



Researcher Application for Renewal (Form DHHS 227-C)

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.

Signature	Date	
	Phone Number	
Name and Title	E-Mail Address	

Section A - Registrant Information

Registrant Name	NC DHHS Registration #
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 I
 Schedule III (Narcotic)
 Schedule V
 Schedule II (Narcotic)
 Schedule IIIN (Non-narcotic)
 Schedule VI (NC General Statutes §90-94)
 Schedule IIN (Non-narcotic)
 Schedule IV

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?	<input type="checkbox"/> Yes	<input type="checkbox"/> 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?	<input type="checkbox"/> Yes	<input type="checkbox"/> 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?	<input type="checkbox"/> Yes	<input type="checkbox"/> 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 may conduct an unannounced inspection of the registrant'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 - Research Protocol

D1. Is a copy of the research protocol(s) on hand and readily available? Yes No

D2. List the identification numbers of all research protocols in which the registrant will be using controlled substances for.

D3. List controlled substances with DEA drug code numbers that are used in research. Are these substances listed in the protocol(s) noted above?

Section E - State Registration History

E1. Date in which the registrant's most recent NC DHHS Registration was issued? (refer to Registration for this date)

E2. Please select from the list below any and all events that the registrant has experienced since the date provided in response to Question E1?

- The registrant has changed the name in which it conducts business under
- The registrant has moved to a new physical address or location
- The registrant has sold greater than 50% of its ownership at a level lower than the parent corporation level
- None of the above events apply. The registrant has not changed its name, moved, nor changed ownership

****IMPORTANT NOTE – IF YOU CHECKED ANY BOXES ABOVE OTHER THAN “NONE OF THE ABOVE...”, YOU ARE NOT ELIGIBLE FOR REREGISTRATION. RATHER, APPLY FOR A NEW REGISTRATION USING FORM DHHS 225 AND COMPLETE THE ACCOMPANYING QUESTIONNAIRE (FORM DHHS 225-C)****

Section F - Drug Enforcement Administration (DEA) Registration

F1. Does the registrant currently possess any controlled substances?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
F2. What is the current status of the registrant's DEA Registration? <i>(choose only one answer from below and provide the requested information)</i>		
<input type="checkbox"/> Valid Registration in possession	Name on Registration:	DEA Number:
<input type="checkbox"/> Applied for Registration	Applicant's Name:	Date Applied:
<input type="checkbox"/> DEA Registration will be applied for pending approval of NC DHHS Registration		
<input type="checkbox"/> Other <i>(explain)</i> :		
F3. Who is responsible for controlled substances? <i>(this is the individual who signed DEA Form 224):</i>		
F4. Has the registrant granted Power of Attorney to any individuals for ordering controlled substances?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
If yes, please provide the name(s) of the individual(s):		

Section G - Primary Supplier of Controlled Substances

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

Section H - Secondary Supplier of Controlled Substances

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

Section I - Storage and Security

I1. How many total storage locations are utilized for the storage of controlled substances? Provide the physical address of the location(s) in which the controlled substances are stored and describe the type of storage equipment for each location (i.e. wall cabinet, combination safe, keyed safe, etc.).

I2. Who has access to the controlled substance inventory location(s)? 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.

3. How are unexecuted controlled substance order forms stored?

Section J - Records

J1. Biennial Inventory Date

J2. Describe the procedure for purchasing and receiving Schedule I, Schedule II, and Schedule VI controlled substances. How are DEA Form-222s, invoices, and any other documents acknowledging the purchase and receipt of Schedule I and Schedule II controlled substances recorded and maintained? Schedule VI refers to North Carolina's controlled substances schedule. If the registrant is not applying for Schedule I, Schedule II, and/or Schedule VI, please write/type "N/A" for this question.

J3. 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 registrant is not applying for Schedule III, IV, and/or V, please write/type "N/A" for this question.

J4. Describe the procedure for dispensing controlled substances. What type of records are maintained to document the dispensation (i.e. sign out logs, automated dispensing technology reports, etc.)?

J5. Describe the records that are maintained for the administration of controlled substances (i.e. patient chart, MAR, eMAR, etc.).

Section K - Effective Controls for the Prevention of Diversion

K1. Other than physical security measures that have already been discussed in previous sections of this document, what steps is the registrant 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.

Section L - Supplemental Materials

The following documents are required as part of your Application for Reregistration:

1. *Copy of all research protocols in which controlled substances are used if different from previous year.*
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