

August 2020

News



Utah Board of Pharmacy

Published to promote compliance of pharmacy and drug law

PO Box 146741 • Salt Lake City, UT 84114-6741
www.dopl.utah.gov/licensing/pharmacy.html

Pharmacy Technician Access to the Utah Controlled Substance Database

On May 12, 2020, the updates to the Controlled Substance Database Act went into effect to allow pharmacy technicians and interns in Utah to obtain independent access to the Utah Controlled Substance Database (CSD). Next quarter's *Newsletter* will provide a more detailed review of the responsibilities and features of the CSD. The following are a few key points:

- ◆ Pharmacy technicians who had delegate access have been transitioned to independent access. No action is necessary to update your access.
- ◆ The CSD contains sensitive patient information that is protected by the Health Insurance Portability and Accountability Act and additional laws and rules contained in the Utah Controlled Substances Database Act and Rule.
- ◆ Inappropriate use of the CSD is not allowed. Please educate yourself about your responsibilities by reading the Controlled Substance Database Act and Rule. You can access these documents on the Utah Division of Occupational and Professional Licensing (DOPL) [website](#) or by visiting the following links:
 - ◇ <https://le.utah.gov/xcode/Title58/Chapter37/58-37.html>
 - ◇ <https://rules.utah.gov/publicat/code/r156/r156-37.htm>
- ◆ The information in the CSD is a great tool that can be used to identify areas of concern. Please consult your supervising pharmacist if you see any information in the CSD that may help him or her make clinical decisions about the patient.
- ◆ If you notice any unusual entries in the CSD, consult your pharmacist. The pharmacy that reported the prescription is responsible for making any corrections. You may also notify the CSD by emailing csd@utah.gov or calling 801/530-6628. Remember to appropriately secure protected health information when sending an email.

Advisory Pharmacy Compounding Education Committee

The newly formed Advisory Pharmacy Compounding Committee has met twice this year and is working on several items in the interest of compounding and public education. One of the committee's priorities includes creating a document with answers to frequently asked questions about specific compounding issues to help individuals better understand some of the complex compounding regulations. The Utah Board of Pharmacy would like to hear from individuals who have questions about compounding or would like the committee to address any other items. Please send an email to pharmacy@utah.gov or talk with any of the committee members listed on the Division's website. The committee's next meeting will be September 24, 2020.

COVID-19

Have you visited DOPL's coronavirus disease 2019 (COVID-19) website? You can find information relating to the practice of pharmacy by visiting <https://dopl.utah.gov/covid19.html>. You will find information regarding Utah's standing order for pharmacists to administer COVID-19 tests, general reminders for pharmacy personnel to mitigate risk of exposure, and temporary suspension of "live" continuing education requirements. Please make sure you check the website often for the most up-to-date information.

August 2020

The *Utah Board of Pharmacy News* is published by the Utah Board of Pharmacy and the National Association of Boards of Pharmacy Foundation® (NABPF®) to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABPF, the State of Utah, or the Board unless expressly so stated.

Utah Board of Pharmacy - State Newsletter Editor
doplbureau3@utah.gov

www.dopl.utah.gov/licensing/pharmacy.html

Lemrey "Al" Carter, PharmD, MS, RPh - National News Editor
& Executive Editor

Amy Sanchez - Communications Manager

National Pharmacy Compliance News

August 2020



NABPF
National Association of Boards
of Pharmacy Foundation

The applicability of articles in the *National Pharmacy Compliance News* to a particular state or jurisdiction can only be ascertained by examining the law of such state or jurisdiction.

FDA Releases MOU on Human Drug Compounding Regulation and Oversight

Acknowledging the vital role states play in reducing the risks associated with compounded drugs, Food and Drug Administration (FDA) has made available a [Final Standard Memorandum of Understanding \(MOU\) Addressing Certain Distributions of Compounded Human Drug Products](#), intended to be entered into between the agency and the states. The release of the MOU is required as part of its [submission to the Office of Management and Budget](#) for review and clearance under the Paperwork Reduction Act of 1995. The MOU was developed in close [consultation with the National Association of Boards of Pharmacy](#)[®] (NABP[®]), as described in the Federal Food, Drug, and Cosmetic Act. The agency also engaged with states, pharmacies, associations, pharmacists, and other stakeholders.

Among the issues addressed in the MOU is the definition of the statutory term “inordinate amounts,” which refers to compounded drugs that are distributed interstate. In addition, the MOU includes the risk-based oversight model from the 2018 revised draft MOU. States that sign the document agree to identify pharmacy compounders that distribute inordinate amounts (greater than 50%) of compounded drug products interstate, as well as report certain information to FDA about those compounders. FDA also provided clarity in the MOU on state investigations of complaints associated with compounded drugs distributed out of state. States that enter into the MOU will investigate complaints about drugs compounded at a pharmacy within their state and distributed outside of the state and advise FDA when they receive reports of serious adverse drug experiences or serious product quality issues, like drug contamination.

To help states to better investigate these issues, FDA has also announced an agreement with NABP to make an information sharing network available to the states. Through this network, states will be able to obtain information from pharmacies in their states and transmit that information to FDA.

“We anticipate the final MOU, once signed, will help to facilitate increased collaboration between the FDA and the states that sign it,” said Janet Woodcock, MD, Director, Center for Drug Evaluation and Research, in an [FDA Voices](#) article. “Working together, we can

help promote quality compounding practices and better address emerging public health concerns that may affect patients.”

FDA Clarifies Compounding Rules, Offers Flexibility to Help Ease Drug Shortages During COVID-19 Pandemic

FDA noted it will use discretion in enforcing certain standards related to 503A and 503B compounding in an effort to ease drug shortages during the coronavirus disease 2019 (COVID-19) pandemic. During an American Pharmacists Association (APhA) webinar on April 30, 2020, the agency clarified it will “look to 503B compounders to grapple with drug shortages” and “turn to 503A compounders to fill in the gaps.”

In addition, the agency clarified that medications on the FDA drug shortage list are effectively considered “not commercially available,” which frees 503A and 503B compounding facilities from limits on compounding drugs that are “essentially a copy” of a product already available on the market. FDA also does not intend to take action if a 503A facility fills orders for a compounded drug that is essentially a copy of an approved drug that has been discontinued and is no longer marketed.

In April 2020, FDA issued a temporary guidance that granted flexibility for pharmacists to compound certain necessary medications under 503A for nonspecific patients hospitalized due to COVID-19. In addition, a temporary guidance was issued that granted enforcement flexibility for 503B outsourcing compounding facilities for drugs in shortage for patients hospitalized during the COVID-19 public health emergency. The guidance documents stipulate the conditions compounders must meet and are available at <https://www.fda.gov/media/137125/download>.

More information on these compounding rule clarifications is available in a May 5, 2020 press release on the [APhA website](#).

CMS Allows Pharmacies to Temporarily Enroll as Clinical Diagnostic Laboratories for COVID-19 Testing

Centers for Medicare & Medicaid Services (CMS) has released a document detailing a process that allows pharmacies to temporarily enroll as independent clinical diagnostic laboratories. This process will allow those

facilities to seek Medicare reimbursement for COVID-19 tests, making it easier for them to provide that service during the pandemic.

“Up until this point in time, most pharmacies could only offer this as a cash service because they were not considered providers through CMS, and really a lot of the third-party payers really didn’t have an interest in a fee-for-service type model,” said Michael E. Klepser, PharmD, FCCP, pharmacy professor at Ferris State University, in an interview with *Bloomberg Law*. “The fact that CMS is saying we’re now authorizing or allowing pharmacists to get reimbursed for these is a great door opening at the federal level and that’s a huge, huge thing.”

Chain pharmacies such as CVS, Walgreens, and Rite Aid are offering drive-through testing at many pharmacies throughout the country.

FDA Issues Updated Guidance for Compounding Pharmacies Experiencing PPE Shortages

FDA has issued an update for its guidance to pharmacy compounders that may experience shortages of personal protective equipment (PPE) during the COVID-19 pandemic. As compounders typically utilize PPE when performing sterile compounding, the updated guidance clarifies that the drugs can be compounded under the policy in a segregated compounding area that is not in a cleanroom. This policy has been adopted to ensure patients continue to have access to medicines they need during the pandemic, and to reduce the risks of compounding when standard PPE is not available.

In addition to FDA guidance, United States Pharmacopoeial Convention has previously issued an informational document for compounders regarding garb and PPE shortages during the pandemic. The document includes recommendations for conserving garb and PPE and what steps might be considered in the case of shortages of garb and PPE used for both sterile and nonsterile compounding.

The updated guidance can be accessed through FDA’s website by visiting www.fda.gov/media/136841/download.

HHS Expands Telehealth Access in Response to COVID-19

In an effort to prevent and respond to the COVID-19 pandemic, the US Department of Health and Human

Services (HHS) has awarded \$20 million to increase telehealth access and infrastructure for health care providers and families. The funds, which are awarded through the Health Resources and Services Administration (HRSA), will increase capability; capacity and access to telehealth and distant care services for providers, pregnant women, children, adolescents, and families; and assist telehealth providers with cross-state licensure.

“This new funding will help expand telehealth infrastructure that is already being used during the pandemic to provide essential care, especially to the most vulnerable, including pregnant women and children with special health care needs,” said HHS Secretary Alex Azar in a press release. “This funding will also help clinicians use telehealth nationally by streamlining the process to obtain multi-state licensure.”

HRSA’s Maternal and Child Health Bureau awarded a total of \$15 million to four recipients; each award supports a key area in maternal and child health, including pediatric care, maternal health care, state public health systems, and family engagement for children with special health care needs. HRSA’s Federal Office of Rural Health Policy awarded a total of \$5 million to two recipients through the Licensure Portability Grant Program, which will assist telehealth clinicians nationally on licensure and credentialing to meet emerging needs related to COVID-19.

Criminals Found Posing as CDC Representatives to Steal Money and Information

Centers for Disease Control and Prevention (CDC) is warning the general public of a new type of phone and phishing scam by criminals posing as CDC representatives, often requesting donations. According to CDC, most of these fraudulent activities are being conducted by phone, utilizing software to “spoof” phone calls to make them appear as if they are coming from phone numbers that may look familiar. CDC advises consumers to avoid answering calls from numbers they do not recognize, and to avoid sharing personal information over the phone. In addition, CDC notes that no federal agency will request donations from the general public. Suspicious phone calls may be reported to the Federal Communications Commission.

More information on the scams is available on the CDC website at <https://www.cdc.gov/media/phishing.html>.