



New Jersey State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

PO Box 45013 • 124 Halsey St, 6th Floor • Newark, NJ 07101 • www.njconsumeraffairs.gov/phar

EPCS for a Pharmacy

Background

In 2010, Drug Enforcement Administration (DEA) approved federal rules to allow for electronic prescriptions for controlled substances (EPCS). In accordance with federal and state rules, **New Jersey practitioners and pharmacies can utilize EPCS for all patient prescriptions.**

Benefits of EPCS

- ◆ Single, streamlined workflow for all prescriptions, both controlled dangerous substances (CDS) and prescription legend drugs
- ◆ Improved legibility
- ◆ Reduce prescription fraud, forgery, and abuse
- ◆ Decrease adverse drug events
- ◆ Condense record keeping for a patient's prescription history
- ◆ Quickly receive, select, and fill/refill a patient prescription

Requirements to Use EPCS

The prescriber and pharmacy must each be EPCS certified.

How to Begin Using EPCS in Pharmacies

1. Contact your pharmacy software vendor and ask if your vendor is certified for EPCS.
2. If your vendor is certified for EPCS:
 - a. Ask for and obtain a copy of your vendor's EPCS certification or third-party audit.
 - b. Initiating use may be as simple as turning on the EPCS "feature."
 - c. Set your access controls (your vendor will assist).
 - d. Create an audit and record-keeping process in compliance with the New Jersey State Board of Pharmacy rules (see N.J.A.C. 13:39-7.11); your vendor will assist.
3. If your software vendor is not certified for EPCS, your vendor first will have to undergo a third-party audit or certification as defined by DEA rules.

Additional Information

For details about the DEA rules for EPCS, please visit the DEA website at www.deadiversion.usdoj.gov/e-comm/e_rx/index.html.

Additional information about EPCS is available from various health care information networks – companies that connect

practitioners, pharmacies, benefit plan managers, and technology partners – to facilitate the processing of prescriptions and health information nationwide. Pharmacies may obtain additional information by visiting network websites such as www.surescripts.com, www.getepcs.com, or www.emdeon.com/eprescribing.

To search whether a practitioner or pharmacy in your area is EPCS enabled, click on the "Find E-Prescribing Physicians" or "Find E-Prescribing Pharmacies" at the top of the Surescripts website.

Physician Issuance of Multiple Schedule II CDS Prescriptions

The New Jersey Division of Consumer Affairs is reissuing the following guidance regarding the issuance of multiple prescriptions of a Schedule II CDS to a patient.

Since March 1, 2010, pursuant to N.J.S.A. 45:9-22.19, only physicians licensed by the New Jersey State Board of Medical Examiners are permitted to issue multiple prescriptions authorizing a patient to receive a total of up to a 90-day supply of a Schedule II CDS.

The corresponding Board regulation N.J.A.C. 13:35-7.6(c)3 now specifies that a physician may issue multiple prescriptions to a patient so that the patient may receive a total of up to a 90-day supply of a Schedule II CDS provided that:

- i. Each separate prescription is issued for a legitimate medical purpose by the physician acting in the usual course of professional practice;
- ii. The physician provides written instructions on each prescription, other than the first prescription if it is to be filled immediately, indicating the earliest date on which a pharmacy may fill each prescription;
- iii. The physician determines that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse; and
- iv. The physician complies with all other applicable state and federal laws and regulations.

Similarly, the New Jersey CDS regulation, N.J.A.C. 13:45H-7.5(a), provides that when up to three separate prescriptions for a total of up to a 90-day supply of a Schedule II CDS 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, and the prescriptions may not be filled until the date indicated on the prescription by the physician as the earliest date for filling.

Continued on page 4



FDA Issues Warning About Name Confusion for Brintellix and Brilinta

Due to similar brand names, there have been incidents where the antidepressant Brintellix® (vortioxetine) and the anti-blood clotting medication Brilinta® (ticagrelor) have been confused, resulting in prescribing and dispensing errors, warns Food and Drug Administration (FDA). The agency notes that no reports indicate that a patient has ingested the wrong medication; however, reports of prescribing and dispensing errors continue. FDA recommends that health care providers include the generic name of the medication in addition to the brand name, as well as the indication for use when prescribing these medications. Patients are advised to check their prescriptions to ensure that the correct medication was dispensed. More information is available in an FDA safety alert at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm456569.htm.

Seven Persistent Safety Gaffes in Community/Ambulatory Settings That Need to Be Resolved!

 This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization 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 provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at www.ismp.org. Email: ismpinfo@ismp.org.

This is part two of a three-part series on seven persistent safety gaffes of 2014.

3) Vaccine Errors: Repetitive Errors Reported in the Last Decade

How often do DTaP (diphtheria and tetanus toxoids, and acellular pertussis) and Tdap (tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis) vaccine mix-ups need to occur before regulatory action is taken to prevent confusion? Whatever the number, we can say that health care providers have probably met that threshold! Yet, vaccine errors like this continue to occur at an alarming rate (based on those reported to ISMP alone). Vaccine mix-ups occur often because of age-dependent formulations of the same vaccine, similar vaccine abbreviations, similar vaccine containers and labels, and storage near each other. Confusion between the diluent and vaccine has led to administration of the diluent alone or use of the wrong diluent. With an unfortunate rise in parents choosing not to vaccinate their children or themselves, health care providers cannot continue to make errors when

vaccinating those who choose to be immunized; the impact on both individual and community immunity may be far-reaching.

4) Wrong Patient Errors: Not Opening the Bag at the Point of Sale

Community pharmacies are vulnerable to dispensing correctly filled prescriptions to the wrong patient at the point of sale, a risk that is well substantiated in the literature. This error is not influenced by the attributes of a specific medication; thus, dispensing any prescription medication to the wrong patient at the point of sale carries a similar level of risk. Based on an ISMP study, the error happens frequently at an estimated rate of 1.22 per 1,000 prescriptions. Among approximately 56,000 community pharmacies in the United States, this error rate suggests that 332,755 prescriptions will be dispensed to the wrong patient each month, or about six every month per pharmacy. One of the most effective ways to prevent this error is to open the bag of filled prescriptions at the point of sale to verify that the medications are for the correct patient. According to the ISMP study, this simple step reduces the risk of error by 56%, yet few pharmacies follow this practice.

5) Disrespectful Behavior: A History of Tolerance in Health Care

Bullying, incivility, and other forms of disrespectful behavior are still rampant in health care and allowed to exist. Health care providers tolerate the behavior, remain silent, or make excuses in an attempt to minimize the profound devastation that disrespectful behavior causes. An ISMP survey conducted in 2003 clearly demonstrated the scope of disrespectful behavior among many levels of interdisciplinary staff, and an ISMP survey conducted a decade later demonstrates little progress. Disrespect diminishes a person's ability to think clearly, make sound judgments, speak up regarding questions, or avoid at-risk behaviors. Disrespectful behaviors also underlie a resistance to collaborate with others, follow procedures that promote safe practices, or implement new safety practices. While a culture of disrespect is harmful on many levels, its effect on patient safety makes it a matter of national urgency.

FDA Advises Caution Against Codeine for Treating Colds in Young Patients

FDA is evaluating the safety of using medicines containing codeine to treat patients under 18 years old for coughs and colds because of the possibility of severe side effects. Codeine, an opioid, may cause slowed or difficult breathing in children, especially for those who already suffer from breathing problems, the agency notes. FDA recommends that health care providers use caution when prescribing or recommending codeine for patients under 18 years old, and that parents and caregivers be alert for signs of shallow or noisy breathing, confusion, or unusual sleepiness. FDA is also considering a European Medicines Agency recommendation made in April to not give children under 12 codeine for coughs and colds, and to not use codeine for patients 12 to 18 years old who have asthma or other chronic breathing problems. More information is provided in an FDA safety alert available at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm453379.htm.



Daytrana Patch May Cause Permanent Skin Color Changes, FDA Warns

In June 2015, FDA warned health care providers and consumers that Daytrana[®], a methylphenidate transdermal system prescribed for treating attention deficit hyperactivity disorder, may cause permanent loss of skin color in the affected area. FDA has added a new warning to the drug label to describe this skin condition, known as chemical leukoderma. Chemical leukoderma is a skin condition that causes the skin to lose color as a result of repeated exposure to specific chemical compounds, according to an FDA safety alert. The condition is not physically harmful, but it is disfiguring.

FDA advises patients and caregivers to watch for new areas of lighter skin, especially under the drug patch, and to immediately report any changes to their health care providers. Patients should not stop using the Daytrana patch without consulting a health care provider. FDA also recommends that providers for patients who experience these skin color changes consider alternative treatments. More details are included in the FDA safety alert available at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm452595.htm.

FDA Expands NSAID Warning Labels Regarding Risks of Heart Attack, Stroke

The labels of certain non-steroidal anti-inflammatory drugs (NSAIDs) will soon contain more detailed information about the risk that the drugs may contribute to heart attack and stroke, reports FDA. Such warnings have been on prescription and over-the-counter NSAIDs since 2005, but the new requirements take into account new data showing that the risk of heart attack and stroke occurs even during the first few weeks of taking an NSAID. People who have cardiovascular and other heart problems are at even greater risk of adverse effects. An FDA alert available at www.fda.gov/ForConsumers/ConsumerUpdates/ucm453610.htm provides more details.

Baxter International, Inc, Recalls Three Lots of IV Solutions Due to Particulate Matter

In July 2015, Baxter International, Inc, voluntarily recalled two lots of intravenous (IV) solutions distributed to hospitals and other health offices because of the presence of particulate matter identified as an insect. The problem was identified before patient administration and no adverse health effects have been reported. The recall affects 0.9% sodium chloride injection, USP 50 mL and 100 mL, lot numbers P319921 and P327635, which were distributed to US customers between October 7, 2014, and July 14, 2015. Additional information is available in an FDA press release at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm455421.htm.

Baxter also voluntarily recalled one lot of IV solution to the hospital/user level because of the potential for leaking containers, particulate matter, and missing port protectors. This recall affects 0.9% sodium chloride injection, USP (AUTO-C) with lot number C964601 (National Drug Code 0338-0049-03; expiration date: April 30, 2016). This recalled lot was distributed to

customers and distributors nationwide between January 22, 2015, and February 12, 2015. Leaking containers, particulate matter, and missing port protectors could result in contamination of the solution and, if not detected, could lead to a bloodstream infection or other serious adverse health consequences, explains FDA. The agency notes further that "injecting a product containing particulate matter, in the absence of in-line filtration, may result in blockage of blood vessels, which can result in stroke, heart attack or damage to other organs such as the kidney or liver. There is also the possibility of allergic reactions, local irritation and inflammation in tissues and organs." More information about this recall is available in an FDA safety alert at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm456793.htm.

FDA Warns Against Unapproved Prescription Ear Drops

FDA has ordered the manufacturers of certain prescription ear drops to stop making and distributing the products because they are not FDA-approved. The product labels do not disclose that they lack FDA approval, and health care providers may not be aware of the unapproved status, notes FDA. The agency took action against unapproved prescription otic drug products containing these ingredients:

- ◆ benzocaine;
- ◆ benzocaine and antipyrine;
- ◆ benzocaine, antipyrine, and zinc acetate;
- ◆ benzocaine, chloroxylenol, and hydrocortisone;
- ◆ chloroxylenol and pramoxine; and
- ◆ chloroxylenol, pramoxine, and hydrocortisone.

These drugs are frequently given to relieve ear swelling and pain in young children, and FDA took this action to protect patients from the risks of taking unapproved drugs with no proven safety or effectiveness information. Further, such drugs may be contaminated or manufactured incorrectly, notes the agency. More information is provided in an FDA news release available at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm453348.htm.

Acino Products in New Jersey Ordered to Stop Selling Rectacort-HC and GRx HiCort 25

Under the direction of FDA, a federal judge for the District of New Jersey has ordered Acino Products, LLC, of Hamilton, NJ, to stop selling and destroy certain unapproved and misbranded prescription drugs in its possession.

According to FDA, Acino has marketed unapproved hydrocortisone acetate 25 mg suppositories, under the brand names Rectacort-HC and GRx HiCort 25, for treatment of medical conditions including inflamed hemorrhoids, chronic ulcerative colitis, and other inflammatory conditions. The drugs have not been FDA-approved and also fail to carry adequate directions for use on their labels. Acino continued to market and sell the products despite several warnings from FDA investigators. The FDA news release is available at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm453466.htm.

The exception provided by N.J.S.A. 45:9-22.19 (P.L. 2009, c. 165) **does not** apply to any other licensed prescriber/practitioner, including dentists, optometrists, veterinarians, advanced practice nurses, certified nurse midwives, and physician assistants.

Discontinuing/Closing of Pharmacies

A number of pharmacies have discontinued their operations suddenly within the last 12 months without following the proper procedures required by law. These abrupt closings can potentially affect the continuity of patient care, prevent access to patient records, and impact the proper disposition of prescription medications as required by law. Permit holders and their representatives are reminded that they must follow the law as outlined below when closing a pharmacy (emphasis added).

N.J.A.C. 13:39-4.10 Discontinued Pharmacies

- a) Whenever a pharmacy is to be discontinued and closed for any reason, including suspension or retirement of the permit holder, sale or insolvency, the permit holder shall immediately send written notification of the anticipated closing to the State Board of Pharmacy, the Office of Drug Control and the Drug Enforcement Administration at least **15 days prior to the anticipated closing date**. Whenever a pharmacy is to be discontinued and closed as a result of an unanticipated occurrence, such as the death of the permit holder, the permit holder's representative shall send written notification to the Board, the Office of Drug Control and the Drug Enforcement Administration, as soon as possible prior to the actual closing date. All medications, including prescription legend and controlled drugs, should be transferred to the holder of a current pharmacy permit; a wholesaler; a reverse distributor; and/or a manufacturer. All medications not properly transferred shall remain on the pharmacy premises with all licenses and registrations in effect until such medications are disposed of in the manner prescribed by the Board, the Office of Drug Control and/or the Drug Enforcement Administration.
- b) **Within 30 days of closing a pharmacy** pursuant to (a) above, the permit holder or his or her representative shall remove all drug signs from both the inside and outside of the discontinued pharmacy and shall notify the Board in writing of the location of the previous five years of prescription and patient profile records, consistent with the requirements of N.J.A.C. 13:39-7.6 and 7.19. The permit holder or his or her representative shall return the permit to the Board for cancellation within 30 days of the closing. Prescription records and other information may be requested by the Board as outlined in N.J.A.C. 13:39-7.6 and 7.19.

N.J.A.C. 13:39-4.11 Availability of Records Upon Termination of Business

- a) When a pharmacy ceases operation as the result of a suspension, retirement or death of the owner, sale or other cause including insolvency, the permit holder, or the one responsible for supervising the disposition of the practice, shall make every effort to notify patrons that they have the right to obtain copies of currently valid prescriptions and/or copies of their patient profile and the location of the prescriptions and patient profile for a one-year period following

notice, using all of the following methods:

- 1) Notification in writing to the Board;
- 2) Publication, once weekly for two successive weeks in a newspaper whose circulation encompasses the geographic area in which the pharmacy is located, of a notice advising patrons that they have the right to obtain copies of their prescriptions and/or patient profile, and the location of the prescriptions and patient profile for a one-year period following publication; and
- 3) A sign placed in the pharmacy location informing the patrons that they have the right to obtain copies of their prescriptions and/or patient profile, and the location of the prescriptions and patient profile.

Any questions regarding the closing of pharmacies should be directed to the Board at 973/504-6450.

Correction to July Newsletter Article 'Licensee Requirements Regarding Adequate Storage'

The above-mentioned article incorrectly referenced United States Pharmacopeia (USP) Chapter <36> in defining controlled room temperature. The definition was revised when this term was moved from the General Notices to USP Chapter <659>. The correct definition of controlled room temperature appears in USP Chapter <659> – Packaging and Storage Requirements as follows:

Controlled Room Temperature: The temperature maintained at the usual and customary working environment of 20 to 25 (68 to 77 F). The following conditions also apply.

The mean kinetic temperature shall not exceed 25. The mean kinetic temperature is a calculated value that may be used as an isothermal storage temperature that simulates the nonisothermal effects of storage temperature variations.

Excursions between 15 and 30 (59 and 86 F) that are experienced in pharmacies, hospitals, and warehouses, and during shipping are allowed, provided the mean kinetic temperature does not exceed 25.

Transient spikes up to 40 are permitted as long as they do not last for more than 24 hours. Spikes above 40 may be permitted only if the manufacturer so instructs.

Articles may be labeled for storage at "controlled room temperature" or at "up to 25", or other wording based on the same mean kinetic temperature.

An article for which storage at Controlled Room Temperature is directed may, alternatively, be stored and shipped in a cool place or refrigerated, unless otherwise specified in the individual monograph or on the label.

This definition is official through April 30, 2016; after that date, USP Chapter <659> is subject to change.