



DEPARTMENT OF HEALTH

Wes Moore, Governor · Aruna Miller, Lt. Governor · Laura Herrera Scott, M.D., M.P.H., Secretary

**Office of Provider Engagement and Regulation (OPER)
Office of Controlled Substances Administration (OCSA)**

1223 West Pratt Street
Baltimore, Maryland 21223
Kimberly Hiner, MPH, Director

OCSA MARYLAND ESTABLISHMENT QUESTIONNAIRE

Establishment Name (dba) _____
Address _____
Telephone _____ Fax. _____
Maryland CDS Registration Number _____ Exp. Date _____
Maryland License or Permit Number _____ Exp. Date _____
DEA Registration Number _____ Exp. Date _____
Hours of Operation M-F _____ Sat. _____ Sun. _____

1. Brief description of the type of work conducted using CDS.

2. List all CDS dispensed/distributed/manufactured AND approximate the quantities of each CDS used per year. *Include strength or concentration of the CDS and container size along with the approximate number units used per year.*

3. Person responsible for accountability of controlled substances at the establishment. *Include job title and/or professional title and/or educational degree.*

4. Name of person(s) who will handle and have access to CDS storage area. *Include job title and/or professional title and/or educational degree.*

5. Exact location in establishment where CDS will be stored. *List the location/name of the building, room number of storage area.*

6. Provide the name, address, phone number, DEA registration number, Maryland CDS registration number and (if applicable) the Maryland Board of Pharmacy distributor permit or pharmacy permit, for ALL suppliers of CDS. *Suppliers of prescription CDS products must have a Maryland Board of Pharmacy distribution permit or pharmacy permit. Suppliers of CDS bulk powders and chemicals do not require a Board permit. You MAY NOT purchase/obtain CDS from a supplier that does not have an active Maryland CDS registration.*

7. Provide the name, address, phone number and DEA number of the reverse distributor used for disposal of outdated/unwanted CDS. (COMAR 10.19.03.10D) *Any alternate disposal procedure must be approved in writing from your local DEA office and kept on file at the establishment.*

8. Procedures employed to ensure secure delivery and receipt of CDS to the establishment.

9. How will CDS be stored? *CDS must be kept either in a lockable safe or under a double lock system (a locked drawer or cabinet within a room with a lockable door). Storage area should be kept locked when not in use and accessible to approved users ONLY.*

10. Describe the method used to document receipt, usage and on-hand counts of CDS.

PLEASE READ AND INITIAL THE FOLLOWING REQUIREMENTS AND RECOMMENDATIONS

- An initial inventory must be taken of all CDS items present prior to the opening of the business. If no CDS products are present, state "No CDS products at opening of business". [21 CFR 1304.11] (initial _____)
- You are required to take a biennial CDS inventory, which is a physical inventory of all controlled substances on hand that is taken at least every two years. The biennial inventory may be taken on any date, which is within two years of the previous biennial or initial inventory. [21 CFR 1304.11] (initial _____)
- When taking a CDS biennial inventory, schedule II items should be listed separately from the schedule III-V items. An exact count must be made of all schedule II items. Schedule III-V items may be estimate, but if fractions or decimals are used, then the container size must also be included. An exact count must be made if CIII-V products are in opened containers of greater than 1,000 tablet or capsules. All CDS, including expired and unwanted items, must be included in the inventory. The entire inventory should be taken on the same day with the same reference point (either before opening of business or after close of business). The date taken and reference point should be present on the inventory. [21 CFR 1304.11] (initial _____)
- Invoices for schedule III-V must be physically dated upon receipt. It is recommended that these invoices be filed separately. [21 CFR 1304.21] (initial _____)
- DEA 222 forms, used to order schedule I-II products, must be signed by the person who signed the most recent application for the establishment's DEA registration. A power-of-attorney may be executed by the person authorized to sign the DEA 222 form, to allow others to sign the DEA 222 form. The power-of-attorney must be kept on file at the registered site. [21 CFR 1305.05] (initial _____)
- When schedule I-II orders are received, the quantity and date received must be recorded for each line item on DEA Form 222. [21 CFR 1305.13(e)] (initial _____)
- Executed DEA 222 Forms must be maintained separately from other records and kept readily available for 2 years. [21 CFR 1305.17] (initial _____)
- The theft or significant loss of CDS must be reported immediately upon discovery, within one business day, in writing, to the local DEA office and the Office of Controlled Substances Administration (OCSA). A DEA Form 106 must be completed for any theft or significant unresolved loss of CDS, with the original sent to DEA and a copy sent to OCSA. The DEA 106 Form may be filed electronically to the DEA, but a copy must be printed and sent to OCSA. [COMAR 10.19.03.12B(4)] (initial _____)

NOTE: Please ensure that all questions have been answered completely. Incomplete answers and missing information will result in a delay in the processing of your CDS application.

Signature of Applicant _____ Date _____

Print Name of Applicant _____

Office of Controlled Substances Administration • 1223 W. Pratt Street • Baltimore, Maryland 21223
410-764-2890 • Fax 410-358-1793 • TTY for Disabled - Maryland Relay Service 1-800-735-2258
Toll Free 1-877-4MD-DHMH • Web Site: www.health.maryland.gov/OCSA