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News

North Carolina Board of Pharmacy

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Item 2256 – Multiple Rule Amendments Principally Concerning Hospital, Long-Term Care, and Similar Health Facility Pharmacy Practices Became Effective March 1, 2013

On March 1, 2013, a number of amendments to the rules primarily governing hospital, long-term care, and similar health care facility oriented practices went into effect. These amendments eliminate unnecessary provisions, and simplify and clarify others.

In many instances, the amendments eliminate, or markedly reduce, record keeping requirements. Moreover, new Rule 21 NCAC 46.2508, which is applicable to all pharmacy practice settings, specifies:

> Unless otherwise specified in the rules in this Section or other applicable law, any documentation required by the rules in this Section may be electronically created and maintained, provided that the system that creates and maintains the electronic record:
>
> (1) is capable of printing the documentation so that the pharmacist-manager can provide it to the Board within 48 hours of a request;
>
> (2) contains security features to prevent unauthorized access to the records; and
>
> (3) contains daily back-up functionality to protect against record loss.

Other areas addressed by the new rule amendments include revisions to the remote medication order entry rule, authorization of default medication quantities for medical orders, and simplification of Rule 21 NCAC 46.1414's provisions governing auxiliary medication inventories.

The text of these recent amendments may be found here: *www.ncbop.org/LawsRules/HospitalLTCRuleChangesEff030113.pdf*. North Carolina Board of Pharmacy staff strongly encourages pharmacists in all practice settings to familiarize themselves with the changes. Board staff is, of course, happy to answer any questions about them.

Item 2257 – Any License, Permit, or Registration Not Renewed or Reinstated for 2013 is Now Inactive

Under North Carolina law, any license, permit, or registration issued by the Board 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, 2013.

As of the date of this publication – April 1, 2013 – 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 2258 – DEA Proposes Rules That Would Allow Pharmacies to Conduct Certain CS Take-Back Programs

As pharmacists know, the federal law prohibition on pharmacies receiving controlled substances (CS) for disposal has been a significant impediment to implementing drug take-back and disposal programs to assist patients.

On December 21, 2012, Drug Enforcement Administration (DEA) published a Notice of Proposed Rulemaking that would allow retail pharmacies to conduct certain CS take-back programs. The DEA no-

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FDA Issues New Guidelines for Sleep Aids Containing Zolpidem

Food and Drug Administration (FDA) has issued new dosing recommendations for sleep aids containing zolpidem. The new recommendations are based upon new data that shows that when taken at night, blood levels of zolpidem remain high enough in the morning to impair activities that require alertness, such as driving. The new guidelines halve the dosage for women because the new data showed that their bodies take longer to eliminate the drug.

FDA urges drug manufacturers and health care providers to follow the new dosing instructions, which apply to brand name and generic drugs containing zolpidem:

- Ambien®, Edluar™, and Zolpimist®: 5 mg for women, 5 mg or 10 mg for men
- Ambien CR®: 6.25 mg for women, 6.25 mg or 12.5 mg for men

Additionally, manufacturers of these drugs have been instructed to follow the new guidelines and print new patient information drug labels containing the new recommendations.

The recommended doses of Intermezzo®, a lower dose zolpidem product approved for middle-of-the-night awakenings, are not changing. At the time of Intermezzo's approval in November 2011, the label already recommended a lower dosage for women than for men. Additional details are available in an FDA Drug Safety Communication, available at *www.fda.gov/Drugs/DrugSafety/ucm334033.htm.*

What is the National Medication Error Rate? What Standards Are Available for Benchmarking?

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.*

A national or other regional medication error rate does not exist. It is not possible to establish a national medication error rate or set a benchmark for medication error rates. Each pharmacy organization is different. The rates that are tracked are a measure of the number of **reports** at a given organization, not the actual number of **events** or the quality of the care given. Most systems for measuring medication errors rely on voluntary reporting of errors and near-miss events. Studies have shown that even in good systems, voluntary reporting only captures the "tip of the iceberg." For this reason, counting **reported** errors yields limited information about how safe a pharmacy actually is. It is very possible that a pharmacy organization with a good reporting system, and thus what appears to be a high error "rate," may have a safer system.

The National Coordinating Council for Medication Error Reporting and Prevention published a statement refuting the use of medication error rates. The statement, which is posted on the council's Web site (*www.nccmerp.org*), states the "Use of medication error rates to compare health care organizations is of no value." The council has taken this position for the following reasons:

- Differences in **culture** among health care organizations can lead to significant differences in the level of reporting of medication errors.
- Differences in the **definition** of a medication error among health care organizations can lead to significant differences in the reporting and classification of medication errors.
- Differences in the **patient populations** served by various health care organizations can lead to significant differences in the number and severity of medication errors occurring among organizations.
- Differences in the **type(s) of reporting and detection systems** for medication errors among health care organizations can lead to significant differences in the number of medication errors recorded.

According to the statement, the council believes that there are no acceptable incidence rates for medication errors. The goal of every health care organization should be to continually improve systems to prevent harm to patients due to medication errors. Pharmacies should monitor actual and potential medication errors that occur within their organization, and investigate the root cause of errors with the goal of identifying ways to improve the medication-use system to prevent future errors and potential patient harm. The value of medication error reporting and other data gathering strategies is to provide the information that allows an organization to identify weaknesses in its medication-use system and to apply lessons learned to improve the system. The sheer number of error reports is less important than the quality of the information collected in the reports, the organization's analysis of the information, and its actions to improve the system to prevent harm to patients.

It is more important to create the open environment that encourages the reporting of errors and near errors than to develop less meaningful comparative error rates.

ISMP Launches Program to Track Vaccine Errors

ISMP has launched a National Vaccine Error Reporting Program (VERP) that allows health care providers to confidentially report vaccine administration errors and near misses. Health care providers from all practice settings, including pharmacies and physicians' offices, are encouraged to report all mistakes related to vaccines, regardless of whether any harm resulted from the incident. The program will help ISMP "better quantify the sources of errors and advocate for vaccine name, labeling, device, information, and other needed product changes to ensure patient safety," stated Michael Cohen, ISMP president. The ISMP VERP was designed with the assistance of the California Department of Public Health and with input from experts in the field, indicates ISMP. Reports sent to the ISMP VERP will be shared with FDA and forwarded to the vaccine manufacturer when applicable. ISMP also plans to work with the Centers for Disease Control and Prevention on information received to address vaccine-related safety. VERP can be accessed at *http://verp.ismp.org/.*

Providers Should Ensure Only Diluted Forms of Acetic Acid Are Used, ISMP Warns

ISMP has issued a National Alert Network (NAN) notice advising that health care organizations should take immediate steps to ensure that only diluted acetic acid solutions are used in patient care. ISMP advises that the use and purchase of glacial acetic acid, the most concentrated form of acetic acid available, should be eliminated. Several cases of severe burns, scarring, and other permanent damage to skin or mucous membranes due to the inadvertent application of glacial acetic acid have been reported to the National Medication Errors Reporting Program operated by ISMP. ISMP provides the following steps for preventing further such events:

- Remove glacial acetic acid, which has no use in its current form in clinical medicine, from the pharmacy and replace with vinegar (5% solution) or commercially available diluted acetic acid 0.25% (for irrigation) or 2% (for otic use).
- Restrict purchasing so that pharmacy staff is purchasing acetic acid for all procedural areas.
- Restrict choices for purchasing so that glacial acetic acid is not selected by mistake.
- Ensure the correct strength is ordered.
- Educate staff about the differences between glacial acetic acid and diluted forms of acetic acid.
- Order 5% as "vinegar," which reduces the potential for confusion with glacial acetic acid.
- Verify the product by requiring an independent double-check of acetic acid solutions before dispensing or applying the product.

Information on the cases reported and common reasons for the cases are included in the NAN alert, which is available on the ISMP Web site at *www.ismp.org/NAN/files/20130121.pdf.*

New FDA Training Video

FDA Drug Info Rounds, a series of online training videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better medication decisions. In the latest Drug Info Rounds video, pharmacists discuss how FDA Drug Safety Communications let health care providers, patients, and consumers know about newly observed potential risks of FDA-approved drugs. Drug Info Rounds videos are developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, and Division of Drug Information and are available on the FDA Web site at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.*

Progress Made in Implementing Recommendations Intended to Prevent Acetaminophen Overdose

Compelling progress has been made by stakeholders seeking to address the public health issue of acetaminophen overdose, indicates a white paper published by the National Council for Prescription Drug Programs (NCPDP). In 2011, NCPDP made recommendations that the health care industry take actions to support the safe use of acetaminophen, including recommending that pharmacies produce prescription labels with the complete spelling of acetaminophen and eliminating use of abbreviations such as "acet" or "APAP." Previous to that, in July 2010, the National Association of Boards of Pharmacy® (NABP®) recommended that "state boards of pharmacy prohibit the use of the abbreviation 'APAP' on prescription labels, and require that 'acetaminophen' be spelled out to assist in preventing the well-recognized danger of acetaminophen induced hepatotoxicity." The recommendation was based on established policy and a letter, sent by FDA to state boards of pharmacy, regarding the pharmacist's role in educating patients about acetaminophen induced hepatotoxicity caused by unintentional overdose. The recommendation was also consistent with the report of the NABP Task Force on Uniform Prescription Labeling Requirements, which made recommendations to encourage use of prescription labels that are organized in a patient-centered manner. NCPDP reports that pharmacy retailers "estimated to collectively represent more than half of the prescriptions dispensed in 2011, have either implemented or committed to a phased implementation" of the recommendation to use the complete spelling of acetaminophen on prescription labels. "This update to our white paper provides additional guidance for those industry stakeholders who have not yet implemented the new pharmacy labeling practices for acetaminophen-containing medicines," states Lee Ann Stember, president, NCPDP. The updated white paper is accompanied by a bulletin (PDF), available at *www.ncpdp.org/pdf/wp/NCPDPAcetaminophenInfoBulletin_PharmacyStakeholders.pdf,* developed for pharmacists that summarizes some of NCPDP's key recommendations regarding acetaminophen. In addition, the white paper, available for download at *www.ncpdp.org/ind_WP.aspx,* includes a list of resources for pharmacists to use in educating staff and pharmacy staff to use in educating patients (see Appendix D of the white paper). More information is available in an NCPDP news release available at *www.ncpdp.org/press/013113_NCPDP_Acetaminophen%20WP_FINAL.pdf.*

Pharmacists Rated High for Honesty and Ethical Standards in Gallup's 2012 Poll

Pharmacists ranked as the second most trusted profession in the 2012 Gallup Poll that asked consumers to rate 22 professions according to their honesty and ethical standards. Pharmacists were ranked as very high or high in this category by 75% of those surveyed, with nurses ranking first at 85%, and medical doctors third at 70%. Additional information on the results of the 2012 poll is available on the Gallup Web site at *www.gallup.com/poll/159035/congress-retains-low-honesty-rating.aspx*.

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tice may be found here: *www.deadiversion.usdoj.gov/fed_regs/rules/2012/fr1221_8.htm*. Board staff prepared a summary of the proposed rule, which may be found here: *www.ncbop.org/PDF/DEADrugDisposalRuleSummaryJan2013.pdf*.

Comments on the proposed DEA rule were due by February 19, 2013. Board staff will continue to monitor the DEA's rulemaking process and update North Carolina pharmacists as events warrant.

Item 2259 – Further Update on Pharmacy Compounding Matters

Item 2252 of the January 2013 *Newsletter* updated North Carolina pharmacists on compounding regulation matters arising as a result of the New England Compounding Center tragedy. The Pharmacy Compounding Working Group has proceeded with its charge to make a report and recommendation to the Board on any needed regulatory changes (whether statutory, rule-based, training-based, or resource-based). That report and recommendation is likely to be presented to the Board this spring.

There continues to be discussion and debate at the federal level about the need for amendments to the federal Food, Drug, and Cosmetic Act to shift, clarify, or both, the line between prescription drug compounding (regulated at the state level by boards of pharmacy) and prescription drug manufacturing (regulated at the federal level by Food and Drug Administration (FDA)). Board staff participated in an intergovernmental conference hosted by FDA in late December 2012, where multiple issues were discussed among federal and state regulators. Indications are that federal legislation will be introduced this spring. Board staff will update North Carolina pharmacists on any developments.

Item 2260 – North Carolina General Assembly's 2013-2014 Session is Underway

The 2013-2014 session of the North Carolina General Assembly convened in late January 2013. As is true each session, many legislative issues affecting pharmacy are being debated. Pharmacists are strongly encouraged to follow these issues and make their views known to their state representatives and senators.

Item 2261 – Pharmacists Strongly Encouraged to Activate Their CSRS Access

As pharmacists are aware, North Carolina has operated a Controlled Substance Reporting System (CSRS) since 2007. All pharmacists are authorized to access the CSRS, and instructions on activating that access may be found here: *www.ncbop.org/faqs/Pharmacist/faq_NCCSRS.htm*.

Unfortunately, access activation among prescribers and pharmacists has not risen to the level it should. Indeed, North Carolina Attorney General Roy Cooper specifically noted this in a recent speech, as reported in the Raleigh *News & Observer* (see "Cooper says prescription drug abuse now epidemic," Raleigh *News & Observer* (October 26, 2012)).

In a recent survey of pharmacists conducted by Board staff, responders across all practice fields who reported that they did not access the CSRS as a component of their practices identified two primary reasons: (1) the pharmacists have not activated access; and (2) employer/place of practice does not provide or allow access to the CSRS.

Access activation is a simple process (see link above). Pharmacists simply must take the few steps necessary.

Board staff surveyed pharmacy employers about access through employer computer systems. Most report that they have recently provided access or will soon do so. Pharmacists whose employers continue to bar access from practice sites are **strongly** encouraged to notify Board staff.

The CSRS is an informational tool, no more, no less. As health care professionals, pharmacists must exercise professional judgment and make reasonable use of information available to them. Certainly, the clinical appropriateness of a prescription cannot be assessed by a CSRS report standing alone. Nor is rote CSRS review of all CS dispensing a practical or helpful activity. But the CSRS can aid a pharmacist to identify a potentially troubling prescription or prescriber. The CSRS can aid a pharmacist to assess a patient receiving potentially inappropriate treatment that has nothing to do with "doctor shopping" or the like. *Eg,* a patient seeing multiple specialists who are not communicating among each other. Take advantage of those opportunities.

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 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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