March 2020

Kentucky Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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2020 Board Officers

The Kentucky Board of Pharmacy has elected Ron Poole as president and Jill Rhodes as vice president for 2020. This is Mr Poole's first term as president and his fourth year on the Board. This is Dr Rhodes' first term as vice president and her third year as a Board member.

2020 Board Calendar

The Board approved the following 2020 meeting dates at its November 13, 2019 meeting:

- March 25, 2020
- May 27, 2020, at Sullivan University's College of Pharmacy and Health Sciences
- July 29, 2020
- September 30, 2020
- November 5, 2020, at University of Kentucky's College of Pharmacy

Meetings are held at the Board office unless designated otherwise and begin at 9 AM. Pharmacists and the public are invited to attend.

KASPER Record Correction

Submitted by Mike Noel and Russ Robbins, Kentucky Cabinet for Health and Family Services

This Kentucky All Schedule Prescription Electronic Reporting (KASPER) tip provides guidance to prescribers and dispensers who report administered or dispensed controlled substance (CS) data to the KASPER Data Collection System on how to correct records that have been submitted in error or that contain errors. Please remember that upon notification of information that was reported to KASPER and confirmation that the data contained errors, you have seven days to correct the data as specified in 902 Kentucky Administrative Regulations (KAR) 55:110 Section 8.

KASPER record correction depends upon the method used to upload the CS prescription data.

- **Scenario 1 – If you manually enter your prescription data using the Prescription Data Entry Form (PDEF):** You can log in to your KASPER uploader account at *https://ekasperupload.chfs.ky.gov* and use the PDEF to make the record correction.
- **Scenario 2 – If your software vendor or another third party uploads prescription data to KASPER on your behalf:** If your software vendor or other third party uploads your data, you may not have a KASPER uploader account. Even though you use a third party to upload your data, you can still register with KASPER and get an upload account that will allow you to use the PDEF to correct records in error. You will continue to upload your daily files through your vendor, but the KASPER uploader account will enable you to log in to the KASPER Data Collection System and take advantage of the PDEF to make a small number of changes that might otherwise be difficult to coordinate through your software vendor. You may also wish to contact your software vendor to determine if its software provides a feature for submitting corrections.
- **Scenario 3 – If your pharmacy is part of a chain that uploads your prescription data at the corporate level:** If the prescription data for your pharmacy is uploaded at a corporate level, the corporate office will need to make the corrections. You will need to contact your corporate office and follow its prescription drug monitoring program data correction procedure.

If you need assistance using the PDEF, contact the eKASPER help desk at 502/564-2703.

Frequently Asked Questions

Q. An error on a prescription previously transmitted to KASPER has been brought to our attention, but it is several months old. Does it matter if we correct the error?

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National Pharmacy Compliance News

March 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.

DEA Proposes New Regulations to Address Opioid Epidemic

Drug Enforcement Administration (DEA) has announced proposed regulations to improve the agency's ability to oversee the production of opioids and other potentially dangerous drugs. The proposed regulation would further limit the quantities of medications that might be vulnerable to diversion and misuse. The proposal would also amend the manner in which DEA grants quotas to certain registered manufacturers to levels aligned with current manufacturing standards aimed at promoting quality and efficiency while also ensuring the country has sufficient quantities of Schedule II controlled substances (CS) necessary for medical, scientific, research, and industrial needs.

The proposal introduces several new types of quotas that DEA would grant to certain DEA-registered manufacturers. These use-specific quotas include quantities of CS for use in commercial sales, product development, packaging/repackaging and labeling/relabeling, or replacement for quantities destroyed. These quotas are intended to improve DEA's ability to respond quickly to drug shortages.

The proposed changes build on 2018 regulatory changes that gave a role to state attorney generals and other federal agencies in setting the aggregate production quotas for Schedule I and II CS. The proposed regulations are available in the October 23, 2019, *Federal Register* announcement at *https://www.federalregister.gov/documents/2019/10/23/2019-21989/management-of-quotas-for-controlled-substances-and-list-i-chemicals*.

FDA Issues Report on Root Causes and Solutions to Drug Shortages

Food and Drug Administration (FDA) has released a new report, *Drug Shortages: Root Causes and Potential Solutions,* which identifies root causes for drug shortages and recommends three "enduring solutions" to address the shortages. These recommendations include:

- creating a shared understanding of the impact of drug shortages on patients and the contracting practices that may contribute to shortages;
- developing a rating system to incentivize drug manufacturers to invest in quality management maturity for their facilities; and
- promoting sustainable private sector contracts (eg, with payers, purchasers, and group purchasing organizations) to make sure there is a reliable supply of medically important drugs.

In addition to these recommendations, the report outlines the agency's ongoing initiatives to mitigate drug shortages and legislative proposals in President Donald J. Trump's Fiscal Year 2020 budget. FDA also highlighted the need for international action, including global implementation of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use's (ICH's) *ICH Guideline Q12: Technical and Regulatory Consideration for Pharmaceutical Product Lifecycle Management,* which provides opportunities for regulatory flexibility in making post-approval changes to the product or its manufacturing process.

"We hope that the recommendations set forth in this report will help to set a framework that all stakeholders can assess and implement as we work together to further mitigate the public health impact that drug shortages have on American consumers," FDA stated. "In the meantime, the FDA's employees remain committed to working behind-the-scenes to anticipate and help mitigate shortages and make sure that patients have access to the drugs they need."

FDA's full statement is available at *https://www.fda.gov/news-events/press-announcements/statement-fdas-new-report-regarding-root-causes-and-potential-solutions-drug-shortages*.

HHS Announces Guide for Appropriate Tapering or Discontinuation of Long-Term Opioid Use

The United States Department of Health and Human Services (HHS) has published a new guide for clinicians intended to provide guidelines for tapering or discontinuing long-term opioid use. The guide, titled *HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics*, covers important issues to consider when changing a patient's chronic pain therapy. The guide also lists issues to consider prior to making a change, when initiating the change, and as a patient's dosage is being tapered, including the need to treat symptoms of opioid withdrawal and provide behavioral health support.

"Care must be a patient-centered experience. We need to treat people with compassion, and emphasize personalized care tailored to the specific circumstances and unique needs

of each patient," said ADM Brett P. Giroir, MD, assistant secretary for health in a press release. "This Guide provides more resources for clinicians to best help patients achieve the dual goals of effective pain management and reduction in the risk for addiction."

FDA Releases Draft Best Practice Document for Postmarket Drug Surveillance

As part of FDA's efforts to enhance the efficiency of its postmarket drug safety surveillance, the agency has released a new best practices document, *Best Practices in Drug and Biological Product Postmarket Safety Surveillance for FDA Staff*. The draft document outlines FDA's approach for timely postmarket analyses of drugs and biologics, and includes a high-level overview of tools, methods, and signal detection and evaluation activities, using varied data sources, for drug safety. The goal is to provide a broader context and a general overview of ongoing efforts and commitments.

"Our best practices document incorporates the guiding principle that postmarket safety surveillance is a dynamic and constantly evolving field," FDA said in a statement announcing the document's release. "By using a risk-based approach, the FDA takes into account the nature of the drug, its potential adverse events, the intended population, and the potential for serious outcomes, as well as the impact on individuals and the overall potential impact on the health of the public."

The full draft document can be accessed at *https://www.fda.gov/media/130216/download*.

FDA Issues Revised Draft Guidance on Regulation of Homeopathic Products, Withdraws 1988 Compliance Policy Guide

FDA is taking two new steps to clarifying their approach to regulating drug products labeled as homeopathic: revising draft guidance previously published in 2017, and withdrawing the Compliance Policy Guide (CPG) 400.400 issued in 1988. These moves were announced in a statement published on the FDA website. Homeopathic products are often marketed as natural alternatives to approved prescription and nonprescription products and are widely available in the marketplace. Homeopathic products, however, are marketed without FDA review and may not meet modern standards for safety, effectivity, quality, and labeling. FDA uses a risk-based approach to monitor these products and to evaluate reports of adverse events.

The revisions to the 2017 draft guidance provide further information about FDA's approach. The guidance details a risk-based enforcement policy prioritizing certain categories of homeopathic products that could pose a higher risk to public health. These include products with particular ingredients and routes of administration, products for vulnerable populations, and products with significant quality issues. FDA has invited public comment on the guidance before it is finalized. The full guidance and instructions for providing comment are available in the *Federal Register* announcement.

CPG 400.400, Conditions Under which Homeopathic Drugs May be Marketed, is being withdrawn due to inconsistency with the agency's risk-based approach to regulatory and enforcement action and is therefore being withdrawn. Specifically, FDA states that it has encountered multiple issues with homeopathic drug products posing significant risk to patients, even though the products, as labeled, appeared to meet the conditions of CPG 400.400.

DEA Warns of Increase in Scam Calls Targeting Pharmacists and Other DEA-Registered Providers

DEA is warning health care providers and other members of the public of another increase in fraudulent phone calls attempting to extort money. Though the tactics change regularly, the callers typically claim to represent DEA and provide either fake names and badge numbers, or the names of well-known senior officials with DEA. The scammers then threaten legal action, including arrest, against the victim unless large fines are paid by wire transfer. Most recently, the scammers appear to be spoofing a DEA number based out of Salt Lake City, UT, according to a DEA press release.

The agency emphasizes that DEA will never contact practitioners by phone to demand money or any form of payment. DEA will not request any personal or sensitive information by phone, and notification of a legitimate investigation or legal action is always made via official letter or in person.

DEA asks anyone who receives a call from a person purporting to be a DEA special agent or other law enforcement official asking for money to refuse the demand and report the threat using the online form or by calling 877/792-2873. Reporting these calls will assist DEA in investigating and stopping this activity.

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A. Yes, you must correct the error. Failure to submit a correction to KASPER is a violation of 902 KAR 55:110 Section 8.

Q. How do I change the prescriber on a prescription that has already been transmitted to KASPER?

A. To correct inaccurate prescriber information, you should follow the correction process identified above that corresponds to the method you use to upload data. If you have a KASPER uploader account, go to the KASPER Data Collection System website by visiting *https://ekasperupload.chfs.ky.gov*, log in with the same username/password you normally use to upload to KASPER, and select "Rx Data Entry Form." This will display the PDEF and allow you to enter the corrected prescriber information. Be sure to click the "REVISE" box at the bottom before clicking on "SUBMIT."

Q. I made a correction on a prescription that had already been transmitted to KASPER, but now I have a duplicate showing on the patient's KASPER report. How do I delete the duplicate prescription?

A. To delete a duplicate prescription record, log in to your KASPER uploader account and select "Rx Data Entry Form." Enter the information for the prescription to be deleted exactly as it was originally entered. Be sure to click the "VOID" box at the bottom before clicking on "SUBMIT."

Q. We made a correction in our pharmacy software system on a prescription that had already been transmitted to KASPER. The prescription is now correct in our system, but it is still incorrect on the patient's KASPER report. Why does KASPER not reflect the corrected data?

A. When a correction is made through your pharmacy software system to a prescription that has previously been uploaded to KASPER, the **revised** record must still be sent to KASPER. Unfortunately, some pharmacy software systems do not do this automatically. Contact your software vendor and ask how its process works. If the software does not automatically send a **revision** record when changes are made, the revised record will have to be submitted manually using the PDEF as described above.

Q. We need to revise a prescription record with errors, and the error is one of the key fields (prescription number, date filled, National Drug Code (NDC) number, or dispenser Drug Enforcement Administration (DEA) number). How do we proceed?

A. The American Society for Automation in Pharmacy (ASAP) standard used for reporting data to KASPER uses these four pieces of information as key indices and, therefore, they cannot be changed. In this situation, you must **void** the original record and submit a **new** record with the correct information to take its place. This can be done by logging in to your KASPER uploader account and using the PDEF to submit the void record and the new record.

Q. When should prescription data be transmitted to KASPER – within one day of when the prescription is filled or within one day of when it is picked up?

A. This is software dependent, based upon the pharmacy software system in use. Most systems upload the data when the prescription is filled, while others report when the prescription is actually released to the patient. Either method is compliant with the KASPER reporting requirement. You may contact your software vendor for more information.

Q. If I submit the same prescription number twice in one day, will both records be accepted or will one record be rejected as a duplicate? What if they are for different quantities (eg, 80 on one fill and 20 on the other because the payment was split between insurance and cash payment)?

A. KASPER has duplicate record checks. Once the first prescription is loaded, the second will be identified as a duplicate and rejected if all of the information is exactly the same. If the quantities are different, both records will be accepted. Partial fills should be marked as such. The current ASAP standard has a field that identifies partial fills. Contact your software vendor if you have questions about how your software handles partial fills.

Q. I filled a prescription and almost two weeks have passed, and I do not believe the patient will pick up the prescription. Should I delete the prescription record?

A. Yes, when you believe the patient will not pick up a previously filled prescription, you need to delete the record. To delete a prescription record that was reported to KASPER when filled, but not picked up by the patient, log in to your KASPER uploader account and select "Rx Data Entry Form." Enter the information for the prescription to be deleted exactly as it was originally entered. Be sure to click the "VOID" box at the bottom before clicking on "SUBMIT." Please remember that failure to void a prescription that

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was not picked up by a patient creates an inaccurate KASPER report that can have an adverse effect on the patient's care.

Q. I filled a prescription using the issuing prescriber's DEA number in our system but on the patient's KASPER report the name of the prescriber is different. Since the prescriber name is different in KASPER from the prescriber name in my pharmacy software system, do I need to do anything?

A. KASPER reports are based on the information reported by the pharmacy, including the DEA number reported by the pharmacy for the prescriber. The KASPER system uses the prescriber's DEA number reported by the dispenser to identify the prescriber's name based on a DEA number cross-reference table provided by DEA and updated weekly within KASPER. In this case, the prescription record specified a prescriber's DEA number that was matched against the KASPER DEA cross-reference table that returned a different prescriber name. In most of these situations, the DEA number in the pharmacy system is linked to the wrong prescriber. The pharmacy should correct the error in its software system and correct all prescription records that have been transmitted to KASPER with this error. KASPER staff cannot make this correction. If after checking your pharmacy software system you still cannot explain the DEA number/prescriber name mismatch, contact your software vendor or other technical support team for further investigation. If you discover that a large number of prescription records must be corrected, please contact the KASPER business office at 502/564-7985 before making the changes.

Q. On some KASPER reports, a number is reported in place of the prescriber's name and/or the drug name. What causes this to occur?

A. As discussed above, prescription data sent to KASPER contains the prescriber's DEA number, not the prescriber's name. The KASPER system uses the DEA number and DEA cross-reference table to identify the prescriber's name for the reports. If KASPER cannot find a match for the DEA number, it will report the DEA number in place of a name. In these situations, please verify with the prescriber that you are using his or her correct DEA number in your system.

The same is true for drug names. Dispensers report the NDC number to KASPER. The KASPER system compares the NDC number with the Kentucky Cabinet for Health and Family Services' master drug database (Wolters Kluwer Medi-Span). If no match is found, the KASPER report will show the NDC number that was in the prescription record. Please verify that you are using the correct NDC number.

Federal Extortion Schemes

Kentucky pharmacists should be on the alert for scams that are targeting health care providers nationwide.

Pharmacists have been receiving phone calls from scammers stating that they are with DEA or the Federal Bureau of Investigation (FBI). Both types of scams claim that if the pharmacist does not pay money, DEA, the FBI, and/or the Board will conduct an investigation. Please be aware that if the Board is conducting an investigation, it will be performed by the pharmacy and drug inspector for that area. The Board does not contract with DEA or the FBI to inform Kentucky pharmacists of an investigation.

For more information, press releases are available on the DEA and FBI websites.

Official Method of Notification

The *Kentucky Board of Pharmacy Newsletter* is considered an official method of notification to pharmacists, pharmacist interns, pharmacies, wholesalers, and manufacturers credentialed by the Board. **These *Newsletters* will be used in administrative hearings as proof of notification.** Please read carefully. The Board encourages you to store them electronically in a folder or keep them in the back of the *Kentucky Pharmacy Law Book* for future reference.

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