STATE OF
MARYLAND

Department of Health and Mental Hygiene
Larry J. Hogan, Governor – Boyd K. Rutherford, Lt. Governor – Dennis R. Schrader

DHMH

MARYLAND BOARD OF PHARMACY
4201 Patterson Avenue ● Baltimore, Maryland 21215-2299
Mitra Gavgani, Board President - Deena Speights-Napata, Executive Director

HOSPITAL INSPECTION FORM

1. PERMITS AND LICENSES

Corporate Pharmacy Name _____
Pharmacy Name-Doing Business As (DBA) or Trade Name _____
Street Address _____
Business Telephone Number_____ **Business Fax Number** _____
Maryland Pharmacy Permit Number _____ **Expiration**_____
CDS Registration Number_____ **Expiration** _____
DEA Registration Number _____**Expiration**_____
Pharmacy Hours: _____
Inspection Date: _____ **Arrival Time:** _____ **Departure Time:** _____
Type of Inspection: Annual ☐ **Follow-up** ☐ **Previous Date:**_____
Name of Inspector: _____

Yes ☐ **No** ☐ If the pharmacy is not open 24 hours, policies and procedures are in place for emergency access to the Pharmacy when locked.

Yes ☐ **No** ☐ The pharmacy orders, stocks, or dispenses controlled drugs.

Yes ☐ **No** ☐ The Pharmacy performs Sterile Compounding.
(If yes, will need to complete Sterile Compounding Inspection Form)

Yes ☐ **No** ☐ The pharmacy wholesale distributes to another pharmacy. COMAR 10.34.37

Yes ☐ **No** ☐ The pharmacy wholesale distributes to a wholesale distributor. COMAR 10.34.37

Yes ☐ **No** ☐ **N/A** ☐ The wholesale distribution business exceeds 5% of the pharmacy annual sales. COMAR 10.34.37

Comments: _____
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2. PERSONNEL

Name of Pharmacist/Manager who is charged with ensuring compliance with all applicable laws

_____

Pharmacist Employees	License #	Exp Date

Registered Technicians	Registration #	Exp Date

Unlicensed Personnel (non-registered)	Title	Duties

3. SECURITY (COMAR 10.19.03.12) (COMAR 10.34.03.06) (COMAR 10.34.05)

Yes ☐ No ☐ The Pharmacy maintains policies and procedures for limiting access to the Pharmacy. (If yes, provide a brief description of how access is restricted)

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Comments: _____

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4. PHYSICAL REQUIREMENTS AND EQUIPMENT (COMAR 10.34.03.07) (COMAR 10.34.07.01) (HO 12-403.(11))

Yes ☐ **No** ☐ The Pharmacy has written (or e-format) Policies and Procedures.
(If yes, date of last review/update.)_____

Yes ☐ **No** ☐ The Pharmacy is of sufficient size with adequate lighting, ventilation and moisture control for the safe storage of drugs and Practice of Pharmacy.

Yes ☐ **No** ☐ **N/A** ☐ The Pharmacy compounds medications (non-sterile products).

Yes ☐ **No** ☐ The Pharmacy has a Class A balance or better.

Yes ☐ **No** ☐ The Pharmacy has hot and cold running water.

Yes ☐ **No** ☐ The refrigerator(s) temperature is checked daily.
(Temperature)_____

Yes ☐ **No** ☐ The references available for the safe and proper dispensing of medications are:

☐ On-line access

☐ Written references (List main references used and year of publication)

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Comments: _____

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5. DRUG SAMPLES HO §12-102

Yes ☐ **No** ☐ **N/A** ☐ There are written policies and procedures on how drug samples are dispensed. There are recording systems for the acquisition and dispensing of drug samples.

Yes ☐ **No** ☐ **N/A** ☐

Yes ☐ **No** ☐ **N/A** ☐ There is a note/order written in the patient's chart/record when a sample is dispensed.

Comments: _____

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6. EMERGENCY ROOM (ER) DISPENSING (HO 12-1-2.(f))

Yes ☐ **No** ☐ The institution's ER dispenses medication directly to the patient.

Yes ☐ **No** ☐ The patient is given "starter doses" for 72 hours or less.

Yes ☐ **No** ☐ The labeling of the "starter doses" complies with HO 12-505.

Comments: _____

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7. LABELING OF MEDICATION FOR USE OUTSIDE THE INSTITUTION (COMAR 10.34.03.10)

Yes ☐ **No** ☐ The labeling on all medications dispensed for use outside the institution (clinics, ambulatory patients, discharged patients) meets the requirements of HO 12-505 as well as any federal or state laws (check all that apply).

- ☐ Name of patient
- ☐ Name and strength of drug
- ☐ Name of Pharmacy and address
- ☐ Directions and any cautionary statements
- ☐ Expiration dates
- ☐ Any special handling or storage requirements

Comments: _____

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8. UNLICENSED PERSONNEL (COMAR 10.34.21.01 to .05)

Yes ☐ **No** ☐ **N/A** ☐ There are policies and procedures to specify duties that may be performed by ancillary personnel under the supervision of a licensed pharmacist.

Yes ☐ **No** ☐ **N/A** ☐ The unlicensed personnel who perform tasks in the Pharmacy have received documented training for the tasks they will perform.

The unlicensed personnel received training in (check all that apply):

Yes ☐ **No** ☐ **N/A** ☐ Maintaining records

Yes ☐ **No** ☐ **N/A** ☐ Patient confidentiality

Yes ☐ **No** ☐ **N/A** ☐ Sanitation, hygiene, infection control

Yes ☐ **No** ☐ **N/A** ☐ Biohazard precautions

Yes ☐ **No** ☐ **N/A** ☐ There are ongoing quality assurance programs that document the competency and accuracy of then licensed personnel performance of assigned tasks.

Yes ☐ **No** ☐ **N/A** ☐ All unlicensed personnel have been given a written job description.

Comments: _____

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9. CONFIDENTIALITY (HG 4-301 to 307)

Yes ☐ **No** ☐ Confidentiality is maintained in the creating, storing, accessing and disclosing of patient's records.

Yes ☐ **No** ☐ Identifiable information contained in a patient's record is not disclosed unless authorized by the patient, or an order of the court, or as authorized pursuant to HG 4-301- 4-307.

Comments: _____

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10. MEDICATION ORDERS (COMAR 10.34.03.12)

Prescribers authorized to write medication orders:

Yes ☐ **No** ☐ **_____MD**

Yes ☐ **No** ☐ **_____NP**

Yes ☐ **No** ☐ **_____PA**

Yes ☐ **No** ☐ **_____Other (Explain):_____**

Yes ☐ **No** ☐ Medications are dispensed from the pharmacy only in response to medication orders issued by authorized prescribers or by clinicians per institution approved protocols.

Yes ☐ **No** ☐ Pertinent patient information necessary for drug monitoring including the patient's sex, age, height, weight, diagnosis, drug interactions, and allergies are readily available to the pharmacist.

Yes ☐ **No** ☐ The institution has specific guidelines for writing medication orders under approved medication protocols and therapeutic interchanges.

Yes ☐ **No** ☐ The pharmacist notes the mode of transmission of a medication order on the prescription when it does not contain the original prescriber's signature. (COMAR10.34.20.03)

Yes ☐ **No** ☐ The institution has a policy and procedure in place for receiving and transcribing verbal medication orders.

Yes ☐ **No** ☐ The Pharmacy and Therapeutics Services Committee or its equivalent has developed automatic stop order policies on medications that are not specifically limited to duration or number of doses.

Comments: _____

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11. EMERGENCY DRUG BOXES, CRASH CARTS (COMAR 10.34.03.11)

Yes ☐ **No** ☐ The Pharmacy and Therapeutics Committee develops and maintains lists and a formulary that includes of antidotes and emergency drugs.

Yes ☐ **No** ☐ A policy exists regarding what medications and quantities are to be contained in emergency drug kits as well as procedures for dispensing medications.

Yes ☐ **No** ☐ The emergency drug kits are stored in an area that permits the preservation of the medications, accessibility is limited to authorized personnel, and kits contain a tamper resistant seal.

The emergency drug kits are labeled as follows:

Yes ☐ **No** ☐ Clear indication that the kit is for emergency use only.

Yes ☐ **No** ☐ Lists the expiration date of each drug and name or initials of the pharmacist who checked the drug kit.

Yes ☐ **No** ☐ The expiration date of the kit is the earliest date of expiration of any drug supplied in the kit.

Yes ☐ **No** ☐ Upon expiration a procedure exists for the pharmacist to replace the expired drug and re-label the kit.

Yes ☐ **No** ☐ The pharmacist restocks the emergency kit as soon as possible or provides another kit once notified that the kit has been opened.

Comments: _____

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12. FORMULARY MANAGEMENT (COMAR 10.07.02.15)

Yes ☐ **No** ☐ There is a Pharmacy and Therapeutics Committee or equivalent.

Yes ☐ **No** ☐ The Pharmacy and Therapeutics Committee develops policies for the safe handling of pharmaceuticals throughout the facility.

Yes ☐ **No** ☐ The Pharmacy & Therapeutics Committee develops and maintains the Formulary for the institution.

Yes ☐ **No** ☐ The Pharmacy and Therapeutics Committee meets at least quarterly.

Dates of last 2 (two) meetings _____

Yes ☐ **No** ☐ The Pharmacy and Therapeutics Committee approves and monitors Quality Assurance Programs for medication use.

Comments: _____

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13. PURCHASING OF PHARMACEUTICALS (COMAR 10.34.03.13)

Yes ☐ **No** ☐ The Pharmacy has written specifications for safe procurement, storage and disposal of drugs.

Yes ☐ **No** ☐ The Pharmacy maintains written records as required by law for accurate control and accountability of all pharmaceuticals.

Yes ☐ **No** ☐ The Pharmacy have written policies and procedures for the safe handling of drug recalls.

Yes ☐ **No** ☐ The Pharmacy maintains records of all drug recalls.

Yes ☐ **No** ☐ The Pharmacy and Therapeutics Committee develops policies for handling and disposal of outdated and deteriorated drugs.

Comments: _____

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14. STORAGE (COMAR 10.34.04.08, 10.07.02.15)

Yes ☐ No ☐ The Pharmacy controls storage of all drugs and investigational medications throughout the institution.

Yes ☐ No ☐ All poisons and external preparations are sequestered from oral and injectable drugs.

Yes ☐ No ☐ All flammables and alcohol preparations are maintained in areas that meet basic local building code requirements for storage of volatiles and such other laws, ordinances, or regulations.

Yes ☐ No ☐ The Pharmacy developed and implemented policies and procedures to ensure that discontinued and outdated drugs and drug containers with worn, illegible, or missing labels are returned to the Pharmacy for proper disposition.

Comments: _____

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15. INVENTORY CONTROL PROCEDURES

Yes ☐ No ☐ N/A ☐ The pharmacy maintains records of wholesale distribution to other pharmacies separately from its other records. COMAR 10.34.37.03

Yes ☐ No ☐ N/A ☐ The pharmacy maintains records of wholesale distribution to wholesale distributors separately from its records of wholesale distribution to other pharmacies. COMAR 10.34.37.03

Comments: _____

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16. INVESTIGATIONAL DRUGS (COMAR 10.34.03.08.R)

Yes ☐ No ☐ N/A ☐ The Pharmacy participate in the development of policies and procedures for identification and handling of investigational drugs.

Yes ☐ No ☐ N/A ☐ The Pharmacy provides information on pharmaceutical and toxicological effects of investigational drugs to medical and nursing staff.

Yes ☐ No ☐ N/A ☐ The Pharmacy and Therapeutics Committee develops policies for protection of patients enrolled in hospital-sponsored research.

Comments: _____

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17. CONTROLLED SUBSTANCES (COMAR 10.34.03.13)

Yes ☐ No ☐ Records are kept regarding use and accountability of Schedule II substances containing at least the following:

Yes ☐ No ☐ N/A ☐ Name and strength of drug

Yes ☐ No ☐ N/A ☐ Dose

Yes ☐ No ☐ N/A ☐ Dosage form

Yes ☐ No ☐ N/A ☐ Prescriber

Yes ☐ No ☐ N/A ☐ Patient

Yes ☐ No ☐ N/A ☐ Date and time of administration

Yes ☐ No ☐ N/A ☐ Individual who administered drug

Yes ☐ No ☐ The Pharmacy performs biennial scheduled drug inventories.

Yes ☐ No ☐ Records (including signatures) are kept of all receipts of controlled substances into the Pharmacy.

Yes ☐ No ☐ Records are kept of all deliveries made by the Pharmacy with signatures of personnel delivering and receiving

Yes ☐ No ☐ Records are kept of partially administered Schedule II drugs whether returned to the Pharmacy or disposed of immediately with verification by a witness.

Yes ☐ No ☐ Access to all controlled substances outside the Pharmacy is restricted to licensed personnel approved by institutional policy.

Yes ☐ No ☐ Controlled substances stored outside the Pharmacy are accounted for at least at the change of shift by a licensed person authorized by the institution, unless an on-demand report of perpetual inventory is available with an automated dispensing system.

Yes ☐ No ☐ A pharmacist or a person designated by the director performs a physical count of each Schedule II substance in the Pharmacy at least monthly to identify any discrepancies.

Yes ☐ No ☐ The Director or a pharmacist designee investigates all discrepancies, report losses as required by law and takes appropriate action.

Yes ☐ No ☐ A procedure is in place for any Schedule II substances that have been dispensed and are no longer needed and must be returned to the Pharmacy.

Comments: _____

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18. AUTOMATED MEDICATION SYSTEMS (COMAR 10.34.28)

Yes ☐ No ☐ N/A ☐ The facility uses automated devices as defined in 10.34.28.02.

Yes ☐ No ☐ N/A ☐ The pharmacy uses the following (check all that apply):

- ☐ Centralized automated medication system.
- ☐ Decentralized automated medication system.
- ☐ Remote automated medication system.

Yes ☐ No ☐ N/A ☐ Policies and procedures exist for (check all that apply):

- ☐ Control of access to the device.
- ☐ Review of orders by a licensed pharmacist prior to removal of the medication.
- ☐ Control of starter doses.
- ☐ Accounting for medication added and removed from the system.

Yes ☐ No ☐ N/A ☐ Sufficient safe guards are in place to ensure accurate replenishment of the automated medication system.

Yes ☐ No ☐ N/A ☐ Adequate records are maintained for at least two years addressing the following (check all that apply):

- ☐ Maintenance records.
- ☐ System failure reports.
- ☐ Accuracy audits.
- ☐ Quality assurance reports.
- ☐ Reports on system access and changes in access.
- ☐ Training records.

Yes ☐ No ☐ N/A ☐ Transaction records for medications dispensed are maintained for five years.

Yes ☐ No ☐ N/A ☐ Devices installed after September 1, 2003 operate in a manner to limit simultaneous access to multiple strengths, forms and drug entities, and minimizes the potential for misidentification of medications, dosages, and dosage forms.

Yes ☐ No ☐ N/A ☐ The Pharmacy maintains records, documents, or other evidence of a multidisciplinary committee, that includes a licensed pharmacist, that is charged with oversight of the remote or decentralized automated medication system, which has:

- ☐ Established criteria and a process for determining which drugs may be stored in a remote or decentralized automated medication system;
- ☐ Reviews the decisions, referred to in regulations, on a regular basis;
- ☐ Develops policies and procedures regarding the remote or decentralized automated medication system; and
- ☐ Ensures that the system complies with the appropriate sections of the law.

Yes ☐ No ☐ N/A ☐ The Pharmacy maintains records, documents, or other evidence of a quality Assurance program regarding the automated medication system in accordance with the requirements of CHAPTER 28, §.10.

Comments: _____

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19. OUTSOURCING Yes ☐ No ☐

Yes ☐ No ☐ N/A ☐ The facility outsources the preparation of medication or performs outsourcing functions for other pharmacies. COMAR 10.34.04.02

Yes ☐ No ☐ N/A ☐ The facility serves as a primary pharmacy outsourcer to other pharmacies. COMAR 10.34.04.02

Yes ☐ No ☐ N/A ☐ The facility serves as a secondary pharmacy. COMAR 10.34.04.02

Yes ☐ No ☐ N/A ☐ The permit holder employs an outside agency/business entity for the provision of any pharmacy services, inclusive of staffing, remote order entry, and management.

If yes: Name of agency, state of incorporation, service contracted, and State of Maryland License/Permit Number: COMAR 10.34.04.06E

Comments:

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Yes ☐ No ☐ N/A ☐ The permit holder has written policies and procedures to specify the duties that may be performed by outside personnel. COMAR 10.34.21.03B(3)

If the pharmacy outsources a prescription order:

Yes ☐ No ☐ N/A ☐ The original prescription order is filed as a prescription order at the primary pharmacy. COMAR 10.34.04.06D

Yes ☐ No ☐ N/A ☐ Written policies exist for maintenance of documentation regarding transfer of prescription records. COMAR 10.34.04.06

Yes ☐ No ☐ N/A ☐ Documentation is maintained, including the names and locations of the pharmacies, names of pharmacists, and a record of the preparations made. COMAR 10.34.04.03 and .05

The pharmacist from the primary pharmacy documents the following in a readily retrievable and identifiable manner: COMAR 10.34.04.06 (Check all that apply)

Yes ☐ No ☐ N/A ☐ That the prescription order was prepared by a secondary pharmacy.

Yes ☐ No ☐ N/A ☐ The name of the secondary pharmacy.

Yes ☐ No ☐ N/A ☐ The name of the pharmacist who transmitted the prescription order to the secondary pharmacy.

Yes ☐ No ☐ N/A ☐ The name of the pharmacist at the secondary pharmacy to whom the prescription order was transmitted if the transmission occurred in an oral manner.

Yes ☐ No ☐ N/A ☐ The date on which the prescription order was transmitted to the secondary pharmacy.

Yes ☐ No ☐ N/A ☐ The date on which the medication was sent to the primary pharmacy.

Yes ☐ No ☐ N/A ☐ The primary and secondary pharmacies are both licensed in the State of Maryland, or operated by the federal government. COMAR 10.34.04.06F

Yes ☐ No ☐ N/A ☐ The primary pharmacy maintains, in a readily retrievable and identifiable manner, a record of preparations received from the secondary pharmacy. COMAR 10.34.04.06G

The permit holder at the secondary pharmacy maintains documentation in a readily retrievable and identifiable manner, which includes: COMAR 10.34.04.07 (Check all that apply)

Yes ☐	No ☐	N/A ☐	That the prescription order was transmitted from another pharmacy.
Yes ☐	No ☐	N/A ☐	The name and information identifying the specific location of the primary pharmacy.
Yes ☐	No ☐	N/A ☐	The name of the pharmacist who transmitted the prescription to the secondary pharmacy if the transmission occurred in an oral manner.
Yes ☐	No ☐	N/A ☐	The name of the pharmacist at the secondary pharmacy who accepted the transmitted prescription order.
Yes ☐	No ☐	N/A ☐	The name of the pharmacist at the secondary pharmacy who prepared the prescription order.
Yes ☐	No ☐	N/A ☐	The date on which the prescription order was received at the secondary pharmacy.
Yes ☐	No ☐	N/A ☐	The date on which the prepared product was sent to the primary pharmacy if it was sent back to the primary pharmacy.

COMMENTS:

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20. QUALITY ASSURANCE – PATIENT SAFETY/MEDICATION ERRORS (COMAR 10.34.26)

Yes ☐ No ☐ The Pharmacy maintains on record policies governing the methods to provide patients with information regarding the patient's role and responsibility in preventing medication errors.

Yes ☐ No ☐ There is evidence of steps taken to inform patients of (check all that apply):

Yes ☐	No ☐	N/A ☐	A patient's rights when receiving a medication or a prescription.
Yes ☐	No ☐	N/A ☐	The patient's role and responsibility in preventing a medication error.
Yes ☐	No ☐	N/A ☐	The procedures to follow when reporting a suspected medication error to the Pharmacy, permit holder, pharmacist, health care facility, or other health care provider.
Yes ☐	No ☐	N/A ☐	How to report a suspected medication error to the Board.

If yes, how is the information presented to the patient. (conspicuously placed posters/handout to patient/etc.)

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_____

Yes ☐ **No** ☐ The Pharmacy maintains two (2) continuous years of records clearly demonstrating the content of annual educational training provided to each member of the pharmacy staff involved in the medication delivery system regarding the role and responsibility of pharmacy staff in preventing medication errors.

Yes ☐ **No** ☐ The Pharmacy maintains records, proceedings, files, and any other documents showing an ongoing Quality Assurance Program that clearly and concisely sets forth policies and procedures to identify, investigate, and promote the prevention of medication errors; and protocols and procedures to minimize the potential for medication errors.

Yes ☐ **No** ☐ The Pharmacy records contain evidence of a periodic review every three (3) months of the quality assurance program and specifically detail:

- **Yes** ☐ **No** ☐ The system's weaknesses found during the periodic review.
- **Yes** ☐ **No** ☐ The actions taken to remedy any weaknesses identified in the medication system.

Yes ☐ **No** ☐ The records contain an analysis of a pharmacy's medication delivery system to identify high-alert medications required under the law and specifically (a) list high-alert medications present in the prescription area of the pharmacy; (b) state the date that a high-alert medication was added to or removed from the list of high-alert medications; (c) state the dates that the list was reviewed by the Pharmacy permit holder; and (d) detail actions taken based on the review of the list of high-alert medications and any medication errors relating to the high-alert medications.

Comments: _____

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21. QUALITY ASSURANCE – GENERAL

Yes ☐ **No** ☐ The permit holder maintains policies and procedures for the participation of the Pharmacy in the institutional quality assurance and improvement program.

Yes ☐ **No** ☐ The Pharmacy conducts an on-going plan for a quality management program that reviews and evaluates pharmaceutical services and recommend improvements thereof.

Comments: _____

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22. NURSING UNITS

Yes ☐ **No** ☐ The Pharmacy maintains policies and procedures for the evaluation of all drug storage areas throughout the institution on a monthly basis and maintain written records of these reviews.

Yes ☐ **No** ☐ Inspections of all drug storage areas throughout the institution are conducted monthly and writtenevaluations are recorded and maintained.

Comments: _____

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23. NON-DISPENSING FUNCTIONS OF PHARMACISTS (COMAR 10.34.03.07)

Yes ☐ **No** ☐ The institution maintains policies and procedures for medication protocols.

If yes:

Yes ☐ **No** ☐ Approved medication protocols authorize the modification, continuation, and discontinuation of therapy.

Yes ☐ **No** ☐ The medication protocols authorize the ordering of laboratory tests and other patient care management measures related to monitoring or improving the outcomes of drug or device therapy.

Yes ☐ **No** ☐ Medication protocols do not authorize the substitution of chemically dissimilar drugs unless permitted in the protocol.

Yes ☐ **No** ☐ A pharmacist therapeutically interchanges medications only if given prior approval by the authorized prescriber, or if the institution has established guidelines and procedures for the therapeutic interchange of medications.

Yes ☐ **No** ☐ Guidelines and procedures have been established regarding the therapeutic interchange of medications.

If yes, where are these policies maintained.

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Comments: _____

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Inspectors Comments:

Inspector Signature_____

Pharmacist Name: _____ **Date:** _____
(Print)

Received a copy of the inspection report on _____ _____
Date and Signature of the Pharmacist

FINAL 9/03/2014

CONTROLLED DANGEROUS SUBSTANCES WORKSHEET

Clear Form

Pharmacy: _____
Permit#: _____
Date: _____
Pharmacist Signature: _____

Rx#:_____
Date Filled:_____

DRUG	NDC Number	ON HAND INVENTORY	PERPETUAL INVENTORY

COMMENTS:

_____
_____
_____
_____

SCHEDULE II AUDIT

Drug _____
Date of last Inspection/Biennial _____

Amount at last inspection/biennial	_____	(A)
Purchased since inspection/biennial	_____	(B)
Total inventory	0	(C) = A + B
Quantity dispensed	_____	(D)
Expected inventory	0	(E) = C - D
Quantity on Hand	_____	(F)
Discrepancy	0 _____	(G) = (F-E) or (E-F)
		Excess Shortage

INVOICE REVIEW

CII:

_____
_____
_____

CIII - CV:

_____
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_____

PRESCRIPTION REVIEW

CII #
DATE

COMMENTS:

_____
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_____

CIII - CV #
DATE

COMMENTS:

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