Going forward, the Board will continue to provide credit for certain categories of non-ACPE and non-NCAP CE (eg, Board meeting attendance, CPR training, precepting, residency, Spanish or other foreign language class, continuing medical education, continuing nursing education, continuing dental education). Those categories should be well known to North Carolina pharmacists and can be reviewed in the FAQs section of the Board Web site: www.ncbop.org/faqs/Pharmacist/faq_ContEducation.htm.

Any pharmacist or organization in need of approval of a CE program may contact NCAP, which stands willing and able to provide accreditation services. Information about NCAP accreditation services may be found at www.ncpharmacists.org/displaycommon.cfm?an=1&subarticlenbr=106.

Item 2238 – Congratulations to Pharmacists Continuously Licensed by the North Carolina Board for 60 Years

Board members and staff extend their heartiest congratulations to the following pharmacists who have been continuously

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DEA Provides Information Regarding Carisoprodol Prescriptions

A Drug Enforcement Administration (DEA) announcement provides information regarding the scheduling of carisoprodol, effective as of January 11, 2012. The DEA Final Rule making the drug a Schedule IV controlled substance was published December 12, 2011, and states that effective January 11, 2012, all prescriptions for drugs containing carisoprodol shall comply with DEA regulations. Specifically, a pharmacy may only fill or refill a prescription for a drug containing carisoprodol if all of the following requirements are met:

- ◆ the prescription was issued for a legitimate medical purpose by a DEA-registered practitioner acting in the usual course of professional practice (21 CFR §1306.04);
- ◆ the prescription contains all the information required by 21 CFR §1306.05; and
- ◆ the number of refills authorized by the prescribing practitioner is five or less (21 USC §829(b)).

The full text of the notice is available on the DEA Web site at www.deadiversion.usdoj.gov/drugs_concern/carisoprodol/index.html.

Pfizer Recalls Several Lots of Two Oral Contraceptive Products

Pfizer Inc recalled 14 lots of Lo/Ovral®-28 (norgestrel and ethinyl estradiol) tablets and 14 lots of norgestrel and ethinyl estradiol tablets (generic) due to potential for inexact count and out-of-sequence tablets. A Pfizer investigation found that some blister packs of the affected products may contain an inexact count of inert or active ingredient tablets and that the tablets may be out of sequence. As a result of this packaging error, the daily regimen for these oral contraceptives may be incorrect and could leave women without adequate contraception, and at risk for unintended pregnancy. Food and Drug Administration (FDA) advises that patients who have the affected product should notify their physician and return the product to the pharmacy. A Pfizer press release includes a list of the affected products with the National Drug Code (NDC) number, lot number, and expiration date for each, and is available at www.fda.gov/Safety/Recalls/ucm289770.htm.

Changes in Medication Appearance Should Prompt Investigation by Pharmacists and Patients

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.

As the numbers of generic products continue to increase, it seems that both patients and practitioners have become desensitized to changes

in medication appearance. So much so that patients may not question a change or, when they do, practitioners may simply reassure them that it was due to a change in manufacturer without actively investigating the reason. It is not uncommon for ISMP to receive reports from both practitioners and consumers where a change in medication appearance was not fully investigated and subsequently contributed to an error.

In one case, a man shared an account of what his 86-year-old father experienced over the course of nine days after his prescription for minoxidil was mistakenly refilled with another medication. He had been taking minoxidil 2.5 mg for years at a dose of 5 mg (2 tablets) twice daily. Due to failing vision, he did not realize that his minoxidil tablets looked different. His daughter noticed the change, but was unconcerned since the tablets had previously changed appearance. The pharmacy was contacted about the change and a staff member explained that it was a different generic for minoxidil, and that the pills could be exchanged for those that he usually received. There was no mention of a mistake being made when the medication was exchanged. He was taken to the hospital the following day, when he could barely walk.

After this incident was explained to hospital staff, they contacted the pharmacy. It was then revealed that he was given methotrexate by mistake because the bottles were stored next to each other. By this time, the man had taken 36 methotrexate 2.5 mg tablets, his white blood cell and platelet counts were extremely low, and he was in critical condition. We later learned that he passed away during that hospital visit.

Your pharmacy may be providing an important patient safety tool on the prescription label that may be overlooked by patients and their caregivers: a description of the shape, color, and imprint code of the medication that should be inside. This information can help ensure accuracy since it's based on the NDC number. Teach patients to look for this description and question any differences. In addition, the patient needs to know if the medication name on the pharmacy generated label is the medication he or she was expecting to receive. Even if the generic manufacturer is different each time the prescription is renewed, the description on the label should match the NDC number and thus the product inside.

With so much information on prescription labels such as patient and doctor name, drug name, instructions, and warnings – this added information can easily be missed. But it's important, so look for it and put it to use!

FDA Reminder: Purchasing Unapproved Injectable Cancer Medications Threatens Patient Safety

FDA is reminding health care providers to obtain and use only FDA-approved injectable cancer medications purchased directly from the manufacturer or from wholesale distributors licensed in the United States. FDA explains that “current shortages of injectable cancer medications may present an opportunity for unscrupulous individuals to introduce non-FDA approved products into the drug supply, which could result in

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



serious harm to patients.” FDA reports that the agency is aware of promotions and sales of unapproved injectable cancer medications directly to clinics in the US and that the medications were likely administered to patients. Examples of products include unapproved versions of FDA-approved medications such as Faslodex® (fulvestrant), Neupogen® (filgrastim), Rituxan® (rituximab), and Herceptin® (trastuzumab). FDA stresses the risks to patients when such unapproved medications are used. The agency outlines several steps health care providers should take to ensure patient safety:

1. Obtain and use only FDA-approved injectable cancer medications purchased directly from the manufacturer or from wholesale distributors licensed in the US. An FDA Web page, www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm, provides the online resource for each state for verifying that a wholesale distributor is appropriately licensed.
2. Determine if the medication you have received is FDA-approved by checking the Orange Book or searching the Drugs@FDA database.
3. Question whether a price sounds too good to be true. Deep discounts may be offered because the product is stolen, counterfeit, or unapproved.
4. Carefully inspect the product and packaging and be alert for signs that the product is not FDA approved, such as if the packaging looks different or the dosing recommendations are unfamiliar.

FDA also notes that if a health care provider receives multiple complaints about the same product, such as a new side effect or lack of therapeutic effect, these may signal a product quality issue.

FDA reminds health care providers that in certain circumstances the agency may authorize limited importation of medications that are in short supply. Such medications are imported from approved international sources and distributed in the US through a controlled network, and would not be sold in direct-to-clinic solicitations. If FDA has arranged for limited importation of the foreign version of a medication, information on obtaining that medication will be available in the Drug Shortages section of the FDA Web site, www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm.

Additional details are provided in an FDA Drug Safety Communication, available at www.fda.gov/downloads/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/UCM287717.pdf.

Insulin Pens Should Not Be Used for Multiple Patients, Stresses CDC

Centers for Disease Control and Prevention (CDC) issued a notice, reminding health care providers that insulin pens are intended for use by a single patient, and should never be used on more than one patient. CDC indicates that the agency has become “increasingly aware of reports of improper use of insulin pens, which places individuals at risk of infection with pathogens including hepatitis viruses and human immunodeficiency virus (HIV).” The notice explains that regurgitation of blood into the insulin cartridge can occur after injection, creating a risk of bloodborne pathogen transmission if the pen is used for more than one person, even when the needle is changed. CDC provides the following recommendations to help protect patient safety:

- ◆ Insulin pens containing multiple doses of insulin are meant for use on a single person only, and should never be used for more than one person, even when the needle is changed.
- ◆ Insulin pens should be clearly labeled with the person’s name or other identifying information to ensure that the correct pen is used only on the correct individual.

- ◆ Hospitals and other facilities should review their policies and educate their staff regarding safe use of insulin pens and similar devices.
- ◆ If reuse is identified, exposed persons should be promptly notified and offered appropriate follow-up including bloodborne pathogen testing.

The notice may be downloaded from the CDC Web site at www.cdc.gov/injectionsafety/PDF/Clinical-Reminder-insulin-pen.pdf.

US Public Health Service Report Supports Maximizing the Scope of the Pharmacist as Part of Health Care Team

Presenting an evidence-based discussion of the comprehensive patient care services that pharmacists currently provide, a new government report calls for expanded support for such pharmacist-delivered patient care models. The report, *Improving Patient and Health System Outcomes through Advanced Pharmacy Practice*, prepared by the Office of the Chief Pharmacist, US Public Health Service (PHS), is organized into four focus points as follows:

- ◆ Focus point 1 discusses how pharmacists are integrated in many practice settings as health care providers, such as through collaborative practice agreements, and provides data showing interprofessional support for such models.
- ◆ Focus points 2 and 3 support recognition of pharmacists as health care providers and compensation models that will allow pharmacists to continue to improve patient and health care system outcomes.
- ◆ Focus point 4 presents a review of numerous peer-reviewed studies that demonstrate favorable outcomes from pharmacist-delivered care.

RADM Scott Giberson, chief professional officer, PHS Pharmacists, and the primary author of the report, stated that “one of the most evidence-based and cost-effective decisions we can make as a nation is to maximize the expertise and scope of pharmacists, and minimize expansion barriers to successful health care delivery models.” The report may be downloaded from the US PHS Web site at www.usphs.gov/corpslinks/pharmacy/comms/pdf/2011AdvancedPharmacyPracticeReporttotheUSSG.pdf.



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

CPE Monitor™ integration is underway. Soon all Accreditation Council for Pharmacy Education (ACPE)-accredited providers will require you to submit your NABP e-Profile ID, assigned when you set up your NABP e-Profile, along with your date of birth (MMDD), in order to obtain continuing pharmacy education (CPE) credit for any ACPE-accredited activity. Many have already begun to do so.

Visit www.MyCPEmonitor.net to set up your e-Profile 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.

licensed in North Carolina for over 60 years. They are a select group, and the Board warmly thanks them for their service to North Carolina pharmacy:

- John A. McNeill**, Whiteville, NC..... June 19, 1940
Hamilton P. Underwood, Fayetteville, NC..... June 18, 1941
Clarence L. Shields, Jacksonville, NC..... July 30, 1943
Merwin S. Canaday, Four Oaks, NC..... June 29, 1944
Hubert G. Dameron, Tabor City, NC January 17, 1945
Charles H. Beddingfield, Clayton, NC..... January 17, 1945
Gerald D. Hege, Whiteville, NC January 17, 1945
Joe E. Hamlet, Rocky Mount, NC March 27, 1946
Ellerbe W. Griffin, Kings Mountain, NC June 18, 1948
Maryellen M. Holt, Burlington, NC February 23, 1949
Leon I. Graham, Wallace, NC February 23, 1949
Willie C. Rose, Wilson, NC..... June 30, 1949
Clifford E. Hemingway, Charlotte, NC..... June 30, 1949
Windfield S. Gardner, Burlington, NC February 24, 1950
John M. Rancke, Lumberton, NC..... July 6, 1950
Ernest J. Rabil, Clemmons, NC..... July 6, 1950
Charles F. Jones, Oxford, NC July 6, 1950
Hunter O. Gammon, Reidsville, NC December 11, 1950
William H. Wilson, Raleigh, NC June 28, 1951
Ray T. Hudson, Gastonia, NC June 28, 1951
Olin H. Welsh, Lumberton, NC October 29, 1951
William N. Robertson, Laurinburg, NC..... March 6, 1952
Alec W. Clelland, Fayetteville, NC July 2, 1952
Keith N. Fulbright, Greensboro, NC July 2, 1952
Joseph C. Harris, Chapel Hill, NC July 2, 1952
John W. Gresham, Wilson, NC July 2, 1952
Loy R. Burris, Valdese, NC July 2, 1952
Warren E. Crispens, Charlottesville, VA... November 5, 1952

Item 2239 – Carolinas Center for Medical Excellence Seeking Pharmacist Participation in a Project to Improve Medication Outcomes in the Medicare Population

The Carolinas Center for Medical Excellence (CCME) is currently recruiting pharmacist-led, community teams that function as the patient’s primary care provider and who would like to improve their percentage of patients with A1c < 9%, increase the percentage of patients in therapeutic range taking long-term anticoagulation therapy, or decrease the number of patients taking an antipsychotic medication that is not being used for a Food and Drug Administration (FDA)-approved indication.

CCME and the Health Resources and Services Administration’s Office of Pharmacy Affairs are currently working together on a project to decrease adverse drug events and improve outcomes in the Medicare population. This project is the Patient Safety and Clinical Pharmacy Services Collaborative (PSPC). CCME would like to invite community-based teams of health care providers and partners to join PSPC in the work to improve patient safety and quality of life. PSPC, now in its

fourth year (PSPC 4.0), is a continually growing action learning program involving several hundred communities across the country working together to deliver safe care that improves health outcomes for high-risk patient groups.

The collaborative achieves its goals using change processes and improvement methods that are proven to be effective. This collaborative uses a combination of face-to-face and virtual meetings, testing periods, national expert faculty, adult learning methods, leadership and change management, Web training, and coaching calls over a 12-month period to help community-based teams adapt, test, and implement successful practices. To learn more about PSPC, visit www.healthcarecommunities.org or contact Jeana Partington BSN, RN, CPHQ, at 919/461-5660 or jpartington@ncqio.sdps.org.

Item 2240 – Drug Shortages and Grey-Market Wholesaling

North Carolina pharmacists are aware of the many nationwide drug shortages – often for critical care medications. A summary of shortages, their causes, and timelines for resolution is maintained by FDA at www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm.

As is the case whenever any critical good is in short supply, unscrupulous actors seize opportunities to take advantage. Board staff has received several reports of pharmacies allegedly using their permits to acquire “shortage” drugs for the purpose of transferring such drugs to grey-market wholesalers, who in turn seek to sell these shortage drugs at exorbitant prices. Board staff recently obtained the surrender of a pharmacy permit and a pharmacist license in a case in which a “pharmacy” was acquiring only “shortage” drugs and transferring them to a grey-market wholesaler. The pharmacy conducted no patient dispensing at all.

Other cases are presently under investigation. Board investigative staff is cooperating closely with officials at the North Carolina Department of Agriculture charged with enforcing laws governing prescription drug wholesalers, as well as federal authorities.

Putting aside the moral and ethical issues associated with profiteering on short-supply critical access drugs (which are, of course, significant), pharmacies engaged in such activities run afoul of numerous provisions of the Pharmacy Practice Act, the North Carolina Food, Drug, and Cosmetic Act, and other statutes, both civil and criminal.