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Item 2231 – Questions Regarding S.L. 2011-349, Photo Identification Prior to Dispensing Certain Controlled Substances

As reported in Item 2227 of the October 2011 North Carolina Board of Pharmacy *Newsletter,* the North Carolina General Assembly passed, and Governor Bev Perdue signed into law S.L. 2011-349, which requires presentation of photo identification prior to the dispensing of certain controlled substances. The statute is an amendment to the North Carolina Controlled Substances Act and codified at NCGS §90-106.1 and is effective March 1, 2012. Board staff has received numerous questions about this statute. In response, Board staff has developed the below frequently asked questions (FAQs) (which is also found at the Board Web site, *www.ncbop.org).* Because this law is part of the North Carolina Controlled Substances Act, the Drug Control Unit of the North Carolina Department of Health and Human Services has administrative responsibility. Bill Bronson, the head of the Drug Control Unit, has reviewed these FAQs and agrees with its content.

1. **Why did the Board pass this law?**

   The Board did not pass this law. It is a statute passed by the North Carolina General Assembly during the 2011 Session.

2. **For which controlled substances is photo identification required prior to dispensing?**

   NCGS §90-106.1 imposes an identification prior to dispensing **all Schedule II controlled substances** and **"Schedule III controlled substances listed in subdivisions 1 through 8 of G.S. 90-91(d)."** Those subdivisions list the "combination" Schedule III controlled substances – ie, Vicodin® and the like.

3. **What is an acceptable form of identification?**

   The statute states that **only** four types of identification are acceptable: a driver's license, a special identification card issued by the North Carolina Department of Motor Vehicles, a military identification card, and a passport. This requirement is likely to pose access problems for a number of patient populations.

4. **May a pharmacist accept an expired identification?**

   No. The statute specifies that the identification be "unexpired." This requirement is likely to pose particular access problems for elderly patients.

5. **If a patient lacks an unexpired identification that meets the statutory requirement, may someone else obtain the prescription?**

   Yes. The statute specifies that "[n]othing . . . shall be deemed to require that the person seeking the dispensation and the person to whom the prescription is issued be the same person." If a patient lacking the requisite identification is able to convince a friend or family member to present his or her identification, that person may receive the prescription on behalf of the patient. The identification of the person receiving the prescription must be documented.

6. **Does the "other person picking up the prescription" provision raise patient privacy issues?**

   Potentially. If the patient for whom the prescription was issued is not present at pickup, questions could arise as to whether person picking up is authorized by the patient to do so. Board staff recommends that pharmacists ask patients to designate authorized "pickup persons" and that pharmacists document that authorization in the patient profile or other appropriate record.

7. **When a patient who presented identification for initial dispensing returns for a refill, and the pharmacist knows it is the same person seeking the refill, does the pharmacist have to again obtain and record the identification?**

   Board staff believes the answer to this question is "no." There is no apparent purpose served by requiring a second presentation and recording of an identification in this circumstance. Nor does repeat identification check in this

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FDA Recommends Use of Sterile Needle and Syringe for Administration of Inactivated Influenza Vaccines

Food and Drug Administration (FDA) recommends that health care providers use a sterile needle and syringe to administer inactivated influenza vaccines. The recommendation was released in response to questions regarding the use of jet injector devices to administer inactivated influenza vaccines. FDA advises that "inactivated influenza vaccines that are approved by FDA have information in their labeling stating how the vaccines should be administered, such as, by intramuscular (IM) or intradermal (ID) administration." Further, FDA clarifies its October 21, 2011 communication "to inform the public that inactivated influenza vaccines labeled for IM injection are intended for administration using a sterile needle and syringe. There is one inactivated influenza vaccine labeled for ID administration, this vaccine is supplied in its own pre-filled syringe. The live attenuated influenza vaccine is given through the nose as a spray; the sprayer is not a jet injector." FDA also notes the following:

- Currently, there is only one vaccine, Measles, Mumps, and Rubella (MMR), that is approved and specifically labeled for administration by jet injector.
- Safety and effectiveness information that would support labeling inactivated influenza vaccines for delivery by jet injector have not been submitted to FDA.
- At this time, there are no inactivated influenza vaccines that are approved and specifically labeled by FDA for administration by jet injector.

FDA recommends that all approved vaccines, including influenza, be administered in accordance with their approved labeling, and FDA advises that if a vaccine has been approved for administration with a jet injector, information specifically addressing vaccine use with a jet injector will appear in the vaccine labeling. Additional background information is available in the communication posted on the FDA Web site at *www.fda.gov/BiologicsBloodVaccines/Vaccines/QuestionsaboutVaccines/ucm276773.htm.*

The Centers for Disease Control and Prevention continues to encourage people to get vaccinated throughout the flu season, which can begin as early as October and last as late as May. For information about the flu vaccine visit *www.cdc.gov/flu.*

'Tell Back' Works Best to Confirm Patient Understanding

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.*

In the past few years, multiple studies have demonstrated that patients often leave medical encounters with a poor understanding of their health conditions and recommended treatment. One recent study on this subject demonstrates the low level of understanding patients have about follow-up care and medication therapy upon discharge from the emergency department (Engel KG et al. Patient Comprehension of Emergency Department Care and Instructions: Are Patients Aware of When They Do Not Understand? Ann Emerg Med. Available on the journal Web site).

Given the importance of patient understanding of medical information, there are surprisingly few studies that point out how to approach this task. However, a study published in 2008 offers some insight into what approach to assessing understanding of medical information patients most prefer and perceive to be the most effective (Kemp EC, et al. Patients Prefer the Method of "Tell Back-Collaborative Inquiry" to Assess Understanding of Medical Information. J Am Board Fam Med 2008;21(1):24-30). Researchers tested three types of inquiry about the patient's understanding:

- Yes-No
- Tell Back-Directive
- Tell Back-Collaborative

The Yes-No approach asked closed-ended questions to assess patient understanding. (Example: "I've given you a lot of information. Do you understand?") The Tell Back-Directive method used open-ended questions that were physician-centered and paternalistic in that it was clear authority and control still remained with the physician. (Example: "It's really important that you do this exactly the way I explained. What do you understand?") The Tell Back-Collaborative approach used open-ended questions that were patient centered, making it clear that power and responsibility were shared between the health care provider and patient. (Example: I imagine you are really worried about your blood pressure. I've given you a lot of information. It would be helpful to me to hear your understanding about your clot and its treatment.)

Patients showed a significant preference for the Tell Back-Collaborative inquiry over other tested approaches. Because of the potential for embarrassment if patient misunderstandings are exposed, one might anticipate health care providers' reluctance to put patients "on the spot" with open-ended questions. But a collaborative approach to Tell Back allows the patient to save face for misunderstandings by acknowledging the large amount of information being provided. Patients might also view the request for Tell Back as evidence of the health care provider's care and concern for them personally, or evidence of the provider's attention to detail and competence. So, when counseling patients about their medications, instead of asking "Do you have any questions?" or "Do you understand?" ask them to restate their understanding of the information you provided in their own words within a shame-free, blame-free environment.

DEA Clarifications on Certification Process for Audits of EPCS Software

Drug Enforcement Administration (DEA) emphasizes that third-party audits of software applications for Electronic Prescriptions for Controlled Substances (EPCS) must encompass all applicable requirements in DEA regulations, including security, and must address "processing integrity" as set forth in the regulations. Further, DEA recommends that where questions or gaps may arise in reviewing a particular applica-

tion, federal guidelines set forth in National Institute of Standards and Technology Special Publication 800 – 53A should be consulted. DEA has also announced the first DEA-approved certification process for EPCS. Certifying organizations with a certification process approved by DEA pursuant to the regulations are posted on DEA's Web site at *www.deadiversion.usdoj.gov/ecomm/e_rx/thirdparty.htm#approved*. Detailed background information is provided in the Federal Register Notice, available for download at *www.gpo.gov/fdsys/pkg/FR-2011-10-19/pdf/2011-26738.pdf*.

'Script Your Future' Provides Tools and Outreach to Encourage Medication Adherence

United States Surgeon General Regina Benjamin called upon pharmacists, physicians, nurses, and other health care providers to talk with their patients about the importance of taking medications as directed to help prevent serious health complications at the recent launch of the national campaign, "Script Your Future." Benjamin also "encouraged patients with chronic conditions to speak with their health care professionals about their medication" as noted in a press release. A survey released by the National Consumer League, the organization that developed Script Your Future, indicates that "patients who do not always take their medication as directed are less likely to have received a full explanation of the consequences of their condition, and are less convinced of the importance of adherence." The Script Your Future campaign is targeting six regional areas with outreach activities and advertising, and more information is available at *www.ScriptYourFuture.org*. The campaign brings together "stakeholders in health care, business, and government to offer practical tools for patients to help them better adhere to their medication, and to help health care professionals better communicate with patients." More information about the campaign is available in a press release at *www.prnewswire.com/news-releases/us-surgeon-general-joins-baltimore-launch-of-the-national-script-your-future-campaign-to-highlight-importance-of-taking-medication-as-directed-133077423.html*.

FDA Releases 'Use Medicines Wisely' Video

FDA Office of Women's Health has released a new public service announcement (PSA) video titled, "Use Medicines Wisely," to help raise awareness about safe medication use. As stated in an FDA news release, "Millions of people benefit from FDA approved medications and are living longer productive lives. However, when medications are used incorrectly, they can cause serious injuries, even death. Many of these injuries can be prevented."

The video shows simple steps women can take to use medications wisely. Viewers are reminded to:

- Make a list of the medications they take
- Keep their medication list with them at all times
- Know the name of each medication, why they are taking it, how much to take, and when to take it
- Talk with their doctor, nurse, or pharmacist to find out how to safely use their medications

In addition to the video, a medications record-keeper, fact sheets, and other safe medication use resources are available on the FDA Web site.

Training Video Provides Tips on Preventing Pharmacy Robbery

Rx Pattern Analysis Tracking Robberies and Other Losses (RxPATROL) has released a training video discussing pharmacy robbery and how to prevent it. The video features a pharmacist and law enforcement liaison as they tour a pharmacy, evaluating security measures and discussing additional steps that can be taken to prevent robbery. RxPATROL is an initiative designed to collect, collate, analyze, and disseminate pharmacy theft intelligence to law enforcement throughout the nation. RxPATROL is designed to gather and disseminate critical information to help protect pharmacists, guard against potential robberies, and assist law enforcement in their efforts to successfully apprehend and prosecute those involved in controlled substance pharmacy crime. The training video can be accessed on the RxPATROL Web site at *http://rxpatrol.org/TrainingVideos.aspx*.

Nearly 20 Products Marketed as Natural Supplements Contain Sibutramine, FDA Warns

FDA has posted public warnings regarding 19 products, frequently marketed as natural supplements, and found to contain sibutramine, a controlled substance that was removed from the US market in October 2010 for safety reasons. These products pose a threat to consumers because sibutramine is known to substantially increase blood pressure and/or pulse rate in some patients and may present a significant risk for patients with a history of coronary artery disease, congestive heart failure, arrhythmias, or stroke. These products may also interact in life threatening ways with other medications a consumer may be taking. FDA warnings included products marketed as "Slender Slim 11," "Dream Body Slimming Capsule," "Acai Berry Soft Gel ABC," and 16 other product names. The products included in the warnings are being sold on Web sites and in some retail stores. FDA advises consumers not to purchase or use the products listed in the warnings. Consumers who have purchased any of these products should stop use immediately. And if consumers have experienced any negative side effects from using these products, they should consult a health care provider as soon as possible. The complete list of warnings is available on the FDA Web site at *www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm234592.htm*.

2012 Survey of Pharmacy Law Now Available

Serving as a convenient reference source for individuals seeking an overview of the state laws and regulations that govern pharmacy practice, the updated 2012 *Survey of Pharmacy Law* is now available and can be purchased online for $195 by visiting the NABP Web site at *www.nabp.net/publications*.

The *Survey,* produced in a CD format, consists of four sections including a state-by-state overview of organizational law, licensing law, drug law, and census data. Newly added this year, a question in Section 17, Wholesale Distributor Licensure Requirements, asks which state agency has regulatory authority over medical device distributors. In addition, a newly added question in Section 22, Electronic Transmission of Prescriptions: Computer-to-Computer, asks whether the state allows electronic prescribing of controlled substances.

Updates for the 2012 *Survey* were graciously provided by the state boards of pharmacy. In addition to the boards' support, NABP requested data from relevant health care associations for the *Survey's* prescribing authority and dispensing authority laws in Sections 24 and 25, and laws pertaining to the possession of non-controlled legend drugs and possession of controlled substances in Sections 26 and 27.

All final-year pharmacy students receive the *Survey* free of charge through the generous grant of Purdue Pharma L.P.

For more information on the *Survey,* please contact Customer Service via phone at 847/391-4406 or via e-mail at custserv@nabp.net.

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circumstance appear to be compelled by the North Carolina Controlled Substance Act's definition of "dispense."

8. What if one person drops off a prescription for filling and another arrives to pick up the prescription? From whom must the pharmacist obtain the requisite identification?

Board staff interprets the "person seeking dispensation" under the statute to be the person who arrives to pick up the prescription or to whom the prescription is delivered (see Question #9 below).

9. If a pharmacy provides delivery service, must delivery personnel obtain and record the identification information at the time of delivery?

Yes.

10. How can an out-of-state pharmacy that provides mail-service-only prescriptions to North Carolina patients comply with this identification requirement?

The statute, on its face, does **not** apply to out-of-state pharmacies. It applies strictly and exclusively to "each pharmacy holding a valid permit pursuant to G.S. 90-85.21." G.S. 90-85.21 sets forth the permit requirements for "each pharmacy **in** North Carolina." G.S. 90-85.21A, a separate statutory section and not a subsection of 90-85.21, sets forth the permit requirement for "any pharmacy operating **outside** the State."

11. Does this statute apply when dispensing to patients in hospitals or other health care facilities?

The statute excludes dispensing in "health care facilities, as that term is defined in G.S. 131E-256(b), when the controlled substances are delivered to the health care facilities for the benefit of residents or patients of such health care facilities." G.S. 131E-256(b) includes adult care homes, hospitals, home care agencies, hospices, nursing facilities, and "community-based providers of services for the mentally ill, the developmentally disabled, and substance abusers that are not required to be licensed under Article 2 of Chapter 122C of the General Statutes."

12. Does the identification check and record requirement apply to outpatient and/or employee pharmacy services at hospitals?

Yes. When a hospital (or other "health care facility") pharmacy provides controlled substances to employees who will then administer those substances to inpatients, the identification requirement does not apply (see Question #11 above). But if a hospital operates an outpatient pharmacy, dispensing is not being provided from that facility to "residents or patients," and the identification check and record provision applies.

13. What does the statute require the pharmacy to record?

The pharmacy must "document the name of the person seeking the dispensation, the type of photographic identification presented by the person seeking the dispensation, and the photographic identification number."

14. Must the pharmacy scan or otherwise image the identification?

No.

15. Does the statute specify a particular format for the documentation?

No.

16. Where and how long do I have to retain the documentation?

The documentation must be retained "on the premises or at a central location apart from the premises as part of its business records for a period of three years following the dispensation."

17. Can't I just send the identification documentation information with my North Carolina Controlled Substance Reporting System (CSRS) updates?

The statute contemplates transmittal of information through the CSRS as a means of maintaining documentation. The software currently used by the North Carolina CSRS is not, however, capable of receiving this information. Bronson reports his anticipation that the CSRS software will be upgraded to receive this information within the next 12 months. The Board will announce any upgrade information upon receiving it.

18. Who can access the identification information from my prescription files?

The statute limits access to those persons authorized to receive information from the Controlled Substance Reporting System:

> (1) Persons authorized to prescribe or dispense controlled substances for the purpose of providing medical or pharmaceutical care for their patients.
>
> (2) An individual who requests the individual's own controlled substances reporting system information.
>
> (3) Special agents of the North Carolina State Bureau of Investigation [SBI] who are assigned to the Diversion & Environmental Crimes Unit and whose primary duties involve the investigation of diversion and illegal use of prescription medication and who are engaged in a bona fide specific investigation related to enforcement of laws governing licit drugs. The SBI shall notify the Office of the Attorney General of North Carolina of each request for inspection of records maintained by the Department.
>
> (4) Primary monitoring authorities for other states pursuant to a specific ongoing investigation involving a designated person, if information concerns the dispensing of a Schedule II through V controlled substance to an ultimate user who resides in the other state or the dispensing of a Schedule

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> II through V controlled substance prescribed by a licensed health care practitioner whose principal place of business is located in the other state.
>
> (5) To a court pursuant to a lawful court order in a criminal action.
>
> (6) The Division of Medical Assistance for purposes of administering the State Medical Assistance Plan.
>
> (7) Licensing boards with jurisdiction over health care disciplines pursuant to an ongoing investigation by the licensing board of a specific individual licensed by the board.
>
> (8) Any county medical examiner appointed by the Chief Medical Examiner pursuant to G.S. 130A–382 and the Chief Medical Examiner, for the purpose of investigating the death of an individual.
>
> G.S. 90-113.74(c)

Note: Neither local law enforcement nor sheriff's departments have an independent authority to access the CSRS, and thus have no independent authority to access documented identification information under this statute.

Item 2232 – Update on Electronic Tracking of Pseudoephedrine Sales

As also reported in Item 2227 of the October 2011 *Newsletter,* the General Assembly passed and Governor Perdue signed into law S.L. 2011-240, which requires "retailers" to electronically report pseudoephedrine sales information through the National Precursor Log Exchange. This statute is effective January 1, 2012. As noted in the October 2011 *Newsletter,* the Drug Control Unit of the North Carolina Department of Health and Human Services has administrative responsibility for this statute, but Board staff agreed to act as a conduit for information about implementation of the statute. As of this writing (December 1, 2011), the Board has received no communications from Drug Control Unit concerning implementation.

Two questions have come to the attention of Board staff, however:

First, some pharmacies (perhaps driven to despair over the increasing record keeping burden) have decided to cease sales of any pseudoephedrine products except pursuant to a prescription. They have asked whether there is any Board of Pharmacy notification requirement in making that decision. There is not. Relatedly, while such a decision is understandable from the standpoint of a record keeping burden, Board staff urges pharmacies to think through such a decision carefully. Pseudoephedrine products do, of course, serve the legitimate health needs of many patients.

Second, do the pseudoephedrine-specific record keeping requirements apply to prescription-based dispensing? They do not. Pharmacists must, of course, maintain prescription records for such dispensing just as they would for any other product.

Item 2233 – 'Pain Clinic' Prescribing Redux: Increase in Illegitimate Prescriptions from Georgia

As pharmacists in the state are (or should be) well aware, proliferation of "pain clinics" through which prescription narcotic analgesics are trafficked for other than legitimate medical purposes raise substantial difficulties. Though the problem is a national one, to date the bulk of illegitimate prescriptions from pain clinics could be traced to Florida. In recent weeks, however, Board staff has received numerous calls from pharmacists in North Carolina concerning prescriptions from "pain centers" in Georgia.

Board staff have seen prescriptions from such pain centers in the Atlanta, GA, area, as well as the Tucker, GA, area. As with prescriptions often seen from Florida, the typical presentation is from a patient from outside of North Carolina (although this is not exclusively the case) who presents a prescription for various narcotics, especially oxycodone, and other controlled substances from a pain clinic in Georgia. If the pharmacist contacts the Georgia facility, he or she is typically unable to speak with the prescriber, but is "assured" by someone in the office that the prescription is "legitimate." Most, if not all, such prescriptions are **not** written for a legitimate medical purpose in the ordinary course of medical practice.

Pharmacists should be appropriately cautious. Filling such prescriptions when the pharmacist knows or reasonably should know that they were not written for a legitimate medical purpose can trigger liability under state and federal law. Moreover, filling even one such prescription is likely to result in a pharmacy being inundated with such prescriptions going forward, with the attendant safety risks to pharmacy personnel and patients.

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