Pharmacy Mail Bag

The following are responses to Utah Board of Pharmacy questions from the November 2017 Utah Pharmacy Association Mid-Year Meeting.

**Q1.** Is there an updated self-inspection form on the Utah Division of Occupational and Professional Licensing (DOPL) website? If there is not one currently available, can an updated self-inspection form be made available?

**A1.** There is not a current updated self-inspection form on the DOPL website. A self-inspection has not been required to be submitted to DOPL since 2014. A current inspection form may be requested by calling or emailing one of the DOPL inspectors or investigators.

**Q2.** How many technicians in training can work per shift if there are two pharmacists working?

**A2.** Per R156-17b-601(5) – Pharmacy Technician and Pharmacy Technician Trainee: “(5) A pharmacy technician trainee shall practice only under the direct supervision of a pharmacist and in a ratio not to exceed one pharmacy technician trainee to one pharmacist.”

**Q3.** How many interns can work if two pharmacists are working?

**A3.** Per R156-17b-606(1)(d)(i) and (ii) – Approved Preceptor:

(d) provide direct, on-site supervision to:

(i) no more than two pharmacy interns during a working shift except as provided in Subsection (ii);

(ii) up to five pharmacy interns at public-health outreach programs such as informational health fairs, chronic disease state screening and education programs, and immunization clinics, provided:

(A) the totality of the circumstances are safe and appropriate according to generally recognized industry standards of practice; and

(B) the preceptor has obtained written approval from the pharmacy interns’ schools of pharmacy for the intern’s participation; and

(e) refer to the intern training guidelines as outlined in the Pharmacy Coordinating Council of Utah Internship Competencies, October 12, 2004, as information about a range of best practices for training interns . . .

**Q4.** Without a set ratio of technicians to pharmacists, what has been viewed as an excessive amount during audits?

**A4.** There is no set ratio number of technicians to pharmacists. The pharmacist-in-charge (PIC) and pharmacies should refer to R156-17b-603(3)(r), which states:

(3) The duties of the PIC or [dispensing medical practitioner-in-charge (DMPIC)] shall include . . .

(r) assuring that no pharmacy operates with a ratio of pharmacist or [dispensing medical practitioner (DMP)] to other pharmacy personnel circumstances that result in, or reasonably would be expected to result in, an unreasonable risk of harm to public health, safety, and welfare . . .

Additionally, pharmacy personnel for the ratio include technicians-in-training, supportive personnel/cashiers, and interns.

**Q5.** What additional requirements are there for pharmacies that deliver?

**A5.** Per 58-17b-613(2) – Patient counseling:

(2) A pharmacist or pharmacy intern at a pharmacy that receives a prescription from a patient by means other than personal delivery, and that dispenses prescription drugs to the patient by means other than personal delivery, shall:

(a) provide patient counseling to a patient regarding each prescription drug the pharmacy dispenses; and

(b) provide each patient with a toll-free telephone number by which the patient can contact a pharmacist or pharmacy intern at the pharmacy for counseling.

Per R156-17b-610(6) – Patient Counseling (emphasis added):

(6) If a prescription drug order is delivered to the patient or the patient’s agent at the patient’s or other designated location, the following is applicable:

continued on page 4
FDA Draft Guidance Addresses Delayed Enforcement of DSCSA Requirements for Product Identifiers

Food and Drug Administration (FDA) issued a draft guidance for industry that informs manufacturers and other supply chain stakeholders that although manufacturers are to begin including a product identifier on prescription drug packages and cases on November 27, 2017, FDA is delaying enforcement of those requirements until November 2018 to provide manufacturers additional time and avoid supply disruptions. The compliance policy outlined in the June 2017 draft guidance, Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy, applies solely to products without a product identifier that are introduced into commerce by a manufacturer between November 27, 2017, and November 26, 2018. While manufacturers work to meet product identifier requirements, they must comply with other Drug Supply Chain Security Act (DSCSA) requirements. The draft guidance can be accessed from FDA’s website at www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm565358.htm.

Amount of Prescribed Opioids Remains High, Reports CDC

The amount of opioids prescribed remains approximately three times as high as in 1999, despite reductions in each year after 2010 through 2015. Centers for Disease Control and Prevention (CDC) researchers analyzed retail prescription data to assess opioid prescribing in the United States from 2006 to 2015 and county-level prescribing patterns in 2010 and 2015. According to a CDC report, results of the study showed higher amounts of opioids were prescribed in counties that had a greater percentage of non-Hispanic white residents, a higher prevalence of diabetes and arthritis, micropolitan status (ie, town/city; nonmetro), and higher unemployment and Medicaid enrollment rates. The researchers conclude that health care providers should carefully weigh the benefits and risks when prescribing opioids outside of end-of-life care, follow evidence-based guidelines (eg, CDC’s Guideline for Prescribing Opioids for Chronic Pain), and consider non-opioid therapy for chronic pain treatment.

Additionally, the researchers conclude that state and local jurisdictions can use these findings along with prescription drug monitoring program (PDMP) data to identify prescribing patterns that place patients at risk for opioid use disorder and overdose and to target interventions with prescribers based on opioid prescribing guidelines. The July 7, 2017 Morbidity and Mortality Weekly Report, “Vital Signs: Changes in Opioid Prescribing in the United States, 2006–2015,” can be accessed on the CDC website at www.cdc.gov/mmwr/index.html in the Weekly Report section.

AMA Opioid Task Force Encourages Co-Prescribing Naloxone to At-Risk Patients

The American Medical Association (AMA) Opioid Task Force encourages physicians to consider co-prescribing naloxone when it is clinically appropriate to do so. The AMA Opioid Task Force offers several questions for determining whether to co-prescribe naloxone to a patient or a patient’s family member or close friend, which may be found in the August 2017 document, “AMA Opioid Task Force naloxone recommendations,” available on the AMA opioid microsite at https://www.end-opioid-epidemic.org.

The Naloxone section of the AMA opioid microsite also offers physicians multiple resources on co-prescribing naloxone in their practice and community. To help end the opioid epidemic, the AMA Opioid Task Force made several recommendations for physicians, including registering and using state PDMPs, training and education on evidence-based treatment, and promoting safe storage and disposal of opioids and medications.

Opioid Addiction Medications Should Not Be Withheld From Patients Taking Benzodiazepines or CNS Depressants

Opioid addiction medications – buprenorphine and methadone – should not be withheld from patients taking benzodiazepines or other drugs that depress the central nervous system (CNS), advises FDA. The combined use of these drugs increases the risk of serious side effects; however, the harm caused by untreated opioid addiction usually outweighs these risks. Careful medication management by health care providers can reduce these risks, notes a safety alert. FDA is requiring this information to be added to the buprenorphine and methadone drug labels along with detailed recommendations for...
minimizing the use of medication-assisted treatment drugs and benzodiazepines together.

Health care providers should take several actions and precautions and should develop a treatment plan when buprenorphine or methadone is used in combination with benzodiazepines or other CNS depressants. Additional information may be found in an FDA Drug Safety Communication announcement at www.fda.gov/Drugs/DrugSafety/ucm575307.htm.

New Study Shows Substantial Variation in the Availability of Pharmacies Across the Country

Despite the rising number of US pharmacies from 2007 to 2015, the availability of pharmacies varied significantly across local areas, indicates a new study. The study, The availability of pharmacies in the United States: 2007–2015, found that the number of community pharmacies increased 6.3% from 63,752 to 67,753 between 2007 and 2015. Although the number of pharmacies per capita remained at 2.11 per 10,000 individuals between 2007 and 2015, the researchers found substantial variation across counties. “Some counties have 13 pharmacies per capita, while others have none,” said Dima Qato, lead study author and assistant professor of pharmacy systems, outcomes and policy, in a University of Illinois at Chicago (UIC) news release.

In 2015, counties in the highest quintile had nearly three-fold more pharmacies than those in the lowest quintile. Counties in the lowest quintile are located in the Pacific West, Southwest, and Great Lakes regions, while counties with the highest tend to be located in the Northeast, Southeast, Northern Appalachia, and Plains states. The researchers conclude that future programs and policies should address the availability of pharmacies and ensure that pharmacy characteristics, including accommodations such as multilingual staffing and home delivery, align with local population needs.

To view the study, visit https://doi.org/10.1371/journal.pone.0183172. The UIC news release is available at https://today.uic.edu/access-to-pharmacies-limited-to-some-patients.

Consent Decree Entered Against Outsourcing Facility Isomeric Pharmacy Solutions

Under a consent decree of permanent injunction entered in August 2017, Isomeric Pharmacy Solutions of Salt Lake City, UT, its owners, and chief operating officer are prohibited from manufacturing, processing, packing, holding, or distributing drugs until they comply with the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its regulations, in addition to other requirements. Isomeric manufactured and distributed purportedly sterile drug products, including injectable and ophthalmic drugs, that were adulterated because the drugs were made under insanitary conditions and in violation of current good manufacturing practice requirements under the FD&C Act, according to the complaint for permanent injunction. The complaint also alleges that Isomeric manufactured and distributed unapproved drugs and drugs that were misbranded because their labeling did not bear adequate directions for use. Isomeric initially registered as an outsourcing facility in July 2015 and reregistered in December 2015 and January 2017. Additional information is available in an FDA news release at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm570130.htm.

FDA Issues Warning on Alcohol Pads or Benzalkonium Chloride Antiseptic Towelettes Made by Foshan

In September 2017, FDA alerted health care providers and patients to not use alcohol pads or benzalkonium chloride antiseptic towelettes made by Foshan Flying Medical Products Co, Ltd, located in China, due to lack of sterility assurance and other quality issues. These products are distributed by Total Resources International, of Walnut, CA, and Simple Diagnostics, Inc, of Williston Park, NY. The use of these alcohol pads and antiseptic towelettes could cause infections.

FDA placed all drug products made by Foshan on import alert on May 23, 2017, to stop these products from entering the US. However, FDA is concerned these products might still be in distribution in the US. FDA also sent Foshan a warning letter on August 1, 2017, for violations of current good manufacturing practice regulations. FDA initially contacted Foshan regarding a recall on May 25, 2017, and had several follow-up meetings with the company. Foshan has not taken action to remove its alcohol pads or antiseptic towelettes from the market. The safety alert posted to FDA’s website may be found at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm574576.htm.

Pharmacies and health care facilities that have alcohol pads and antiseptic towelettes labeled by Total Resources or Simple Diagnostics should immediately stop using them and discard the products. Adverse events or side effects related to the use of these products may be reported to FDA’s MedWatch Safety Information and Adverse Event Reporting Program at www.fda.gov/MedWatch/report.
Invoices of controlled substance (CS) medications not expired stock medications or “return-to-stock” are February 2018.

Q6. What additional requirements are there for pharmacies that mail prescriptions?


(9) A pharmacy may only deliver a prescription drug to a patient or a patient’s agent:

(a) in person at the pharmacy; or

(b) via the United States Postal Service, a licensed common carrier, or supportive personnel, if the pharmacy takes reasonable precautions to ensure the prescription drug is:

(i) delivered to the patient or patient’s agent; or

(ii) returned to the pharmacy.

R156-17b-608 – Common Carrier Delivery states:

A pharmacy that employs the United States Postal Service or other common carrier to deliver a filled prescription directly to a patient shall, under the direction of the PIC, DMPIC, or other responsible employee:

(1) use adequate storage or shipping containers and shipping processes to ensure drug stability and potency. The shipping processes shall include the use of appropriate packaging material and devices, according to the recommendations of the manufacturer or the United States Pharmacopeia Chapter 1079, in order to ensure that the drug is kept at appropriate storage temperatures throughout the delivery process to maintain the integrity of the medication;

(2) use shipping containers that are sealed in a manner to detect evidence of opening or tampering;

(3) develop and implement policies and procedures to ensure accountability, safe delivery, and compliance with temperature requirements. The policies and procedures shall address when drugs do not arrive at their destination in a timely manner or when there is evidence that the integrity of a drug was compromised during shipment. In these instances, the pharmacy shall make provisions for the replacement of the drugs;

(4) (i) provide for an electronic, telephonic, or written communication mechanism for a pharmacy to offer counseling to the patient as defined in Section 58-17b-613; and

(ii) provide documentation of such counseling; and

(5) provide information to the patient indicating what the patient should do if the integrity of the packaging or drug was compromised during shipment.

Q7. What are the most common issues investigators are finding during audits (DOPL inspections)?

A7. The following are the most common issues:

♦ Expired stock medications or “return-to-stock” are expired or without dates.

♦ Invoices of controlled substance (CS) medications not signed and/or dated.
Q8. Does Drug Enforcement Administration (DEA) require pharmacies to perform and maintain a CS inventory form? Can the annual state inventory meet this requirement?

A8. Per Code of Federal Regulations Title 21 §1304.11 requirements, DEA requires a biennial inventory (once every two years), and pharmacies must retain CS records for only two years. However, Utah requires records to be retained for five years (see below).

Per R156-17b-605 – Inventory Requirements, the state requires an annual inventory, and the records must be retained and readily available for inspections for five years. For more information, review this section of the Rule (printed version, pages 22 and 23). Additionally, DOPL inspectors have created a “Controlled Substances Inventory Log” cover sheet that contains all of the required information for the CS inventory. A copy of this form may be requested by calling or emailing one of the DOPL inspectors or investigators.


The records which must be maintained by a pharmacy are:

1. Executed and unexecuted official order forms (DEA Form 222) or the electronic equivalent
2. Power of Attorney authorization to sign order forms
3. Receipts and/or invoices for schedules III, IV, and V controlled substances
4. All inventory records of controlled substances, including the initial and biennial inventories, dated as of beginning or close of business
5. Records of controlled substances distributed (i.e., sales to other registrants, returns to vendors, distributions to reverse distributors)
6. Records of controlled substances dispensed (i.e., prescriptions, schedule V logbook)
7. Reports of Theft or Significant Loss (DEA Form 106), if applicable
8. Inventory of Drugs Surrendered for Disposal (DEA Form 41), if applicable
9. Records of transfers of controlled substances between pharmacies
10. DEA registration certificate
11. Self-certification certificate and logbook (or electronic equivalent) as required under the

Q9. Some pharmacies will not transfer a controlled prescription until it has been filled once. Is this required of all pharmacies?


A DEA registered pharmacy may transfer original prescription information for schedules III, IV, and V controlled substances to another DEA registered pharmacy for the purpose of refill dispensing between pharmacies, on a one time basis only. However, pharmacies electronically sharing a real-time, online database may transfer up to the maximum refills permitted by law and the prescriber’s authorization.

Per a National Association of Boards of Pharmacy® (NABP®) memo to the boards on July 20, 2017, DEA recently clarified its position on the forwarding of unfilled electronic prescriptions for controlled substances (EPCS) from one DEA-registered pharmacy to another DEA-registered pharmacy. In a letter from DEA’s Loren T. Miller, associate section chief, Liaison and Policy Section, Diversion Control Division, to Carmen Catizone, NABP executive director, Miller states:

The DEA has addressed the forwarding of an EPCS prescription. The DEA published information in the preamble of the notice of proposed rulemaking (NPRM) on EPCS, 73 FR 36722, and the preamble of the interim final rule (IFR) on EPCS, 75 FR 16235. Note, because this was in the preamble and not in the EPCS regulations, it represents the DEA’s policy. As posted in the preambles of the NPRM and the IFR, an unfilled original EPCS prescription can be forwarded from one DEA registered retail pharmacy to another DEA registered retail pharmacy, and this includes Schedule II controlled substances.
Q10. Is it possible to have emails sent out when changes are made in rules and laws?

A10. Members of the Board have requested that a group email be sent when rule changes have been posted. It is always a good idea to periodically check the DOPL website home page (www.dopl.utah.gov) under the Licensing tab for Proposed Rule Changes.

Q11. In the 2017 Utah Legislative Session, a bill was passed to allow pharmacies to partial fill prescriptions. New rules are now almost finalized. What does this mean in regard to co-pays, etc? Also, should we anticipate that DOPL or the Board will take any further action to help clarify this process?

A11. R156-17b-610.7. Partial Filling of a Schedule II Controlled Substance Prescription went into effect on December 12, 2017, and states:

In accordance with Section 58-17b-610.7, a pharmacy that partially fills a prescription for a Schedule II controlled substance shall specify by prescription number for each partial fill the:
(a) date;
(b) quantity supplied; and
(c) quantity remaining of the prescription partially filled.

It is up to each pharmacy’s software vendor as to whether or not it supports the partial dispensing of Schedule II CS prescriptions. Additionally, each third-party payer or pharmacy benefits manager will have its own specifications for covering partial prescriptions and the payment (or waiver) of co-pays by the patient.

Compounding Task Force Section

Q1. Are you and your facility ready for USP Chapter <800>?

A1. USP has delayed implementation of USP Chapter <800> until December 1, 2019. Although implementation has been deferred, compounding experts recommend immediate efforts to prepare your staff and facility to meet the requirements and expectations of USP <800>. The Board’s USP <800> task force team has some recommendations to help you get started in the meantime.

In preparation for USP <800>, the task force recommends:
♦ Download and read a free copy of Chapter <800> at www.usp.org/usp-chapter-800-download.
♦ Download and read a copy of the National Institute for Occupational Safety and Health (NIOSH) hazardous drug list at www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf.
♦ Perform a gap analysis to recognize your exposure risk. Templates are available at:
◊ www.readyfor800.com
◊ https://compoundingtoday.com/Compliance/USP_Gap.cfm
◊ https://www.pppmag.com/article/2021
♦ Designate a hazardous medication handling educator and USP <800> compliance officer for your facility.
♦ Create a list of all hazardous medications that your facility stores and handles.
♦ Begin assessing the exposure risk to your employees.
♦ Additional resources to improve your knowledge and understanding of USP <800>:
◊ The Hazardous Drug Consensus Group created a helpful document that may be found at http://compoundingtoday.com/Compliance/HDCS_Consensus_Statement.pdf.
◊ Order your copy of The Chapter <800> Answer Book by Patricia Kienle (sponsored by the American Society of Health-System Pharmacists).

Q2. Will Utah adopt the full chapter of USP <800>?

A2. The Board formed a USP <800> task force group, and the group was charged with analyzing best practices to achieve safety in regard to handling hazardous medications in the workplace and balancing against excessive barriers to commerce within the state of Utah. This task force has been working diligently over the last six months, holding many meetings and discussions with many stakeholders. One alternative being considered is implementing a modified version of USP <800>, which would closely mirror the full version regarding NIOSH Group 1 antineoplastics and establish an alternative approach for NIOSH Group 2 and 3 (medications such as estradiol, progesterone, testosterone, spironolactone, finasteride, clonazepam, etc). Certain parameters and requirements would be necessary for this alternative approach. There will be more details forthcoming in early to mid-2018.

Page 6 – February 2018

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