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DEA Form 222

By Jennifer O'Toole, RPh, Board Compliance Officer

A Drug Enforcement Administration (DEA) Form 222 must be completed any time a Schedule II controlled substance (CS) is transferred to another pharmacy or to a prescriber, or returned to your wholesaler. Remember, Copy 2 (green copy) of the DEA Form 222 must be completed and sent to the local DEA office within 30 days of executing the form. Also, all items on the form must be completed, including the quantity shipped, date shipped, and the National Drug Code for each product shipped. If the form is incomplete, you may be contacted by DEA for completion. Any question regarding the proper execution of this form can be directed to your compliance officer or your local DEA office.

Patient-Prescriber Relationship Is Severed – What Can Be Filled?

By Mark Mather, RPh, Board Compliance Officer

Iowa Board of Pharmacy compliance staff receives many inquiries about the validity of current or written prescriptions after the prescriber-patient relationship no longer exists. This could result from the prescriber moving out of town, the patient moving away from the office, or the prescriber retiring. What happens to a prescription for which the patient has refills? What about newly written prescriptions for controlled and non-controlled drugs – can they be filled as well?

The answer hinges on Chapter 8, Universal Practice Standards, in the Iowa Administrative Code (IAC), more specifically, **Rule 657—8.20(155A) Valid prescriber/patient relationship,** which states:

> Prescription drug orders and medication orders shall be valid as long as a prescriber/patient relationship exists. Once the prescriber/patient relationship is broken and the prescriber is no longer available to treat the patient or oversee the patient's use of a prescription drug, the order loses its validity and the pharmacist . . . shall cancel the order and any remaining refills.

With that as a backdrop, the most important part of **Rule 657-8.20** comes next. In a nutshell, it states that the pharmacist shall "exercise prudent judgment based upon **individual circumstances** to ensure that the patient is able to obtain a sufficient amount of the prescribed drug to continue treatment" (emphasis added). Therefore, a pharmacist may continue filling a patient's controlled or non-controlled medications just long enough so the patient can reasonably obtain the services of another prescriber and a new order can be issued. This window of time comes down to the best judgment of the pharmacist; Board compliance staff believes the typical transition window to be somewhere between 30 and 90 days, depending on prescriber availability.

Responsible Prescribing of Opioids

By Jennifer Tiffany, RPh, Board Compliance Officer

On March 18, 2016, the *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016* was published in the *Morbidity and Mortality Weekly Report, Recommendations and Reports.* This comes after a marked increase in the rate of deaths associated with opioid pain medication over the last 10 years. The guideline is tailored for primary care clinicians who prescribe opioids for chronic pain unrelated to cancer treatment, palliative care, and end-of-life care for patients ages 18 and older. Chronic pain – a condition that often leads to reduced quality of life and lost work productivity – is defined in the guideline as "pain that typically lasts greater than 3 months or past the time of normal tissue healing."

Twelve specific guidelines are presented in the publication, and each falls under one of the three following considerations:

- Determining when to initiate or continue opioids for chronic pain;
- Opioid selection, dosage, duration, follow-up, and discontinuation; or
- Assessing risk and addressing harms of opioid use.

Guideline #11 specifically references pharmacists by recommending that clinicians involve pharmacists as part of the "management team when opioids are co-prescribed with other central nervous system depressants."

Please visit *www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm* for the guideline in its entirety.

CS Registrations and Emergency Medical Service

Pharmacies may provide prescription products, including CS, to a properly licensed emergency medical service (EMS) provider. IAC 657-11 details the proper procedures and record-keeping requirements for this practice; but who is responsible for the CS? It depends. If the EMS provider is operating under a pharmacy-based operation, the pharmacy maintains responsibility for the CS located within the service. If the EMS provider chooses to operate as a medical director-based

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FDA Approves Naloxone Nasal Spray to Prevent Opioid Overdose Deaths

Food and Drug Administration (FDA) has approved Narcan® Nasal Spray (also known as naloxone), a life-saving medication that can stop or reverse the effects of an opioid overdose. Prior to this approval, naloxone was only approved in injectable forms, most commonly delivered by syringe or auto-injector, explains FDA in a news release.

Narcan Nasal Spray does not require assembly and delivers a consistent, measured dose when used as directed. This prescription product can be used on adults or children and is easily administered by anyone, even those without medical training. The drug is sprayed into one nostril while the patient is lying on his or her back, which can be repeated if necessary. However, it is important to note that it is not a substitute for immediate medical care, and the person administering Narcan Nasal Spray should seek further immediate medical attention on the patient's behalf. The use of Narcan Nasal Spray in patients who are opioid dependent may result in severe opioid withdrawal characterized by body aches, diarrhea, increased heart rate (tachycardia), fever, runny nose, sneezing, goose bumps (piloerection), sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness, and increased blood pressure. Narcan Nasal Spray is distributed by Adapt Pharma, Inc, of Radnor, PA. The FDA news release is available at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm473505.htm.*

Selected Medication Safety Risks to Manage in 2016

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.*

It is a nearly impossible task to list all the risks associated with medication use that could lead to harmful medication errors. So where do health care professionals start to improve medication safety? Most people frequently resort to playing "whack-a-mole," addressing risks only after they pop up and become visible after an adverse event.

Listed below are two serious medication safety risks that might fall off the radar screen unless an adverse event happens to draw attention to them. Additional serious risks will be published in future issues of the National Association of Boards of Pharmacy® *National Pharmacy Compliance News.*

Patient Information – Placing Orders on the Wrong Patient's Electronic Health Record

A potentially hidden vulnerability that can lead to serious errors is placing orders on the wrong patient's electronic health record. A recent study published in the *Journal of the American Medical Informatics Association* identified and quantified close calls that would have resulted in wrong-patient errors. According to this study, about 14 wrong-patient electronic orders are placed every day in a large hospital system with approximately 1,500 beds, or about 68 wrong-patient errors per 100,000 medication orders. By this measure, one in 37 hospitalized patients will have an order placed for them that was intended for another patient.[1]

These errors are sometimes due to juxtaposition but more often caused by interruptions and having more than one patient's electronic health record open.

Multiple studies have demonstrated ways to reduce these events. Requiring verification of the patient's identity has reduced errors by 16% to 30%, and requiring re-entry of the patient's identification has reduced errors by 41%.[1,2] Prompting clinicians for an indication when certain medications are ordered without an indication on the patient's problem list has intercepted errors at a rate of 0.25 per 1,000 alerts.[3] In one study, most emergency department (ED) staff (81%) felt a room number watermark on the patient's electronic health record would eliminate most wrong-patient orders in the ED.[4]

Communication About Drug Therapy – Confusing the Available Concentration as the Patient's Dose on Electronic Records

Another risk deals with how home medications appear on computer screens. For example, a physician accidentally ordered 100 units of Lantus® (insulin glargine) instead of the correct dose of six units because the list of medications used at home displayed the concentration right next to the drug name on the first line, and the patient's dose below it on the second line: "Insulin glargine (Lantus) 100 units/mL," followed on the next line with "6 units subcutaneous daily every evening."

Now that insulin is available in 100 units/mL, 200 units/mL, 300 units/mL, and 500 units/mL concentrations, the risk

of receiving an overdose of insulin is high if the presentation of the order lists the product's concentration before the patient's dose. ISMP's recommendation is to list the drug name, patient-specific dose, and directions for use on the first line of the electronic medication administration record and patient medication lists, and the available concentration and any directions on how to measure the patient's dose below it.

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FDA Provides Training Videos on MedWatch Resources and Breakthrough Therapy

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the January 2016 Drug Info Rounds video, "MedWatch Tips and Tools," pharmacists discuss reporting adverse events to FDA's MedWatch Safety Information and Adverse Event Reporting Program and the resources available for health care professionals to report safety information. In the December 2015 Drug Info Rounds video, "Breakthrough Therapy," pharmacists discuss the breakthrough therapy designation program, which is intended to expedite the development and review of drugs for serious or life-threatening conditions. Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research (CDER), Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.*

Reading Medicine Labels Helps Reduce Acetaminophen Overdoses

The Acetaminophen Awareness Coalition (AAC) reminds pharmacists and other health care providers to encourage patients to properly read medicine labels to avoid unintentional acetaminophen overdoses. The coalition also encourages pharmacists and other health care providers to talk to their patients about medicine safety and acetaminophen use.

AAC's "Know Your Dose" campaign reminds patients to take these four steps to avoid acetaminophen overdose:

(1) Always read and follow the medicine label.
(2) Know if their medicines contain acetaminophen.
(3) Take only one medicine at a time that contains acetaminophen.
(4) Ask their health care provider about any questions.

Additionally, pharmacists may download or order free educational materials, including posters, flyers, and talking points, to give their patients on the Know Your Dose website at *www.knowyourdose.org.*

Over-the-Counter Children's Medicine Recalled Due to Incorrect Dose Markings

In January 2016, Perrigo Company voluntarily recalled two lots of children's guaifenesin grape liquid cough medicine (100 mg/5 mL) and three lots of children's guaifenesin DM cherry liquid cough medicine (100 mg guaifenesin and 5 mg dextromethorphan HBr/5 mL) sold in 4 oz bottles. The recall was initiated because some packages contain an oral dosing cup with incorrect dose markings. The affected products were sold by distributors nationwide and distributed through retail stores. The recalled lots and store brands are available in the Perrigo press release posted on the company's website, *www.perrigo.com,* under "Investors." To date, the company has not received reports of overdose. Distributors and retailers that have the affected lots should stop distribution and return the product using the information provided in the press release.

Adverse reactions or quality problems may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at *www.fda.gov/MedWatch.*

FDA Offers Webinars on Online Drug Information Resources for Students and Clinicians

FDA's Division of Drug Information, CDER, presents a series of continuing education webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Past topics have included "Introduction to FDA's MedWatch Adverse Reporting Program" and "An Overview of the FDA's Breakthrough Therapy Designation Program." Upcoming webinars, previous webinars, and presentation slides can be accessed on FDA's website at *www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm228391.htm*.

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operation, ownership and control of the CS is transferred to the medical director once the product leaves the pharmacy.

In practice, the procedure for replenishment or exchange of CS is vastly different under the medical director-based option compared to the pharmacy-based operation. Most notably, the pharmacy must be provided with a DEA Form 222 **"preprinted with the address of the primary program site,"** per IAC 657-11.27. This means that the medical director cannot use his or her practice site DEA Form 222 (unless the medical director's practice site is the primary program site). Rather, the medical director must also register with DEA with the EMS primary program site address listed as the practice address. Additionally, in order for DEA to approve this registration, the medical director must also register with the board of pharmacy that lists the primary program site as the medical director's practice location.

Expired Technician Registrations – Who Is Responsible?

All personnel working in a pharmacy who have direct access to prescription drugs must maintain current registration with the Board. Technicians must renew their registration with the Board on a biennial basis. Registrations expire on the last day of the technician's birth month and are renewed on a two-year cycle; ie, if a technician's birth month is January and he or she obtains registration in July 2016, that registration would expire the last day of January 2018. What happens when a technician fails to renew his or her registration in a timely manner? Is the technician, the pharmacy, or the pharmacist-in-charge (PIC) responsible for ensuring that a technician's registration is current? This is actually a shared responsibility. The technicians are personally responsible for renewing their own registration with the Board. The PIC is responsible for ensuring that individuals working in the pharmacy are properly registered with the Board. The pharmacy and the PIC share a responsibility in ensuring that policies and procedures related to this issue are carried out.

A pharmacy and a PIC should develop, implement, and adhere to policies and procedures to ensure that all individuals with direct access to prescription drugs maintain current registration with the Board.

Iowa Monitoring Program for Pharmacy Professionals

Like many other professional boards, the Board allocates funding for the operation of a confidential monitoring program for pharmacy professionals who are struggling with alcohol or chemical dependency or who have a mental or physical disability that is potentially threatening to the individual or to the safety of the public. The purpose of the Board's program is to protect public health and safety by evaluating and monitoring individuals with impairment.

Beginning July 1, 2016, pharmacists, pharmacist interns, and pharmacy technicians struggling with chemical, mental, or physical impairment can self-report to the Board office for assistance in obtaining necessary treatment for impairment. **This program is completely confidential and provides our Iowa pharmacy professionals the opportunity to seek the help they need without the risk of public discipline.**

So what happens when you self-report? The Board of Pharmacy will be working in collaboration with the Iowa Board of Medicine to administer and manage the monitoring program. Staff from the Board of Medicine will review the report and collect additional information as necessary. An initial agreement with the professional will be developed and executed. A referral for an evaluation will be made. This evaluation is then reviewed to determine if the individual qualifies for the program. If it is determined that the individual qualifies, a contract is drafted. Once the contract is signed, active confidential monitoring will begin.

It is estimated that up to 20% of pharmacy professionals struggle with substance abuse. If you need help, please call the Board of Pharmacy for more information.

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