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North Carolina Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

Item 2160 – Compounding OTC Products

North Carolina Board of Pharmacy staff periodically receives questions about the compounding of over-the-counter (OTC) products. Compounding of OTC products can involve at least two scenarios.

First, a pharmacist may receive a patient-specific prescription order from a physician or other authorized prescriber to compound a medication using OTC active ingredients. Such orders may of course be compounded, subject to the laws, rules, and standards governing compounding.

Second, some pharmacies in North Carolina are apparently compounding OTC medications **not** pursuant to a patient-specific prescription, but rather for general resale in the pharmacy. This type of "compounding" does not comply with law. A product composed of OTC active ingredients is nonetheless a "drug" under the Federal Food, Drug, and Cosmetic Act. Marketing of an OTC drug does not necessarily require submission of a new drug application with proof of safety and efficacy. But any entity that wishes to market an OTC product must, among other things, register with Food and Drug Administration (FDA) as a drug establishment, comply with current Good Manufacturing Practices, and market OTC products that comply in all respects with FDA labeling requirements.

Item 2161 – Tamper Proof Rx Pad Requirement for Medicaid Prescriptions Now Effective

Barring unforeseen developments between the time this copy was submitted and the publication date of the *Newsletter*, the "tamper proof prescription pad" requirement for Medicaid prescriptions will have gone into effect. The North Carolina Division of Medical Assistance (DMA) has issued some guidance to pharmacists and other health care providers about this requirement. Board staff posts these guidance documents, when received, on the Board's Web site.

Pharmacists with questions about the meaning and operation of the tamper proof requirements should direct them to the DMA at 919/855-4300. The Board of Pharmacy does not administer this statute.

Item 2162 – Internet Veterinary Pharmacies

Effective April 1, 2007, the North Carolina Board of Pharmacy implemented rules governing Internet pharmacies. Rule .1601(d) provides:

(d) In addition to all of the other requirements for issuance and renewal of a pharmacy permit imposed by statute and rules of the Board, the Board shall not issue any original or annual renewal pharmacy permit to any Internet pharmacy until the Board is satisfied that:

(1) The Internet pharmacy is certified by the National Association of Boards of Pharmacy as a Verified Internet Pharmacy Practice Site (VIPPS);

(2) The Internet pharmacy has certified the percentage of its annual business conducted via the Internet on a form required by the Board, when it applies for permit or renewal; and

(3) The Internet pharmacy has provided the Board with the names, addresses, social security numbers, phone numbers, facsimile numbers, email addresses, and titles of all principal corporate officers of the Internet pharmacy; the names, addresses, social security numbers, phone numbers, facsimile numbers, email addresses, and titles of all principal officers of any company, partnership, association, or other business entity holding any ownership interest in the Internet pharmacy; the names, addresses, social security numbers, phone numbers, facsimile numbers, email addresses, and titles of any individual holding any ownership interest in the Internet pharmacy.

This Paragraph does not relieve an out-of-state pharmacy from compliance with all provisions of 21 NCAC 46 .1607 governing out-of-state pharmacies.

An Internet pharmacy is defined by Rule .1317(17) as follows:

Internet Pharmacy

(a) A pharmacy that maintains an Internet Web site for the purpose of selling or distributing prescription drugs; or

(b) A pharmacy that uses the Internet, either itself, or through agreement with a third party, to communicate with or obtain information from patients; uses such communication or information, in whole or in part, to solicit, fill or refill prescriptions; or uses such communication or information, in whole or in part, to otherwise engage in the practice of pharmacy.

Notwithstanding Sub-items (a) and (b) above, a pharmacy shall not be deemed an Internet pharmacy if it maintains an Internet web site for the following purposes only:

(i) Mere advertisements that do not attempt to facilitate, directly or through agreement with a third party, an actual transaction involving a prescription drug;

(ii) To allow a patient to communicate a request for a refill of a legitimate prescription originally filled by the pharmacy that maintains the Internet Web site;

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NABP Launches Pharmacy Curriculum Outcomes Assessment Program

NABP launches its Pharmacy Curriculum Outcomes Assessment™ (PCOA®) mechanism in April 2008 for use by schools and colleges of pharmacy in evaluating their curricula. NABP invited schools and colleges of pharmacy to participate in the 2008 administration of the PCOA, scheduled for April 7-18. There will be no fee for participation in this first year of administration.

Those schools and colleges of pharmacy that participate in the April 2008 administration will receive detailed score reports for their students that sit for the assessment, as well as national comparative data. NABP developed the PCOA at the request of schools and colleges of pharmacy and accreditation stakeholders that have expressed a need for a national assessment that is psychometrically validated to assist with measuring curriculum development and student performance.

Details are posted under Assessment Programs on the NABP Web site, *www.nabp.net,* or by contacting NABP Customer Service at custserv@nabp.net.

An e-Educated Consumer is Your Best Customer (Patient)

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and Food and Drug Administration (FDA) in analyzing 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 recommendations for prevention of reported errors that you can put into practice today, subscribe to ***ISMP Medication Safety Alert!® Community/Ambulatory Edition*** *by visiting www.ismp.org. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

According to the Pew Internet and American Life Project, Online Health Search 2006, 80% of American Internet users, or some 113 million adults, have searched for information on at least one of 17 health topics. Many Americans turn to the Internet before, or instead of, seeking information from their doctor or pharmacist. People want to make better decisions in their lives and therefore seek more in-depth research, research that is offered online.

Patients and caregivers have a vested interest to keep up-to-date on their own or their loved ones' medical conditions. The average doctor's appointment is just 10 minutes – hardly enough time to get into lengthy conversations about treatment options and medication side effects. Long lines, busy and distracted pharmacists, and lack of privacy and confidentiality deter patients from seeking more information from their community pharmacists. It is no wonder then, when patients do not understand medical terminology or want to explore the medication treatment options that are available, they do not call their doctor or pharmacist – they just log on. In the privacy of their home they can find practical information such as lists of foods they should or should not take with certain medical conditions or certain medications. Instead of bothering busy pharmacists who do not appear to have the time to answer questions, they can get peace of mind when dealing with chronic conditions. They surf the net for reassurance and answers to their questions.

But what about the quality of those online sources? Some are better than others; obviously, Medline offered by the National Institutes of Health is a reliable source, but what if the site is sponsored by a pharmaceutical company? How does the consumer know which information to trust? Research suggests that most health information seekers do not check the source and date of the information they find online. Most Internet users use a search engine and key words from their own limited medical knowledge and rely on the algorithms of the search engines to find them reliable Web sites and scientific articles.

How can you, the pharmacist, help your patients find a credible health care information site? Patients need an easy-to-use, comprehensive medical Web site where they can learn about health conditions and medications. Patients should look for Web sites that offer unbiased health information written by medical professionals.

Tell patients to always check sources and dates of the information provided. For example, information on hormone replacement therapy has changed significantly in the last few years. Articles offering advice and recommendations on drug therapy from 10 years ago could be detrimental to the reader.

The patient-doctor-pharmacist triad has changed. We now live in an era of the square – the patient, doctor, pharmacist, and Internet. Help patients understand what they are reading. Go to the sites yourself and confirm the information is reliable and timely. And of course, find time to answer their questions. Look for a soon to be released consumer Web site being developed by ISMP.

FDA Warns against Using OTC Cold Medicines in Babies

FDA issued a public health advisory on January 17, 2008, recommending that over-the-counter (OTC) cough and cold medicines should not be used to treat infants and children younger than 2 years of age, citing the risk of "serious and potentially life-threatening side effects." FDA held a public advisory committee meeting October 18-19, 2007, to discuss the issue, after which many pharmaceutical manufacturers voluntarily withdrew cough and cold medicines marketed for use in this age group.

FDA says the agency is in the process of evaluating the safety of OTC cough and cold medicines in children 2-11 years of age and will announce its recommendations "in the near future."

The public health advisory is available on the FDA Web site at *www.fda.gov/cder/drug/advisory/cough_cold_2008.htm.*

Bayer Diabetes Care Recalls Contour Test Strips

Bayer Diabetes Care recently recalled test strips (sensors) for use with the Contour TS Blood Glucose Meter. The company recalled the product because test strips from specific lots could result in blood glucose readings with a positive bias that could demonstrate 5% to 17% higher test results.

This issue is unrelated to the Contour TS meter itself and pertains only to certain test strips used with the meter. Strips used with other Bayer meters are unaffected.

Health care professionals are advised to check the lot number of the Contour test strips in their inventory and contact Bayer Diabetes Care for information on the return and replacement of strips.

More information is available in the manufacturer's press release at *www.fda.gov/medwatch/safety/2007/contourTS_recall.htm.*

Compliance News

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FDA Takes Action against Compounded BHRT Drugs

FDA sent letters warning seven pharmacy operations that the claims they make about the safety and effectiveness of their so-called bio-identical hormone replacement therapy, or BHRT, products are unsupported by medical evidence, and are considered false and misleading by the agency. FDA has expressed concern that unfounded claims like these mislead women and health care professionals.

The pharmacy operations receiving warning letters use the terms "bio-identical hormone replacement therapy" and "BHRT" to imply that their drugs are natural or identical to the hormones made by the body. FDA regards this use of "bio-identical" as a marketing term implying a benefit for the drug, for which there is no medical or scientific basis.

The FDA news release is available at *www.fda.gov/bbs/topics/NEWS/2008/NEW01772.html.*

Manufacturers to Restrict Distribution of Methadone

As of January 1, 2008, manufacturers of methadone hydrochloride tablets 40 mg (dispersible) have voluntarily agreed to restrict distribution of this formulation to only those facilities authorized for detoxification and maintenance treatment of opioid addiction, and hospitals. Manufacturers will discontinue supplying this formulation to any facility not meeting these criteria.

The 5 mg and 10 mg formulations indicated for the treatment of pain will continue to be available to all authorized registrants, including retail pharmacies. The 40 mg methadone formulation is indicated for the treatment of opioid addiction; it is not FDA-approved for use in the management of pain. This measure comes in response to the reported increase in methadone-related adverse events.

For more information, see "Studies Show Increased Methadone-Associated Mortality Related to Pain Management" in the January issue of the *NABP Newsletter,* available on the NABP Web site at *www.nabp.net.*

New Compounding Standards Effective June 1; USP Offers Webinars

New standards for sterile compounding will become effective on June 1, 2008. United States Pharmacopeia (USP) published the revised General Chapter 797, "Pharmaceutical Compounding – Sterile Preparations" on its Web site in December 2007 to give the compounding community time to implement changes before the effective date.

These revisions tighten standards and conditions for sterile compounding over the previous version of Chapter 797 to help improve patient safety. (See "Sterile Compounding 'Checklist' Revised to Better Protect Patient Health" in the February 2008 issue of the *NABP Newsletter.)* The revisions are included in USP 32–NF 27 and in the second edition of the *Pharmacists' Pharmacopeia,* published in March 2008.

USP is offering a series of educational Webinars and workshops to help compounding professionals appropriately interpret and implement the newly revised standard. The Webinars will provide direct dialogue with two compounding experts and ample time to address questions related to the standard. The workshops will provide added interaction plus hands-on demonstrations related to environmental monitoring, contamination control, and aseptic testing.

Full details on these programs are available on the USP Web site at *www.usp.org/hottopics/generalChapter797.html?hlc.*

CMS Names MSAs, Products for Round Two of DMEPOS Bidding

Centers for Medicare and Medicaid Services (CMS) recently announced the metropolitan statistical areas (MSAs) and product categories for the second round of the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program.

All suppliers must meet quality standards and be accredited by a CMS-recognized accreditation organization, such as NABP, to obtain a contract under the Medicare DMEPOS competitive bidding program. The final deadline for all suppliers to obtain accreditation is September 30, 2009. However, CMS encourages suppliers to seek accreditation as soon as possible to avoid any potential difficulties that would affect their ability to bid.

The competitive bidding program is designed to improve the effectiveness of Medicare's DMEPOS payments, reduce beneficiary out-of-pocket costs, and save the Medicare program money while ensuring beneficiary access to quality DMEPOS items and services. More information, including the lists of MSAs and product categories, is available on the CMS Web site at *www.cms.hhs.gov/CompetitiveAcqforDMEPOS.*

Adverse Event Reporting Requirements in Effect for OTC Products

FDA recently issued new adverse event reporting requirements for manufacturers, packers, and distributors of dietary supplements and over-the-counter (OTC) drug products marketed without an approved application. The new reporting requirements, as described in Public Law 109-462, became effective on December 22, 2007.

The act, as well as the FDA *Guidance for Industry: Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed without an Approved Application,* is available via the FDA MedWatch site at *www.fda.gov/medwatch/otc.htm.*

FDA Rule Calls for Toll-Free Number for Adverse Events on Drug Labels

FDA recently issued an interim final rule requiring certain medication labels to include a toll-free number for reporting adverse events. The interim final rule codifies provisions of the proposed rule "Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products" that became effective on January 1, 2008, under the FDA Amendments Act of 2007. The rule does not apply to over-the-counter medications approved as new drugs if the product packaging includes a manufacturer's or distributor's toll-free number for reporting complaints.

To allow manufacturers, dispensers, and pharmacies time to update their labeling and systems to comply with the new requirements, FDA will delay enforcement actions regarding these regulations until January 1, 2009.

More information is available in the *Federal Register* (Docket No. 2003N-0342) at *www.fda.gov/OHRMS/DOCKETS/98fr/E7-25426.pdf.*

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(iii) To allow a customer to research drug interactions and clinical pharmacology information; or

(iv) To allow a patient to send an electronic mail message to a pharmacist licensed in North Carolina.

After implementation, the Board learned that the National Association of Boards of Pharmacy does not issue the VIPPS accreditation to veterinary pharmacies. Accordingly, the Board has decided that, as a matter of enforcement discretion for 2008 renewals, an Internet veterinary pharmacy would not be expected to comply with the VIPPS accreditation provision in Rule .1601(d)(1). But an Internet veterinary pharmacy that wished to renew its license in North Carolina did have to comply with the disclosure requirements of Rule .1601(d)(2) and (d)(3). No renewal was granted absent compliance with these requirements.

Internet veterinary pharmacies must be aware, however, that the Board's decision to overlook compliance with the VIPPS accreditation provision for 2008 renewals is **not** a promise, guarantee, or other representation that the pharmacy will be permitted to renew its license for 2009 on the same terms. The Board intends to study this issue in the coming months. Possible solutions include identification of an alternate certification mechanism or a decision that the risk to the public health and safety created by Internet-based veterinary pharmacies is simply too great to allow their permitting in North Carolina at all.

Pharmacists, pharmacies, veterinarians, and other stakeholders are encouraged to provide any thoughts they have on this issue to the Board.

Item 2163 – Executive Director Emeritus David Work Receives ASPL Joseph L. Fink III Founders Award

Executive Director Emeritus David Work received the Joseph L. Fink III Founders Award from the American Society for Pharmacy Law (ASPL) at the 2008 American Pharmacists Association Annual Meeting. The award recognizes sustained and outstanding service and contributions to the professions of pharmacy law.

David is a founding member of ASPL. And as readers of this *Newsletter* know, David made innumerable contributions to pharmacy and law during his 30-year tenure as executive director. David's candidacy drew supporting letters from Fred Eckel, executive director of the North Carolina Association of Pharmacists, and Carmen A. Catizone, executive director/secretary of the National Association of Boards of Pharmacy. Jay Campbell, the Board's current executive director and president of ASPL, presented the award.

Item 2164 – Changes to Schedule II Prescriptions

The frequently asked questions section of the Board's Web site provides guidance on changes that may be made to a prescription for a Schedule II controlled substance after consultation with the prescriber: *http://www.ncbop.org/faqs/Pharmacist/faq_ChangestoSchIICS.htm*. This guidance comes directly from a letter sent to boards of pharmacy by the Drug Enforcement Administration (DEA) in 2006.

A number of pharmacists have contacted the Board stating that DEA has passed a "new rule" on this topic and now prohibits any change to a Schedule II prescription. This is not so. The confusion apparently stems from a *Pharmacist's Letter* article. Based on what Board staff knows about the *Pharmacist's Letter* article, it is in error. The article seizes on one clause of one sentence in an introductory paragraph to the new rules governing "do not fill until" Schedule II prescriptions (detailed in the January 2008 *Newsletter*) and extrapolates from that a sea change in DEA policy.

That clause arguably could be read as saying all changes to Schedule II prescriptions are prohibited, but it is hardly the only interpretation that can be drawn in context. Moreover, any such change in DEA policy would be a substantial reversal that would not be communicated in a throw-away clause in a sentence preceding a rule on an entirely different topic. Unless and until the DEA issues a clear repudiation of its prior stance on Schedule II prescription changes, pharmacists should feel comfortable following the guidance on the Board's Web site.

The *North Carolina Board of Pharmacy News* is published by the North Carolina Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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