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North Carolina Board of Pharmacy

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Item 2146 – Pharmacist Administration of Zostavax

North Carolina Board of Pharmacy staff has received numerous questions about pharmacist administration of Zostavax®. Many pharmacists have been asked by physicians around the state to administer this vaccine to patients. And, as most pharmacists are aware, the Medicare reimbursement scheme for Zostavax – which will go to a Medicare Part D only scheme January 1, 2008 – coupled with the vaccine's omission from the current rule governing pharmacist administration of vaccines has made it difficult for many seniors to obtain the vaccination. Board staff began working with the North Carolina Medical Board in March of this year to amend the vaccination rule to permit pharmacist administration of Zostavax. While that process did not move as swiftly as Board staff would have preferred, Medical and Pharmacy Board staff have reached agreement on a proposed amendment that would classify Zostavax with the pneumococcal vaccine for purposes of pharmacist administration.

By the time this *Newsletter* is published, Board staff expects that the proposed amendment will be winding its way through the rulemaking process. One question that is certain to arise is whether the amended rule will be effective by January 1, 2008. Board staff hopes that this will be the case, but owing to the vagaries of the rulemaking process – in particular the requirement that the Rules Review Commission (RRC) pass on any proposed rule amendment – staff believes that timeline to be optimistic. Board staff hopes that if the amendment is simply moving through the final procedural steps on January 1, Medical Board staff will agree to a practical means of dealing with that issue so that North Carolina seniors will have access to Zostavax. Pharmacists should monitor the Board's Web site for further developments.

Item 2147 – Board Adopts Amendments to Rule .2201 Governing Continuing Education Requirements

In August, the Board of Pharmacy approved the proposed amendments to Rule .2201 detailed in the July *Newsletter*. During the notice and comment period on this rule, the Board received three (3) comments, each of which was substantively identical. The commenters – the North Carolina Retail Merchants Association, the National Association of Chain Drug Stores, and an individual pharmacist – supported the increase in total continuing education (CE) hours required for licensure. Each, however, expressed concern about the increase in required contact CE hours from five (5) to eight (8). Each stated a concern that pharmacists in rural areas could have difficulty meeting this requirement.

The Board considered these comments and debated them extensively. The Board, however, decided to adopt the amendments as proposed for the following reasons:

First, the Board deems "contact" CE as particularly valuable to pharmacists from both pedagogical and professional standpoints.

Second, the commenters' concern overlooks the Board's statement – issued nearly a year ago – that online CE programs may satisfy the contact-hour requirement. Accordingly, pharmacists in any part of the state will have ready access to a variety of online contact-hour CE programs throughout the year. The Board's statement is found in the October 2006 Board *Newsletter* (*www.ncbop.org/Newsletters/Oct2006.pdf*) and on the Board's Web site in the Frequently Asked Questions section (*www.ncbop.org/faqs/Pharmacist/faq_ContEducation.htm*).

Third, discussions with numerous other pharmacists in rural North Carolina established that contact-hour CE programs are readily available throughout the state from a large variety of providers, including the Area Health Education Center system and local pharmacist associations.

Fourth, the commenters' concern presupposes that CE providers will not increase the number and type of contact-hour programs to meet the needs of pharmacists in North Carolina. The Board deems that presupposition unwarranted.

Finally, the Board notes that the amendments to Rule .2201 were suggested by the Tripartite Committee, a body composed of representatives from the Board of Pharmacy, the North Carolina Association of Pharmacists, the schools of pharmacy in North Carolina, and practitioners from a variety of settings and geographical locations. Accordingly, a wide variety of viewpoints informed the amendments.

As required by North Carolina law, the amendments to Rule .2201 now go to the RRC for review. The Board anticipates that the RRC will demand some technical changes in the language, but that amended Rule .2201 will be effective January 1, 2008.

Item 2148 – Reminder Concerning Rule .2512, Pharmacist Work Conditions

October 1, 2007, marked the beginning of the Board's enforcement of Rule .2512, Pharmacist Work Conditions. Pharmacists will recall that the rule provides:

> A permit holder shall not require a pharmacist to work longer than 12 continuous hours per work day. A pharmacist working longer than six continuous hours per work day shall be allowed during that time period to take a 30 minute meal break and one additional 15 minute break.

This rule was effective April 1, 2007 – this following nearly nine years of litigation over the Board's authority to promulgate the rule.

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Public Hearing Garners Recommendations on Use of Medication Guides

Participants in a public hearing held in June 2007 by the Food and Drug Administration (FDA) Center for Drug Evaluation and Research suggested ways to improve the FDA Medication Guide program. The program provides for the distribution of FDA-approved written patient information for certain medications that pose serious and significant public health concerns.

FDA officials heard testimony from a member of Congress and 40 individuals representing academia, consumers and consumer groups, the pharmaceutical industry, health care professional groups, practicing physicians, pharmacists, and pharmacy organizations.

Participants acknowledged the importance of patients receiving appropriate risk information in the form of Medication Guides to make informed decisions about certain prescribed medications. Some said the current program is too cumbersome and lacks a standard distribution system. Participants urged FDA to increase awareness of Medication Guides, make them easier to read and understand, move toward facilitating electronic distribution, and consider combining the information contained in Medication Guides with other information such as in Consumer Medication Information.

The public hearing is summarized on the FDA Web site at *www.fda.gov/cder/meeting/medication_guides_200706.htm.*

Reporting Makes a Difference

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 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.*

In both Institute of Medicine (IOM) reports, *To Err is Human: Building a Safer Health System,* and *Identifying and Preventing Medication Errors,* the importance of error reporting is highlighted. The reports suggest that greater effort is needed to identify medication errors in most care settings, both to measure the extent and scope of errors and to assess the impact of prevention strategies. Although no single recommendation or activity offers a full solution to medical error, error prevention experts agree that successful error reduction strategies depend heavily on responsible detection and open reporting of errors.

According to the IOM report, reporting programs, whether voluntary or mandatory, must satisfy two primary purposes:

1. to hold providers accountable for performance and patient safety; and
2. to provide information that leads to new knowledge and improved patient safety.

Reports to voluntary systems typically come from front-line practitioners or others similarly close to the error, who can best describe the specific conditions that led to that error. Better error descriptions make possible more effective analysis of the system-based causes of errors. This first-hand reporting and the improved analysis it affords has been used by error prevention experts to create a "road map" for improvement that easily and realistically can be extrapolated and implemented at the broadest variety of health care organizations. These practical recommendations for safe practice have been established, published, and widely disseminated throughout the health care community.

Further, voluntary reporting programs have learned that many errors are caused by factors outside the health care practice site and beyond the direct control of a health care practitioner. Thus, safe practice recommendations have been communicated to medical device manufacturers, pharmaceutical companies, automation technology companies, health care reimbursement systems, and others less directly involved in patient care, but nonetheless influential in the safe provision of care.

The success of current voluntary reporting systems also stems from the trust and respect that has typically developed between reporters and recipients who use the information to improve patient safety across the nation. Reporting is perceived to have immense value when those who report an error or potentially hazardous situation can readily see that the information is swiftly acted upon and used confidentially and proactively to develop and publish safe practice recommendations that can prevent errors.

The USP-ISMP Medication Errors Reporting Program (MERP) operated by the United States Pharmacopeia (USP) in cooperation with ISMP is a confidential national voluntary reporting program that provides expert analysis of the system causes of medication errors and disseminates recommendations for prevention. Regulatory agencies and manufacturers are notified of needed changes in products when safety is of concern.

Without reporting, such events may go unrecognized and thus important epidemiological and preventive information would be unavailable. Errors, near-errors, or hazardous conditions may be reported to the program. These include, but are not limited to, administering the wrong drug, strength, or dose of medications; confusion over look-alike/sound-alike drugs; incorrect route of administration; calculation or preparation errors; misuse of medical equipment; and errors in prescribing, transcribing, dispensing, and monitoring of medications.

Providing causative information on actual or potential errors, or near misses to USP and ISMP, which is automatically shared with FDA and the involved manufacturers, has resulted in drug name changes. For example:

- Losec® (error reports indicating mistaken as Lasix®) to Prilosec®,
- Levoxine (error reports indicating mistaken as Lanoxin®) to Levoxyl®,
- Reminyl® (error reports indicating mistaken as Amaryl®) to Razadyne™ (and unfortunately new error reports show Razadyne being mistaken as Rozerem™)

♦ and the most recent, Omacor® (error reports indicating mistaken as Amicar®) to Lovaza.

To those who report medication errors, keep up the great work. The actions resulting in the name changes listed above, alone, demonstrate the tremendous impact you make when you report your experiences to USP-ISMP MERP. Many other error reports have resulted in manufacture label and stock bottle changes. For more information on reporting incidents, visit *www.ismp.org* and click on "Report Errors."

FDA Finds Consumers Still Buying Potentially Risky Medications via Internet

FDA continues to warn the American public about the dangers of buying medications over the Internet.

New data collected by FDA show that consumers who are trying to save money on prescription drugs need not take chances by buying prescription drugs from foreign Internet sites because low-cost generic versions are available in the United States. These findings also indicate that some consumers are likely buying foreign drugs online to avoid having to obtain a prescription from their doctors or health care professionals, as many Web sites do not require a prescription.

FDA urges consumers to obtain prescriptions from their doctors or other health care professionals before using prescription drugs, stating that the use of prescription medications without a prescription is an "intrinsically unsafe practice." FDA also encourages consumers to review *www.fda.gov* for information on buying medications online before making such purchases.

FDA cites the following potential risk factors associated with buying medications from unregulated Internet sellers:

♦ inadequate labeling for safe use;
♦ inappropriate packaging and, therefore, uncertain product integrity;
♦ possible previous withdrawal from the US market for safety or efficacy reasons;
♦ drug-specific risks requiring initial screening and/or periodic patient monitoring;
♦ potential harm or abuse, such as with the use of controlled substances; and
♦ potential drug-drug interactions.

Recent examinations of a sample of drugs shipped to US consumers found several drugs are associated with higher risks if used without the supervision of a doctor or health care professional. For example: the use of warfarin requires close monitoring to prevent stroke or death; amoxicillin and other antibiotics should not be used for self-treatment because of the risk of antibiotic-resistant infections; levothyroxine use requires close monitoring to ensure effective treatment; and clopidogrel may pose increased risk of cardiac events, such as heart attack, if used in suboptimal doses, which might be found in imported tablets.

Improper labeling also presents a risk to consumers. For example, alendronate sodium labeling should warn patients of significant side effects with improper use. In addition, imported eye drop preparations may have been manufactured under unsterile conditions, presenting a risk of contamination that may result in serious infections.

In light of these and other risks associated with medications purchased over the Internet, FDA stresses the importance of obtaining only FDA-approved drugs along with health care provider monitoring.

Death in Canada Tied to Counterfeit Drugs Bought via Internet

Canada's first confirmed death from counterfeit drugs purchased over the Internet reinforces long-stated concerns of the Canadian Pharmacists Association (CPhA), the association states in a recent press release.

A British Columbia coroner's report concludes that pills bought from a fake online pharmacy are to blame for the March death of a Vancouver Island woman. These drugs were later determined to be contaminated with extremely high quantities of metal.

CPhA is calling on Canadian pharmacists to be especially vigilant and discuss these issues with patients when necessary.

Since 1999, NABP, through its Verified Internet Pharmacy Practice Sites™ program, has warned of the dangers of purchasing potentially counterfeit drugs from illegitimate online pharmacies.

FDA Sets Standards for Dietary Supplements

FDA recently issued a final rule requiring current good manufacturing practices (CGMP) for dietary supplements. The rule is intended to ensure that dietary supplements are produced in a quality manner, free of contaminants and impurities, and accurately labeled.

The regulations establish the CGMP needed to ensure quality throughout the manufacturing, packaging, labeling, and storing of dietary supplements. The final rule includes requirements for establishing quality control procedures, designing and constructing manufacturing plants, and testing ingredients and finished products, as well as requirements for record keeping and handling consumer product complaints.

Manufacturers also are required to evaluate the identity, purity, strength, and composition of their dietary supplements. If dietary supplements contain contaminants or lack the dietary ingredient they are represented to contain, FDA would consider those products to be adulterated or misbranded.

FDA also issued an interim final rule that would allow manufacturers to request an exemption to the CGMP requirement for 100% identity testing of specific dietary ingredients used in the processing of dietary supplements. To be eligible for an exemption, the manufacturer must provide sufficient documentation that less frequent testing would still ensure the identity of the dietary ingredients. FDA is soliciting comments from the public on the interim final rule until September 24, 2007. Comments may be addressed to the Division of Dockets Management Branch at *www.fda.gov/dockets/ecomments.*

The final CGMP and the interim final rule became effective on August 24, 2007. The rule has a three-year phase-in for small businesses. Companies with more than 500 employees have until June 2008, companies with fewer than 500 employees have until June 2009, and companies with fewer than 20 employees have until June 2010 to comply with the regulations.

The FDA Web site provides background information at *www.cfsan.fda.gov/~dms/dscgmps7.html* and a fact sheet at *www.cfsan.fda.gov/~dms/dscgmps6.html.*

More information is available on the FDA Unapproved Drugs Web site at *www.fda.gov/cder/drug/unapproved_drugs/default.htm.*

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The Board elected to give a six-month grace period during which pharmacists, pharmacist-managers, and permittees could make appropriate adjustments to comply with the rule. Board staff expects pharmacists and pharmacies to be in compliance with Rule .2512.

Item 2149 – Renewal of Permits for "Internet Pharmacies"

Board staff reminds any pharmacy that meets the definition of "Internet pharmacy" under 21 NCAC 46.1317(17) that it will **not** be eligible to renew an existing permit for 2008 unless the pharmacy meets all the requirements of 21 NCAC 46.1601(d), which requires Verified Internet Pharmacy Practice Sites™ (VIPPS®) accreditation and various disclosure requirements. One current permit holder has asked whether a pending application for VIPPS accreditation will allow renewal. The answer is **no.** And permittees are reminded that any "false representations or withheld material information in connection with securing a . . . permit" is grounds for discipline including revocation or voiding of the permit. NCGS §§90-85.38(a)(1), (c).

Item 2150 – "Tamper Resistant" Prescription Pads for Medicaid Prescriptions

Pharmacists in the state undoubtedly are aware that Congress amended the Medicaid statute to state that pharmacies will not be reimbursed for filling Medicaid prescriptions "for which the prescription was executed in written (and non-electronic) form unless the prescription was executed on a tamper-resistant pad." 42 USC §1936b(i)(23). There are innumerable policy concerns and questions that attend this amendment. Almost none of those questions were asked or debated because the amendment was tacked onto a defense appropriation bill without so much as notice to the pharmacy profession, much less any debate. Notwithstanding, the requirement is now law and the Centers for Medicare and Medicaid Services (CMS) has not wavered from its intent to begin enforcement on October 1, 2007.

A number of pharmacists have asked Board staff what the Board intends to do with respect to this statute. The answer, put simply, is nothing. A prescription that does not meet the tamper-resistant standard is not "illegal" in any sense. Rather, it is simply ineligible for Medicaid reimbursement. Thus, the statute is purely a condition-of-payment regulation and thus not within the Board's jurisdiction to "enforce." Pharmacists with questions about this program should contact the North Carolina Division of Medical Assistance, CMS, or both.

Item 2151 – Wholesale Prescription Drug Distributors Laws' Applicability to Pharmacies

Board staff is frequently asked whether and under what circumstances a transfer of prescription drugs to another pharmacy could trigger wholesaler obligations. Dan Ragan – the drug administrator for the North Carolina Department of Agriculture and Consumer Services, Food and Drug Protection Division – clarifies. North Carolina Wholesale Prescription Drug Distributors Laws provide (NCGS 106-145.2(10)(e)):

> The sale, purchase, or trade of a prescription drug or an offer to sell, purchase or trade a prescription drug for emergency medical reasons. Emergency medical reasons include transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage when the gross dollar value of the transfer does not exceed 5% of the total prescription drug sales revenue of either the transferor or transferee pharmacy during a 12 consecutive month period.

Transfers between pharmacies that fall outside these guidelines would require a North Carolina wholesaler license. Note that the simple sale of excess stock to another pharmacy would be a wholesale activity. Pharmacists should also be aware that federal pedigree requirements could bear on transfers. And transfer of controlled substances between pharmacies requires compliance with all pertinent provisions of the federal Controlled Substances Act and associated regulations.

Item 2152 – 2008 Renewals Begin November 1

Please go to the Board's Web site, *www.ncbop.org*, and follow the prompts to renew online beginning November 1, 2007. While there is a small charge for this service, it does enable pharmacists and others to get immediate evidence of renewal and the speedy processing of their applications. **This is especially important for hospital pharmacists who may be facing a visit from The Joint Commission in early 2008.** There is no doubt that online renewals are the quickest and most certain way to provide evidence of current licensure. An immediate confirmation is available for all online renewals with certificates being mailed within approximately three days of the online process. You are encouraged to take advantage of the online renewal process.

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