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Pharmacy Reporting of Immunizations to the Kentucky Immunization Registry

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The Kentucky Immunization Registry (KYIR) is a web-based, computerized system that provides valuable immunization data on both the clinic and population level. KYIR is a birth-to-death system, which allows immunizing providers to follow a patient throughout his or her lifetime of care. The system provides high-quality immunization data to a variety of users and other stakeholders, many of whom directly contribute to increasing immunization rates and preventing disease.

- **Clinicians** use immunization data to inform patient care, to identify patients in need of vaccination, and to assess and improve clinical immunization practices. These clinicians may be independent or part of clinics, hospitals, pharmacies, or long-term care facilities.
- Public health **immunization programs** use immunization and patient data to assess population coverage rates, to respond to outbreaks of vaccine-preventable disease, to inform strategies to improve immunization coverage, and to provide accountability for publicly funded vaccines.
- **Other public health programs,** such as Women, Infants, and Children and Lead Prevention, use Immunization Information System data to support health improvement programs.
- **Schools and childcare centers** use immunization records to assess student compliance with statewide immunization requirements.
- **Insurers** use Healthcare Effectiveness Data and Information Set data to assess and improve clinical immunization practices among providers in a health plan.
- **Individuals and families** use immunization records for childcare, school, camps, sports, employment, and personal health records.

With the accessibility and quantity of pharmacist-provided immunizations, it has become important for pharmacies and pharmacists to ensure that the vaccines being administered are reported to KYIR. Pharmacists can contribute data to KYIR in two ways:

1. By manual entry or an electronic connection through the Kentucky Health Information Exchange (KHIE). For manual entry, users can log in to KYIR directly and enter historical or newly administered vaccine information manually into the system, forecast upcoming immunizations, print certificates, run coverage statistic reports, generate reminder/recalls, and more.
2. Through an electronic interface, patient historical or newly administered vaccine information can be exchanged electronically from the facility or pharmacy's electronic health records (EHRs) to KYIR through a connection from KHIE. Users can still have direct access to KYIR to research immunization records and print certificates, run reports, etc – even if an electronic connection is established. Some EHRs can query KYIR and will not require users to directly access KYIR for immunization research. Other pharmacies may need direct access to KYIR for research, which is available at no cost and with no reporting requirements.

KYIR offers a variety of tools that are easily accessible to its users, including clinical decision support through the vaccine forecaster, certificate printing for school entry, generating reminders/recalls for those who are coming due or who are overdue for vaccines, vaccine coverage assessment reports, and more. If you are interested in gaining direct access to KYIR, or if you would like additional information on KYIR's capabilities, please contact the help desk by phone at 502/564-0038, or email at KYIRHelpdesk@ky.gov.

If a pharmacy chooses to establish an electronic connection to KYIR through KHIE, there are many additional benefits to assist pharmacists in caring for their patients. As the state's designated health information exchange, KHIE strives to be the single trusted source of patient health information aggregated from all participating providers across the commonwealth. This network consists of more than 100 hospitals and 2,500 ambulatory health

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National Pharmacy Compliance News

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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 Pharmacopeial 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.*

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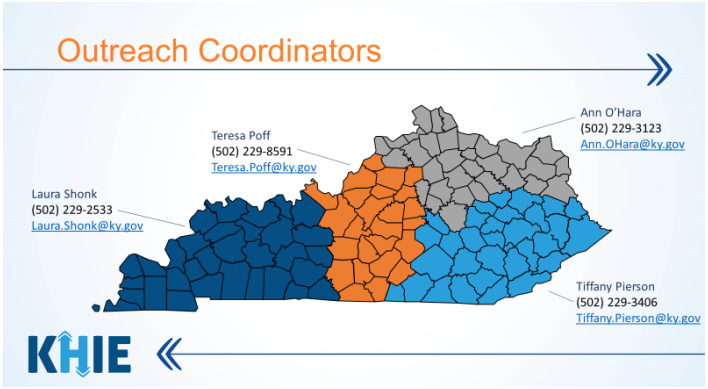
care locations, representing 5,600 data feeds. KHIE participants have access to the following types of data: patient demographics; lab results and pathology; transcribed radiology reports; other transcribed reports; summaries of care; admission, discharge, and transfer data; behavioral health data; health data from correctional facilities; emergency medical services data; and immunizations.

Currently, 13% of Kentucky-registered pharmacies electronically report to KYIR through KHIE, and 8% of pharmacies electronically receive immunization information back from KYIR through KHIE. KHIE is onboarding pharmacies now. Some pharmacy operating systems may require a third-party data bridge to submit vaccine information to KHIE.

Becoming a KHIE participant is a four-step process.

1. To begin, contact the KHIE outreach coordinator in your area. **See the map below.**
2. Next, your outreach coordinator will set up a short preliminary call to discuss the benefits of KHIE and determine your service path and connectivity with KHIE. This will be based on your pharmacy's needs and your system's interoperability.
3. You will be required to complete and return the KHIE participation agreement and addendums.
4. Finally, you will participate in the KHIE official intake call, during which KHIE will answer any outstanding questions you may have and explain the process for technical onboarding.

KHIE values the significance of the immunization information pharmacies could contribute to the KYIR and realizes that developing an interface to KHIE to submit that information may come with a financial burden. Subsequently, to alleviate some of that financial burden, KHIE will be launching a grant opportunity for health care organizations. Please contact your outreach coordinator to find out more about the application process.



CE Highlights

1. Kentucky requires 15 credit hours **every calendar year.**
2. The Kentucky Board of Pharmacy audits **every** CPE Monitor® account **every year.**
3. Check your CPE Monitor account today to ensure that you have 15 continuing education (CE) hours. Please do not procrastinate if you do not have your 15 CE hours yet.
4. Extension waivers are very rare. Please do not count on a waiver.

Physician Assistants CS Prescriptive and Administrative Authority

The 2020 Kentucky Legislature updated Kentucky Revised Statute (KRS) 311.856 and KRS 311.858(5) to allow physician assistants (PAs) to prescribe and administer controlled substances (CS) on a limited basis. The updated statutes became effective July 15, 2020.

PAs are under the authority of the Kentucky Board of Medical Licensure (KBML). Before a PA may prescribe and/or administer a CS, the PA must:

- have one year of experience as a licensed, practicing PA;
- submit an application to KBML, signed by the supervising physician;
- receive approval from KBML; and
- obtain a Drug Enforcement Administration registration.

PAs may prescribe and administer the following CS:

- Schedule II – may not prescribe or administer;
- Schedule III – limited to a 30-day supply with no refills; and
- Schedule IV and V – limited to the original prescription and refills not to exceed a six-month supply, with exceptions of all benzodiazepines and carisoprodol being limited to a 30-day supply with no refills.

PAs may not dispense CS.

At this time, KBML is in the process of updating regulation 201 Kentucky Administrative Regulations 9:270 Professional standards for prescribing or dispensing Buprenorphine-Mono-Product or Buprenorphine-Combined-with Naloxone to address PA prescribing of these products for substance use disorder.

Please see the chart of Kentucky practitioner prescriptive authority on the next page.

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Kentucky Prescriptive Authority

Kentucky Provider	Authority to Prescribe
Physician (MD/DO) KRS 311.550 201 KAR 9:260 (CS) 201 KAR 9:016 (stimulants) 201 KAR 9:270 (MAT)	♦ Profession limits prescribing to **humans** only ♦ CS limits: CII Rx for acute pain limited to a 3 day supply (see exceptions)*
Veterinarian (DVM) KRS 321.181 201 KAR 16:110	♦ Profession limits prescribing to **animals** only ♦ No other profession-specific statutory or regulatory limits
Dentist (DMD/DDS) KRS 313.035 201 KAR 8:540	♦ Profession limits prescribing to **conditions of the mouth and associated structures** only ♦ CS limits: CII Rx for acute pain limited to a 3 day supply (see exceptions)*
Podiatrist (DPM) KRS 311.380201 KAR 25:090	♦ Profession limits prescribing to **conditions of the feet and associated structures** only ♦ CS limits: CII Rx for acute pain limited to a 3 day supply (see exceptions)*
Optometrist (OD) KRS 320.240201 KAR 5:130	♦ Therapeutically Certified ODs limited prescribing to **conditions of the eye or its appendages** only ♦ CS limits: ◊ **CII HCP (hydrocodone combination product):** 72 hr supply ◊ **CII (other):** Not authorized to prescribe other C-IIs ◊ **CIII-V:** 72 hr supply with no refill
Advanced Practice Registered Nurse (APRN) KRS 314.011(8) 201 KAR 20:057 (CS) 201 KAR 20:063 (stimulants) 201 KAR 20:065 (MAT)	♦ Profession limits prescribing to **humans** only ♦ Prescriptive authority defined by Collaborative Care Agreement: CAPA-NS and/or CAPA-CS ♦ Collaborating physician must be licensed in KY but does not have to be on the premises ♦ CS limits: ♦ CII (generally): 72 hr supply ♦ CII HCP: 30 day supply; 3 day supply if treating acute pain (see exceptions)* ♦ CII Psychostimulant: APRN certified in psych-mental health may prescribe 30 day supply ♦ CIII: 30 day supply with no refill ♦ CIV: original Rx with refills not to exceed 6 months ♦ CIV Exceptions: diazepam, clonazepam, lorazepam, alprazolam, and carisoprodol → 30 day supply with no refill
Physician Assistant (PA) KRS 311.854 KRS 311.856 KRS 311.858 KRS 311.860	♦ Profession limits precribing to humans only ♦ Prescriptive authority delegated by Supervising Physician and defined by KBML approved applications including Application for Prescriptive Authority for Controlled Substances ♦ Supervising physician must be on the premises unless KBML waiver has been granted and a supervising physician is available via telecommunication. ♦ CS Limits: ♦ CII: not authorized to prescribe CIIs ♦ CIII: 30 day supply with no refill ♦ CIV: original Rx with refills not to exceed 6 month supply ♦ CIV Exceptions: benzodiazepines and carisoprodol limited to a 30 day supply with no refill ♦ CV: original Rx with refills not to exceed 6 month supply

HCP = hydrocodone combination product
CS = controlled substance
NS = non-scheduled or non-controlled substance

CII Prescriptions for Acute Pain - Exceptions to the 3 Day Supply Limit

KRS 218A:205 (3)(b) Prescriptions issued for a Schedule II controlled substance intended to treat acute pain must be limited to a 3 day supply, unless:

1. In the professional judgement of the practitioner, more than a 3 day supply is needed. The need must be documented. For the purposes of pharmacy dispensing, the medical necessity for the Schedule II CS as documented by the practitioner and the Rx for more than a 3 day supply are presumed to be valid;
2. Treating chronic pain;
3. Treating cancer pain;
4. Treating a patient at end of life or in Hospice;
5. Prescribing as part of a narcotic treatment program;
6. Treating pain after major surgery or significant trauma as defined by the licensing Board and the Office of Drug Control Policy;
7. Dispensing or adminsitering directly to a patient in an inpatient setting;
8. Authorized by the applicable licensure board.