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News



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Resource for Prescribing of Opioids

In March, the Centers for Disease Control and Prevention (CDC) published in the *Morbidity and Mortality Weekly Report* the “CDC Guideline for Prescribing Opioids for Chronic Pain,” available at <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>.

The guideline provides recommendations for clinicians for the prescribing of opioids for chronic pain outside of active cancer treatment.

The guideline addresses:

- (1) when to initiate or continue opioids for chronic pain;
- (2) opioid selection, dosage, duration, follow-up, and discontinuation; and
- (3) assessing risk and addressing harms of opioid use.

Information provided in the guideline is evidence-based and peer-reviewed. The guidelines include 12 recommendations, each with rationale and implementation considerations.

The guideline specifically notes the role of pharmacists, recommending that clinicians “consider involving pharmacists and pain specialists as part of the management team when opioids are co-prescribed with other central nervous system depressants.”

Pharmacists may find this to be an interesting and relevant resource.

Legislation Affecting Pharmacy – 2016

Vermont Act 173

The opioid crisis has moved legislatures throughout the country to enact legislation in an attempt to combat this crisis. The General Assembly in Vermont recently passed Act 173 (Senate 243), titled “An act relating to combating opioid abuse in Vermont,” which adds to or modifies several existing Vermont statutes.

The act has several important implications for Vermont pharmacists. The act identifies those circumstances under which a pharmacist must query the Vermont Prescription Monitoring System (VPMS); acknowledges the expanding role of pharmacists and defines “practice of pharmacy,” “practice of clinical pharmacy,” and “collaborative practice agreement”; adds a specific continuing education requirement related to controlled substances (CS) that requires two hours every licensing period for those pharmacists who have a Drug Enforcement Administration number or dispense CS; creates a Controlled Substances and Pain Management Advisory Council that includes pharmacist members; and creates an Unused Prescription Drug Disposal Program.

Listed here are excerpts of those sections of the act that may be of particular interest to pharmacists.

Sec. 2. 18 V.S.A. § 4289 is amended to read:

§ 4289. Standards and Guidelines for Health Care Providers and Dispensers . . .

(d)(1) Each dispenser who dispenses any Schedule II, III, or IV controlled substances shall register with the VPMS . . .

Sec. 2a . . . (b) The Commissioner of Health, after consultation with the Board of Pharmacy, retail pharmacists, and the Controlled Substances and Pain Management Advisory Council, shall adopt rules regarding the circumstances in which dispensers shall query the Vermont Prescription Monitoring System, which shall include:

(1) prior to dispensing a prescription for a Schedule II, III, or IV opioid controlled substance to a patient who is new to the pharmacy;

(2) when an individual pays cash for a prescription for a Schedule II, III, or IV opioid controlled substance when the individual has prescription drug coverage on file;

(3) when a patient requests a refill of a prescription for a Schedule II, III, or IV opioid controlled substance substantially in advance of when a refill would ordinarily be due;

(4) when the dispenser is aware that the patient is being prescribed Schedule II, III, or IV opioid controlled substances by more than one prescriber; and

(5) an exception for a hospital-based dispenser dispensing a quantity of a Schedule II, III, or IV opioid controlled substance that is sufficient to treat a patient for 48 hours or fewer . . .

Sec. 5. 26 V.S.A. § 2022 is amended to read:

§ 2022. Definitions . . .

(14)(A) “Practice of pharmacy” means:

(i) the interpretation and evaluation of prescription orders;

(ii) the compounding, dispensing, and labeling of drugs and legend devices (except labeling by a manufacturer, packer, or distributor of nonprescription drugs and commercially packaged legend drugs and legend devices);

(iii) the participation in drug selection and drug utilization reviews;

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FDA

National Pharmacy

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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 $154 \text{ mEq}/0.9\% = x/3\%$ 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 ($77 \text{ mEq}/0.9\% = x/3\%$).

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

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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.

References

1. Coleman EA, Smith JD, Raha D, Min SJ. Posthospital medication discrepancies: prevalence and contributing factors. *Arch Intern Med.* 2005;165(16):1842-1847.
2. Mesteig M, Helbostad JL, Sletvold O, Røsstad T, Saltvedt I. Unwanted incidents during transition of geriatric patients from hospital to home: a prospective observational study. *BMC Health Serv Res.* 2010;10:1.
3. Lalonde L, Lampron AM, Vanier MC, Levasseur P, Khaddag R, Chaar N. Effectiveness of a medication discharge plan for transitions of care from hospital to outpatient settings. *Am J Health Syst Pharm.* 2008;65(15):1451-1457.
4. Mixon AS, Myers AP, Leak CL, et al. Characteristics associated with postdischarge medication errors. *Mayo Clin Proc.* 2014;89(8):1042-1051.
5. Kanaan AO, Donovan JL, Duchin NP, et al. Adverse drug events after hospital discharge in older adults: types, severity, and involvement of Beers criteria medications. *J Am Geriatr Soc.* 2013;61(11):1894-1899.
6. American Hospital Association. Rethinking the hospital readmissions reduction program. *TrendWatch.* March 2015.

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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- (iv) the proper and safe storage of drugs and legend devices and the maintenance of proper records therefor;
- (v) the responsibility for advising, where necessary or where regulated, of therapeutic values, content, hazards, and use of drugs and legend devices;
- (vi) the providing of patient care services within the pharmacist's authorized scope of practice;
- (vii) the optimizing of drug therapy through the practice of clinical pharmacy; and
- (viii) the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management, and control of pharmacy.

(B) "Practice of clinical pharmacy" means:

- (i) the health science discipline in which, in conjunction with the patient's other practitioners, a pharmacist provides patient care to optimize medication therapy and to promote disease prevention and the patient's health and wellness;
- (ii) the provision of patient care services within the pharmacist's authorized scope of practice, including medication therapy management, comprehensive medication review, and postdiagnostic disease state management services; or
- (iii) the practice of pharmacy by a pharmacist pursuant to a collaborative practice agreement . . .

(19) "Collaborative practice agreement" means a written agreement between a pharmacist and a health care facility or prescribing practitioner that permits the pharmacist to engage in the practice of clinical pharmacy for the benefit of the facility's or practitioner's patients.

Sec. 6. 26 V.S.A. § 2023 is added to read:

§ 2023. Clinical Pharmacy

In accordance with rules adopted by the Board, a pharmacist may engage in the practice of clinical pharmacy . . .

Sec. 9. Continuing Education

(a) All physicians, osteopathic physicians, dentists, pharmacists, advanced practice registered nurses, optometrists, and naturopathic physicians with a registration number from the U.S. Drug Enforcement Administration (DEA), who have a pending application for a DEA number, or who dispense controlled substances shall complete a total of at least two hours of continuing education for each licensing period beginning on or after July 1, 2016 on the topics of the

abuse and diversion, safe use, and appropriate storage and disposal of controlled substances; the appropriate use of the Vermont Prescription Monitoring System; risk assessment for abuse or addiction; pharmacological and nonpharmacological alternatives to opioids for managing pain; medication tapering and cessation of the use of controlled substances; and relevant State and federal laws and regulations concerning the prescription of opioid controlled substances . . .

Sec. 14. 18 V.S.A. § 4255 is added to read:

§ 4255. Controlled Substances and Pain Management Advisory Council

(a) There is hereby created a Controlled Substances and Pain Management Advisory Council for the purpose of advising the Commissioner of Health on matters related to the Vermont Prescription Monitoring System and to the appropriate use of controlled substances in treating acute and chronic pain and in preventing prescription drug abuse, misuse, and diversion.

(b)(1) The Controlled Substances and Pain Management Advisory Council shall consist of the following members: . . .

(K) a representative of the Vermont Board of Pharmacy, who shall be a pharmacist; . . .

(DD) a retail pharmacist, to be selected by the Vermont Pharmacists Association . . .

Sec. 14a. 18 V.S.A. § 4224 is added to read:

§ 4224. Unused Prescription Drug Disposal Program

The Department of Health shall establish and maintain a statewide unused prescription drug disposal program to provide for the safe disposal of Vermont residents' unused and unwanted prescription drugs. The program may include establishing secure collection and disposal sites and providing medication envelopes for sending unused prescription drugs to an authorized collection facility for destruction.

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