



Kansas State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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Announcements

- ◆ Regular updates regarding Kansas State Board of Pharmacy guidance and information on coronavirus disease 2019 (COVID-19) can be found on the Board [website](#). This includes information about operations, waivers, renewals, exams, fingerprinting, inspections, pharmacy frequently asked questions, and more.
- ◆ Expect a new look and feel on Board inspection reports, in addition to some revisions consistent with new and updated laws and regulations. Enhancements were completed in August. All facility preopening and routine inspection reports are available in the [eLicense portal](#). Copies of blank inspection forms are available on the Board website for general guidance to assist facilities in self-assessment and compliance at <https://pharmacy.ks.gov/licensing-registration/business-facility>.
- ◆ Follow us on Twitter @KSBOP or on Facebook (www.facebook.com/KansasStateBoardOfPharmacy) for news, updates, and more!

New Board Members Appointed

The Board is pleased to announce Governor Laura Kelly's appointment of **Erick Axcell, PharmD**, and **Andrew Truong, PharmD**, to the Board. They will each serve a four-year term, ending in 2024.

Dr Axcell is the owner of Jayhawk Pharmacy, an independent retail pharmacy, located in Lawrence, KS. He is a native of Lawrence. He received two degrees from the University of Kansas – a bachelor of general studies in communication studies in 2004 and a doctor of pharmacy degree in 2012. Dr Axcell has also been awarded the Aya and Takeru Higuchi Award for excellence in pharmaceutical chemistry research. He is currently a member of both the National Community Pharmacists Association and the Kansas Pharmacists Association.

Dr Truong is the pharmacy manager of Community, a Walgreens Pharmacy, which is a local specialty pharmacy in Wichita, KS. Dr Truong is regularly involved with community events such as Positive Directions' AIDS Walk, National HIV Testing Day, and Leukemia and Lymphoma Society's Light the Night Walk. He earned his doctor of pharmacy degree from Southwestern Oklahoma State University College of Pharmacy in 2013, and is a brother of the Phi Delta Chi pharmacy fraternity. He has previously served as a board member for the Wichita Academy of Pharmacists. Dr Truong is a Wichita native and currently resides there with his wife, Resti, and their husky, Willie.

The Board also wishes to thank John Worden, PharmD, and Michael Lonergan, RPh, for their eight years of dedication and service to the Board.

Pharmacy Technician Examination, CE, and Renewal Examination

The Board now requires all technicians registered after July 1, 2017, to pass a national certification examination before their first renewal. Technicians who meet this criterion and are renewing in September through October 2020 must pass either the Pharmacy Technician Certification Exam or Exam for the Certification of Pharmacy Technicians before renewing their registration.

Kansas Administrative Regulation 68-5-17 allows for a technician to request a six-month extension if he or she is unable to take or pass the examination. The Board has created the [LA-75 Technician Certification Extension Request Form](#), which should be used to make such a request. Additional information can be found in the Board's June 2019 [Newsletter](#). Requests must be submitted to the Board before the technician renews and no later than October 1, 2020. Requests received after this date will be denied.

If a technician has not been granted a waiver and has not successfully passed a national certification exam prior to October 31, 2020, the technician should not renew and should stop working as a technician after the registration expires. Renewing without proof of passing an exam will result in denial. Any technician whose renewal is denied or expires will need to pass a national certification examination before filing a new technician registration application.

Continuing Education

All Kansas pharmacy technicians with registrations expiring October 31, 2020, must have completed 20 hours of continuing education (CE) – or the prorated amount of CE based on the issue date and expiration date of the technician registration – before renewal. Those 20 hours must have been earned between September 1, 2018, and the day of renewal in 2020.

CE may be approved for pharmacists or pharmacy technicians, or may be earned for national certification. However, all CE must be approved by one of the following:

1. **Accreditation Council for Pharmacy Education:** To receive credit, register for [CPE Monitor](#)[®].
2. **Another state board of pharmacy:** To receive credit, submit a copy of the certificate of completion to the Kansas Board within 30 days of course completion.
3. **The Kansas State Board of Pharmacy:** To receive CE approval from the Board, submit a request for approval to the Board at least 10 days prior to the course using the [E-200 Request](#)

National Pharmacy Compliance News

September 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>.

continued from page 1

Form. A list of [pre-approved Kansas CE courses](#) is also available on the Board website. To receive credit, submit a copy of your certificate of completion to the Board within 30 days of course completion.

Renewal

Pharmacy technicians with licenses expiring October 31, 2020, can renew online beginning in early September. Renewal instructions:

- ◆ Visit http://ksbop.licensesoftware.com/portal_logon.aspx.
- ◇ New users: click “Sign-Up” and create a username and password.
- ◆ Log in and select “Renew License.”
- ◆ Review and update information, certify completion of the required CE hours, answer disciplinary questions, and submit the renewal.
- ◆ Use the secure online payment portal to pay \$20 plus a small transaction fee by credit/debit card or electronic check, or follow the instructions to print and mail a \$20 check or money order to the Board.
- ◆ Allow 10 business days for the Board to process your renewal.
- ◆ Visit the [License Verification](#) page to check for an updated expiration date.

Failing to renew on or before 11:59 PM CDT on October 31, 2020, will result in the registration being canceled. Technicians with canceled registrations cannot work and will be required to complete a new application and fingerprint card to continue working (\$67 cost).

Pharmacies utilizing/employing technicians with canceled registrations will be in violation of the Kansas Pharmacy Practice Act and may be disciplined by the Board.

Alert: Phishing Scams Against Licensees and Registrants

The Board has recently learned about malicious actors calling pharmacists and pharmacy technicians, representing themselves as staff members at the Board. These actors indicate that there are complaints, investigations, or outstanding disciplinary actions pending against licensees and registrants. In some cases, malicious actors are able to spoof caller ID or mask email addresses, and may even have publicly available licensee names and license numbers. These inquiries are fraudulent! While the Board does make phone calls and send mail/email correspondence to its licensees and registrants, staff will always allow you to terminate the communication. If you receive a call or email and are unsure of its validity, contact one of the direct email addresses or phone numbers on the Board’s website so you can be assured that you are legitimately communicating with a Board staff member. Notification of disciplinary action will always be made by mail or email to your address of record. Board staff members are listed by name, and contact information is updated regularly on the Board website at <https://pharmacy.ks.gov/home/board-staff>.

K-TRACS Launches New Website

K-TRACS, the Kansas Prescription Drug Monitoring Program (PDMP), has launched a new website aimed at providing additional training and educational opportunities for users.

Found at pharmacy.ks.gov/k-tracs/, the website highlights many how-to aspects of using the state’s PDMP to inform clinical decisions and put patient safety first.

For pharmacists, the website features:

- ◆ Tips on how to register for a K-TRACS account and how to add and manage delegates
- ◆ How to integrate pharmacy systems with K-TRACS to streamline operations
- ◆ Information on becoming a medication collection and disposal location
- ◆ Information on signing the statewide naloxone protocol

The goal of the site is to emphasize patient safety while promoting healthy communities and preventing prescription drug misuse, abuse, and diversion. A Provider Toolkit is available for download, which contains several print and digital materials that can help pharmacists reinforce education and prevention with patients. To learn more about K-TRACS, visit pharmacy.ks.gov/k-tracs/.

Upcoming Events

September 3, 2020, 9 AM, WebEx

Board of Pharmacy Quarterly Meeting – <https://intercall.webex.com/intercall/j.php?MTID=m7af4b2d0786915e7922b0bee5b1a6d16>

September 25, 2020, 9 AM, WebEx

K-TRACS Advisory Committee Meeting (in person) – <https://intercall.webex.com/intercall/j.php?MTID=mb19caf0a878ab534446034a957809c74>

November 6, 2020, 11:30 AM, WebEx

K-TRACS Advisory Committee Meeting – <https://intercall.webex.com/intercall/j.php?MTID=m0c9e746f8aedf9ad4563d8bd43178af0>

December 4, 2020, 9 AM, WebEx

K-TRACS Advisory Committee Meeting (in person) – <https://intercall.webex.com/intercall/j.php?MTID=mbf5a04737b66a7678a9d4082d77eba85>

December 10, 2020, 8:30 AM, WebEx

Board of Pharmacy Quarterly Meeting – <https://intercall.webex.com/intercall/j.php?MTID=mbc35e1b4d0ab81cd18cd1e4a1bbd83a5>

Page 4 – September 2020

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