Clinic Application for Registration
(Form DHHS 224-D)

NC Department of Health and Human Services

Division of Mental Health, Developmental Disabilities, and Substance Abuse Services – Drug Control Unit

3008 Mail Center Service Center

Raleigh, North Carolina 27699-3008

(919) 733-1765

Application Instructions – PLEASE READ THESE INSTRUCTIONS CAREFULLY

*This application will be used by the North Carolina Department of Health and Human Services' Drug Control Unit to initiate a registration renewal under the North Carolina Controlled Substances Act of 1971 as well as assist in determining whether or not the registrant is in compliance with State and Federal laws pertaining to controlled substances. Therefore, please fill out this application in its entirety. Do not leave any fields blank, rather indicate that a field is not applicable by typing "N/A" in the space provided. Failure to complete the entire form will result in the application being returned to the registrant along with a request for additional information. To submit this Application for Reregistration, e-mail both the completed electronic PDF and a signed PDF copy to nccsareg@dhhs.nc.gov along with a signed PDF copy of a Registrant Disclosure of Loss, Diversion, or Destruction of Controlled Substances (Addendum to Forms DHHS 226 and 227). In accordance with 10A NCAC 26E.0104, the registrant must also submit a required, **nonrefundable** application fee in the amount of $125.00.*

Attestation

By signing below, you attest that you are an administrator or an agent of the registrant who is authorized to answer the questions presented in this document. Furthermore, you attest that all of the information provided on this form is true, accurate, and complete to the best of your knowledge. All responses are subject to verification by the North Carolina Department of Health and Human Services' Drug Control Unit.

		Date	
Signature		**Phone Number**	
Name and Title		**E-Mail Address**	

Section A - Registrant Information

Facility Name			
Facility's Address		**Facility's County**	
Facility's State, City, Zip			
Mailing Address		**Facility's Phone Number**	
Mailing State, City, Zip			
Administrator	Name:	Title:	

Section B - Registration Classification

B1. Check all applicable drug schedules in which you are applying for:

☐ Schedule II (Narcotic) ☐ Schedule III (Narcotic) ☐ Schedule IV

☐ Schedule IIN (Non-narcotic) ☐ Schedule IIIN (Non-narcotic) ☐ Schedule V

B2. Are you currently authorized to manufacture, distribute, dispense, prescribe, conduct research, or otherwise handle controlled substances in the schedules for which you are applying under the laws of North Carolina or the Federal Government?	☐ Yes	☐ No
B3. Has the registrant been convicted of a felony under State or Federal law relating to the manufacture, possession, distribution, or dispensing of controlled substances?	☐ Yes	☐ No
B4. Has any previous registration held by the registrant, corporation, firm, partner, or officer of registrant under Federal CSA or NCCSA been surrendered, revoked, suspended, denied, or is it pending such action?	☐ Yes	☐ No

If you answered "Yes" to questions B3 and/or B4, please submit a letter along with this application setting forth the circumstances of such action.

Section C - Point of Contact

A Drug Control Inspector will conduct an unannounced inspection of the applicant's facility at some point during the registration period. Please provide a list of up to three individuals for whom the Inspector should ask for upon arrival at the facility. The names and titles provided should be listed in the desired order of contact and should include individuals who are knowledgeable of and possess some degree of responsibility for the disposition of controlled substances at the facility. Any phone numbers provided for points of contact in Section C should be a direct line in order to assist the Drug Control Unit with reaching the correct individual(s) if needed – the central phone number provided in Section A will serve as a backup. Please note that the Inspector may also interview other persons other than those listed below at his/her discretion.

Primary Contact	Name:	Title:
	E-mail:	Phone:
Secondary Contact	Name:	Title:
	E-mail:	Phone:
Tertiary Contact	Name:	Title:
	E-mail:	Phone:

Section D - State Registration History

D1. Please select the event below that best describes your reason for submitting an Application for Registration (Form DHHS 224) and provide an answer to each supporting question for that event *(choose only one answer from below)*

☑ The application is for a new clinic / first time registrant

Anticipated Opening Date:

☑ The application reflects a name change for a registrant

Name on Previous Registration:

Previous DHHS Registration No:

☑ The application reflects a change of location/address for a registrant

Name on Previous Registration:

Previous Address (Line 1):

Previous Address (Line 2):

Previous City:

Previous DHHS Registration No:

☑ The application reflects a change in ownership

Name on Previous Registration:

Previous DHHS Registration No:

Was Business Sold or Merged:

Percentage of Ownership Sold:

Corporate or Branch Level Sold:

Section E - Drug Enforcement Administration (DEA) Registration

E1. Does the applicant currently possess any controlled substances? ☐ Yes ☐ No

E2. What is the current status of the applicant's DEA Registration? *(choose only one answer from below and provide the requested information)*

☐ Valid Registration in possession — Name on Registration: — DEA Number:

☐ Applied for Registration — Applicant's Name: — Date Applied:

☐ DEA Registration will be applied for pending approval of NC DHHS Registration

☐ Other *(explain)*:

E3. Who is responsible for controlled substances? *(this is the individual who signed DEA Form 224):*

E4. Has the applicant granted Power of Attorney to any individuals for ordering controlled substances? ☐ Yes ☐ No

If yes, please provide the name(s) of the individual(s):

E5. Is each physician registered with the DEA? ☐ Yes ☐ No

If no, how do non-registered physicians prescribe controlled substances?:

E6. Does the applicant currently possess any controlled substance samples? ☐ Yes ☐ No

If yes, how were they obtained?:

Section F - Primary Supplier of Controlled Substances

Supplier Name			
Address		**City**	
State		**Zip Code**	
Sales Rep's Name		**Phone Number**	

Section G - Secondary Supplier of Controlled Substances

Supplier Name			
Address		**City**	
State		**Zip Code**	
Sales Rep's Name		**Phone Number**	

Section H - Storage and Security

H1. How many total storage locations are utilized for the storage of controlled substances at the facility? Describe the type of storage equipment for each location (i.e. wall cabinet, combination safe, keyed safe, etc.).

H2. How is access to the controlled substance inventory location(s) controlled? List the persons and/or titles and number of individuals with access, describe how key control is practiced, and provide any other information deemed pertinent to assuring the security of controlled substances at the facility.

H3. Does the clinic use prescription pads or are prescriptions issued electronically? If prescription pads are still used, where are they stored?

H4. How are unexecuted controlled substance order forms stored?

H5. Does the facility take possession of patients' personal controlled substances? If so, describe how patients' personal controlled substances are stored and the records that are maintained for them.

Section I - Records

I1. Biennial Inventory Date

I2. Describe the procedure for purchasing and receiving Schedule II controlled substances. How are DEA Form-222s, invoices, and any other documents acknowledging the purchase and receipt of Schedule II controlled substances recorded and maintained? *If the applicant is not registered for Schedule II, please write/type "N/A" for this question.*

I3. Describe the procedure for purchasing and receiving Schedule III, IV, and V controlled substances. How are pharmacy provider requisition forms, invoices, and any other documents acknowledging the purchase and receipt of Schedule III, IV, and V controlled substances recorded and maintained? *If the applicant is not registered for Schedule III, IV, and V, please write/type "N/A" for this question.*

I4. Describe the procedure for dispensing controlled substances. Describe the packaging used to dispense controlled substances. What type of records are maintained to document the dispensation (i.e. sign out logs, automated dispensing technology reports, etc.)?

I5. Describe the records that are maintained for the administration of controlled substances (i.e. patient chart, MAR, eMAR, etc.).

Section J - Effective Controls for the Prevention of Diversion

J1. Other than physical security measures that have already been discussed in previous sections of this document, what steps is the applicant taking to maintain effective controls for the prevention of diversion of controlled substances? Answers should include, but are not limited to, software reporting systems being utilized to monitor user and drug activity as well as the frequency and individuals involved in the review of such material.