



STATE OF MARYLAND

DHMH

Maryland Department of Health and Mental Hygiene

Larry Hogan, Governor - Boyd Rutherford, Lt. Governor - Van Mitchell, Secretary

Howard M. Haft, M.D., Deputy Secretary, Public Health Services

DDC ANNOUNCES NEW CDS REGISTRATION DETAILS!

Effective the beginning of calendar year 2016, the Division of Drug Control (DDC) is pleased to announce that, as a part of the Governor's Statewide Fee Rollback and DHMH's improved customer services platform, DDC is implementing a plan to expand its renewal period from two years to three years, while maintaining the Controlled Dangerous Substances (CDS) Registration/Certification fee at \$120. This means you pay \$120 for a three-year renewal or new CDS Registration.

•In order to implement this cost-cutting plan, over the next two-years, renewing registrants will be staggered into the new 3-year renewal periods. Some registrants will continue to be issued 2-year registrations, while others will be concurrently converted to 3-year. New applicants will automatically be registered for the 3-year renewal periods. The staggered process for renewals is expected to be completed by the end of the Calendar Year 2017. Beginning Calendar Year 2018 ALL registrants will be issued CDS registrations with a 3 year renewal period.

•The DDC renewal notice and application mailed to you will identify your registration period as a 2-year or 3-year renewal period. The designated renewal periods are programmed and randomly assigned through the DDC database. The fee for two-year registrations is \$80 and the fee for three-year registrations is \$120. The 3-year registration will decrease the number of registrations DDC processes for each year and ultimately, will allow DDC to more proficiently issue registrations.

•DDC has also revised its applications, with instructions. ***Please review the instructions posted on this web site prior to submitting the CDS application and payment to DDC for registration. Note that there are two separate updated applications posted - one for practitioner and one for establishment. The new three-year applications are also posted on this web site. Be sure to include payment of \$120 for applications downloaded and submitted from this DDC web site. Only three-year application forms are posted and acceptable for submission to DDC.*** (Bear with us as we continue to perfect our application forms.)

•**DDC anticipates implementing its CDS On-Line Application, Payment and Collection System by June 30, 2016. The On-Line System will accept both 2-year and 3-year renewal applications until all registrants have been converted to 3-year renewals.** DDC looks forward to getting the new program off to a good start and we very much appreciate your cooperation as we proceed with our new initiatives. If you have any questions or concerns, please do not hesitate to contact our **Customer Services Lines at: 410-764-7980, 410-764-5910 or 410-764-4159.**

It is a pleasure to do business with you and we will continue to serve you to the best of our capability, with the hopes of getting higher marks from you for customer services. A copy of DDC's COMAR regulations (Chapter 03 Controlled Dangerous Substances .03 Registration; Registration Certificate) follows this notice for your information and review. Thank you for being a CDS Registrant!

Respectfully, the Division of Drug Control

ATTACHMENT: COMAR 10.19.03 Registration; Registration Certificate

10.19.03.00

Title 10 DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 19 DANGEROUS DEVICES AND SUBSTANCES

Chapter 03 Controlled Dangerous Substances

Authority: Criminal Law Article, Title 5; Health-General Article, §21-220; Annotated Code of Maryland

10.19.03.03

.03 Registration; Registration Certificate.

A. Requirement. A person shall register with the Department and obtain and maintain a registration certificate before the person:

- (1) Manufactures, distributes, or dispenses controlled dangerous substances;
- (2) Conducts research or instructional activities with controlled dangerous substances listed in Schedules II through V of Criminal Law Article, §§5-403—5-406, Annotated Code of Maryland;
- (3) Conducts research or instructional activities with a controlled dangerous substance listed in Schedule I of Criminal Law Article, §5-402, Annotated Code of Maryland; or
- (4) Conducts a chemical analysis with controlled dangerous substances listed in any schedule.

B. Application.

- (1) A person required to obtain and maintain a registration certificate as set forth under this chapter shall:
 - (a) Obtain, complete, and submit an application for a registration certificate on a form provided by the Department; and
 - (b) Pay the appropriate fee as set in §C of this regulation, unless the applicant is eligible for a fee exemption.
- (2) The application and any accompanying document or statement required for registration by the Secretary shall be signed by the:
 - (a) Applicant, if an individual;
 - (b) General partner, if the applicant is a partnership; or
 - (c) Officer responsible for the applicant, if the applicant is a corporation or other entity.
- (3) If the information requested on the application is not applicable to the applicant, the applicant shall indicate this on the form.
- (4) The Secretary may require additional documentation pertinent to the registration to:
 - (a) Clarify application information; or
 - (b) Determine if the applicant meets the requirements of this chapter.
- (5) A person shall submit an application and fee for each separate place of business, professional practice, or location for which registration is required.
- (6) The registration certificate shall be readily available to any agent or representative of the Secretary within the registered location.

C. Fees.

- (1) A person required to obtain and maintain a registration certificate as set forth under this chapter shall pay the appropriate fees as set in this regulation. Fees include the following:
 - (a) Registration every 3 years — \$120;
 - (b) Amend an unexpired registration certificate — \$50; and
 - (c) Replace a lost registration certificate — \$30.
- (2) Persons Exempt from Fee.

(a) The following persons are exempt from payment of a fee for registration or renewal of registration:

- (i) A hospital, clinic, institution, facility, or unit operated by the State or by the United States;
- (ii) An agency, excluding State employees, for which the State is responsible for payment of the fee, provided that the exemption is approved by the Secretary; and
- (iii) A person included in 21 CFR §§1301.21—1301.24.

(b) A person exempt from payment of a registration fee is required to obtain and maintain a registration certificate.

(3) Payment of Prorated Fees.

(a) A registrant applying for a registration certificate shall pay a prorated registration fee when a registration certificate is issued for less than 36 months.

(b) The prorated fee shall be based on the total number of full plus partial months for which the registration certificate is issued.

(4) Refunds and Credits. The Secretary may not issue a refund or credit or return any registration fees to a registrant, including if a registrant:

- (a) Withdraws a registration application; or
- (b) Voluntarily or involuntarily ceases to manufacture, distribute, or dispense a controlled dangerous substance before a registration certificate expires.

(5) Failure to Pay Fees. The Secretary may not issue a new or a renewed registration certificate until all required fees are paid.

D. Issuance. The Secretary may issue a registration certificate that:

- (1) Is valid for not more than 3 years; and
- (2) Shall be renewed before its expiration date if the registrant intends to operate as described in §A of this regulation.

E. Expiration and Renewal.

- (1) A registration certificate expires on the date shown on the certificate.
- (2) The Secretary shall mail a renewal application or a notice to renew to a registrant not less than 30 days before the expiration date shown on the certificate.

F. Assignment, Transfer, or Termination.

- (1) A registration certificate is not transferable.
- (2) A registration certificate becomes void when the registrant:
 - (a) Dies;
 - (b) Discontinues business or professional practice in the State; or
 - (c) Changes ownership, including when:
 - (i) Partners are added or deleted from the partnership;
 - (ii) There is a change in the president or chief executive officer of the corporation; or
 - (iii) There is a change in the ownership of 10 percent or more of the outstanding shares in the corporation.
- (3) A registrant who discontinues business or professional practice in the State shall:

- (a) Notify the Secretary in writing;
 - (b) Surrender the registrant's current registration certificate; and
 - (c) Legally transfer or dispose of any controlled dangerous substances relative to the registrant's operation.
- (4) Change of Ownership.

(a) A registrant who changes ownership of the business or professional practice as stated in §C(2)(c) of this regulation, shall:

- (i) Notify the Secretary in writing;
- (ii) Submit a registration application to change the current registration and a \$144 3-year registration fee at least 30 days before the change in the ownership of the registrant's business or professional practice occurs; and
- (iii) Surrender the registrant's current registration certificate after the ownership change is finalized.

(b) After a change in ownership, the Secretary may inspect the business or professional practice of the new owners as provided in §G of this regulation.

(5) Change of Location. A registrant shall submit an application to amend a current registration certificate along with a \$50 fee at least 30 days before there is a change in the location of the registrant's place of business or professional practice from the location which is stated on the registration certificate to a new location within the State.

G. Inspection. After an application for registration has been filed, the Secretary may:

- (1) Inspect the place of business or professional practice described in the application; and
- (2) Investigate the applicant to determine whether the applicant meets the requirements of this chapter.

10.19.03.9999

Administrative History

Effective date: January 19, 1977 (4:2 Md. R. 87)

Regulation .03A amended effective December 17, 1984 (11:25 Md. R. 2134); February 17, 1992 (19:3 Md. R. 304); December 24, 2001 (28:25 Md. R. 2190)

Regulation .07E and J amended effective August 17, 1992 (19:16 Md. R. 1474)

Regulation .07H amended effective July 12, 1998 (25:14 Md. R. 1132)

Regulations .07N, R and .10B amended effective February 10, 1978 (5:3 Md. R. 138)

Regulation .08G amended effective March 30, 1992 (19:6 Md. R. 673)

Regulation .09A amended effective April 18, 1980 (7:8 Md. R. 771)

Chapter revised effective April 26, 2004 (31:8 Md. R. 646)

Regulation .03 repealed and new Regulation .03 adopted effective April 24, 2006 (33:8 Md. R. 732)

Regulation .03 amended effective January 1, 2016 (42:22 Md. R. 1377)

Regulation .13 adopted as an emergency provision effective October 18, 2011 (38:24 Md. R. 1495); adopted permanently effective December 26, 2011 (38:26 Md. R. 1697)