KENTUCKYBOARD OF PHARMACY

Newsletter to Promote Pharmacy and Drug Law Compliance.

2025 Board Officers

The Kentucky Board of Pharmacy elected Tony Tagavi as president and Meredith Figg as vice president for 2025. This is Tagavi's first term as president; he is currently serving his fourth year on the Board. This is Figg's first term as vice president; she is also serving her fourth year as a Board member.

Governor Appoints Ron Poole to Vacant Seat

Governor Andy Beshear appointed Ronald Poole of Central City, KY, as a member of the Board, representing licensed pharmacists, to replace John Fuller and to serve the remainder of the term expiring on January 1, 2027.

Access the National Pharmacy Compliance News

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Kentucky Board of Pharmacy Licensure Gateway Portal – Now Live

Please visit the Licensing Gateway
Portal to gather more information
about applying for or renewing
a license, permit, or registration
with the Board. The Licensure
Gateway provides a single portal

to manage licenses, permits, and registrations associated with the Board. It grants access to printable license/registration/permit certificates, change-of-contact and employment information, and

Kentucky Board of Pharmacy Licensure Gateway PortalNow Live

(cont)

online renewal applications and is used to submit all applications and changes.

For Individuals: The first time you visit the Licensure Gateway, you will register by creating a

username and password; you will need to link your Kentucky Board of Pharmacy license/registration at the beginning of the process.

For Facilities: The pharmacist-incharge (if applicable) will be the

facility administrator. Additional facility admins will need to register and create their own unique login within the Licensure Gateway.

Pharmacy Technician Registration Renewals

Pharmacy technician registrations expire on March 31, 2025. As a reminder, no person shall assist in the practice of pharmacy without being duly registered as a pharmacy technician, unless exempt under Kentucky Revised Statutes 315.135(2). Every pharmacy technician shall keep a current certificate of registration conspicuously displayed in their primary place of employment. Renewals must be made online via the Licensure Gateway Portal.

Facility License/Permit Renewals

Pharmacy permits, third-party logistics provider licenses, and outsourcer licenses expire on June 30, 2025. Renewals will

open in the Licensure Gateway on May 1, 2025. The Board will no longer be mailing renewal reminder postcards. Please make sure the facility email is up to date to ensure that reminder communications are received.



Senate Bill 188

Written by Alexis Skinner, PharmD Candidate, University of Kentucky College of Pharmacy, with edits by Eden Davis, General Counsel, Kentucky Board of Pharmacy

As of January 1, 2025, Senate Bill (SB) 188 is in effect. This new law applies to all pharmacy benefit manager (PBM) contracts issued, renewed, extended, or amended on or after the effective date; contracts finalized prior to January 1, 2025, are not subject to the requirements of SB 188. This law is designed to improve patient access to pharmacy benefits by regulating the pharmacy-related practices of insurance companies and PBMs.

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Senate Bill 188 (cont)

Now through December 31, 2026, insurers and PBMs are required to reimburse ambulatory "retail independent" pharmacies a minimum dispensing fee of \$10.64.

Other ambulatory pharmacies must be reimbursed at least the National Average Drug Acquisition Cost (NADAC), or wholesale acquisition cost if the NADAC is not available. Ambulatory pharmacies are defined in SB 188 as those that are open to the general public and dispense outpatient prescription drugs. The "retail independent" designation is a pharmacy type selected during the Board's permitting process.

Starting on January 1, 2027, dispensing fees will be determined by the commissioner of the Kentucky Department of Insurance. Data are to be collected by the Kentucky Board of Pharmacy and submitted to the commissioner to make this determination. The process will be repeated for subsequent dispensing fee adjustments every two years.

To collect the necessary data, the Board filed an emergency administrative regulation, 201 Kentucky Administrative Regulations (KAR) 2:416E, requiring ambulatory pharmacies to submit dispensing data to the Board. Starting on March 1, 2026, and annually thereafter, pharmacies will be required to report data from the previous calendar year. Data required for submission will include the cost of labor, materials. facilities, operations, software, office supplies, and equipment. The full list of required data can be found in 201 KAR 2:416E. An identical ordinary administrative regulation (201 KAR 2:416) is pending and open to public comment submissions through March 31, 2025.

In addition to mandatory reimbursement rates, insurers and PBMs are also prohibited from reimbursing a pharmacy at a net amount lower than what they would reimburse an affiliated pharmacy for the same drug or service provided.

SB 188 also requires insurers and PBMs to establish a "reasonably adequate" network of pharmacies, including at least one location within 30 miles from each insured's home, not including mail-order locations. To ensure compliance with this requirement, PBMs must file an annual report with the insurance commissioner describing their pharmacy network for patients. Patient steering, either by requiring or incentivizing patients to use mailorder pharmacies or insurer- or PBM-affiliated pharmacies, is now prohibited.

Pharmacists should familiarize themselves with all provisions of SB 188 and 201 KAR 2:416 to ensure that they are collecting and maintaining necessary data to be submitted to the Board of Pharmacy by March 2026. If pharmacists become aware of any violation of these laws by insurers or PBMs, they should file a complaint with the commissioner of the Kentucky Department of Insurance.

New NIOSH List of Hazardous Drugs in Healthcare Settings, 2024 Published

The National Institute for Occupational Safety and Health (NIOSH) has published the NIOSH List of Hazardous Drugs in Healthcare Settings, 2024 which updated the 2016 list by adding 25 new drugs, with 12 having manufacturer special handling information (MSHI), and removing seven others. Additionally, the list includes updates to the American Hospital Formulary Services classification and drug nomenclature of various drugs.

New NIOSH List of Hazardous Drugs in Healthcare Settings, 2024 Published (cont)

Key Updates

- The following drugs meet at least one of these criteria: they have MSHI in the package insert, they meet the NIOSH definition of hazardous drugs, and they are classified as either:
 - "known to be a human carcingen" by the National Toxicology Program (NTP);
 - Group 1 ("carcinogenic to humans") by the International Agency for Research on Cancer (IARC); or
 - Group 2A ("probably carcinogenic to humans") by the IARC.
- These drugs include the following: belantamab mafodotin, enfortumab vedotin, fam-trastuzumab deruxtecan, inotuzumab-ozogamicin,

- loncastuximab tesirine, lurbinectedin, melphalan flufenamide, mirvetuximab soravtansine, polatuzumab vedotin, sacituzumab govitecan, tisotumab-vedotin, and trabectedin.
- The following new drugs meet the definition of a hazardous drug but:
 - do not have an MSHI package insert;
 - are not classified by the NTP as "known to be a human carcinogen"; and
 - are not classified by the IARC as Group 1 ("carcinogenic to humans") or Group 2A ("probably carcinogenic to humans").
- They are: blinatumomab, ceritinib, clobazam, cobimetinib, dihydroergotamine, exenatide,

- isotretinoin, ivabradine, lenvatinib, miltefosine, olaparib, sonidegib, and urofollitropin.
- The drugs also list whether they received approval under a biologics license application.
- Drugs that were removed include bacillus calmette guerin, ergonovine, liraglutide, paliperidone, pertuzumab, risperidone, and telavancin.

More information about the new drugs added to the NIOSH List of Hazardous Drugs in Healthcare Settings, 2024 can be found here. Centers for Disease Control and Prevention recommends viewing the Managing Hazardous Drug Exposures: Information for Healthcare Settings and Procedures for Developing the NIOSH List for Hazardous Drugs in Healthcare Settings guides for properly handling and identifying hazardous drugs.

The Kentucky Board of Pharmacy News is published by the Kentucky 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 or the Board unless expressly so stated.

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