Maryland
DEPARTMENT OF HEALTH

Update: Suspension of disciplinary actions - Epidiolex
December 22, 2021

Purpose – The purpose of this statement is to provide clarification to Maryland pharmacists, pharmacies and other licensees dealing with patient prescriptions for Epidiolex on or after December 22, 2021.

As a result of actions under the federal Agriculture Improvement Act (AIA), the drug Epidiolex was descheduled under the federal Uniform Controlled Substances Act (CSA). On August 21, 2020, the U.S. Drug Enforcement Administration (DEA) issued an Interim Final Rule incorporating the AIA into DEA regulations officially removing any federal controlled substance designation from the prescribing and dispensing of the drug, Epidiolex. Following descheduling by Congress, 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. Accordingly, pursuant to the AIA, Epidiolex is not a controlled substance under the CSA and is therefore no longer subject to the CSA and its implementing regulations.

The Maryland Uniform Controlled Substances Act still lists the drug's ingredient as a Schedule V controlled substance (See, MD Code Ann. Crim. Law §5-406(f)) and cannot be updated until the 2022 legislative session, as such this has created a temporary conflict between federal and state law. In order to maintain alignment with the federal government, until the Maryland Legislature can take action to deschedule Epidiolex, MDH will exercise its regulatory discretion.

Effective December 22, 2021, MDH and the Office of Controlled Substance Administration will no longer pursue disciplinary action against licensees or registrants that appropriately receive, process, and dispense Epidiolex prescriptions as a non-controlled drug.