



Iowa Board of Pharmacy

Published to promote compliance of pharmacy and drug law

400 SW 8th St, Suite E • Des Moines, IA 50309-4688 • Tel: 515/281-5944

Fax: 515/281-4609 • Website: <https://pharmacy.iowa.gov>

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. Also, all items on the form must be completed, including the quantity shipped, date shipped, and National Drug Code for each product shipped. If the form is incomplete, you may be contacted by DEA for completion. When a pharmacy **purchases** CS from another pharmacy or a wholesaler by way of the triplicate DEA Form 222, state rules require the pharmacy (or other purchaser) to record the quantity of each substance received and the date of receipt on Copy 3 (blue copy). Additionally, the purchaser "shall initial each line identifying a substance received" on Copy 3. While there is not a specific location on each line where that is to be done, it is recommended to do so away from the written documentation of the quantity and date received. As Copy 3 is the official record of receipt for those CS, it is critical that information not be obscured by the purchaser's initials. It is recommended for the individual checking in the order to place his or her initials on the far left side of the DEA Form 222 between the margin of the paper and the "Line No." column. Any questions regarding the completion of this form can be directed to your compliance officer or your local DEA office at 515/284-4709.

Drug Identification – Who Can Perform?

By Terry Witkowski, Board Executive Officer

The identification of medication may be performed by a pharmacy technician as long as the pharmacist-in-charge and the supervising pharmacist agree to permit the technician to perform that function. Policies and procedures should clearly define who can perform the function, when the pharmacist should be consulted (eg, if the technician cannot clearly identify the medication), the resources to be used to assist in identifying the medication, and the limits of the technician's interaction with the practitioner. For example, the technician

may identify the medication to the practitioner, but should not advise the practitioner regarding the advisability of the patient's continued use of the medication or the implied diagnosis that prompted the patient's need or use of the medication.

Emergency Supplies for Immunizations

By Sue Mears, RPh, Board Compliance Officer

If your pharmacy provides immunizations, be it seasonal influenza and pneumococcal or year-round Zostavax[®], etc, Iowa Board of Pharmacy compliance officers would like to remind you of the importance of maintaining adequate supplies for an emergency. While anaphylaxis is highly unlikely, you want to be sure you have the right materials available to take care of the patient. You are reminded to have all the items identified in the immunization protocol (such as epinephrine and diphenhydramine, blood pressure cuff(s), etc), that you have the minimum quantities or number of doses identified in the protocol, and that they are not expired. It is highly recommended that the pharmacy have a kit or container of all the emergency supplies identified in the protocol and have the supplies readily available in the area where immunizations are provided, while maintaining adequate security for the drug products. If your immunization staff is unaware of the location of these products, that will not do much good in an emergency. Additionally, if the pharmacy does not have adequate stock of the emergency drugs (for example, the protocol calls for at least three doses of EpiPen Jr[®] but the pharmacy only stocks one twin pack), the pharmacy should not provide immunizations until adequate supplies are available.

Proposed Legislation for the 87th General Assembly

The Board has proposed three bills for the 2017 Iowa legislative session. One component of the first bill, currently known as Senate Study Bill (SSB) 1074, would add a new section to the Pharmacy Practice Act (155A) allowing formation of a pool of up to seven alternate Board members. Situations can arise at Board meetings where a quorum is unattainable due to illness, need for recusal, or other extenuating circumstances. Alternates would serve as a

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FDA Issues Final Rule Amending List of Drug Products That May Not Be Compounded

Food and Drug Administration (FDA) issued a final rule amending FDA's list of drug products that may not be compounded under certain sections of the Federal Food, Drug, and Cosmetic Act (FD&C Act) that allow the marketing of unapproved compounded drugs. Drug products on the list may not be compounded because the drug products have been withdrawn or removed from the market for safety or effectiveness reasons, indicates FDA. The list may be found in the Code of Federal Regulations at Title 21, Section 216.24, at www.ecfr.gov.

The final rule adds 24 types of drugs to the withdrawn or removed list; modifies the withdrawn or removed list to allow one type of drug product to be compounded under certain circumstances; and clarifies that the withdrawn or removed list applies to sections 503A and 503B of the FD&C Act. The final rule is available at www.gpo.gov/fdsys/pkg/FR-2016-10-07/pdf/2016-24333.pdf. FDA provides more information online at www.fda.gov/Drugs/DrugSafety/ucm524320.htm.

Selected Medication Risks to Manage in 2017

 *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.*

Some medication safety risks are painfully apparent in an organization, while many others lie dormant in the system until an error or adverse event draws attention to them. ISMP thought it would be useful to describe selected medication safety risks for organizations to manage in 2017 that might otherwise fall off the radar screen.

Environmental Factors, Workflow, and Staffing Patterns – Poor Quality Lighting

Lighting is a crucial aspect of the physical environment that has been linked to medication safety.¹ Poor quality lighting has often impaired the highly visual tasks associated with medication use, thus leading to medication errors. Examples include tubing misconnections due to low lighting in a patient's room, infusion pumps that have been misprogrammed because of dim backlighting on the screens, and product selection errors in the pharmacy and patient care units caused by low lighting under a pharmacy hood or shadows around an automated dispensing cabinet (ADC).

Despite existing guidelines for lighting in health care, it has been a challenge to implement optimal lighting conditions for prescribing, dispensing, and administering medications. Recent literature reviews found that little system-wide action has been

taken to increase staff awareness of the problem or improve the lighting.^{1,2} This is largely because the tasks associated with medication use are varied and carried out under diverse physical conditions and in differing locations, and because there are differences in an individual's light requirements based on visual acuity and age. With an ever-increasing population of older health care providers, eye fatigue from computer work and task complexity, small font sizes on medication labels, poor background contrast, and glare or shadows have taken their toll on visual accuracy.^{1,2}

Proper illumination improves both the accuracy and efficiency of medication-related tasks. Fluorescent cool white lamps or compact fluorescent lamps should be used in areas where critical tasks are performed, including on mobile medication carts, near ADCs, and in patients' rooms for nighttime administration of medications.^{3,4} Administration of medications at night under low lighting to avoid disturbing the patient is an unsafe practice and should be avoided. Adjustable 50-watt high-intensity task lights are recommended when difficult-to-read prescriptions and product labels are encountered.⁴ Illumination levels for computer order entry areas should be at least 75 foot-candles (fc), while 100-150 fc are needed when interpreting handwritten orders.⁴ Medication preparation areas, medication verification areas, and patient counseling areas should have illumination levels between 90-150 fc.⁴ Medication rooms should provide illumination at 100 fc.⁴ Lighting levels should be increased if the workforce has an average age above 45 years. A magnifying glass and task light together can also significantly improve accuracy³ and should be used on mobile medication carts (including those used with bar code medication verification systems)⁴ and near ADCs.

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3. Grasha AF. Psychosocial factors, workload, and risk of medication errors. *US Pharm.* 2002;27(4):HS32-52.
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DEA to Decrease Manufacturing Amount of Opioid Controlled Substances in 2017

Drug Enforcement Administration (DEA) is reducing the amount of almost every Schedule II opiate and opioid medication that may be manufactured in 2017 by 25% or more. Other medicines were reduced by more, such as hydrocodone, which will be 66% of last year's level, indicates the DEA news release. DEA notes that demand for these opioid medicines has declined based on sales data from IMS Health, a company that provides insurance companies with data on prescriptions written and prescription medications sold in the United States.

The aggregate production quota (APQ) established by the final order is the total amount of a controlled substance (CS) necessary to meet the estimated medical, scientific, research, industrial, and export needs for the year and for the maintenance

News to a particular state or jurisdiction can only be ascertained such state or jurisdiction.

of reserve stocks. The 2017 APQ has been reduced for oxycodone, hydrocodone, fentanyl, hydromorphone, morphine, and other such medications. Much of this reduction is attributed to the elimination of a 25% buffer that was added to the APQ annually in 2013 through 2016 to guard against shortages. The purpose of quotas is to provide an adequate and uninterrupted supply for legitimate medical need of the types of Schedule I and II CS that have a potential for abuse, while limiting the amounts available to prevent diversion.

Additional details may be found in the DEA news release available at www.dea.gov/divisions/hq/2016/hq100416.shtml and in the final order available at <https://www.gpo.gov/fdsys/pkg/FR-2016-10-05/pdf/2016-23988.pdf>.

New CDC Brochure Offers Pharmacists Tips for Addressing Prescription Opioid Abuse and Overdose

Centers for Disease Control and Prevention (CDC) released a brochure encouraging pharmacists, who are an essential part of the health care team, to help prevent opioid abuse and overdose. The brochure, “Pharmacists: On the Front Lines,” offers tips for communicating with patients who are receiving opioid therapy. In addition, the brochure offers tips on how to identify forged prescriptions and urges pharmacists to maintain collaborative working relationships with prescribers to improve patient outcomes. The brochure is available at www.cdc.gov/drugoverdose/pdf/pharmacists_brochure-a.pdf.

FDA Requires Boxed Warnings and Patient-Focused Medication Guides Indicating Serious Risks Related to Combined Use of Certain Opioid Medications and Benzodiazepines

FDA is requiring class-wide drug labeling changes to inform health care providers and patients of the serious risks associated with the combined use of certain opioid medications and benzodiazepines. Specifically, after an extensive review of the latest scientific evidence, FDA is requiring boxed warnings and patient-focused Medication Guides for prescription opioid analgesics, opioid-containing cough products, and benzodiazepines that provide information about the serious risks associated with using these medications at the same time. Risks include extreme sleepiness, respiratory depression, coma, and death.

FDA’s news release indicates the changes are part of the agency’s Opioids Action Plan, which focuses on policies aimed at reversing the prescription opioid abuse epidemic while providing patients in pain with access to effective and appropriate pain management. The public health crisis is evident through the significant rise of preventable overdose and death associated with the concurrent use of two drug classes, indicates FDA Commissioner Robert Califf, MD, in the press release, available at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm518697.htm.

FDA’s Division of Drug Information Offers CE Webinars for Students and Clinicians

FDA’s Center for Drug Evaluation and Research (CDER), Office of Communications, Division of Drug Information 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 drug shortages and prescription drug promotion. The webinars and presentation slides can be accessed on FDA’s website at www.fda.gov/DDIWebinars.

FDA Approves Labeling Changes for All Prescription Testosterone Products

In October 2016, FDA approved class-wide labeling changes for all prescription testosterone products regarding the risks associated with abuse and dependence of the drug. The changes include adding a new warning as well as updating the Abuse and Dependence section to include new safety information from published literature and case reports regarding the risks associated with abuse and dependence of testosterone and other anabolic androgenic steroids (AAS). The Anabolic Steroids Control Act of 1990 placed AAS, including testosterone, in Schedule III of the Controlled Substances Act.

Prescription testosterone products are FDA-approved as hormone replacement therapy for men who have low testosterone due to certain medical conditions. However, testosterone and other AAS are abused by adults and adolescents, including athletes and body builders, notes FDA. FDA indicates the new warning will “alert prescribers to the abuse potential of testosterone and the serious adverse outcomes, especially those related to heart and mental health that have been reported in association with testosterone/AAS abuse.” In addition, new labeling information in the Warning and Precautions section advises prescribers of the importance of measuring serum testosterone concentration if abuse is suspected.

FDA explains that abuse of testosterone, usually at doses higher than those typically prescribed and usually in conjunction with other AAS, is associated with serious safety risks affecting the heart, brain, liver, mental health, and endocrine system. Reported serious adverse outcomes include heart attack, heart failure, stroke, depression, hostility, aggression, liver toxicity, and male infertility. Individuals abusing high doses of testosterone have also reported withdrawal symptoms, such as depression, fatigue, irritability, loss of appetite, decreased libido, and insomnia. The FDA announcement is available at www.fda.gov/Drugs/DrugSafety/ucm526206.htm.

Latest FDA Drug Info Rounds Training Videos Available

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, “Extortion Scam,” pharmacists discuss steps a potential victim could take if they receive a call from individuals posing as FDA and DEA agents. Drug Info Rounds is developed with contributions from pharmacists in FDA’s 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.

valuable addition in keeping Board action from being delayed. A second component of the bill would allow for the Board to determine on an annual basis how much of its retained fees can be allocated toward the pharmaceutical collection and disposal program. Current Iowa Code caps the annual program allocation at \$175,000. In an effort to curb the abuse and misuse of unwanted pharmaceuticals, the Board aims to provide DEA-compliant disposal receptacles to all eligible in-state pharmacies. Removal of the cap will help facilitate that goal.

The Board's second proposed bill, currently known as SSB 1073, relates entirely to the already established Iowa Prescription Monitoring Program (PMP). Current legislation requires pharmacies, both in-state and nonresident, to report all prescriptions filled for drugs in Schedules II, III, and IV. Adding a requirement for reporting of Schedule V CS, dispensed pursuant to a prescription, is included in the bill. Additionally, it has been proposed to require practitioners who dispense CS out of their practice location to submit data of those direct patient distributions to the PMP database. The ability to provide unsolicited reports to pharmacies and prescribers is a third major component of the bill. If granted this function, the Board and the PMP Advisory Council would be responsible for determining criteria used to identify patients with potentially problematic CS drug therapies and/or use patterns. All aforementioned components of the bill dovetail with a newly defined program goal of reducing drug overdoses and deaths attributable to prescription drug use and abuse.

The third bill introduced by the Board, SSB 1085, updates Iowa Code to mirror the federal status of hydrocodone-containing products as Schedule II and tramadol as Schedule IV. It also places four synthetic opioids – furanyl fentanyl, butyryl fentanyl, beta-hydroxythiofentanyl, and U-47700 – into Schedule I to fall in line with federal law.

All bills can be tracked on the Iowa legislature website at www.legis.iowa.gov. Visit the Legislation section, then Bill Tracking Tools, then Bills & Rules Watch for updates on the status of proposed bills.

New Database on the Way for Board

Board executive and administrative staff have been working hard with the state's Office of the Chief Information Officer to develop a request for proposal for a new database that, among other upgrades, would allow for online license renewals for all categories of licensees and registrants. It is paramount that the new system chosen by the selection committee allows for a streamlined, electronic process whereby pharmacies, pharmacists, technicians, support persons, wholesalers, and CS registrants can submit their renewals at required intervals. The new system is also slated to enable remote access by compliance officers located throughout the state. Implementation of the new database is scheduled to begin in June 2017. Pharmacists due to renew their licenses in June 2018 will be doing so online.

Secret Shopper Visits

In December 2016, the *Chicago Tribune* published an article detailing results of a study that their reporters conducted involving attempts to fill risky combinations of prescription drugs at pharmacies. The majority of the pharmacies visited by *Tribune* reporters were in the Chicago, IL area, but others were

in Indiana, Michigan, and Wisconsin. Of the 255 pharmacies visited, 52% sold medications to patients without counseling patients on dangerous drug interactions, such as concomitant use of simvastatin and clarithromycin.

In light of the study results coming out of Illinois and as part of the Board's charge to protect the safety of patients, the Board will be conducting its own "secret shopper" visits at pharmacy locations in Iowa. Iowa pharmacy regulations require that a pharmacist or pharmacist intern counsel a patient on every new prescription. As a reminder, Iowa Administrative Code 657-6.14(1) reads as follows:

6.14(1) *Counseling required.* Upon receipt of a new prescription drug order, or upon receipt of a change in drug therapy including but not limited to a change of dose, directions, or drug formulation, and following a prospective drug use review pursuant to 657—8.21(155A), a pharmacist shall counsel each patient or patient's caregiver. An offer to counsel shall not fulfill the requirements of this rule. Patient counseling shall be on matters which, in the pharmacist's professional judgment, will enhance or optimize drug therapy. Appropriate elements of patient counseling may include:

- a. The name and description of the drug;
- b. The dosage form, dose, route of administration, and duration of drug therapy;
- c. Intended use of the drug, if known, and expected action;
- d. Special directions and precautions for preparation, administration, and use by the patient;
- e. Common severe side effects or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
- f. Techniques for self-monitoring drug therapy;
- g. Proper storage;
- h. Prescription refill information;
- i. Action to be taken in the event of a missed dose;
- j. Pharmacist comments relevant to the individual's drug therapy including any other information peculiar to the specific patient or drug.

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