

Statement on the Descheduling of Epidiolex

Updated 4/17/2020

On March 20, 2020, United States Drug Enforcement Administration (DEA) confirmed Epidiolex® has been descheduled and that it is no longer subject to the Federal Controlled Substances Act (CSA).

Additionally, the DEA also confirmed that if the drug's active pharmaceutical ingredient (API) is cannabis-derived material (to include hemp) that contains no more than 0.3% delta-9-THC on a dry weight basis, that material would also not be considered a controlled substance.

Pursuant to section <u>3719.43</u> of the Revised Code, Epidiolex®, as listed in rule <u>4729:9-1-05(C)</u>, is no longer deemed a schedule V controlled substance in the state of Ohio (as of March 20, 2020) and is therefore exempted from all laws and regulations governing controlled substances, including, but not limited to, the following:

- Suspicious order monitoring pursuant to rule <u>4729:6-3-05</u> of the Administrative Code;
- Security and control requirements for controlled substances as required by Board of Pharmacy laws and rules;
- Controlled substance prescription requirements, including the inclusion of an ICD-10 diagnosis code, pursuant to rule <u>4729-5-30</u> of the Administrative Code;
- Reporting of wholesale transactions to OARRS pursuant to section 4729.78 of the Revised Code;
- Reporting patient-specific dispensations or prescriber personally furnishing to OARRS pursuant to sections 4729.77 and 4729.79 of the Revised Code.

The Board intends to update rule 4729:9-1-05(C) in the coming months to reflect this change.

