**MEMORANDUM**

**TO: Interested Parties**

**FR: Gail Grossman, Assistant Commissioner**

 **Office of Quality Management**

**DT: July 30, 2015**

**RE: DDS Guidance: CBD Study Medication Administration and Storage**

The Department of Developmental Services (DDS) has learned that several individuals who receive services from DDS and its vendor programs are participating in a clinical investigation for the treatment of drug resistant epilepsy known as “Cannabidiol as New Treatment for Drug Resistant Epilepsy” (“CBD Study”). In response to questions from programs concerning the storage of and who can administer CBD Study medication in DDS licensed or funded programs, DDS is issuing this limited guidance. DDS expresses no opinion as to the risks, benefits, or efficacy of the CBD Study and cannot answer any questions concerning the CBD Study protocols.

Questions concerning the CBD Study should be directed to[[1]](#footnote-1):

Elizabeth Thiele, MD, PhD, the person in charge of this research study, at (617) 726-6540

Ronald Thiber, DO, MPH at (617) 726-6540

Patricia Bruno, RN, BSN at (617) 724-7551

Jan Paolini, RN, MSN at (617)-726-0238

On nights, weekends, and holidays call (617) 726-2000 and ask to page Dr. Thiele.

**Administration of CBD Study Medication:**

Only authorized licensed medical professionals (registered nurses, licensed practical nurses, or physicians) or an authorized family member may administer CBD Study medication at a DDS licensed or funded program.

**Medication Administration Program (“MAP”) Certified staff are prohibited from and may not administer CBD Study medication.**

**Storage of CBD Study Medication in DDS Licensed Programs:**

CBD Study medication may be stored at a DDS licensed or funded program that holds a Medication Administration Program (“MAP”) Massachusetts Controlled Substances Registration (“MCSR”) using any one of the following three methods:

1. **PREFERRED METHOD FOR STORAGE AT A PROGRAM:** CBD Study medication can be stored in a different location from other medications maintained within a program in a separate, secure, and locked container to which only licensed professional or an authorized family member may have the key or combination. This storage method is preferred as storing CBD Study medication in the same location as other medications would require that a MAP Certified staff person be available in order for the person administering the CBD Study medication to access the medication storage room/locker.
2. CBD Study medication can be stored in the study subject’s room or with their possessions in a separate, secure, and locked container if the provider has determined it is safe to do so.
3. CBD Study medication can be stored in the same location (medication room) as other medications maintained within the program site; however, it must be stored in a separate, secure, and locked container to which only the licensed professional or authorized family member may have the key or combination.

**Please note that if more than one individual within a program is participating in the CBD Study, CBD Study medication for each individual must be stored in separate, secure, locked containers.**

**Only the licensed personnel (RN, LPN, or physician) or authorized family member who will be administering the CBD can have the key or combination to the locked box/container.**

**Alternative to On-site CBD Study Medication Storage**:

As an alternative to storing CBD Study medication on-site at a DDS licensed or funded program, licensed medical professionals, such as Registered Nurses, or authorized members of an individual’s family may bring the CBD Study medication into the program site each time it is to be administered and take it with them when they leave. CBD Study medication should be stored as directed by the CBD Study protocol.

**DDS Documentation Instructions for CBD Study Medication:**

1. MAP Certified staff shall have no role in administering or documenting the administration of CBD Study medication. MAP Certified staff shall not document the presence of a separate, secure, and locked storage box(es) or the CBD Study medication in the program Countable Controlled Substance Book.

1. Program staff should enter that an individual is participating in the CBD Study on the individual's Medication Sheet/Medication Administration Record (MAR) and Emergency Forms and should note that CBD Study medication is being administered by licensed professionals or an authorized family member(s). (Entry of documentation pertaining to CBD Study medication onto MARs should be entered in a manner similar to how insulin HCP orders are entered.)
2. The licensed person or family member who will be administering the CBD Study medication shall have full responsibility for documenting the administration and security of CBD Study medication in accordance with the protocols provided by the CBD Study. Questions pertaining to CBD Study documentation and storage requirements should be directed to Dr. Elizabeth Thiele.

If you have any questions please contact your MAP Coordinator or Sharon Oxx, DDS, Director of Health Services at (6717) 624-7792.

1. Source of CBD Study contact information: Partners HealthCare Systems, Research Consent Form, Cannabidiol as New Treatment for Drug Resistant Epilepsy, IRB Protocol No: 2013P002313. [↑](#footnote-ref-1)