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IAC 657-11: Drugs in Emergency Medical Service Programs

By Sue Mears, MBA, RPh, Board Compliance Officer

Registrations Required in Medical Director-Based EMS Programs

Iowa Administrative Code (IAC) 657-11 defines "emergency medical services (EMS)" as well as the responsibilities of service directors in EMS program sites. In each EMS program that is medical director-based and maintains controlled substances (CS) in its program, the primary program site must obtain and maintain registration through the Iowa Board of Pharmacy under the Iowa Uniform Controlled Substances Act (CSA) and through Drug Enforcement Administration (DEA) for the specific location of the primary program site. A medical director who already holds CSA and DEA registrations at another location (for example, his or her primary place of employment) is not automatically "covered" by these other registrations. **Every individual location in Iowa that handles or stocks CS must have such registrations for the individual location.** In service programs that maintain multiple stations, only the primary program site requires such registrations, so long as the substations only have the CS on hand that are needed to immediately treat their patients. If a substation has any replenishment stock of CS, it effectively becomes another primary program site and must obtain and maintain appropriate CSA and DEA registrations for that location. A medical director-based service program that does not include CS in its program is not required to maintain such registrations.

Procurement of Drug Products in Medical Director-Based EMS Programs

When a medical director-based program needs to obtain prescription drugs for use in the program, such drugs must be obtained from a pharmacy, wholesaler, or practitioner that is licensed in Iowa. Such purchase of drugs is essentially a wholesale transaction to transfer ownership of the drug products to the medical director. As such, these transactions are not considered "prescription" transactions, and the medical director or designee should not be issuing a prescription in the name of the service program or practitioner to present to a pharmacy. When buying products from a pharmacy, the medical director or designee needs to simply identify the products that the service program needs to purchase. The pharmacy should then provide the products as a wholesale transaction without processing the products through the pharmacy's computer system as a prescription transaction. The pharmacy needs to create a disbursement record that contains all required information as identified in the Board's rules to provide to the service program as well as maintain a copy in its records. The service program is required to maintain this record as its receipt record for at least two years from the date of the transaction. For Schedule II CS, the service program must provide a completed DEA Form 222 that is specific to the location where the substances will be utilized.

Transfer of CS Between Sites in a Medical Director-Based EMS Program

In a service program that has multiple primary program sites, each site where CS are stored (beyond what is needed to immediately treat its patients) must obtain and maintain Iowa CSA and DEA registrations. As such, each site that is individually registered must account for the CS at the individual site. When the individual location obtains CS, the required documentation must be maintained for at least two years from the date of the transaction. If a primary program site needs to transfer CS to another primary program site, all the required documentation must be completed, as this is effectively a transfer of ownership between the two registered locations. Such documentation includes a disbursement record (created by the seller to provide to the buyer and a copy maintained by the seller) and, if a Schedule II CS, a DEA Form 222.

Iowa Monitoring Program for Pharmacy Professionals

The Board has launched its new monitoring program for pharmacy professionals. The Iowa Monitoring Program for Pharmacy Professionals (IMP3) was established to succeed the Board's previous program administered by the Iowa Pharmacy Recovery Network. IMP3 is a completely confidential program designed to assist pharmacists, pharmacy technicians, and pharmacist interns with obtaining necessary assistance to aid in the recovery from substance abuse or mental and physical impairments. Board staff will be working in cooperation with staff from the Iowa Board of Medicine to administer this program.

Any currently licensed or registered pharmacist, technician, or intern struggling with impairment is encouraged to report to the program. Reporting can be done through the Board's website, *https://pharmacy.iowa.gov,* under the "Misc." tab, or by contacting Iowa Physician Health Program Coordinator Amy Van Maanen with the Board of Medicine via email at amy.vanmaanen@iowa.gov or by calling 515/281-6006.

FDA Calls for Review of Opioids Policy, Announces Action Plan

As part of a broad national campaign to address opioid abuse, dependence, and overdose, Food and Drug Administration (FDA) Deputy Commissioner for Medical Products and Tobacco, Dr Robert Califf, along with other FDA leaders, developed a comprehensive action plan to reassess the agency's approach to opioid medications. The objective of the plan is to "focus on policies aimed at reversing the epidemic, while providing patients in pain access to effective relief," indicates the FDA news release. FDA's plan is to:

- Re-examine the risk-benefit paradigm for opioids and ensure that the agency considers their wider public health effects;
- Convene an expert advisory committee before approving any new drug application for an opioid that does not have abuse-deterrent properties;
- Assemble and consult with the Pediatric Advisory Committee regarding a framework for pediatric opioid labeling before any new labeling is approved;
- Develop changes to immediate-release (IR) opioid labeling, including additional warnings and safety information that incorporate elements similar to the extended-release/long-acting (ER/LA) opioid analgesics labeling that is currently required;
- Update Risk Evaluation and Mitigation Strategy requirements for opioids after considering advisory committee recommendations and review of existing requirements;
- Expand access to, and encourage the development of, abuse-deterrent formulations of opioid products;
- Improve access to naloxone and medication-assisted treatment options for patients with opioid use disorders; and
- Support better pain management options, including alternative treatments.

FDA will also seek guidance from outside experts in the fields of pain management and drug abuse. The National Academies of Sciences, Engineering, and Medicine has been asked by FDA to help develop a framework for opioid review, approval, and monitoring that balances individual need for pain control with considerations of the broader public health consequences of opioid misuse and abuse. The news release is available on FDA's website at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm484765.htm.*

More 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.*

Manufacturer Drug Labeling, Packaging, Nomenclature – Per Liter Electrolyte Content on Various Sizes of Manufacturers' IV Bags

The way electrolyte concentrations are expressed on intravenous (IV) bags in volumes less than or greater than one liter has tripped up many practitioners over the years. Concentrations are listed per liter, not per container volume. For example, a 250 mL 0.9% sodium chloride injection container label lists the sodium chloride content as 154 mEq/1,000 mL, rather than 38.5 mEq/250 mL. Commercially available parenteral nutrition products available in containers greater than one liter also express the electrolyte ingredients "per liter."

An error occurred while a pharmacist was preparing a bag of 3% sodium chloride after the pharmacy unexpectedly ran out of the commercially available bags. The pharmacist mistakenly set the proportion up as 154 mEq/0.9% = x/3% and calculated that he needed 513 mEq of sodium chloride, when he actually only needed 256-257 mEq of sodium chloride for a 500 mL bag (77 mEq/0.9% = x/3%).

For single- and multiple-dose injectables, the United States Pharmacopeial Convention (USP) requires the strength per total volume as the primary, prominent display on the label, followed in close proximity by the strength per mL enclosed in parentheses. This should apply to large volume parenterals as well. Until it does, pharmacists who calculate electrolyte quantities should seek out an independent double check. Sufficient quantities of commercially available products should be used whenever possible. For products that routinely require admixture, an instruction sheet should be available to guide the process.

Patient Education – Discharging Patients Who Do Not Understand Their Discharge Medications

Despite the importance of teaching patients about the medications to take after discharge, studies suggest health care providers are not successfully preparing patients for the transition home. Between 30% and 70% of patients make a medication error in the immediate weeks following hospitalization,[1-5] and the Centers for Medicare & Medicaid Services reports an average national hospital readmission rate of 17.5% to 19.5%.[6] The discharge process is often rushed and interrupted, making it difficult to ensure patients know what medications to take, the correct doses, and how to take them after discharge. Immediately prior to discharge is not an ideal time for education either, as patients may be overwhelmed with the amount of information being provided at once.

Medication errors that occur during the first few weeks after discharge from the hospital can cause significant harm. In fact, one study showed that almost a quarter of all post-discharge errors were considered serious or life-threatening, and that

most of these errors happened within the first 14 days after discharge.[5] The highest predictors of post-discharge errors included low health literacy and low subjective numeracy (self-reported measure of the ability to perform mathematical tasks and the preference for numerical versus prose information (ie, ordinary words)).[4]

Perhaps this risk is best addressed with a redesigned discharge process that facilitates the most effective means of teaching patients about their medications, initiating education earlier in the hospital stay, and providing post-discharge support.

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USP Publishes Chapter on Handling Hazardous Drugs in Health Care Settings

A new general chapter, <800> *Hazardous Drugs—Handling in Healthcare Settings,* has been published as part of a suite of health care quality standards included in the *United States Pharmacopeia – National Formulary (USP–NF)* by USP to help prevent and/or limit hazardous drug exposures in health care. The standard applies to all health care personnel, such as physicians, nurses, veterinarians, pharmacists, and technicians, and all health care facilities where hazardous drugs are handled or manipulated, including their storage and distribution. Health care facilities have more than two years to conform to the new requirements and have until July 1, 2018, to implement the new standard, indicates a USP press release, which is available at *www.usp.org* in the News section. General Chapter <800> is available in both the First Supplement to *USP 39–NF 34* and the *USP Compounding Compendium.*

FDA Provides Training Video on Keeping Medications Safe in Emergency Situations

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 February 2016 Drug Info Rounds video, "Emergency Preparedness – Keeping Medications Safe," pharmacists discuss educating patients about having a plan in place for emergency medication and medical supplies and the resources available for pharmacists to use when advising their patients. Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, 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 Requires Class-Wide Labeling Changes for IR Opioid Analgesics

FDA is requiring class-wide safety labeling changes for IR opioid pain medications, which will include a new boxed warning about the serious risks of misuse, abuse, addiction, overdose, and death. The announcement is part of the agency's effort to educate prescribers and patients about the potential risks related to opioid use. FDA is also requiring several safety labeling changes across all prescription opioid products to include additional information on the risk of these medications. The new requirements are part of a plan to reassess the agency's approach to opioid medications. The plan is focused on reversing the epidemic of abuse and overdose while still providing patients in pain access to effective relief, indicates the FDA news release at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery.*

Further, FDA is requiring updated labeling for all opioids (both IR and ER/LA products) to include safety information about potentially harmful drug interactions with other medicines that can result in a serious central nervous system condition called serotonin syndrome. In addition, updated labeling will include information about opioid effects on the endocrine system, including a rare but serious disorder of the adrenal glands (adrenal insufficiency) and decreased sex hormone levels (androgen deficiency). More information about these risks is available in FDA's Drug Safety Communication announcement, available at *www.fda.gov/Drugs/DrugSafety/ucm489676.htm.*

FDA Issues Alert Regarding All Unexpired Sterile Drug Products Produced by Medaus Pharmacy

On April 1, 2016, FDA alerted health care providers and patients not to use products marketed as sterile from Medaus Pharmacy in Birmingham, AL. Insanitary conditions, including poor sterile production practices, were identified by FDA investigators during a recent inspection at Medaus' facility. The affected products were distributed nationwide and internationally. The alert applies to all unexpired drug products that are intended to be sterile. Health care providers should check their medical supplies, quarantine any drug products marketed as sterile from Medaus, and not administer them, indicates the FDA Safety Alert, available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsForHumanMedicalProducts/ucm493871.htm.*

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Iowa PMP User Accounts

By Terry Witkowski, Board Executive Officer

Iowa Prescription Monitoring Program (PMP) login credentials are not issued to a pharmacy – login credentials are issued to an individual user and may not be shared among pharmacy staff members. Each individual who will be accessing the Iowa PMP to check a patient's prescription history must have his or her own unique username and password. A pharmacist registers online at *https://pmp.iowa.gov/IAPMPWebCenter* as a pharmacist user. When the pharmacist's registration has been processed, the pharmacist will receive an email with the pharmacist's unique username and password. These credentials must remain confidential and may be used by the registered pharmacist only. A pharmacist PMP user may authorize as many as three technicians to act as the pharmacist's agent to access patient information in the Iowa PMP. A pharmacist's agent (technician) must register using the agent user registration form available on the Board's website at *https://pharmacy.iowa.gov/document/pmp-agent-user-registration*. The form must be completed, signed on both pages by the pharmacist and the technician, and submitted to the Board office. Once the agent registration is approved, the technician will receive an email with the technician's unique username and password. These credentials are confidential and may be used by the registered technician only.

A pharmacy staff person should not be checking Iowa PMP patient information for a prescriber. The pharmacist or technician is not an agent of the prescriber. A prescriber should register to access the Iowa PMP and should use his or her own unique login credentials to check a patient's prescription history. A PMP user may only check a prescription history on the Iowa PMP if the subject of the request is a patient of the user. If the pharmacy has not filled a prescription for the patient or has not been presented with a prescription to be filled for the patient, a pharmacist or technician user may not request PMP information regarding the patient. A pharmacist or technician who violates the confidentiality provisions of the Iowa PMP, including inappropriate access, use, or disclosure of PMP information, may be subject to disciplinary action by the Board, including license sanctions and a fine of $25,000. In addition, the pharmacist or technician may be prosecuted for violation of the Health Insurance Portability and Accountability Act, which may include a fine of up to $25,000 per violation and may also be subject to Iowa criminal felony prosecution. All PMP users should be familiar with the appropriate Use Policy available on the Board's website under "PMP Information for Practitioners."

Drug Disposal Programs

The state of Iowa has executed a contract with Assured Waste Solutions, LLC (AWS) to provide the state with DEA-compliant pharmaceutical collection receptacles. General pharmacies (community pharmacies) interested in becoming a CS collector may contact Compliance Officer Jennifer Tiffany via email at jennifer.tiffany@iowa.gov for more information or to express interest in receiving a receptacle. Program funding will be supported by the Board through its license and registration fees. No additional costs will be incurred by the participating pharmacies. The pharmacy will be responsible for the proper installation of the receptacle, but may consult with Board compliance staff as necessary. Funding is limited. Not all pharmacies expressing interest are guaranteed to receive a receptacle during fiscal year 2017.

The state of Iowa has executed an additional drug disposal contract with the Iowa Pharmacy Association (IPA) to continue to provide boxes for the collection of non-CS. As with the CS receptacles, the TakeAway boxes are funded by and through the Board's license and registration fees. For more information, or to order a TakeAway box, please contact IPA at 515/270-0713.

Pharmacies utilizing a Board-issued CS receptacle through AWS are permitted and encouraged to utilize the receptacle for non-CS as well as for CS. Because of limited funding, pharmacies that receive a CS receptacle from Board funds are not eligible to receive TakeAway boxes for non-CS.

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