Statement on Descheduling of Epidiolex®
Approved by Kansas State Board of Pharmacy: September 3, 2020

Purpose – The purpose of this statement is to provide clarification to Kansas pharmacists and pharmacies receiving patient prescriptions for Epidiolex® on or after September 3, 2020.

Statutory Authority – See K.S.A. 65-1627, 65-1643, 65-1658, 65-4111, and all Board regulations adopted thereunder.

On its meeting of September 3, 2020, the Board reviewed a request from Greenwich Biosciences concerning its drug, Epidiolex®. As a result of actions under the federal Agriculture Improvement Act (AIA), the drug was descheduled under the federal Uniform Controlled Substances Act. On August 21, 2020, the U.S. Drug Enforcement Administration (DEA) issued and Interim Final Rule incorporating the AIA into DEA regulations officially removing any federal controlled substance designation from the prescribing and dispensing of the drug. Following congress's descheduling, the FDA approved the drug's revised non-scheduled label. The FDA's National Drug Code directory also shows the current status of the drug as non-scheduled.

Pursuant to K.S.A. 65-4102(b), the Kansas State Board of Pharmacy is required to submit to the Speaker of the Kansas House of Representatives and the President of the Kansas Senate a report on substances proposed by the Board for scheduling, rescheduling or deletion by the legislature with respect to any one of the schedules as set forth in the Kansas Uniform Controlled Substances Act, K.S.A. 65-4101 et seq. The Board strives to mirror the federal schedules in its recommendations to the Kansas legislature and generally recommends amending the state laws to match the federal laws in order to facilitate uniformity while maintaining and enhancing the consumer protections afforded by the regulatory system. Unfortunately, the Kansas Uniform Controlled Substances Act still lists the drug's active ingredient as a Schedule IV controlled substance in Kansas. While the Board has emergency scheduling authority for any new substance which may emerge outside the legislative session in order to ensure ongoing protection of the public health, the Board has no corresponding emergency authority to delete substances.

This temporary conflict between federal and state law has created inconsistencies and confusion in the written prescription requirements for dispending Epidiolex® resulting in significant delays for thousands of patients receiving their prescription medications. Based on the actions of the DEA and FDA, during the 2021 legislative session, the Board plans to recommend deletion of the drug from the Kansas Uniform Controlled Substances Act. This action is consistent with 24 other states. However, until action can be affected by the Kansas legislature, the Board will exercise its regulatory discretion and not pursue disciplinary action against licensees or registrants that receive, process, and dispense Epidiolex® prescriptions as a non-controlled drug.