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Only Physicians Are Permitted to Issue Multiple Prescriptions for a 90-Day Supply of Schedule II Medications

Amendments to N.J.A.C. 13:45H-7.5 (formerly 8:65-7.5), which became effective on January 3, 2012, establish requirements for the filling of multiple prescriptions for a Schedule II medication issued by a physician on a single date. Under recent amendments to N.J.S.A. 45:9-22.19, New Jersey physicians are permitted to issue multiple prescriptions so that a patient may receive up to a 90-day supply of a Schedule II medication. The statutory authority to issue such prescriptions, however, applies only to physicians. **All other prescribers in New Jersey, including advance practice nurses and physician assistants, are precluded from issuing multiple Schedule II prescriptions to a patient for a 90-day supply.** The language (below) makes clear how such prescriptions are to be filled:

N.J.A.C. 13:45H-7.5 Manner of Issuance of Prescriptions

(a) All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use and the full name, address, proper academic degree or other definitive identification of the professional practice for which he or she is licensed and registration number of the practitioner. All prescriptions for controlled substances, regardless of schedules, shall be presented to the pharmacist for filling within 30 days after the date when issued, except as provided in (a)1 below. A practitioner may sign a prescription in the same manner as he would sign a check or legal document (for example, J.H. Smith or John H. Smith). Where an oral order is not permitted, prescriptions shall be written in ink or indelible pencil or typewriter and shall be manually signed by the practitioner. The prescription may be prepared by a secretary or agent of the practitioner for the signature of the practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law or rules. A corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed by these rules.

1. When up to three separate prescriptions for a total of up to a 90-day supply of a Schedule II controlled substance are issued to a patient by a physician pursuant to N.J.S.A. 45:9-22.19 (P.L. 2009, c. 165), a pharmacist shall fill such prescriptions.
   i. All three prescriptions may be accepted at one time and held pending filling as indicated below:
      (1) The first prescription shall be filled no later than 30 days after the date of issuance; and
      (2) The second and third prescriptions shall be filled no later than 30 days after the date indicated on the prescription as the earliest date on which the prescription may be filled.

Do Your Part to Prevent Prescription Drug Abuse: Register to Access the NJPMP Today

Pharmacists know full well that prescription drug abuse is threatening lives at epidemic rates. Prescription painkiller addiction sends 7,000 New Jerseyans into addiction treatment centers each year, and overdose kills 40 Americans every day.

This too-often-ignored face of our nationwide drug problem kills more people in the United States than heroin and cocaine combined.

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DEA Provides Information Regarding Carisoprodol Prescriptions

A Drug Enforcement Administration (DEA) announcement provides information regarding the scheduling of carisoprodol, effective as of January 11, 2012. The DEA Final Rule making the drug a Schedule IV controlled substance was published December 12, 2011, and states that effective January 11, 2012, all prescriptions for drugs containing carisoprodol shall comply with DEA regulations. Specifically, a pharmacy may only fill or refill a prescription for a drug containing carisoprodol if all of the following requirements are met:

- the prescription was issued for a legitimate medical purpose by a DEA-registered practitioner acting in the usual course of professional practice (21 CFR §1306.04);
- the prescription contains all the information required by 21 CFR §1306.05; and
- the number of refills authorized by the prescribing practitioner is five or less (21 USC §829(b)).

The full text of the notice is available on the DEA Web site at *www.deadiversion.usdoj.gov/drugs_concern/carisoprodol/index.html.*

Pfizer Recalls Several Lots of Two Oral Contraceptive Products

Pfizer Inc recalled 14 lots of Lo/Ovral®-28 (norgestrel and ethinyl estradiol) tablets and 14 lots of norgestrel and ethinyl estradiol tablets (generic) due to potential for inexact count and out-of-sequence tablets. A Pfizer investigation found that some blister packs of the affected products may contain an inexact count of inert or active ingredient tablets and that the tablets may be out of sequence. As a result of this packaging error, the daily regimen for these oral contraceptives may be incorrect and could leave women without adequate contraception, and at risk for unintended pregnancy. Food and Drug Administration (FDA) advises that patients who have the affected product should notify their physician and return the product to the pharmacy. A Pfizer press release includes a list of the affected products with the National Drug Code (NDC) number, lot number, and expiration date for each, and is available at *www.fda.gov/Safety/Recalls/ucm289770.htm.*

Changes in Medication Appearance Should Prompt Investigation by Pharmacists and Patients

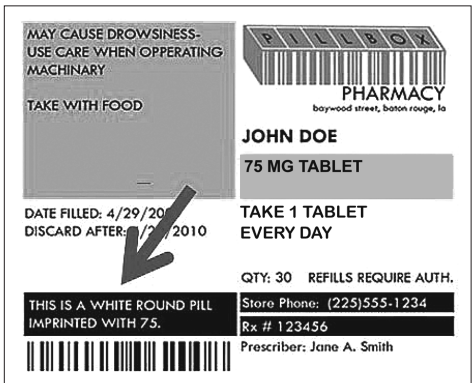
This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies 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.*

As the numbers of generic products continue to increase, it seems that both patients and practitioners have become desensitized to changes in medication appearance. So much so that patients may not question a change or, when they do, practitioners may simply reassure them that it was due to a change in manufacturer without actively investigating the reason. It is not uncommon for ISMP to receive reports from both practitioners and consumers where a change in medication appearance was not fully investigated and subsequently contributed to an error.

In one case, a man shared an account of what his 86-year-old father experienced over the course of nine days after his prescription for minoxidil was mistakenly refilled with another medication. He had been taking minoxidil 2.5 mg for years at a dose of 5 mg (2 tablets) twice daily. Due to failing vision, he did not realize that his minoxidil tablets looked different. His daughter noticed the change, but was unconcerned since the tablets had previously changed appearance. The pharmacy was contacted about the change and a staff member explained that it was a different generic for minoxidil, and that the pills could be exchanged for those that he usually received. There was no mention of a mistake being made when the medication was exchanged. He was taken to the hospital the following day, when he could barely walk.

After this incident was explained to hospital staff, they contacted the pharmacy. It was then revealed that he was given methotrexate by mistake because the bottles were stored next to each other. By this time, the man had taken 36 methotrexate 2.5 mg tablets, his white blood cell and platelet counts were extremely low, and he was in critical condition. We later learned that he passed away during that hospital visit.

Your pharmacy may be providing an important patient safety tool on the prescription label that may be overlooked by patients and their caregivers: a description of the shape, color, and imprint code of the medication that should be inside. This information can help ensure accuracy since it's based on the NDC number. Teach patients to look for this description and question any differences. In addition, the patient needs to know if the medication name on the pharmacy generated label is the medication he or she was expecting to receive. Even if the generic manufacturer is different each time the prescription is renewed, the description on the label should match the NDC number and thus the product inside.



With so much information on prescription labels such as patient and doctor name, drug name, instructions, and warnings – this added information can easily be missed. But it's important, so look for it and put it to use!

FDA Reminder: Purchasing Unapproved Injectable Cancer Medications Threatens Patient Safety

FDA is reminding health care providers to obtain and use only FDA-approved injectable cancer medications purchased directly from the manufacturer or from wholesale distributors licensed in the United States. FDA explains that "current shortages of injectable cancer medications may present an opportunity for unscrupulous individuals to introduce non-FDA approved products into the drug supply, which could result in

serious harm to patients." FDA reports that the agency is aware of promotions and sales of unapproved injectable cancer medications directly to clinics in the US and that the medications were likely administered to patients. Examples of products include unapproved versions of FDA-approved medications such as Faslodex® (fulvestrant), Neupogen® (filgrastim), Rituxan® (rituximab), and Herceptin® (trastuzumab). FDA stresses the risks to patients when such unapproved medications are used. The agency outlines several steps health care providers should take to ensure patient safety:

1. Obtain and use only FDA-approved injectable cancer medications purchased directly from the manufacturer or from wholesale distributors licensed in the US. An FDA Web page, *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm,* provides the online resource for each state for verifying that a wholesale distributor is appropriately licensed.
2. Determine if the medication you have received is FDA-approved by checking the Orange Book or searching the Drugs@FDA database.
3. Question whether a price sounds too good to be true. Deep discounts may be offered because the product is stolen, counterfeit, or unapproved.
4. Carefully inspect the product and packaging and be alert for signs that the product is not FDA approved, such as if the packaging looks different or the dosing recommendations are unfamiliar.

FDA also notes that if a health care provider receives multiple complaints about the same product, such as a new side effect or lack of therapeutic effect, these may signal a product quality issue.

FDA reminds health care providers that in certain circumstances the agency may authorize limited importation of medications that are in short supply. Such medications are imported from approved international sources and distributed in the US through a controlled network, and would not be sold in direct-to-clinic solicitations. If FDA has arranged for limited importation of the foreign version of a medication, information on obtaining that medication will be available in the Drug Shortages section of the FDA Web site, *www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm.*

Additional details are provided in an FDA Drug Safety Communication, available at *www.fda.gov/downloads/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/UCM287717.pdf.*

Insulin Pens Should Not Be Used for Multiple Patients, Stresses CDC

Centers for Disease Control and Prevention (CDC) issued a notice, reminding health care providers that insulin pens are intended for use by a single patient, and should never be used on more than one patient. CDC indicates that the agency has become "increasingly aware of reports of improper use of insulin pens, which places individuals at risk of infection with pathogens including hepatitis viruses and human immunodeficiency virus (HIV)." The notice explains that regurgitation of blood into the insulin cartridge can occur after injection, creating a risk of bloodborne pathogen transmission if the pen is used for more than one person, even when the needle is changed. CDC provides the following recommendations to help protect patient safety:

- Insulin pens containing multiple doses of insulin are meant for use on a single person only, and should never be used for more than one person, even when the needle is changed.
- Insulin pens should be clearly labeled with the person's name or other identifying information to ensure that the correct pen is used only on the correct individual.
- Hospitals and other facilities should review their policies and educate their staff regarding safe use of insulin pens and similar devices.
- If reuse is identified, exposed persons should be promptly notified and offered appropriate follow-up including bloodborne pathogen testing.

The notice may be downloaded from the CDC Web site at *www.cdc.gov/injectionsafety/PDF/Clinical-Reminder-insulin-pen.pdf.*

US Public Health Service Report Supports Maximizing the Scope of the Pharmacist as Part of Health Care Team

Presenting an evidence-based discussion of the comprehensive patient care services that pharmacists currently provide, a new government report calls for expanded support for such pharmacist-delivered patient care models. The report, *Improving Patient and Health System Outcomes through Advanced Pharmacy Practice,* prepared by the Office of the Chief Pharmacist, US Public Health Service (PHS), is organized into four focus points as follows:

- Focus point 1 discusses how pharmacists are integrated in many practice settings as health care providers, such as through collaborative practice agreements, and provides data showing interprofessional support for such models.
- Focus points 2 and 3 support recognition of pharmacists as health care providers and compensation models that will allow pharmacists to continue to improve patient and health care system outcomes.
- Focus point 4 presents a review of numerous peer-reviewed studies that demonstrate favorable outcomes from pharmacist-delivered care.

RADM Scott Giberson, chief professional officer, PHS Pharmacists, and the primary author of the report, stated that "one of the most evidence-based and cost-effective decisions we can make as a nation is to maximize the expertise and scope of pharmacists, and minimize expansion barriers to successful health care delivery models." The report may be downloaded from the US PHS Web site at *www.usphs.gov/corpslinks/pharmacy/comms/pdf/2011AdvancedPharmacyPracticeReporttotheUSSG.pdf.*

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By taking the simple step of registering to access the New Jersey Prescription Monitoring Program (NJPMP), pharmacists can help prevent themselves and their colleagues from being used as unwitting pawns by those seeking to make prescription controlled dangerous substances (CDS) available for abuse.

Since September 1, 2011, New Jersey-licensed pharmacies have populated the NJPMP database with information on more than 6 million prescriptions for CDS and human growth hormone. This highly-detailed data has helped identify users who allegedly took advantage of doctors, pharmacists, and insurance companies, by purchasing astronomical quantities of narcotic CDS.

Several of these cases came to light thanks to individual pharmacists, who registered to access the NJPMP and learn about the CDS histories of clients. The NJPMP empowers registered users to identify warning signs of abuse and diversion, by learning whether a client has purchased CDS from an excessive number of pharmacies, or has obtained prescriptions from an excessive number of prescribers.

Pharmacists who are licensed by the state of New Jersey, and in good standing with the New Jersey State Board of Pharmacy, can sign up for their own NJPMP access account today. Visit *www.NJRxReport.com*, click "Not a Member? Register," and follow the directions. Most importantly, you will need to verify your identity by printing out the "Request for Access" form, signing it before a Notary Public, and sending the notarized original to the address provided on the form. For much more information about the NJPMP and prescription drug abuse, visit *www.NJConsumerAffairs.gov/pmp.*

Disciplinary Actions

The actions listed below include only those where the individual's license to practice has been revoked, surrendered, suspended, restricted, or reinstated and do not include any other actions taken by the Board. Information regarding the current status of a pharmacist's license may be obtained either at the Division of Consumer Affairs Web site or by calling the License Verification Line at 973/273-8090.

Suspensions

Eileen T. Burkett, Pharmacy Technician – As of September 8, 2010, a final order of discipline was entered. The Board received information from respondent's employer informing that respondent admitted to stealing medications including CDS without a valid prescription while employed as a pharmacy technician from October 2007 through July 15, 2008. **Ordered:** Respondent's registration to practice as a pharmacy technician in the state of New Jersey shall be suspended for a minimum of five (5) years from the date of the entry of this final order of discipline, said suspension to be served as a period of active suspension.

Ruben Aguilar, RPh – As of October 13, 2010, a consent order was filed. The Board received information that respondent entered a guilty plea before a US district judge to one count charging him with conspiracy to commit health care fraud. Respondent knowingly and intentionally conspired and agreed with other pharmacists where he was employed as a pharmacist, to fill prescriptions with generic brand versions of certain medications and then submit claims to health care benefit programs, including Medicaid, for the reimbursement of the more expensive brand-name version of the medication. It was a further part of the conspiracy that respondent and his co-conspirators would submit false claims to health care benefits programs, including Medicaid, for prescription medications that the pharmacy never dispensed thereby defrauding them of more than $700,000. **Ordered:** Respondent's license to practice pharmacy in the state of New Jersey shall be suspended for a minimum of four years retroactive to and effective November 1, 2009, the date respondent voluntarily ceased practicing pharmacy. After a two-year successful completion of active suspension, respondent may petition the Board to convert the remaining two (2)-year period of suspension to be stayed and served as a term of probation, which shall not be unreasonably withheld.

Elizabeth M. Hanks, Pharmacy Technician – As of October 13, 2010, a final order of discipline was filed. The Board received information that respondent was arrested for theft of prescriptions drugs including CDS from the pharmacy where she was employed as a pharmacy technician. Respondent admitted to taking the drugs for her own personal use. **Ordered:** Respondent's registration to practice as a pharmacy technician in the state of New Jersey is suspended for five (5) years. Prior to any restoration of registration, respondent must appear before the Board.

Rashid Naveed, RPh – As of November 1, 2010, a consent order was filed. The Board received information that respondent entered a plea agreement with the US Attorney General's office filed in the Federal Court, District of New Jersey. Specifically, respondent pled guilty to conspiring to adulterate drugs in interstate commerce. **Ordered:** Respondent's license to practice pharmacy in the state of New Jersey shall be suspended for two (2) years, effective upon the entry of this order, six (6) months to be served as active suspension with the remainder to be stayed and served as a period of probation, contingent on compliance with the terms of this consent order and the laws governing the practice of pharmacy.

Petition for Reinstatement

Daniel Shack, RPh – As of October 13, 2010, a consent order was filed. This matter was opened to the Board upon receipt of respondent's application for reinstatement of his license to practice pharmacy in the state of New Jersey. Respondent's license was revoked by a final order of discipline, entered by the Board in November 2005, based upon a guilty plea to a charge of conspiracy to defraud the

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US, to unlawfully buy and sell prescription drug samples, and to misbrand prescription drugs. Among other things in the final order of discipline, respondent was to appear before the Board for the reinstatement of his license. Respondent appeared with counsel. **Ordered:** Respondent shall provide to the satisfaction of the Board proof of successful completion of all the reinstatement application requirements including a criminal history background check, payment of all reinstatement fees, documentation that he passed the Multistate Pharmacy Jurisprudence Examination® with a score of 75 or better, proof of successful completion of 35 hours of Accreditation Council for Pharmacy Education-accredited continuing education credits, and proof of successful completion of a 500-hour internship under the supervision of a preceptor who has been pre-approved by the Board. Once respondent demonstrates compliance with all of the above, his license to practice pharmacy in the state of New Jersey will be reinstated. Respondent shall not act as a preceptor or pharmacist-in-charge at any pharmacy for a period of one (1) year, and shall not own or have ownership interest in any pharmacy until further order of the Board.

Reinstatement with Restrictions

Marcus Lonky, RPh – As of October 12, 2010, a final order of discipline was entered. The Board received information that respondent was arrested in New York charged with criminal possession of CDS. Respondent diverted 900 pills of butalbital/caffeine/APAP/codeine for his personal use from the pharmacy where he was employed. Respondent voluntarily surrendered his license to practice pharmacy in the state of New York. Respondent pled guilty and entered the Albany County Drug Treatment Court program. On June 19, 2008, respondent's license was reinstated with restrictions, and began a period of post-restoration monitoring by the New York Professional Assistance Program (NYPAP) for a minimum of two (2) years, to conclude on June 18, 2010, at the earliest. **Ordered:** Respondent's license to practice pharmacy in New Jersey is subject to the same restrictions imposed on his pharmacy license in New York on June 19, 2008. Respondent can not apply for an unrestricted license in the state of New Jersey until he demonstrates proof of compliance with all requirements with the NYPAP, his Drug Court Treatment Plan, and proof that he holds an active unrestricted license to practice pharmacy in the state of New York.

Kenneth Rizzo, RPh – As of November 10, 2010, a consent order of reinstatement was filed. On August 3, 2006, a final order of discipline was filed with the Board, which suspended respondent's license for three (3) years. Respondent had pled guilty to having over-billed Medicaid in connection with his home infusion business. As a result of the guilty plea, he served six (6) months in prison and made restitution to Medicaid of approximately $900,000. **Ordered:** Respondent's license to practice pharmacy in the state of New Jersey shall be reinstated subject to conditions.

Reprimand

Vitthal I. Patel, RPh – As of October 13, 2010, a consent order was filed. The Board received information that respondent violated the terms of a reinstatement order filed on February 24, 2005. Among other things, respondent was required to serve a copy of the order to any employer prior to commencing work and ensure that each employer forwarded documentation to the Board that he or she had reviewed the entire order. On July 21, 2010, the Board received information via fax from Robert Wood Johnson University Hospital that respondent failed to provide the hospital with a copy of the reinstatement order. **Ordered:** Respondent is reprimanded for failing to comply with the terms of the reinstatement order. Respondent shall immediately serve a copy of the reinstatement order filed February 24, 2005, to any current employer and any future employer prior to commencing work as a licensee and shall ensure that each employer forwards documentation to the Board that he or she reviewed the entire order.

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