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Item 2227 – 2011 Legislative Session Brings Changes to Pharmacy Practice

The North Carolina General Assembly adjourned its long session in June. The General Assembly passed, and Governor Bev Perdue signed, several bills that impact pharmacy practice.

Photo Identification Prior to Dispensing Certain Controlled Substances

S474 (Session Law 2011-349) requires that pharmacists obtain a valid identification – defined as a driver's license, a special Department of Transportation issued identification card, military identification card, or passport – prior to dispensing any Schedule II controlled substance or certain Schedule III controlled substances. The Schedule III controlled substances that require identification are the combination products identified at NCGS §90-91(d)(1) – (8) (eg, Vicodin® and its equivalents).

Pharmacists are required to "retain this identifying information on the premises or at a central location apart from the premises as part of its business records for a period of three years." Pharmacists are also required to make identifying information available to those persons legally authorized to access the North Carolina Controlled Substance Reporting System (CSRS) within 72 hours of a request. The statute specifies that this availability requirement may be satisfied by submitting identifying information to the CSRS electronically. However, officials at the Drug Control Unit of the North Carolina Department of Health and Human Services (which administers the CSRS) report that the system is not configured to receive such information and offers no timeline as to if or when such capability will exist.

The statute specifies that the person seeking dispensing of a covered controlled substance does not have to be the same person to whom the prescription was issued. But whoever seeks to obtain the prescription must present one of the authorized forms of identification.

This statute does not apply to hospitals and certain other "health care facilities" as defined in the North Carolina General Statutes when controlled substances are delivered "for the benefit of residents or patients of such health care facilities."

This statute is **effective March 1, 2012.**

Electronic Tracking of Pseudoephedrine Sales

H12 (Session Law 2011-240) requires all "retailers" to submit required information to the National Precursor Log Exchange – or NPLEx (not to be confused with NAPLEX®) – an electronic tracking system for pseudoephedrine sales administered by the National Association of Drug Diversion Investigators. The statute specifies that this electronic system shall be used only if it "is available to retailers in the State without a charge for accessing the system."

As pharmacists know, the pseudoephedrine sales statutes are administered by the Drug Control Unit of the North Carolina Department of Health and Human Services, not the North Carolina Board of Pharmacy. In an effort to assist that unit, however, the Board will be passing along information about implementation of this statute by electronic mail to all pharmacies in the state. Pharmacist managers should watch their Board-identified electronic mail account for further information.

This statute is **effective January 1, 2012.**

Administration of Flu Vaccine to Patients Age 14 and Up

The North Carolina Association of Pharmacists (NCAP) sought passage of a bill that would greatly increase pharmacists' authority to administer vaccines. The broader bill passed the Senate, but was referred to a subcommittee in the House. Near the end of the session, though, a provision was added to S609 (Session Law 2011-315) allowing any pharmacist who meets the immunizing pharmacist requirements of Board Rule .2507 to administer influenza vaccine to patients aged 14 years and older. That provision was **effective June 27, 2011.**

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2011-2012 Influenza Vaccines Approved by FDA

Food and Drug Administration (FDA) announced that it has approved the 2011-2012 influenza vaccine formulation for all six manufacturers licensed to produce and distribute influenza vaccine for the United States. The vaccine formulation protects against the three virus strains that surveillance indicates will be most common during the upcoming season and includes the same virus strains used for the 2010-2011 influenza season. The Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) recommends that everyone six months of age and older receive an annual influenza vaccination. Details about the new vaccines are available in an FDA news release at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm263319.htm,* and information about the ACIP recommendations are available on the CDC Web site at *www.cdc.gov/media/pressrel/2010/r100224.htm.*

Another TEAspoon – mL Mix-Up

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 few weeks ago ISMP heard from a mother whose child was accidentally given an overdose of an antibiotic. A pharmacist accidentally provided instructions on the prescription label for her child to receive 3.5 **TEA**spoonfuls of a liquid antibiotic for 10 days instead of 3.5 **mL.** The medication was dispensed in a 60 mL bottle. The child was given 3.5 **TEA**spoonfuls each day for three days. By the fourth day only one **TEA**spoonful (5 mL) was left in the bottle, so the mother called the pharmacy and learned that the dosage amount on the label was incorrect. The child experienced bouts of diarrhea and a yeast and fungal infection in the vaginal area.

Mix-ups between teaspoons and mL are common and have been happening for many years. ISMP first mentioned the problem in its June 28, 2000 newsletter article, "Oral liquid medications may be more vulnerable to errors than previously recognized" *(www.ismp.org/Newsletters/acutecare/articles/20000628_2.asp).* ISMP has received more than 50 similar errors in recent years, most resulting in patient harm. It is time to standardize to a single way of measuring liquid medications, using the metric system with volumes expressed in mL. If we all used the metric measurement when prescribing, dispensing, and administering medications, these types of mix-ups would no longer happen.

In response to ongoing errors, in June 2009, ISMP called for elimination of **TEA**spoonful and other non-metric measurements to prevent errors *(www.ismp.org/pressroom/PR20090603.pdf).* In May 2011, FDA published a guidance suggesting ways for manufacturers to improve the labeling of over-the-counter (OTC) liquid drug products to minimize the risk of accidental overdoses *(www.fda.gov/Drugs/DrugSafety/MedicationErrors/ucm253715.htm).* Unfortunately, the guidance still mentions both **TEA**spoon and **TABLE**spoon. The Consumer Healthcare Products Association has also published guidelines *(www.chpa-info.org/scienceregulatory/Voluntary_Codes.aspx#volumetricmeasure)* to improve the format for volume measures within the dosing directions for OTC products. The abbreviation "mL" is recommended for use on accompanying dosing devices that measure OTC oral liquid drug products so they match the dosing directions in labeling for children. The group has also told companies to avoid directions that mention tablespoon, cubic centimeters (cc), dram, fluid ounce (Fl Oz), and dropper(ful), and to use mL as the sole unit of measure in the dosing directions or, alternatively, mL **and** the **"TEA**spoonful" equivalent (eg, 5 mL (1 **TEA**spoon)).

While these are excellent moves to improve safety, ISMP would like to see the complete elimination of **TEA**spoonful amounts and the abbreviation "tsp." Doses expressed using mL alone would be the best way to eliminate the risk of mix-ups. The ISMP board fully supports this initiative and is currently in the process of approving a formal ISMP position on this issue. ISMP hopes the health care industry will also support this initiative.

'Know Your Dose' Campaign Aims to Prevent Acetaminophen Overdose

The Acetaminophen Awareness Coalition, has launched *www.KnowYourDose.org,* a Web site aimed to educate consumers about the dangers of acetaminophen overdose and how to ensure that the correct, safe dosage is administered. "Know Your Dose" stresses to patients the importance of checking the labels of both prescription and over-the-counter medications for the amount of acetaminophen contained in order to ensure that they do not exceed recommended maximum dosage levels. Health care providers may order a free Know Your Dose kit that includes materials to help educate patients about safely using medications containing acetaminophen. The kit includes posters, information cards for patients, and a display holder for use in distributing the cards. Members of the Acetaminophen Awareness Coalition include Alliance for Aging Research, American Academy of Nurse Practitioners, American Academy of Physician Assistants, American Pain Foundation, American Pharmacists Association, CHPA Educational Foundation, National Association of Boards of Pharmacy® (NABP®), National Association of Chain Drug Stores, National Community Pharmacists Association, National Consumers League, and the National Council on Patient Information and Education. The campaign was developed under advisement from the American Academy of Pediatrics, CDC, and FDA.

Methylene Blue and Linezolid May Interact With Certain Psychiatric Medications

FDA has issued two safety communications regarding adverse drug reactions in patients taking certain psychiatric medications, and also given methylene blue or linezolid (Zyvox®). Specifically, FDA has received reports of serious central nervous system reactions in patients taking serotonergic psychiatric medications who are also given methylene blue, a product commonly used in diagnostic procedures. FDA explains that "[a]lthough the exact mechanism of this drug interaction is unknown, methylene blue inhibits the action of monoamine oxidase A – an enzyme responsible for breaking down serotonin in the brain. It is believed that when methylene blue is given to patients taking seroto-

nergic psychiatric medications, high levels of serotonin can build up in the brain, causing toxicity. This is referred to as Serotonin Syndrome. Signs and symptoms of Serotonin Syndrome include mental changes (confusion, hyperactivity, memory problems), muscle twitching, excessive sweating, shivering or shaking, diarrhea, trouble with coordination, and/or fever." FDA has published a list of the serotonergic psychiatric medications that can interact with methylene blue, available at *www.fda.gov/Drugs/DrugSafety/ucm263190.htm#table,* and advises that "Methylene blue should generally not be given to patients taking serotonergic drugs." Exceptions and more information for health care providers and patients are available in an FDA Drug Safety Communication available at *www.fda.gov/Drugs/DrugSafety/ucm263190.htm.*

Similar reports of interactions between certain serotonergic psychiatric medications and the antibacterial drug, linezolid (Zyvox) have also been reported to FDA. FDA has published a list of the serotonergic psychiatric medications that can interact with linezolid, available at *www.fda.gov/Drugs/DrugSafety/ucm265305.htm#table,* and advises that "Linezolid should generally not be given to patients taking serotonergic drugs." Exceptions and more information about the linezolid interaction for health care providers and for patients are available in an FDA Drug Safety Communication available at *www.fda.gov/Drugs/DrugSafety/ucm265305.htm.*

NABP Looking For Item Writers to Develop New Questions for NAPLEX, MPJE, FPGEE, and PCOA

NABP is seeking individuals to serve as item writers for the North American Pharmacist Licensure Examination® (NAPLEX®), Multistate Pharmacy Jurisprudence Examination® (MPJE®), the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®), and the Pharmacy Curriculum Outcomes Assessment® (PCOA®).

Pharmacists in all areas of practice and faculty from schools and colleges of pharmacy are encouraged to apply. To be considered as an item writer for the NAPLEX and MPJE, pharmacists must have at least two years of pharmacy practice experience.

Item writers will be selected based on the specific needs of the programs. Those who are chosen will be asked to attend a workshop at NABP Headquarters with travel, lodging, and ancillary expenses paid by NABP.

Attendees will receive detailed instructions and training materials describing the item-writing process and content-related requirements for their designated examination. Item writers will then be asked to develop new test items that will be considered for inclusion in NABP licensure and certification and assessment examination programs.

The NAPLEX is an examination consisting of 185 selected-response and constructed-response test questions, the majority of which are asked in a scenario-based format, that covers important information about the knowledge, judgment, and skills an entry-level pharmacist is expected to demonstrate. The three competency areas of the examination are:

- Assess pharmacotherapy to ensure safe and effective therapeutic outcomes
- Assess safe and accurate preparation and dispensing of medications
- Assess, recommend, and provide health care information that promotes public health

The MPJE is a computer-based examination that consists of 90 select-response items. It combines federal and state-specific questions that test the pharmacy jurisprudence knowledge of prospective pharmacists on the following areas:

- Legal aspects of pharmacy practice, including responsibilities with regard to the distribution and dispensing of pharmaceuticals and for the care of patients
- Licensure, registration, certification, and operational requirements
- Regulatory structure and terms of the laws and rules that regulate or affect pharmacists, pharmacies, manufacturers, and distributors

The FPGEE is a comprehensive examination consisting of 250 multiple-choice questions that measures four major pharmacy content areas:

- Basic biomedical sciences
- Pharmaceutical sciences
- Social/behavioral/administrative pharmacy sciences
- Clinical sciences

The PCOA is a 220-question, multiple-choice assessment that is administered to pharmacy students in all four professional years. The assessment follows a blueprint that reflects actual curriculum hours established through a national sample of PharmD programs in the US and is broken down into the following four areas:

- Basic biomedical sciences
- Pharmaceutical sciences
- Social, behavioral, and administrative pharmacy sciences
- Clinical sciences

Interested individuals should mail or fax a letter of interest indicating their current practice/educational setting, specialties/certifications, and years of experience, along with a resume or curriculum vitae via mail to NABP Executive Director/Secretary Carmen A. Catizone at 1600 Feehanville Drive, Mount Prospect, IL 60056; via e-mail at exec-office@nabp.net; or via fax at 847/391-4502.

Please note, applications are accepted on a continuous basis and kept on file for a period of five years. For more information about item writing, contact NABP at custserv@nabp.net.

Clarification Regarding Pradaxa Storage and Handling Requirements

An FDA alert released in March 2011 details important storage and handling guidelines for Pradaxa® (dabigatran etexilate mesylate) capsules, as reported in the third quarter NABP *National Pharmacy Compliance News.* As a point of clarification, the FDA-approved Pradaxa label states that once opened, the product must be used within 30 days. FDA is currently reviewing data that indicate no significant loss of potency up to 60 days after the bottle is opened as long as Pradaxa is stored in the original bottle and the handling requirements are met. An FDA Drug Safety Communication available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm249005.htm* provides more details, and the manufacturer's Pradaxa safety information is available at *www.pradaxa.com* by clicking on the link for "Important Storage & Handling Information" at the top of the page.

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S246 is the NCAP-sponsored bill to more broadly expand pharmacists' ability to serve the public health by administering vaccines, and it could come up for action in the 2012 short legislative session.

Pharmacy Audit Rights

H644 (Session Law 2011-375), introduced by Representative (and pharmacist) Tom Murry sets forth requirements aimed at curbing abusive audit practices by pharmacy benefit managers and other third-party payers. It contains notice requirements, limitations on the types and numbers of records that may be required by an auditor, limitations on the scope and breadth of audits, and procedural protections that an auditor must afford a pharmacy.

Importantly from a Board of Pharmacy standpoint, the statute provides that recoupment claims may **not** be based on "documentation requirements in addition to or exceeding requirements for creating or maintaining documentation prescribed by the State Board of Pharmacy" or on "a requirement that a pharmacy or pharmacist perform a professional duty in addition to or exceeding professional duties prescribed by the State Board of Pharmacy." Board staff has received numerous calls from pharmacists confused about legal requirements concerning prescriptions, often after an insurance auditor has asserted a recoupment claim based on a supposedly "illegal" prescription. Board staff's experience is that these assertions of "illegality" by auditors often bear little or no resemblance to actual legal requirements.

This statute is **effective January 1, 2012.**

Bills Affecting the Practice of Pharmacy That Remain Alive for Consideration in the 2012 Short Session

As noted above, S246 concerning pharmacist administration of vaccines passed the Senate and remains alive in the House. Pharmacists should contact NCAP (919/967-2237) for more information on how to provide support for passage of S246.

H606 went through a number of substantial revisions during the legislative session. At one point, H606 would have granted sheriffs and deputy sheriffs direct access to controlled substance prescription files in a pharmacy. That provision was **removed from the bill.** A separate provision to give sheriffs access to the CSRS remains in the bill. Pharmacists are advised that neither sheriffs nor deputy sheriffs have any present legal authority to access the CSRS. A pharmacist faced with a request for such information by a sheriff or deputy sheriff should refer the requester to Bill Bronson, program manager, Drug Control Unit, North Carolina Department of Health and Human Services at 919/933-1765.

Item 2228 – Unit Dose Technician Rule Now Effective

With the General Assembly's adjournment in June, Board Rule .1418 governing use of validating technicians for unit dose medication systems is now in effect. Pharmacist managers of in-patient hospital pharmacies should, if they have not already, review the rule carefully. The text of the rule may be found here: *www.ncbop.org/pdf/21NCAC46.1418SupervisionUnitDoesMedSys.pdf.*

Item 2229 – Nurse Practitioners May Now Prescribe Refills for Schedule III Controlled Substances

A rule change implemented by the Medical and Nursing Boards has now aligned nurse practitioner (NP) and physician assistant (PA) prescribing authority where Schedule III controlled substances are concerned. Pharmacists may recall that, until this change, nurse practitioners were not allowed to write refills on a Schedule III controlled substance. That limitation has now been lifted. Both NPs and PAs may write for 30-day supplies of Schedule III controlled substances, and both NPs and PAs may authorize refills as allowed under federal law.

Item 2230 – Addition of a DEA Number to a Controlled Substance Prescription

Board staff has received a number of inquiries from pharmacists asking whether it is "legal" for a pharmacist to add a Drug Enforcement Administration (DEA) number to a controlled substance prescription when the prescriber omits that information. These inquiries have been provoked, it appears, by a number of third-party plan auditors who have demanded recoupment based on supposedly "illegal" controlled substance prescriptions on which the pharmacist has added the prescriber's DEA number (see Item 2227 in this *Newsletter* for commentary on how the recently enacted Pharmacy Audit Rights Act should curtail this sort of abusive audit practice).

Assertions that the addition of a DEA number to a controlled substance by a pharmacist is "illegal" are, in a word, false. DEA's own Web site states that "pharmacists are instructed to adhere to state regulations or policy" concerning changes or additions to controlled substance prescriptions, and recent correspondence from DEA confirms that statement remains DEA policy. Furthermore, Board Rule .2301 (21 NCAC 46.2301) specifically states that pharmacists may retain and add a DEA number to a controlled substance prescription when the provider inadvertently leaves it off.

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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