



Hospital Application for Registration (Form DHHS 224-A)

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 for the applicant under the North Carolina Controlled Substances Act of 1971 as well as assist in determining whether or not the applicant 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 applicant along with a request for additional information. To submit this Application for Registration, e-mail both the completed electronic PDF and a signed PDF copy to nccsareg@dhhs.nc.gov along with a signed PDF copy of an Applicant Disclosure of Loss, Diversion, or Destruction of Controlled Substances (Addendum to Forms DHHS 224 and 225). In accordance with 10A NCAC 26E.0104, the applicant must also submit a required, **nonrefundable** application fee in the amount of \$300.00. For payment submission questions, please contact the Drug Control Unit.

Attestation

By signing below, you attest that you are an administrator or an agent of the applicant 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 - Applicant Information

Facility Name			
Facility’s Address			Facility’s County
Facility’s State, City, Zip			Facility’s Phone Number
Mailing Address			Number of Beds
Mailing State, City, Zip			Board of Pharmacy No.
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?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
B3. Has the applicant 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 applicant, corporation, firm, partner, or officer of applicant 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 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)

<input type="checkbox"/> The application is for a new hospital / first time registrant Anticipated Opening Date: _____	<input type="checkbox"/> The application reflects a name change for a registrant Name on Previous Registration: _____ Previous DHHS Registration No: _____
<input type="checkbox"/> 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: _____	<input type="checkbox"/> 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?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
E2. What is the current status of the applicant's DEA Registration? (choose only one answer from below and provide the requested information)		
<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 (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?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
If yes, please provide the name(s) of the individual(s): _____		
E5. Is each physician registered with the DEA?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
If no, how do non-registered physicians prescribe controlled substances?: _____		
E6. Does the applicant currently possess any controlled substance samples?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
If yes, how were they obtained?: _____		

Section F - Controlled Substances Wholesaler

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

Section G - Additional Supplier of Controlled Substances

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

Section H - Additional Supplier of Controlled Substances

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

Section I - Additional Supplier of Controlled Substances

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

Section J - Pharmacy Staffing

Number of Full-Time Pharmacists	
Number of Part-Time Pharmacists	
Number of Pharmacy Technicians	
Other Pharmacy Staff Titles and Numbers	
Pharmacy Hours (M-F)	
Pharmacy Hours (SAT)	
Pharmacy Hours (SUN)	

Section K - Pharmacy Storage and Security

K1. How is access to the central inpatient pharmacy area gained (i.e. badge reader, keys, etc.)? List the persons and/or titles and number of individuals with access and describe how key control is practiced if keys are used. Who has permission and access to the pharmacy after hours for the retrieval of controlled substances?

K2. Describe the storage and security of Schedule II controlled substances in the central inpatient pharmacy, including the type of storage equipment (i.e. wall cabinet, combination safe, keyed safe, automated dispensing cabinet, etc.) and the names or titles and number of persons with access.

K3. Describe the storage and security of Schedule III, IV, and V controlled substances in the central inpatient pharmacy, including the type of storage equipment (i.e. wall cabinet, combination safe, keyed safe, automated dispensing cabinet, etc.) and the names or titles and number of persons with access.

K4. How is access to the controlled substance inventory location of the central inpatient pharmacy controlled? List the persons or titles of individuals with access, describe how key control is practiced, and provide any other information deemed pertinent to assuring the security of controlled substances in the pharmacy.

K5. Does the hospital use prescription pads or are prescriptions issued electronically? If prescription pads are still used, where are they stored?

K6. How are unexecuted controlled substance order forms stored?

K7. Does the facility take possession of patients' personal controlled substances when they are admitted? If so, describe how patients' personal controlled substances are stored and the records that are maintained for them.

K8. Does the hospital have an OR satellite pharmacy that maintains a controlled substance inventory location? If yes, please describe any variances for this location from the answers provided in questions K1 through K4 that pertained to the central inpatient pharmacy.

K9. Does the hospital have a pediatric satellite pharmacy that maintains a controlled substance inventory location? If yes, please describe any variances for this location from the answers provided in questions K1 through K4 that pertained to the central inpatient pharmacy.

K10. Are there any other satellite pharmacy locations that maintains a controlled substance inventory other than what has already been covered in questions K1 through K9? If yes, please describe any variances for these locations from the answers provided in questions K1 through K4 that pertained to the central inpatient pharmacy.

Section L - Records

L1. Biennial Inventory Date

L2. 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?

L3. 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?

L4. Describe the procedure for dispensing controlled substances from the pharmacy. What type of records are maintained to document the dispensation (i.e. sign out logs, automated dispensing technology reports, etc.)?

L5. Describe the records that are maintained at the hospital for the administration of controlled substances (i.e. patient chart, MAR, eMAR, etc.).

Section M - Hospital Affiliated Clinics

M1. Does the hospital supply controlled substances to any onsite clinics? If yes, how many? Are there any onsite clinics that have a different Federal Taxpayer Identification number than the hospital? If yes, please provide the name of each clinic. *For the purposes of this question, the term "onsite" means that the clinic is located within the walls of the hospital (same address).*

M2. Describe the procedure for dispensing and/or selling controlled substances to onsite clinics. What type of records are maintained to document the dispensation/sale? *For the purposes of this question, the term "onsite" means that the clinic is located within the walls of the hospital (same address).*

M3. Does the hospital supply controlled substances to any offsite clinics? If yes, how many? Please provide the name and address for each offsite clinic that routinely acquires controlled substances from the hospital. If there is not enough room in the space below to list each clinic's name and address, please write "see attached" and submit the supplemental document with this application. *For the purposes of this question, the term "offsite" means that the clinic is located at a different physical address. This includes clinics that are located on the same campus as the hospital, but are located in a different building.*

M4. Describe the procedure for dispensing and/or selling controlled substances to offsite clinics. What type of records are maintained to document the dispensation/sale? *For the purposes of this question, the term "offsite" means that the clinic is located at a different physical address. This includes clinics that are located on the same campus as the hospital, but are located in a different building.*

M5. Does the hospital permit clinics to return controlled substances to the hospital? If so, under what circumstances? What does the hospital do with returned controlled substances?

Section N - Hospital Affiliated Researchers

N1. Does the hospital supply controlled substances to any researchers? If yes, how many? Please provide the name and address for each researcher that routinely acquires controlled substances from the hospital. If there is not enough room in the space below to list each clinic's name and address, please write "see attached" and submit the supplemental document with this application.

N2. Describe the procedure for dispensing and/or selling controlled substances to researchers. What type of records are maintained to document the dispensation/sale?

N3. Does the hospital permit researchers to return controlled substances to the hospital? If so, under what circumstances? What does the hospital do with returned controlled substances?

Section O - Emergency Room

O1. Please select the most appropriate answer from the list below:

- The hospital does not have an Emergency Room *(if so, please answer "N/A" for Questions O2 through O6)*
- The hospital has an Emergency Room but the unit does not maintain a controlled substance inventory *(if so, please provide a detailed response for Questions O4 through O6 and answer "N/A" for Questions O2 and O3)*
- The hospital has an Emergency Room and controlled substances are stored in the unit *(if so, please answer all questions below)*

O2. How many storage locations are utilized for the storage of controlled substances in the Emergency Room? Describe the type of storage equipment for each location (i.e. wall cabinet, combination safe, keyed safe, automated dispensing cabinet, etc.).

O3. How is access to the controlled substances inventory location(s) in the Emergency Room controlled? How many individuals have access to controlled substances in the unit? Describe how key control is practiced and provide any other information deemed pertinent to ensuring the security of controlled substances in the Emergency Room.

O4. Describe the procedure for dispensing controlled substances from the Emergency Room. What type of records are maintained to document the dispensation (i.e. sign out logs, automated dispensing technology reports, etc.)?

O5. Describe the procedure for administering controlled substances in the Emergency Room and the records that are maintained that document the administration (i.e. patient chart, MAR, eMAR, etc.).

O6. Describe the procedure for wasting controlled substances in the Emergency Room and the records that are maintained that document the waste.

Section P - Operating Room

P1. Please select the most appropriate answer from the list below:

- The hospital does not have an Operating Room (*if so, please answer "N/A" for Questions P2 through P6*)
- The hospital has an Operating Room but the unit does not maintain a controlled substance inventory (*if so, please provide a detailed response for Questions P4 through P6 and answer "N/A" for Questions P2 and P3*)
- The hospital has an Operating Room and controlled substances are stored in the unit (*if so, please answer all questions below*)

P2. How many storage locations are utilized for the storage of controlled substances in the Operating Room? Describe the type of storage equipment for each location (i.e. wall cabinet, combination safe, keyed safe, automated dispensing cabinet, etc.).

P3. How is access to the controlled substances inventory location(s) in the Operating Room controlled? How many individuals have access to controlled substances in the unit? Describe how key control is practiced and provide any other information deemed pertinent to ensuring the security of controlled substances in the Operating Room.

P4. Describe the procedure for dispensing controlled substances from the Operating Room. What type of records are maintained to document the dispensation (i.e. sign out logs, automated dispensing technology reports, etc.)?

P5. Describe the procedure for administering controlled substances in the Operating Room and the records that are maintained that document the administration (i.e. patient chart, MAR, eMAR, etc.).

P6. Describe the procedure for wasting controlled substances in the Operating Room and the records that are maintained that document the waste.

Section Q - Anesthesiology Department

Q1. Please select the most appropriate answer from the list below:

- The hospital does not have an Anesthesiology Department (*if so, please answer "N/A" for Questions Q2 through Q6*)
- The hospital has an Anesthesiology Department but the department does not maintain a controlled substance inventory (*if so, please provide a detailed response for Questions Q4 through Q6 and answer "N/A" for Questions Q2 and Q3*)
- The hospital has an Anesthesiology Department and controlled substances are stored in the department (*if so, please answer all questions below*)

Q2. How many storage locations are utilized for the storage of controlled substances in the Anesthesiology Department? Describe the type of storage equipment for each location (i.e. wall cabinet, combination safe, keyed safe, automated dispensing cabinet, etc.).

Q3. How is access to the controlled substances inventory location(s) in the Anesthesiology Department controlled? How many individuals have access to controlled substances in the unit? Describe how key control is practiced and provide any other information deemed pertinent to ensuring the security of controlled substances in the Anesthesiology Department.

Q4. Describe the procedure for dispensing controlled substances from the Anesthesiology Department. What type of records are maintained to document the dispensation (i.e. sign out logs, automated dispensing technology reports, etc.)?

Q5. Describe the procedure for administering controlled substances in the Anesthesiology Department and the records that are maintained that document the administration (i.e. patient chart, MAR, eMAR, etc.).

Q6. Describe the procedure for wasting controlled substances in the Anesthesiology Department and the records that are maintained that document the waste.

Section R - PACU

R1. Please select the most appropriate answer from the list below:

- The hospital does not have a PACU (*if so, please answer "N/A" for Questions R2 through R6*)
- The hospital has a PACU but the unit does not maintain a controlled substance inventory (*if so, please provide a detailed response for Questions R4 through R6 and answer "N/A" for Questions R2 and R3*)
- The hospital has a PACU and controlled substances are stored in the unit (*if so, please answer all questions below*)

R2. How many storage locations are utilized for the storage of controlled substances in the PACU? Describe the type of storage equipment for each location (i.e. wall cabinet, combination safe, keyed safe, automated dispensing cabinet, etc.).

R3. How is access to the controlled substances inventory location(s) in the PACU controlled? How many individuals have access to controlled substances in the unit? Describe how key control is practiced and provide any other information deemed pertinent to ensuring the security of controlled substances in the PACU.

R4. Describe the procedure for dispensing controlled substances from the PACU. What type of records are maintained to document the dispensation (i.e. sign out logs, automated dispensing technology reports, etc.)?

R5. Describe the procedure for administering controlled substances in the PACU and the records that are maintained that document the administration (i.e. patient chart, MAR, eMAR, etc.).

R6. Describe the procedure for wasting controlled substances in the PACU and the records that are maintained that document the waste.

Section S - Labor and Delivery (L&D)

S1. Please select the most appropriate answer from the list below:

- The hospital does not have an L&D suite (*if so, please answer "N/A" for Questions S2 through S6*)
- The hospital has an L&D suite but the unit does not maintain a controlled substance inventory (*if so, please provide a detailed response for Questions S4 through S6 and answer "N/A" for Questions S2 and S3*)
- The hospital has an L&D suite and controlled substances are stored in the unit (*if so, please answer all questions below*)

S2. How many storage locations are utilized for the storage of controlled substances in Labor and Delivery? Describe the type of storage equipment for each location (i.e. wall cabinet, combination safe, keyed safe, automated dispensing cabinet, etc.).

S3. How is access to the controlled substances inventory location(s) in Labor and Delivery controlled? How many individuals have access to controlled substances in the unit? Describe how key control is practiced and provide any other information deemed pertinent to ensuring the security of controlled substances in Labor and Delivery.

S4. Describe the procedure for dispensing controlled substances from Labor and Delivery. What type of records are maintained to document the dispensation (i.e. sign out logs, automated dispensing technology reports, etc.)?

S5. Describe the procedure for administering controlled substances in Labor and Delivery and the records that are maintained that document the administration (i.e. patient chart, MAR, eMAR, etc.).

S6. Describe the procedure for wasting controlled substances in Labor and Delivery and the records that are maintained that document the waste.

Section T - Intensive Care Units

T1. Please select the most appropriate answer from the list below:

- The hospital does not have an Intensive Care Unit (*if so, please answer "N/A" for Questions T2 through T6*)
- The hospital has an Intensive Care Unit but the unit does not maintain a controlled substance inventory (*if so, please provide a detailed response for Questions U4 through U6 and answer "N/A" for Questions T2 and T3*)
- The hospital has an Intensive Care Unit and controlled substances are stored in the unit (*if so, please answer all questions below*)

T2. How many storage locations are utilized for the storage of controlled substances in the Intensive Care Units? Describe the type of storage equipment for each location (i.e. wall cabinet, combination safe, keyed safe, automated dispensing cabinet, etc.).

T3. How is access to the controlled substances inventory location(s) in the Intensive Care Units controlled? How many individuals have access to controlled substances in the unit? Describe how key control is practiced and provide any other information deemed pertinent to ensuring the security of controlled substances in the Intensive Care Units.

T4. Describe the procedure for dispensing controlled substances from the Intensive Care Units. What type of records are maintained to document the dispensation (i.e. sign out logs, automated dispensing technology reports, etc.)?

T5. Describe the procedure for administering controlled substances in the Intensive Care Units and the records that are maintained that document the administration (i.e. patient chart, MAR, eMAR, etc.).

T6. Describe the procedure for wasting controlled substances in the Intensive Care Units and the records that are maintained that document the waste.

Section U - Medical/Surgical Floors

U1. How many storage locations are utilized for the storage of controlled substances on Medical/Surgical floors? Describe the type of storage equipment for each location (i.e. wall cabinet, combination safe, keyed safe, automated dispensing cabinet, etc.).

U2. How is access to the controlled substances inventory location(s) on Medical/Surgical floors controlled? How many individuals have access to controlled substances in the unit? Describe how key control is practiced and provide any other information deemed pertinent to ensuring the security of controlled substances on Medical/Surgical floors.

U3. Describe the procedure for dispensing controlled substances from Medical/Surgical floors. What type of records are maintained to document the dispensation (i.e. sign out logs, automated dispensing technology reports, etc.)?

U4. Describe the procedure for administering controlled substances on Medical/Surgical floors and the records that are maintained that document the administration (i.e. patient chart, MAR, eMAR, etc.).

U5. Describe the procedure for wasting controlled substances on Medical/Surgical floors and the records that are maintained that document the waste.

Section V - Additional Unit That Stores, Dispenses, or Administers Controlled Substances

V1. Please provide the name and function of another unit not covered in Sections O through U:

V2. How many storage locations are utilized for the storage of controlled substances in the unit identified in Question V1? Describe the type of storage equipment for each location (i.e. wall cabinet, combination safe, keyed safe, automated dispensing cabinet, etc.).

V3. How is access to the controlled substances inventory location(s) identified in Question V1 controlled? How many individuals have access to controlled substances in these areas? Describe how key control is practiced and provide any other information deemed pertinent to ensuring the security of controlled substances.

V4. Describe the procedure for dispensing controlled substances from the controlled substances inventory location(s) identified in Question V1. What type of records are maintained to document the dispensation (i.e. sign out logs, automated dispensing technology reports, etc.)?

V5. Describe the procedure for administering controlled substances in the controlled substances inventory location(s) identified in Question V1 and the records that are maintained that document the administration (i.e. patient chart, MAR, eMAR, etc.).

V6. Describe the procedure for wasting controlled substances in the controlled substances inventory location(s) identified in Question V1 and the records that are maintained that document the waste.

Section W - Additional Unit That Stores, Dispenses, or Administers Controlled Substances

W1. Please provide the name and function of another unit not covered in Sections O through V:

W2. How many storage locations are utilized for the storage of controlled substances in the unit identified in Question W1? Describe the type of storage equipment for each location (i.e. wall cabinet, combination safe, keyed safe, automated dispensing cabinet, etc.).

W3. How is access to the controlled substances inventory location(s) identified in Question W1 controlled? How many individuals have access to controlled substances in these areas? Describe how key control is practiced and provide any other information deemed pertinent to ensuring the security of controlled substances.

W4. Describe the procedure for dispensing controlled substances from the controlled substances inventory location(s) identified in Question W1. What type of records are maintained to document the dispensation (i.e. sign out logs, automated dispensing technology reports, etc.)?

W5. Describe the procedure for administering controlled substances in the controlled substances inventory location(s) identified in Question W1 and the records that are maintained that document the administration (i.e. patient chart, MAR, eMAR, etc.).

W6. Describe the procedure for wasting controlled substances in the controlled substances inventory location(s) identified in Question W1 and the records that are maintained that document the waste.

Section X - Additional Unit That Stores, Dispenses, or Administers Controlled Substances

X1. Please provide the name and function of another unit not covered in Sections O through W:

X2. How many storage locations are utilized for the storage of controlled substances in the unit identified in Question X1? Describe the type of storage equipment for each location (i.e. wall cabinet, combination safe, keyed safe, automated dispensing cabinet, etc.).

X3. How is access to the controlled substances inventory location(s) identified in Question X1 controlled? How many individuals have access to controlled substances in these areas? Describe how key control is practiced and provide any other information deemed pertinent to ensuring the security of controlled substances.

X4. Describe the procedure for dispensing controlled substances from the controlled substances inventory location(s) identified in Question X1. What type of records are maintained to document the dispensation (i.e. sign out logs, automated dispensing technology reports, etc.)?

X5. Describe the procedure for administering controlled substances in the controlled substances inventory location(s) identified in Question X1 and the records that are maintained that document the administration (i.e. patient chart, MAR, eMAR, etc.).

X6. Describe the procedure for wasting controlled substances in the controlled substances inventory location(s) identified in Question X1 and the records that are maintained that document the waste.

Section Y - All Other Units

Y1. How many other storage locations are utilized for the storage of controlled substances in areas of the hospital not covered in Sections O through X? Describe the function of each area and the type of storage equipment for each location (i.e. wall cabinet, combination safe, keyed safe, automated dispensing cabinet, etc.).

Y2. How is access to the controlled substances inventory location(s) identified in Question Y1 controlled? How many individuals have access to controlled substances in these areas? Describe how key control is practiced and provide any other information deemed pertinent to ensuring the security of controlled substances.

Y3. Describe the procedure for dispensing controlled substances from the controlled substances inventory location(s) identified in Question Y1. What type of records are maintained to document the dispensation (i.e. sign out logs, automated dispensing technology reports, etc.)?

Y4. Describe the procedure for administering controlled substances in the controlled substances inventory location(s) identified in Question Y1 and the records that are maintained that document the administration (i.e. patient chart, MAR, eMAR, etc.).

Y5. Describe the procedure for wasting controlled substances in the controlled substances inventory location(s) identified in Question Y1 and the records that are maintained that document the waste.

Section Z - Effective Controls for the Prevention of Diversion

Z1. 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.