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Proper Writing of Multiple Schedule II Prescriptions

By Mark Mather, RPh, Compliance Officer

Recently, there has been some confusion among prescribers and pharmacists on the proper way to write and fill multiple Schedule II prescriptions written for the same drug and patient. Let's start with the overarching law, in the Iowa Administrative Code (IAC), which says (emphasis added): **"657—10.25(124) Schedule II—issuing multiple prescriptions.** An individual prescriber may issue multiple prescriptions authorizing the patient to receive a total of up to a **90-day supply** of a Schedule II controlled substance pursuant to the provisions and limitations of this rule." The subsection of this law that pertains to our topic is as follows (emphasis added):

> **10.25(3)** *Dates and instructions.* Each prescription issued pursuant to this rule **shall be dated as of and manually signed** by the prescriber on the **day the prescription is issued.** Each separate prescription, other than the first prescription if that prescription is intended to be filled immediately, **shall contain written instructions indicating the earliest date on which a pharmacist may fill each prescription.**

Many prescribers tend to forget that each prescription needs to be signed and dated on the same day the prescriptions are issued. Most currently, there has been confusion surrounding the "do not fill dates" required on these Schedule II prescriptions. With the exception of the first month's fill, the prescriber must write on all subsequent Schedule II prescriptions the earliest date on which that prescription may be filled. It is not sufficient to just write "#1," "#2," "#3," etc, on each prescription; there must be a "do not fill date" on each subsequent prescription after the first one. If there is not a "do not fill date," the prescription is not valid and will need to be rewritten. The pharmacist is **not** allowed to add or change the "do not fill date" on the prescription. Lastly, the prescriber may write as many separate Schedule II prescriptions, to be filled sequentially, as deemed necessary as long as they do not exceed a 90-day supply.

Approved Activities: Technicians vs. Interns

By Danielle Watznauer, Pharmacist Intern

Often there may be confusion as to what the differences are regarding what pharmacy technicians and pharmacist interns may do within the pharmacy. The greatest difference lies within activities entailing professional judgment. Pharmacy technicians are not authorized to perform tasks requiring professional judgment. Such activities include interpreting prescription drug orders, conducting prospective drug use review, and performing final product verification, except for participation in an approved tech-check-tech program. Technicians cannot provide patient counseling, consultation, or patient-specific drug information; tender an offer of patient counseling on behalf of a pharmacist; or accept a refusal of patient counseling from a patient or patient's agent. They also cannot transfer a prescription to another pharmacy or receive the transfer of a prescription from another pharmacy.

Pharmacist interns, however, are allowed to perform activities requiring professional judgment. These tasks, usually restricted to a pharmacist, may be delegated to interns registered by the Iowa Board of Pharmacy at the discretion of the supervising pharmacist. These judgmental functions include, but are not limited to, verifying the accuracy, validity, and appropriateness of filled prescriptions, reviewing and assessing patient records, providing patient counseling, and administering vaccinations. In addition, interns may answer patient-specific drug information questions and transfer a prescription into or out of the pharmacy under the pharmacist's supervision. A licensed pharmacist on duty in the pharmacy is responsible for all actions of the intern.

Dissolution of Prescriber/Patient Relationship

By Melanie Reineke, Pharmacist Intern

It is common for patients to stop seeing a prescriber and find a new prescriber without the pharmacist becoming aware that the relationship associated with the patient's current refills has ended. However, in the instance of

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WHO Launches Global Patient Safety Challenge on Medication Safety

To reduce severe, avoidable medication-associated harm in all countries by 50% over the next five years, the World Health Organization (WHO) has launched a worldwide initiative, the Global Patient Safety Challenge on Medication Safety. Medication errors cause at least one death every day and injure approximately 1.3 million people every year in the United States. In addition, low- and middle-income countries are estimated to have similar rates of medication-related adverse events as high-income countries.

The Global Patient Safety Challenge on Medication Safety aims to make improvements in each stage of the medication use process including prescribing, dispensing, administering, monitoring, and use. WHO intends to provide guidance and develop strategies, in addition to plans and tools to ensure that the medication process has the safety of patients at its core in all health care facilities.

Previous WHO Global Safety Challenges have included the Clean Care is Safer Care challenge on hand hygiene in 2005 and the Safe Surgery Saves Lives challenge in 2008. Additional information is available in the WHO press release available at *http://who.int/mediacentre/news/releases/2017/medication-related-errors/en.*

Continuous Quality Improvement and Patient Safety Organizations

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.*

Data from the ISMP Medication Errors Reporting Program reveals that medication-related problems are repetitive in nature. An incident of misuse in one setting is likely to repeat itself in another. Most importantly, the system changes that are necessary to prevent errors are similar, and a growing body of literature is available to guide these efforts. Tragically, too many organizations and individual providers do not believe similar incidents could happen to them. They fail to use information about errors occurring elsewhere as a roadmap for improvement in their own organization or practice. It is not until a serious error hits home that aggressive prevention efforts are implemented. With so much evidence-based information about error prevention at hand, there is little excuse for reacting to errors after they happen instead of preventing them.

The development and implementation of continuous quality improvement (CQI) efforts should be the highest priority in all pharmacies. Such efforts must be aimed specifically at preventing well-known and repetitive dispensing errors. Pharmacies should seek out medication safety information and use it proactively to prevent medication errors. At the same time, safety issues recognized internally and/or reported by patients should be documented and analyzed, with a process to determine the best strategies to prevent future problems and methods to ensure implementation. An annual survey to assess consumer perceptions of the quality of pharmaceutical products and professional services could supply additional information upon which to base improvement strategies. For more information on CQI programs, visit Section 7 of Model Rules for the Practice of Pharmacy in *The Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy.*

Informational tools like the *ISMP Medication Safety Alert!* publication, or ISMP's *Quarterly Action Agenda,* which is a readily available list of medication problems compiled from the nation's reporting programs, can be a backbone of any CQI effort. The very purpose of the ISMP Medication Errors Reporting Program – indeed the purpose of any type of safety reporting program and the expert recommendations that stem from it – is to guide the implementation of quality improvement initiatives by practitioners and organizations.

It is important that certain information from the CQI proceedings and records of review be protected from discovery. Patient safety organizations (PSO) are organizations that share the goal of improving the quality and safety of health care delivery. Patient Safety Work Product (PSWP) is the information protected by the privilege and confidentiality protections of the Patient Safety Act and Patient Safety Rule. PSOs serve as independent, external experts who can collect, analyze, and aggregate PSWP locally, regionally, and nationally to develop insights into the underlying causes of patient safety events, thus improving quality by identifying and reducing the risks and hazards associated with patient care. Communications with PSOs are protected to allay fears of increased risk of liability because of collection and analysis of patient safety events.

For more information on PSOs, visit *https://www.pso.ahrq.gov/faq.*

NCPDP Releases Guide to Ensure Patients Get Their Medications During a Disaster

The National Council for Prescription Drug Programs (NCPDP) released the *NCPDP Emergency Preparedness Information* guide to assist pharmacists and other health care providers during a declared emergency. Prepared by the NCPDP Emergency Preparedness Committee, the guide provides resource information for eligibility and claims processing affecting displaced individuals. The guide is available at *www.ncpdp.org/NCPDP/media/pdf/NCPDPEmergencyPreparednessInformation_v1_4.pdf.* Additional information for pharmacists about emergency preparedness is available on the NCPDP website at *www.ncpdp.org/Resources/Emergency-Preparedness.*

FDA Warns of Illnesses and Deaths in Pets Exposed to Fluorouracil

Food and Drug Administration (FDA) is alerting pharmacists that patients' pets are at risk of illness and death when exposed to the topical cancer medication fluorouracil cream USP 5% (5-FU) that is intended for use in people. Fluorouracil may also be marketed under the brand names Carac®, Efudex®, and

Fluoroplex®. Very small amounts could be dangerous to household pets; thus, patients should use care when applying and storing the medication. FDA has received reports of five dogs that became ill and died after accidentally ingesting the topical cream, notes a Center for Veterinary Medicine Update available at *www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm537434.htm.*

Although FDA has not received any reports involving cats to date, cats are also expected to be extremely sensitive to fluorouracil cream. For instance, if an owner applies fluorouracil cream to an afflicted area and touches his or her cat, the cat may accidentally ingest the medication when grooming itself and suffer adverse events.

FDA advises that pharmacists who fill these prescriptions should advise patients with pets to prevent exposing their pet to the medication. Adverse events may be reported to FDA using the Form FDA 1932a, which may be obtained at *www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm055305.htm.*

FDA Revises Final Guidance Documents on Bulk Drug Substances Used in Compounding

In January 2017, FDA issued revised versions of two final guidance documents regarding the use of bulk drug substances in compounding.

- Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act
- Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act

FDA clarified that the policies described in the guidances do not apply to inactive ingredients. Inactive ingredients are not included in the definition of a "bulk drug substance" and can be used in compounding without appearing on the bulk drug substances lists developed under sections 503A or 503B of the Federal Food, Drug, and Cosmetic Act, if all applicable conditions are met.

As indicated on its website at *www.fda.gov/Drugs/DrugSafety/ucm502075.htm,* FDA will also provide regular updates to the categories of bulk drug substances described in the guidances. FDA previously stated that it would not evaluate new nominations for placement in one of the three categories until after it completed its review of substances already nominated with adequate supporting information.

Now, the guidances state that FDA will determine after submissions are received whether new nominations, including renominations of substances with additional supporting information, have sufficient information for FDA to review them. After making that determination, FDA will place nominated substances in the appropriate category on FDA's website. FDA intends to update the categories with any new nominations the first business day of each month. This revised policy will further minimize unnecessary disruptions to patient treatment while FDA develops the lists of bulk drug substances for use in compounding.

The guidances are available online at *www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469120.pdf* and *www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469122.pdf.*

APhA Resource Guide Applies JCPP Pharmacists' Patient Care Process to Immunization Services

The American Pharmacists Association (APhA) published a resource guide that applies the Joint Commission of Pharmacy Practitioners (JCPP) Pharmacists' Patient Care Process to pharmacy-based immunization services. The components of the Pharmacists' Patient Care Process to collect, assess, plan, implement, and follow-up should be implemented as routine practice along with the National Vaccine Advisory Committee Standards for Adult Immunization Practice, as noted in the resource guide, *Applying the Pharmacists' Patient Care Process to Immunization Services.* "[P]harmacists and other vaccine providers need to strive to constantly improve collaboration, communication, and documentation," indicates the APhA guide. For more information, visit the APhA Immunization Center at *www.pharmacist.com/immunization-center.*

CPE Training on Older Adult Fall Prevention Available Online

Developed in collaboration with the Centers for Disease Control and Prevention (CDC) and the APhA, the Stopping Elderly Accidents, Deaths, and Injuries (STEADI) initiative is offering continuing pharmacy education (CPE) training for pharmacists to prevent falls in adults 65 and older. The training will provide strategies to help pharmacists screen older adults for fall risk, conduct medication review and management, and offer patient education. To participate in the free online training, "STEADI: The Pharmacist's Role in Older Adult Fall Prevention," visit the CDC website at *www.cdc.gov/steadi/training.html* for more information.

New FDA Drug Info Rounds Training Video Addresses the Combat Methamphetamine Epidemic Act

Drug Info Rounds, a series of online videos by FDA, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the latest Drug Info Rounds video, "Combat Methamphetamine Epidemic Act," pharmacists discuss the legal requirements for the sale of over-the-counter drug products that contain pseudoephedrine. Drug Info Rounds was 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.*

FDA Presents Series of CE Webinars for Students and Clinicians

FDA's Division of Drug Information in the CDER presents a series of continuing education (CE) 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. Previous webinar topics have included an overview of FDA's role in medication error prevention and prescription drug labeling. The webinars and presentation slides can be accessed on FDA's website at *www.fda.gov/DDIWebinars.*

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advanced notice of a prescriber's relocation/termination, the pharmacist needs to decide the appropriate reaction in order to optimize patient safety.

Iowa Board of Pharmacy rule IAC 657—8.20(155A) states that prescriptions are only valid while a prescriber/patient relationship exists. However, it also allows for prudent judgment (by the pharmacist) based on individual circumstances to ensure continuity of therapy until the patient can obtain a relationship with a new provider.

There are many instances where an interruption in therapy is dangerous to patient safety, and unfortunately, they often overlap with the type of prescriber who is hard for patients to gain access to, such as neurologists and mental health practitioners. For example, if a patient has an appointment with a new prescriber that is a few months away, it is justifiable to continue using the patient's current refills from the previous prescriber to avoid an interruption in therapy if the patient has a history with the pharmacy and is stable on the medications in question.

Perils From the 2017 DEA PDAC: Pharmacy Robberies and Burglaries

By Chris Caracci, Pharmacist Intern

On July 16, 2017, United States Drug Enforcement Administration (DEA) hosted a pharmacy diversion awareness conference (PDAC) in Des Moines, IA. During this conference, DEA Task Force Officer Frank Magel, from the Tactical Diversion Squad in St Louis, MO, discussed DEA's policy and procedures for robberies and what to do to prevent them from occurring. Below is a summary of suggestions made by Officer Magel and DEA. These are recommendations based on DEA's experience with burglaries and robberies.

The most important aspect during any robbery is to ensure the safety of the community, your employees, and yourself. You should never resist the robber or burglar but should always follow their orders. To mitigate any potential harm, never try to stop the burglar yourself; avoid any sudden movements and wait for law enforcement. Additionally, you should try to make mental notes of any physical aspects of the robber that can be used when talking to local law enforcement later. Some things to try to remember would be the robber's race, approximate height and weight, piercings, tattoos, hair, clothes, skin or physical deformities, and shoes. Try to write these notes down as quickly as possible after the incident to avoid forgetting any important details.

After a robbery, make sure to get treatment for any individuals who may have been harmed. You should try to sound an alarm or contact the authorities as soon as possible. Lock the store to prevent anyone else from entering the scene and tampering with any potential evidence, such as fingerprints. Ask customers who witnessed the robbery to stick around until law enforcement arrives to provide any additional testimony about what they witnessed. Document what was stolen from the pharmacy and fill out all required paperwork to comply with local, state, and federal regulations.

Thieves and burglars often target people or locations with weaker security. The more security measures you have in place and the more prepared you are, the less likely you are to be a target. The following are some tips you can follow to help prevent robberies from occurring:

- Install an alarm system and make sure to test it frequently.
- Utilize security cameras that give you good visibility of all areas of the pharmacy. Make sure to put up visible signage stating that the area is under surveillance.
- Install a panic button and use it as soon as you see a thief escaping out the door.
- Give local police departments a store discount so they may establish a more pronounced presence in the store. This deters thieves from targeting a store with frequent visits from law enforcement. You can also invite law enforcement to conduct a security assessment of the pharmacy.
- Install height markers at exits to the store and also near the pharmacy area. These can help witnesses take note of the thief's height and may also tend to deter targeting by thieves.
- Use appropriate physical layouts for the pharmacy. For example, banks do not display money; likewise, avoid displaying medications.
- Conduct criminal background checks on every pharmacy employee.
- Greet customers as they enter the pharmacy. The more attentive the pharmacy staff is, the more likely thieves will be deterred from targeting the pharmacy.
- Be vigilant of any suspicious behavior, including individuals spending a lot of time around the pharmacy without buying anything.

Nonresident Pharmacy PIC Registration Required for 2018

By Chris Caracci, Pharmacist Intern

The Board recently approved new rules regarding nonresident pharmacy practice that will become effective September 6, 2017, and enforceable beginning January 1, 2018. Beginning with calendar year 2018, the pharmacist-in-charge (PIC) at every nonresident pharmacy will be required to register with the Board. This registration will be a one-year registration that will begin on January 1 of the calendar year and expire on December 31 of the same year. Nonresident pharmacies are those that are located outside of the state of Iowa that deliver, dispense, or distribute prescription drugs or devices to an ultimate user who is physically within the state of Iowa.

This adaptation of the current process does not require Iowa licensure for the PIC, but will increase the accessibility for the Board to contact the PIC at the nonresident pharmacy. In the past, the Board has had some difficulty contacting the PIC at some nonresident pharmacies due to frequent staffing changes. The change will also require completion of an educational training module regarding

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the Iowa rules as they relate to nonresident pharmacy practice. The Board is currently in the process of creating this module.

The application itself will require basic information about the PIC, including name and contact information, the pharmacist's license or registration number in the state the nonresident pharmacy is located, verification that the license is current and in good standing, the PIC's current place of employment, and any criminal and disciplinary history information. It will also require a $75 nonrefundable administrative fee for processing. Similar to resident pharmacies in the state, a change in the PIC requires submission of a new application and fee. The pharmacy must submit notification of a temporary PIC within 10 days of the change, and a permanent PIC must be identified and registered with the Board no later than 90 days following the vacancy. Any changes in PIC information (name, contact information, home state license or registration status, and place of employment) must be reported to the Board in writing within 10 days of the change. Currently, there are approximately 1,000 nonresident pharmacies in the state of Iowa.

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