Nursing Home Application for Renewal (Form DHHS 226-B)

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 $100.00.*

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		**NC DHHS Registration #**	
Facility's Address		**Facility's County**	
Facility's State, City, Zip		**Facility's Phone Number**	
Mailing Address		**Number of Beds**	
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 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: E-mail:	Title: Phone:
Secondary Contact	Name: E-mail:	Title: Phone:
Tertiary Contact	Name: E-mail:	Title: Phone:

Section D - State Registration History

D1. Date in which the registrant's most recent NC DHHS Registration was issued? *(refer to Registration for this date)*

D2. Please select from the list below any and all events that the registrant has experienced since the date provided in response to Question D1?

- ☐ 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 224 AND COMPLETE THE ACCOMPANYING QUESTIONNAIRE (FORM DHHS 224-B)****

Section E - Pharmacy Supplier

E1. Does the registrant own its own pharmacy at the registering location? *(if no, please provide the pharmacy supplier's information below; if yes, please fill in spaces below with "N/A")* ☐ Yes ☐ No

Pharmacy Name			
Address		**Zip Code**	
City		**Phone Number**	

Section F - Pharmacist Consultant

Consultant Name			
Address		**Phone Number**	
City		**Zip Code**	
Hours at Facility per Month			

Section G - Drug Enforcement Administration (DEA) Registration for Controlled Substances Emergency Kit

G1. Does the registrant maintain a controlled substance inventory at the facility that is separate from patient specific orders dispensed by the pharmacy; also known as a controlled substances emergency kit? *(if no, answer this question then skip the rest of the questions in Section G and proceed to Section H)*	☐ Yes	☐ No
G2. Who is the legal owner of the controlled substance inventory described in Question G1? *(if the answer to this question is the pharmacy supplier from Section E (Rx Supplier), please answer all remaining questions in Section G EXCEPT for Questions G4 through G6 – please answer "N/A" for Questions G4 through G6)*	☐ Nursing Home	☐ Rx Supplier

G3. What is the current status of the DEA Registration of the legal owner identified in Question G2 for the controlled substance inventory described in Question G1? *(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)*:		

G4. Biennial Inventory Date:

G5. Who is responsible for controlled substances? *(this is the individual who signed DEA Form 224):*

G6. Has the registrant granted Power of Attorney to any individuals for ordering controlled substances?	☐ Yes	☐ No or N/A
If yes, please provide the name(s) of the individual(s):		
G7. Does the kit contain no more than seven controlled substance entities?	☐ Yes	☐ No
List each item in the emergency kit:		
G8. Does the kit contain five doses or less of each controlled substance entity per 50 licensed beds?	☐ Yes	☐ No
If no, how many doses of each controlled substance entity are present per 50 licensed beds?		
G9. Is each controlled substance in single unit dose form?	☐ Yes	☐ No
G10. Are controlled substances only used for bona fide medical emergencies and its necessity of use is documented in patient's medical record as such?	☐ Yes	☐ No

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, automated dispensing cabinet, etc.). Be sure to differentiate between the controlled substance emergency kit location described in Section G and all other controlled substance inventory locations.

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. Be sure to differentiate between the controlled substance emergency kit location described in Section G and all other controlled substance inventory locations.

H3. 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. Describe the procedure for purchasing and receiving Schedule II controlled substances for the purposes of an emergency kit. How are DEA Form-222s, invoices, and any other documents acknowledging the purchase and receipt of Schedule II controlled substances recorded and maintained?

I2. Describe the procedure for receiving Schedule II controlled substances that are patient specific blister cards. How are packing slips or any other documents acknowledging the receipt of Schedule II controlled substances recorded and maintained?

I3. Describe the procedure for purchasing and receiving Schedule III, IV, and V controlled substances for the purposes of an emergency kit. 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?

I4. Describe the procedure for receiving Schedule III, IV, and V controlled substances that are patient specific blister cards. How are packing slips or any other documents acknowledging the receipt of Schedule II controlled substances recorded and maintained?

I5. Describe the procedure for the 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.)?

I6. Describe the procedure for administering controlled substances. What type of records are maintained to document the administration (i.e. patient chart, MAR, eMAR, etc.)?

I7. Describe the procedure for the returning unused and/or outdated controlled substances to the pharmacy supplier. What records are maintained that attest to the return of controlled substances?

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 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.