Continuing Education Reminders

A total of 20 contact hours of continuing education (CE) must be completed by December 31 of each calendar year. Unless specified, each condition below is a yearly requirement.

♦ Only a maximum of eight contact hours per calendar day will be accepted.
♦ At least five contact hours must be “live.” Visit http://elearning.ashp.org/acpe-designations for help in determining whether a webinar would be considered “live.”
♦ At least two contact hours must be in the area of pharmacy law. It does not need to be “live,” nor does it have to be specific to Massachusetts.
♦ Pharmacists involved in a collaborative drug therapy management (CDTM) agreement must complete at least five additional contact hours (ie, total of 25 contact hours yearly) that address topics related to their general practice areas.
♦ Pharmacists who are engaged in or oversee sterile compounding activities must complete five contact hours in the area of sterile compounding.
♦ Pharmacists who are engaged in or oversee complex nonsterile compounding activities must complete three contact hours on this topic. An advisory that reviews the levels of nonsterile compounding is available at www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy/advisories/advisory-non-sterile.pdf.
♦ Beginning January 1, 2017, immunizing pharmacists must complete one contact hour every other year in the area of vaccination.

The Massachusetts Board of Registration in Pharmacy accepts three types of credit: Accreditation Council for Pharmacy Education (ACPE), continuing medical education Category 1, and Board-approved programs. Currently, only ACPE-accredited continuing pharmacy education (CPE) credit is stored in CPE Monitor®; therefore, certificates of completion must be retained for the other approved program types. Pharmacists must retain documentation of completed CE hours for at least two years.

All pharmacists, including nonresident pharmacists practicing in other states, must complete the immunization, CDTM, compounding, and other CE requirements if they oversee or engage in these practices.

For more information regarding compounding CE criteria and other CE information, please visit www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy/alerts/pharmacist-continuing-education.pdf.

Common Inspectional Deficiencies

Refrigerators with internal freezers (eg, dorm-style) are not permitted. The ice buildup affects the internal temperature, causing unacceptable variations. Remember that food and beverages may not be placed in any refrigerators or freezers that are used for medication storage. Review Board policy 2011-01 for more details: www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy/pharmacy-policy-2011-01-fridge.pdf.

All returned-to-stock medication should be appropriately labeled with the product name, strength, and expiration date assigned at the time of filling. It is also vital to remove patient-sensitive information, including the prescription number. It should be assumed that any returned-to-stock bottle that does not have a lot number on the label would be included in the event of a recall.

Perpetual inventory must be performed at least once every 10 days. In addition to remaining on the perpetual inventory, all expired or damaged controlled substances must remain in a secure location (eg, safe) until they are returned.

Compounding pharmacies must retain master formulation records and compounding logs for each compounded product. Compounded products may only be dispensed with valid patient-specific prescriptions.

Mid-Level Practitioner Prescriptions

Prescriptions issued by nurse practitioners, psychiatric nurses, nurse anesthetists, or pharmacists must include...
.Pharmacy Domain Signals Safety on the Web

With only 4% of websites selling prescription drugs online following United States pharmacy laws and practice standards, consumers seeking medications online are faced with the daunting task of finding a safe site. To assist consumers and those legitimate pharmacies with an online presence, NABP has streamlined its website verification programs. As of September 1, 2017, NABP is only offering the .Pharmacy Verified Websites Program and the Verified Internet Pharmacy Practice Sites® (VIPPS®) program, providing an easy choice for safety-minded consumers and pharmacies alike. The .Pharmacy Program, which was launched in 2014, enables qualified pharmacies and pharmacy-related businesses to register a web address with the .pharmacy domain. A .pharmacy domain (pronounced “dot pharmacy”) is part of a website’s address like “.com” or “.biz”: www.safe.pharmacy. It enables people to identify an online pharmacy or pharmacy-related website as safe and legitimate. Since .pharmacy is a verified domain, websites are evaluated against a set of safety standards before an applicant is approved to register the domain.

In addition to showing patients that they operate a safe website, the .pharmacy domain allows pharmacies and related entities to advertise online through Google, Bing, and Yahoo! The .Pharmacy Program replaces the e-Advertiser Approval™ and Veterinary-VIPPS® programs for those entities that are not eligible to apply for VIPPS but want to advertise with the search engines.

For more information about the .Pharmacy Program, including the application and domain name registration process and fees, visit www.safe.pharmacy/apply.

**Quality Processes, Risk Management, and Culture: HR-Related Policies That Conflict with a Just Culture**

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 online at www.ismp.org. Email: ismpinfo@ismp.org.

As health care organizations move toward a “Just Culture,” one of the areas potentially overlooked is human resource (HR)-related policies and procedures. Because these policies and procedures typically describe staff expectations, individual accountability, and disciplinary processes, they must be reviewed and often revised to ensure alignment with the tenets of a Just Culture. Otherwise, the journey will be long and unsuccessful if the policies are in conflict with a Just Culture.

In a Just Culture, HR-related policies and procedures regarding safety should hold all individuals equally accountable for the quality of their behavioral choices and should not focus on errors (which are not a behavioral choice), except for the expectation to report them. Policies and procedures should reflect a tone that is proactive toward risk identification, rather than reactive to errors and adverse outcomes. They should define human error as inadvertent, with a response of consoling individuals and conducting an investigation to determine how to redesign systems to prevent errors or detect them before reaching the patient. Policies and procedures should describe how to investigate a procedural violation to determine its causes and scope, and how to coach staff who have engaged in at-risk behaviors under the mistaken, but good faith, belief that the risks were insignificant or justified. For outcome-based duties related to a business code of conduct, such as arriving to work on time and wearing identification badges, policies should be clear about expectations and the actions that will be taken when they are not met. When describing reckless behavior (actions involving a conscious disregard of what an individual knows is a substantial and unjustifiable risk), remove any reference to “negligent” or “criminal” conduct as the basis for disciplinary action. Regrettably, mere human error can result in legal action (criminal negligence), but human error is never reckless behavior. Also ensure that event reporting and investigation policies and procedures support the tenets of a Just Culture.

While HR-related policies and procedures cannot guarantee that the desired actions will be realized in practice, they are a critical step for building an organizational foundation for success. Old punitive policies risk slipping back into an unjust culture. As organizations align actual practice with a Just Culture, they also need to align supporting policies and procedures.

**AMA Task Force to Reduce Opioid Abuse Promotes Safe Storage, Disposal of Opioids**

The American Medical Association (AMA) Task Force to Reduce Opioid Abuse released a resource document that urges physicians and other health care providers to promote safe storage and disposal of opioids and all medications. The AMA document indicates physicians and other providers need to:

♦ educate patients about safe use of prescription opioids;
♦ remind patients to store medications out of children’s reach in a safe place; and
♦ talk to patients about the most appropriate way to dispose of expired, unwanted, and unused medications.

The AMA resource document and additional information can be found at www.ama-assn.org/opioids-disposal. Options for disposing of medications safely are available in the Initiatives section of the NABP website at www.nabp.pharmacy under AWARXE®.

**CDC Guide Shows Importance of Physicians, Pharmacists Working Together**

Collaborative care by at least two practitioners working together with the patient to accomplish shared goals has been shown to improve hypertension control and cholesterol management, especially when the team involves a physician or nurse and a pharmacist, notes a new guide developed by the Centers for Disease Control and Prevention (CDC) Division for Heart Disease and Stroke Prevention, in collaboration with the American Pharmacists Association and AMA. The guide,
Creating Community-Clinical Linkages Between Community Pharmacists and Physicians, discusses the importance of community-clinical linkages specific to community pharmacists and physicians and provides a framework for how community pharmacists and physicians might approach the development of a link to help patients. In addition, the guide provides examples of existing community-clinical linkages between community pharmacists and physicians and discusses common barriers to and potential solutions for creating community-clinical linkages. The guide is available at www.cdc.gov/dhdsp/pubs/docs/ccl-pharmacy-guide.pdf.

FIP Report Shows Value of Pharmacists’ Role in Consumers’ Self-Care

Support from pharmacists will assist consumers in better health maintenance and greater health system efficiency, indicates a recently released report from the International Pharmaceutical Federation (FIP). The report, Pharmacy as a gateway to care: Helping people towards better health, discusses the various factors involved in individual self-care and the evidence that pharmacists can increase value for those individuals through many opportunities because informed, engaged, and educated consumers will play a greater and critical role in caring for themselves. The definition of self-care this report adopts is that of the World Health Organization: “the ability of individuals, families and communities to promote health, prevent disease, and maintain health, and to cope with illness and disability with or without the support of a health care provider.”


FDA Restricts Use of Codeine and Tramadol Medicines in Children; Recommends Against Use in Breastfeeding Women

As of April 2017, Food and Drug Administration (FDA) is restricting the use of codeine and tramadol medicines in children. FDA is also recommending against the use of these medicines in breastfeeding mothers due to possible harm to their infants. Codeine and tramadol medicines carry serious risks, including slowed or difficult breathing and death, which appear to be a greater risk in children younger than 12 years, and should not be used in this age group. These medicines should also be limited in some older children. Single-ingredient codeine and all tramadol-containing products are FDA-approved only for use in adults.

As indicated in the FDA Drug Safety Communication available at www.fda.gov/Drugs/DrugSafety/ucm549679.htm, FDA is requiring several changes to the labels of all prescription medicines containing these drugs. These new actions further limit the use of these medicines beyond their 2013 restriction of codeine use in children younger than 18 years to treat pain after surgery from removal of tonsils and/or adenoids. FDA is now adding:

♦ A Contraindication to the drug labels of codeine and tramadol, alerting that codeine should not be used to treat pain or cough and tramadol should not be used to treat pain in children younger than 12 years.
♦ A new Contraindication to the tramadol label, warning against its use in children younger than 18 years to treat pain after surgery from removal of tonsils and/or adenoids.
♦ A new Warning to the drug labels of codeine and tramadol to recommend against their use in adolescents between 12 and 18 years who are obese or have conditions such as obstructive sleep apnea or severe lung disease, which may increase the risk of serious breathing problems.
♦ A strengthened Warning to mothers that breastfeeding is not recommended when taking codeine or tramadol medicines due to the risk of serious adverse reactions in breastfed infants.

FDA urges health care providers to report side effects involving codeine- and tramadol-containing medicines to the FDA MedWatch program at www.fda.gov/safety/medwatch.

AVMA Warns Pharmacists and Pet Owners About Xylitol Pharmaceutical Products

Pharmaceutical products containing xylitol may be dangerous and fatal to dogs, warns the American Veterinary Medical Association (AVMA). Xylitol stimulates an insulin release that can result in severe hypoglycemia and fatal liver damage. Pharmacists and pet owners need to be aware of and protect against xylitol toxicoses, indicates AVMA. FDA-approved gabapentin capsules and tablets do not contain xylitol, but the liquid form does. In addition, xylitol-containing media might be used in compounding products if the pharmacist is uninformed about not using it.

AVMA urges pharmacists to not use xylitol-containing products when compounding for canine patients and to contact the veterinarian if a prescribed product contains xylitol. The veterinarian may be unaware that this sweetener is in the product. AVMA also encourages pet owners and caretakers to verify with the pharmacist when picking up their dog’s medication at a human pharmacy that the medication does not contain xylitol. Xylitol-containing peanut butter should not be used to help a dog take its medication.

For more information, visit atwork.avma.org/2017/05/30/eliminate-xylitol-from-canine-prescriptions.

CDC Publishes Guide to Help Pharmacists Initiate CPAs With Prescribers

CDC published a guide that provides pharmacists with information and resources to empower them to initiate collaborative practice agreements (CPAs) with collaborating prescribers. The guide, Advancing Team-Based Care Through Collaborative Practice Agreements: A Resource and Implementation Guide for Adding Pharmacists to the Care Team, contains a sample CPA and sample language that can be customized by pharmacists and prescribers using their specific state laws to create a CPA. The guide includes an overview of state laws, including which states currently allow CPAs. The guide is available at www.cdc.gov/dhdsp/pubs/docs/CPA-Team-Based-Care.pdf.


Drug Enforcement Administration (DEA) released the 2017 edition of Drugs of Abuse. A DEA Resource Guide, which serves as a resource on the most commonly abused and misused drugs in the US. The latest edition, which is an update to the 2015 publication, describes the consequences of drug use, a drug’s effects on the body and mind, overdose potential, origin, legal status, and other key facts. It also includes the most current information on new and emerging trends in drug misuse and abuse, including fentanyl, other opioids, and synthetic drugs. The 2017 edition can be found at www.dea.gov/pr/multimedia-library/publications/drug_of_abuse.pdf.
Complex compounding includes making preparations that require special training, environment, facilities, equipment, and procedures to ensure appropriate therapeutic outcomes.

Simple and moderate compounding are commonly performed in typical retail settings and include such examples as “magic mouthwash” and captopril oral solution.

The Board does not consider simple reconstitution to be compounding.

See the Board’s advisory regarding nonsterile compounding at www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy/advisories/advisory-non-sterile.pdf.

A memo that references Food and Drug Administration’s position on the compounding of commercially available drugs may be viewed at www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy/compounding-commercial-drugs.pdf.

Investigational Drug Studies

Retail pharmacies may only participate in investigational drug studies if the principal investigator (PI) of the study submits a research Massachusetts Controlled Substances Registration (MCSR) application with the Drug Control Program requesting to include the pharmacy. Each research MCSR application that incorporates a retail pharmacy will be reviewed, and a pharmacy representative may be required to appear before the Board for clarification. The pharmacy must maintain all documents related to drug study participation on site for Board inspection. It is important to note that a research MCSR is only valid for one year and one study. If a study lasts longer than a year, a renewal MCSR application must be submitted by the PI. A separate research MCSR is required for each research study even if the PI is the same.

Pharmacy documents that must be submitted with the research MCSR application include:

1. On pharmacy letterhead, a signed statement from the pharmacy manager of record or designated pharmacist-in-charge of the study, including the following:
   a. Board license number(s);
   b. Identification of each pharmacy site participating in the study;
   c. Manner of prescription receipt by retail pharmacy; and
   d. Detailed description of the pharmacy’s specific role in procuring, receiving, handling, storing, compounding, repackaging, labeling, record keeping, dispensing of study medication(s) (eg, direct to patient, prescriber’s office), and/or any other responsibilities of the pharmacy in the study (eg, randomization, blinding).

2. Example of the product label(s)

3. Example of patient prescription(s)

4. List of specific Board regulations that conflict with practices included in the study protocol;

5. Signed attestation that the pharmacy maintains master formulation record(s) for all compounded medications involved in the study and that said master formulation record(s) complies with Board regulations and all USP chapters

Did You Know?

♦ You can email the Board with practice inquiries at Pharmacy.Admin@MassMail.State.MA.US.

♦ Vitamin D2 (ergocalciferol) and vitamin D3 (cholecalciferol) are not interchangeable. Obtain provider clarification if there is any uncertainty.

♦ A “retired” license status is now available for pharmacists. This is intended to be a permanent change, not an “inactive” status that can be easily reversed. The application may be found at www.mass.gov/eohhs/gov/departments/dph/programs/hcq/dhpl/pharmacy/licensing/applications-and-forms.html#misc.

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