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California Department of Public Health



GAVIN NEWSOM
Governor

February 14, 2019

AFL 19-06

TO: All Facilities

SUBJECT: Transfer of Epidiolex® (Cannabidiol or CBD) from Schedule I to Schedule V of the Controlled Substances Act

AUTHORITY: Health and Safety Code section 11150.2
Title 21 Code of Federal Regulations section 1308.15

All Facilities Letter (AFL) Summary

- This AFL notifies health facilities that the Drug Enforcement Administration (DEA) has moved the cannabidiol (CBD) drug *Epidiolex*® from federal Schedule I to Schedule V.
- Only drugs approved by the Food and Drug Administration (FDA) that contain CBD derived from cannabis and no more than 0.1 percent residual tetrahydrocannabinols (THC) have been moved to Schedule V.
- *Epidiolex*®, and any subsequent CBD drug that meets the criteria of FDA approval and THC content, may be lawfully prescribed and dispensed under federal and California law.

On September 28, 2018, the Federal Register issued the final rule *Schedules of Controlled Substances: Placement in Schedule V of Certain FDA-Approved Drugs Containing Cannabidiol; Corresponding Change to Permit Requirements*. The final rule places FDA-approved drugs containing CBD with no more than 0.1 percent THC in Schedule V of the Controlled Substances Act.

Epidiolex®, an oral solution that contains CBD extracted from the cannabis plant, is the only drug currently included in Schedule V. The FDA approved *Epidiolex*® on June 25, 2018, for treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, in patients two years of age and older. With the enactment of Assembly Bill 710 (Chapter 62, Statutes of 2018), *Epidiolex*® and any subsequent CBD drug that meets the criteria of FDA approval and THC content, may be lawfully prescribed and dispensed under federal and California law.

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The FDA has not yet approved any other CBD products or products that contain CBD; therefore, the vast majority of cannabis and/or CBD products remain as Schedule I under federal and California law. Drugs containing cannabis/marijuana, or any of its component parts or derivatives, that do not meet criteria of FDA approval and THC content may **not** be prescribed or dispensed.

Health facilities must continue to comply with state and federal law for pharmaceutical services.

If you have questions about this AFL, please contact the L&C Pharmaceutical Consultants Unit at at CHCQRxInbox@cdph.ca.gov.

Sincerely,

Original signed by Heidi W. Steinecker

Heidi W. Steinecker
Deputy Director