

Purpose: To provide guidance to Authorized Providers of DDS services regarding providing assistance to service recipients with cannabis derivative medications or products, in accordance with federal and state regulations.

Scope: DDS Authorized Service Providers who assist with medication administration in the following settings:

- Provider-managed residential settings
 - Neighborhood Group Homes
 - Staffed Apartments
 - Shared Living Homes
- Provider-managed day services settings
 - Day Habilitation
 - Community Participation
 - Prevocational Services
 - Individual Supported Employment (for agency staff who have completed LLAM training)
 - Group Supported Employment (for agency staff who have completed LLAM training)
- Respite settings
 - Waiver-funded Respite provided by a PASA or Home Health Agency
 - State-funded self-directed respite
 - Respite camp

Guidance:

FDA Approved Cannabis Derivative Medications including Epidiolex, Marinol, Syndos and Casemet:

The Agriculture Improvement Act of 2018, Pub. L. 115-334, (also known as the “2018 Farm Bill”) was signed into federal law on Dec. 20, 2018. The 2018 Farm Bill removed the Cannabis sativa L. plant and all derivatives containing less than 0.3% THC from the Controlled Substances Act. This means that cannabis plants and derivative products containing less than 0.3% THC on a dry weight basis are no longer controlled substances under federal law.

The Food and Drug Administration (“FDA”) retains the authority to regulate cannabis and cannabis derived products under the 2018 Farm Bill. The FDA has approved one cannabis-derived medication and three cannabis-related medications for prescription use when prescribed by a licensed healthcare provider. These four medications are currently the only FDA approved cannabis, cannabis derivative, or cannabis related products:

- **Epidiolex:** a purified form of the drug substance CBD used for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age and older.
- **Marinol** and **Syndros:** contain the active ingredient dronabinol, a synthetic delta-9-tetrahydrocannabinol (THC), used for the treatment of anorexia associated with weight loss in AIDS patients and the treatment of severe nausea and vomiting caused by cancer chemotherapy.

- **Cesamet:** contains the active ingredient nabilone, which has a chemical structure similar to THC and is synthetically derived, used for treatment of severe nausea and vomiting caused by cancer chemotherapy.¹

When these medications are prescribed by a licensed healthcare provider, the following staff who work for DDS Authorized Providers are permitted to provide service recipients assistance with med administration:

- Staff certified in Limited Lay Administration of Medication (LLAM) providing Residential Habilitation, Day Habilitation, Pre-vocational Services, Supported Employment. LLAM guidance and procedures must be followed.
- Shared Living Providers or Agency with Choice Self-Directed services providers who have completed the Shared Living Medication Administration (SLMA) annual training program. SLMA guidance and procedures must be followed.
- Personal Assistance Services Agency (PASA) staff who have completed a DHSS approved medication administration training program, may assist a self-directing service recipient with self-administering these medications, or may assist a service recipient under the direction of the responsible caregiver, in accordance with Delaware Code Title 24, Chapter 19, Section 1921.
- Staff providing non-waiver self-directed respite services funded by DDS may assist a self-directing service recipient with self-administering these medications, or may assist a service recipient under the direction of the responsible caregiver.
- Registered Nurses administering medications under a current Delaware nursing license.
- Licensed Practical Nurses administering medications at the direction of a registered nurse or a person licensed to practice medicine, surgery, or dentistry.

Medical Marijuana:

The Delaware Medical Marijuana Act (16 Del.C.Ch.49A) signed into law in 2011, legalized the distribution, possession and use of medical marijuana for patients with a written certification from a physician and an identification card. The Division of Public Health, Office of Medical Marijuana provides oversight, monitoring and enforcement of the Delaware Medical Marijuana Act.²

The use of marijuana for any purpose, including medical, is still prohibited under Federal law. The Controlled Substance Act Schedule (21 U.S.C. §813) lists marijuana as a Schedule 1 substance, which is defined as “drugs

¹ Sources: <https://www.govinfo.gov/app/details/BILLS-115hr2enr/summary>, <https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-questions-and-answers#farmbill>, <https://www.drugs.com/epidiolex.html>, <https://www.drugs.com/marinol.html>, <https://www.drugs.com/mtm/syndros.html>, <https://www.drugs.com/cesamet.html>

² Sources: <https://delcode.delaware.gov/title16/c049a/index.shtml>, <https://www.dhss.delaware.gov/dhss/dph/hsp/medmarhome.html>,

with no currently accepted medical use and a high potential for abuse.”³ Furthermore, Delaware law prohibits the possession or use of medical marijuana “in any health care or treatment facility (emphasis added) operated by the Department or funded contractually through the Department.”⁴

The possession or use of marijuana by service recipients who live in DDDS Authorized Provider-managed settings is prohibited under federal law. Provider-managed residential programs are funded by the Medicaid Lifespan Waiver, which is partially funded with federal funds. In order to continue to receive federal Medicaid funds, Delaware must ensure that waiver services operate in compliance with all Federal laws.

A self-directed “Designated Caregiver”, as defined under the Delaware Medical Marijuana Program, authorized by 16 Del.C.Ch.49A - Delaware’s Medical Marijuana Act, who provides respite or personal care with both state funding or waiver funds may assist a DDDS service recipient who possesses properly authorized medical marijuana to use this substance. Designated Caregivers may also support a service recipient to possess, obtain from an authorized dispensary, and/or dispense medical marijuana.

CBD oil/Cannabidiol:

Cannabidiol, “CBD,” or “CBD oil” products that contain no more than 0.3% THC on a dry weight basis were also legalized under the 2018 Farm Bill. These products are now for sale at a variety of easily accessible venues, such as convenience stores, online, and other retail outlets, and are often marketed as “supplements” or as having a “therapeutic or medical use.” CBD products ARE NOT FDA approved. The FDA has issued warning letters to firms marketing their CBD products as “supplements” or having “therapeutic or medical use” because those labels are reserved only for FDA approved drugs⁵. Because these CBD products are not FDA approved, LLAM certified staff working for DDDS authorized providers cannot assist service recipients with med administration of CBD products⁶.

CBD products prescribed by a medical profession CAN ONLY be administered by a provider staff certified or trained under the following programs:

- Shared Living Medication Administration (SLMA)
- Registered Nurses administering medications under a current Delaware nursing license⁷.
- Licensed Practical Nurses administering medications at the direction of a registered nurse or a person licensed to practice medicine, surgery, or dentistry.

The aforementioned professionals CANNOT administer or assist a DDDS service recipient to administer CBD products if the CBD products were not prescribed by a medical professional.

³ Sources: <https://www.law.cornell.edu/uscode/text/21/813>, <https://www.dea.gov/drug-scheduling>

⁴ Sources: <https://delcode.delaware.gov/title16/c049a/index.shtml>

⁵ Source: <https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-questions-and-answers>

⁶ Source: <http://regulations.delaware.gov/AdminCode/title24/1900.shtml>

⁷ Source: <https://delcode.delaware.gov/title24/c019/>

However, because CBD products containing less than 0.3% THC, are legal under both state and federal law to own and sell, and are readily available for purchase, DDDS does not have the authority or will to prohibit service recipients from purchasing and owning these products. DDDS recommends that service recipient owned CBD products in provider-managed settings be:

- Individually labeled with the owner's name;
- Stored securely and separately away from medications;
- Be self-administered by the owner, or with assistance from a family member or guardian.

CBD products may be used by self-directing service recipients who live in their own homes. Caregivers providing state funded, non-waiver self-directed respite or personal care services may assist a self-directing service recipient with self-administering these products, or may assist a service recipient under the direction of the responsible caregiver.

Effective with the enactment of the "Share the Care Act" on June 13, 2019, Personal Assistance Services Agency (PASA) staff who have completed a DHSS approved medication administration training program, may assist a service recipient to administer CBD products under the direction of the responsible caregiver.⁸

Important Details

The legal use and ownership of cannabis related medical products is a new and not yet fully defined and regulated area. DDDS has done significant research in order to assist service recipients, their families, guardians, friends, and service providers in understanding what is currently legal and allowable under federal and state regulations. As the laws and regulations change, DDDS will endeavor to change this guidance document to reflect current information.

⁸ Source: <https://delcode.delaware.gov/title24/c019/index.shtml>