SEPTEMBER 2023

KENTUCKY BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

A Message From the Office of the Inspector General on Reporting a Loss or Theft of CS

In order to monitor the theft/loss of controlled substance (CS) prescriptions, a number of legislative requirements were enacted. These requirements include reporting the theft/loss to several agencies, including the Kentucky Board of Pharmacy, Drug Enforcement Administration (DEA), law enforcement, and the Commonwealth of Kentucky Cabinet for Health and Family Services (CHFS) Drug Enforcement and Professional Practices Branch.

201 Kentucky Administrative Regulations (KAR) 2:205(3)(g) requires a pharmacy to report:

> "any theft or loss to: 1. The U.S. Department of Justice Drug Enforcement Agency [*sic*] as required by 21 C.F.R. 1301.76(b); 2. The Department of the Kentucky State Police as required by KRS 315.335; and 3. The board by providing a copy to the board of each report submitted."

Kentucky Revised Statutes (KRS) 315.335 requires reporting theft/loss to the Board, local law enforcement, and Kentucky State Police.

Per KRS 218A.200(6), a copy of the detailed list of CS lost, destroyed, or stolen shall be forwarded to CHFS as soon as practical.

To be compliant with this statute, please send a copy of your DEA 106 or other reporting form for theft/loss via email to eKASPER.Admin@ky.gov or fax at 502/564-7568. Please do not send forms to an individual Board staff member.

National Pharmacy Compliance News
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Pharmacists' Role in Decreasing Children's Accidental Ingestions

By Amanda Harding, PharmD, BCSCP, and Celine Hummer, PharmD Candidate 2024

Ensuring patient safety is one of the most important roles that a pharmacist has in patient care, no matter what field of pharmacy they work in. According to the American Academy of Pediatrics (AAP), children under the age of five have the highest rate of emergency room visits for unintentional drug-related poisonings.[1] This is an issue that has been targeted with the use of child-safety lids for prescription bottles. The Poison Prevention Packaging Act was enacted in 1970 and stated that prescription medication packaging must be designed to be child resistant.[2] This was successful in decreasing the number of deaths in children due to accidental ingestion. Despite these efforts, accidental ingestion by children is still occurring, and child-proof packaging is not enough to prevent these accidental poisonings. Since 2015, the Child Fatality and Near Fatality External Review Panel has documented a 350% increase in overdose/ingestion cases in Kentucky.[3] The National Poison Data System collects data from 55 poison centers across the United States. In 2021, Kentucky callers contacted the poison centers for 35,143 human exposure cases, 45% of which were for children ages five and under.[4] Pharmacists have an opportunity to play a part in decreasing accidental ingestion by educating patients about the importance of medication safety.

Medications for opioid use disorder (MOUD), such as Suboxone®, buprenorphine, and methadone, accounted for 18% of fatal and near-fatal ingestions in Kentucky children in 2022.[3] These medications are potentially lethal in children, and pharmacists should educate all patients who are receiving MOUD on medication safety. Recipients of MOUD should be provided with face-to-face messaging regarding safe medication storage, and they should be encouraged to obtain medication lockboxes to prevent unintentional ingestion.[3] Other medications that are commonly implicated in accidental ingestions include opioids, clonidine, and over-the-counter medications such as allergy, cold, and cough medications.

Data from the AAP show that, of fatal pediatric poisonings occurring from 2005-2018, 60.9% of cases involved the substance responsible for the poisoning being stored in an open area, and 28.4% of cases involved a substance that was not stored in its original container.[1]

There are several actions that can be taken by caregivers to avoid these fatal and near-fatal ingestions. Patients should be educated to keep their medications up and away from small children. Many times, keeping them in a medicine cabinet is not enough; in 17.6% of fatal pediatric poisonings occurring from 2005-2018, the substance responsible was stored in a cabinet.[1] Patients should pick a place in their home that children cannot reach or even see. Never leave medication out, and put it

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1 *https://publications.aap.org/pediatrics/article/151/4/e2022059016/190819/Characteristics-of-Fatal-Poisonings-Among-Infants?autologincheck=redirected*

2 White ND, Kibalama W. Prevention of Pediatric Pharmaceutical Poisonings. *Am J Lifestyle Med.* 2017 Dec 9;12(2):117-119. doi: 10.1177/1559827617745014. PMID: 30283248; PMCID: PMC6124998.

3 *https://justice.ky.gov/Boards-Commissions/cfnferp/Documents/Old%20Site/annual%20reports/2022%20Annual%20Report.pdf*

4 *https://www.aapcc.org/national-poison-data-system*

away after each use, no matter how soon it will be used again. Even if a medicine bottle has a safety cap, children may be able to open it. Ask any house guests and/or family members to be conscious about medications kept in purses or coats, and request that medications be up and away from children while visiting.[5] Additionally, children can mistake medication for candy due to the flavoring that is added to make many medications more palatable; caregivers should never treat medication as candy to encourage kids to take it. Pharmacists should educate patients about drug take-back programs where they can return unused medications in a safe way. These actions can help to prevent fatal and near-fatal ingestions in children.

201 KAR 2:380 Board Authorized Protocols Regulation Amended

The amended version of 201 KAR 2:380 became effective on June 21, 2023.

The highlights of the changes or clarifications made to 201 KAR 2:380 include:

- The protocol may only be signed by a Kentucky-licensed physician or advanced practice registered nurse practitioner. No other practitioner (eg, a physician assistant) will have the authority to sign a Board-authorized protocol.
- The protocol must state the permit number of the Kentucky pharmacy where the protocol will be utilized.
- Only pharmacists who are party to the protocol agreement are allowed to implement/utilize the protocol.
- Pharmacists utilizing the protocol must be employed by or contracted with the permit holder and appropriately licensed by the Board.
- The pharmacist-in-charge is responsible for submitting the fully executed protocol to the Board and for submitting notification of discontinuation of the protocol no later than 30 days after discontinuing the protocol.
- The protocol must be sent to the Board prior to implementation.
- The Board will maintain a protocol registry.
- A Protocol Review Committee will be appointed and will meet at least quarterly to:
    - evaluate new protocols proposed; and
    - review previously authorized protocols.
- Coronavirus disease 2019 infection, pursuant to the recommendations by the Centers for Disease Control and Prevention, has been added as an authorized condition.

All Board-authorized protocols currently signed and utilized must be submitted to the Board so they can be added to the registry. The registry is specific to protocols pursuant to 201 KAR 2:380.

5 *https://www.cdc.gov/patientsafety/features/medication-storage.html*

Immunization and naloxone protocols are not authorized under 201 KAR 2:380 and, therefore, do not require submission to the Board.

A list of Board-authorized protocols can be found on the Board website. Only protocols authorized by the Board will be accepted for inclusion into the registry. Any newly authored protocol to be considered should be submitted to the Board for consideration by the Protocol Review Committee.

Important CE Reminders

- The Board audits every continuing education (CE) account each year for every Kentucky-licensed pharmacist. The Board uses the National Association of Boards of Pharmacy®'s CPE Monitor® to ensure that all licensees have completed 15 CE hours.
- The CE year is the calendar year, **not** the license-renewal-to-license-renewal year.
- Please check your CPE Monitor transcript well in advance of December 31 to ensure that you have the required 15 hours.
- Please check that your CPE Monitor e-Profile® includes your Kentucky license information; otherwise, the Board will be unable to view your transcript for the audit.
- CE that is not Accreditation Council for Pharmacy Education (ACPE) accredited must be approved by the Board and will not appear on your CPE Monitor transcript.
- Starting in licensing year 2023 and continuing through 2028, one contact hour must be completed on the opioid epidemic or opioid use disorder. The ACPE Topic Number 08 will meet this regulatory requirement.
- Please note that ACPE-accredited CE providers have up to 60 days to report your credits to CPE Monitor.

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