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

COMPREHENSIVE CARE PHARMACY INSPECTION FORM

1. PERMITS AND LICENSES

Corporate Pharmacy Name _____
Pharmacy Name-Doing Business as (d/b/a) or Trade Name _____
Street Address _____
Business Telephone Number _____ **Business Fax Number** _____
Inspection Date: _____ **Arrival Time:** _____ **Departure Time:** _____
Type of Inspection: ☐ **Annual** ☐ **Follow-up Previous Date:** _____
Name of Inspector: _____

Yes ☐ **No** ☐ The pharmacy department provides service 24 hours. COMAR 10.34.05.

Yes ☐ **No** ☐ The pharmacy hours of operation and after hour procedures are provided to the Comprehensive Care Facility. COMAR 10.34.05.03B

Pharmacy Hours M-F: _____ **Sat:** _____ **Sun:**_____

Yes ☐ **No** ☐ All permits, licenses, and registrations are posted conspicuously.
HO §12-311, HO §12-408(b) and HO §12-6B-08

Maryland Pharmacy Permit Number _____ **Expiration** _____
CDS Registration Number _____ **Expiration** _____
DEA Registration Number _____ **Expiration** _____

Yes ☐ **No** ☐ The pharmacy performs sterile compounding. (If yes, complete Sterile Compounding Inspection Form) COMAR 10.34.19

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. PERSONNEL TRAINING

All personnel have received training in: (check all that apply) COMAR 10.34.21.03

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 ☐ Patient safety and medication errors COMAR 10.34.26.03

Yes ☐ No ☐ There are written policies and procedures to specify duties that may be performed by unlicensed personnel under the supervision of a licensed pharmacist. COMAR 10.34.21.03

Yes ☐ No ☐ N/A ☐ All unlicensed personnel who perform tasks in the pharmacy receive documented training for the tasks they perform. COMAR 10.34.21.03

Yes ☐ No ☐ There is a written ongoing quality assurance program that documents the competency and accuracy of all assigned tasks. COMAR 10.34.21.03

Comments:_____
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4. POLICIES AND PROCEDURES COMAR 10.34.23.03

Yes ☐ No ☐ Personnel access to the pharmacy COMAR 10.34.23.03C
Yes ☐ No ☐ Scope and method of pharmacy service COMAR 10.34.23.03B
Yes ☐ No ☐ Labeling requirements and distribution methods for medications provided in a single container COMAR 10.34.23.03E (1)
Yes ☐ No ☐ Procedures for interim boxes. COMAR 10.34.23.03E (2)
Yes ☐ No ☐ Documentation of policy and procedure manual provided to personnel of the pharmacy and comprehensive care facility. COMAR 10.34.23.03F
Yes ☐ No ☐ Reporting adverse drug reactions. COMAR 10.34.23.09K
Yes ☐ No ☐ Written policies related to re-use of returned medications.
Yes ☐ No ☐ Documented contingency plans for continuing operations in an emergency and for disaster recovery of required records.

Comments:_____
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5. SECURITY COMAR 10.34.05

Yes ☐ **No** ☐ The pharmacy is designed to prevent unauthorized entry when the prescription area is closed during any period that the rest of the establishment is open. (Briefly describe how access is restricted.) COMAR 10.34.05.02A (5)

_____

_____

Yes ☐ **No** ☐ The pharmacy and/or pharmacy department has a security system. COMAR 10.34.05.02A (2)

Yes ☐ **No** ☐ The permit holder prevents individuals from being in the prescription area when a pharmacist is not immediately available on the premises to provide pharmacy service. COMAR 10.34.23.05C

Comments:_____

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6. PHYSICAL REQUIREMENTS AND EQUIPMENT COMAR 10.34.23.05

Yes ☐ **No** ☐ Pharmacy area is clean, neat, and organized. HO §12-403(b)(11)(ii)2 and COMAR 10.34.10.01A(3).

Yes ☐ **No** ☐ The pharmacy provides a compounding service (non-sterile procedures).

Yes ☐ **No** ☐ If yes, the pharmacy maintains equipment that enables it to prepare and dispense prescriptions properly within its scope of practice. COMAR 10.34.07.02

Yes ☐ **No** ☐ The pharmacy has a Class A prescription balance and weights, or a prescription balance with equivalent or superior sensitivity. COMAR 10.34.07.01-1A

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

Yes ☐ **No** ☐ The medication refrigerator(s) contain only prescription items. COMAR 10.34.07.01-1B

Yes ☐ **No** ☐ The medication refrigerator(s) have a thermometer. COMAR 10.34.07.01-1B

Yes ☐ **No** ☐ The current temperature of the medication refrigerator(s) is between (36F-46F). USP

Temperature_____

Yes ☐ **No** ☐ The current temperature of the pharmacy department is between [59 to 86 degrees F]. COMAR 10.34.05.02A (1) (a)

Temperature_____

Yes ☐ **No** ☐ **N/A** ☐ If the pharmacy stocks medications requiring freezing, the freezer is maintained at temperatures required by the medication stored within it.

Temperature_____

Yes ☐ **No** ☐ The pharmacy maintains a library of current reference sources consistent with its scope of practice that is accessible to all appropriate personnel. COMAR 10.34.07.03

Yes ☐ No ☐ The pharmacy has online resources. HO §12-403(b)(15) and COMAR 10.34.07.03

Yes ☐ No ☐ The pharmacy possesses the current edition of *The Maryland Pharmacy Laws and Regulations*. HO §12-403(b) (10) (ii)

Yes ☐ No ☐ Medications and supplies within the pharmacy are properly stored according to the manufacturer's specifications and State and federal laws and regulations with respect to:

- Yes ☐ No ☐ Sanitation
- Yes ☐ No ☐ Temperature
- Yes ☐ No ☐ Light
- Yes ☐ No ☐ Ventilation
- Yes ☐ No ☐ Segregation
- Yes ☐ No ☐ Security

Comments:_____
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7. PRESCRIPTION LABELING, FILES, AND STORAGE

Yes ☐ No ☐ N/A ☐ Hard copy prescription files are maintained chronologically for 5 years. HO §12-403(b) (13)

The following label requirements are met if a drug is dispensed pursuant to a prescription. COMAR 10.34.23.08:

- Yes ☐ No ☐ N/A ☐ The name and address of the pharmacy;
- Yes ☐ No ☐ N/A ☐ The serial number of the prescription;
- Yes ☐ No ☐ N/A ☐ The date the prescription was dispensed;
- Yes ☐ No ☐ N/A ☐ The name of the prescriber;
- Yes ☐ No ☐ N/A ☐ The name of the patient;
- Yes ☐ No ☐ N/A ☐ The name and strength of the drug or devices;
- Yes ☐ No ☐ N/A ☐ The quantity of the drug or device;
- Yes ☐ No ☐ N/A ☐ The required precautionary information regarding controlled substances;
- Yes ☐ No ☐ N/A ☐ The required cautionary statements or auxiliary labels;
- Yes ☐ No ☐ N/A ☐ The name of generic manufacturer;
- Yes ☐ No ☐ N/A ☐ The expiration date is indicated;
- Yes ☐ No ☐ N/A ☐ (Medications in Parenteral Admixtures) The name and amount of drug(s) added;
- Yes ☐ No ☐ N/A ☐ (Medications in Parenteral Admixtures) The name of the pharmacist responsible for the admixture;
- Yes ☐ No ☐ N/A ☐ (Medications in Parenteral Admixtures) The rate of infusion; and (Medications in Parenteral Admixtures) The frequency of infusion

Yes ☐ No ☐ N/A ☐ Medication provided per dosing period in a single container, slot, blister package, any other method of delivering an entire single dosing unit, or as part of a multi-dose dispensing package, are labeled with at least the following:

- Yes ☐ No ☐ N/A ☐ (1) Drug name;
- Yes ☐ No ☐ N/A ☐ (2) Drug strength;
- Yes ☐ No ☐ N/A ☐ (3) Name of manufacturer;
- Yes ☐ No ☐ N/A ☐ (4) Name of the patient;

Yes ☐ No ☐ N/A ☐ (5) Lot number; and

Yes ☐ No ☐ N/A ☐ (6) Expiration date.

Yes ☐ No ☐ N/A ☐ The pharmacist and technician initials are on prescriptions or patient drug profiles or computerized patient records. COMAR 10.34.08.01

Comments:_____

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8. QUALITY ASSURANCE – PATIENT SAFETY / MEDICATION ERRORS

Yes ☐ No ☐ There are written procedures to follow when reporting a suspected medication error to the permit holder, pharmacist, health care facility, or other health care provider. COMAR 10.34.26.04

Yes ☐ No ☐ The pharmacy maintains a minimum of 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. COMAR 10.34.26.03B

Comments:_____

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9. CONFIDENTIALITY

Yes ☐ No ☐ Confidentiality is maintained in the creation, storage, access, disposal and disclosure of patient records. HO §12-403(b)(13), COMAR 10.34.10.03A and HIPAA Regulations.

Yes ☐ No ☐ Any 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 through §4-307.COMAR 10.34.10.03B

Comments:_____

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10. DRUG CONTROL AND ACCOUNTABILITY COMAR 10.34.23.09

Yes ☐ No ☐ N/A ☐ The pharmacy maintains invoices as required by law for accurate control and accountability of all pharmaceuticals. COMAR 10.34.24.03

Yes ☐ No ☐ N/A ☐ The pharmacy has written policies and procedures for the safe handling of drug recalls. See www.recalls.gov

Yes ☐ No ☐ N/A ☐ The pharmacy maintains records of all recalls. See www.recalls.gov

Yes ☐ No ☐ N/A ☐ The pharmacy has a written procedure in place for removal of all expired drugs; (both prescription and OTC) COMAR 10.34.12.01

Yes ☐ No ☐ N/A ☐ The pharmacy has a process for discontinued medication and returned medication that accounts for proper storage and labeling. COMAR 10.34.23.09

Comments:_____

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11. EMERGENCY DRUG KIT COMAR 10.34.23.09.F

Yes ☐ **No** ☐ The emergency drug kit is secured with a tamper evident seal or electronic security system. COMAR 10.34.23.09.F.(1)

Yes ☐ **No** ☐ The emergency drug kit meets the labeling requirements as set forth on COMAR 10.34.23.09.F.(2).

Yes ☐ **No** ☐ A written policy exits regarding what medications and quantities are to be contained in interim drugs box as well as procedures for restocking medications. COMAR 10.34.23.03

Comments:_____
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12. CONTROLLED SUBSTANCES

Yes ☐ **No** ☐ Hard copy prescription files are maintained chronologically for 5 years. COMAR 10.34.20.03; HO §12-403(b)(13). (CDS-Federal law requires record retention for 7 years)

Yes ☐ **No** ☐ A perpetual inventory is maintained for Schedule II controlled substances. (Recommended)

Yes ☐ **No** ☐ Schedule II controlled substances are dispersed throughout the stock of non-controlled substances, or stored in such a manner as to obstruct theft or diversion. COMAR 10.19.03.12B (2)

Yes ☐ **No** ☐ The pharmacy has a copy of the most recent required biennial inventory of Schedule II- V controlled substances. COMAR 10.19.03.05B

Inventory date: _____

Yes ☐ **No** ☐ Inventory completed at: ☐ Opening or ☐ Closing (Check one)

Yes ☐ **No** ☐ The inventories and records of Schedule II-V drugs are maintained and readily available. COMAR 10.19.03.05 and 21 CFR 1304.03

Yes ☐ **No** ☐ Records are kept of all receipts of controlled substances entered into the pharmacy inventory (including DEA Form 222 or CSOS orders). COMAR 10.19.03.05

Yes ☐ **No** ☐ The prescription label for controlled drugs include the following warning: "**CAUTION** ***Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed***", in 6-point type or the Pharmacy utilizes an auxiliary label that contains this warning. COMAR 10.19.03.08D (1)

Yes ☐ **No** ☐ All controlled substances prescriptions comply with COMAR 10.19.03

Yes ☐ **No** ☐ The permit holder or pharmacist designee(s) has written policies and procedures for investigating discrepancies and reporting of theft or loss. COMAR 10.19.03.12B (4)

Yes ☐ **No** ☐ For the return of Schedule III-V drugs, the pharmacy uses a distribution system that classifies medications as pharmacy inventory until the utilization of the medication by the patient. COMAR 10.34.23.09.C

Comments:_____
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13. AUTOMATED MEDICATION SYSTEMS Yes ☐ No ☐ (if No, go to #14)

Yes ☐ No ☐ N/A ☐ The facility uses an automated device(s) as defined in COMAR 10.34.28.02.

Written policies and procedures exist for (check all that apply): COMAR 10.34.28.05

Yes ☐ No ☐ N/A ☐ Control of access to the device.

Yes ☐ No ☐ N/A ☐ Accounting for medication added and removed from the system.

Yes ☐ No ☐ N/A ☐ Sufficient safeguards are in place to ensure accurate replenishment of the automated medication system. If yes, describe safeguards. COMAR 10.34.28.06

Comments:_____

Yes ☐ No ☐ N/A ☐ Adequate records are maintained for at least two years addressing the following (check all that apply). COMAR 10.34.28.11

Yes ☐ No ☐ N/A ☐ Maintenance records.

Yes ☐ No ☐ N/A ☐ System failure reports.

Yes ☐ No ☐ N/A ☐ Accuracy audits.

Yes ☐ No ☐ N/A ☐ Quality Assurance Reports.

Yes ☐ No ☐ N/A ☐ Reports on system access and changes in access.

Yes ☐ No ☐ N/A ☐ Training records.

Yes ☐ No ☐ N/A The pharmacy has records, documents, or other evidence of a quality assurance program regarding the automated medication system in accordance with the requirements of COMAR 10.34.28

Comments:_____

14. OUTSOURCING Yes ☐ No ☐ (if No, go to #13)

Yes ☐ No ☐ N/A ☐ The facility outsources the preparation of medications 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 ☐ 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

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

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

Yes ☐ No ☐ N/A ☐ 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 preparation 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 (check all that apply):
COMAR 10.34.04.07

Yes ☐ No ☐ N/A ☐ Records of the prescription orders transmitted from another pharmacy.

Yes ☐ No ☐ N/A ☐ The date on which the prescription order was transmitted from the primary 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 verified/performed the final check of the prescription order.

Comments:_____

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15. DISTRIBUTION

Yes ☐ No ☐ N/A ☐ Sales of prescription drugs other than by patient specific prescription orders exceeds 5% of the pharmacy's annual sales.

If yes, Maryland distributors license # _____ COMAR 10.34.22.01.

Comments:_____

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16. MEDICATION ORDERS (COMAR 10.34.23.09.H)

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

17. MEDICATION PACKAGING (COMAR 10.34.23.07)

Yes ☐ No ☐ N/A ☐ The pharmacy prepares packaged medications. (If yes complete questions below)

Packaged from the original manufacturer's container:

Yes ☐ No ☐ N/A ☐ The pharmacy uses a lot number and expiration date assigned by the pharmacy instead of the distributor or manufacturer information in a master log if kept with respect to drugs that are packaged within the pharmacy facility from the original manufacturer's container which includes the:

Yes ☐ No ☐ N/A ☐ Name of drug;

Yes ☐ No ☐ N/A ☐ Strength;

Yes ☐ No ☐ N/A ☐ Manufacturer;

Yes ☐ No ☐ N/A ☐ Lot Number assigned by the pharmacy;

Yes ☐ No ☐ N/A ☐ Lot number assigned by the distributor or manufacturer;

Yes ☐ No ☐ N/A ☐ Quantity packaged;

Yes ☐ No ☐ N/A ☐ Manufacturer's expiration date;

Yes ☐ No ☐ N/A ☐ Lot number assigned by the distributor or manufacturer;

Yes ☐ No ☐ N/A ☐ Date of packaging;

Yes ☐ No ☐ N/A ☐ Name of the pharmacy technician who performed packaging functions; and

Yes ☐ No ☐ N/A ☐ Name and initials of verifying licensed pharmacist.

Packaged from Another Pharmacy:

Yes ☐ No ☐ N/A ☐ The licensed pharmacist packages medication received from another pharmacy licensed in Maryland or operated by the government of the United States provided that:

Yes ☐ No ☐ N/A ☐ (1) The licensed pharmacist determines that the medication has been handled in a manner which preserves the strength, quality, purity, and identity of the drug or device during an interim period between the time it was dispensed by the original pharmacy and to directly send medication to the packaging pharmacy;

Yes ☐ No ☐ N/A ☐ (2) The licensed pharmacist packages and dispenses all at one time the entire quantity of the prescription medications received from another pharmacy for packaging;

Yes ☐ No ☐ N/A ☐ (3) The manufacturer's name is present on the container received from the other pharmacy; and

Yes ☐ No ☐ N/A ☐ (4) The licensed pharmacist maintains a master log that includes the following information:

Yes ☐ No ☐ N/A ☐ (a) Name of the drug;

Yes ☐ No ☐ N/A ☐ (b) Lot number assigned by the packaging pharmacy;

Yes ☐ No ☐ N/A ☐ (c) Strength;

Yes ☐ No ☐ N/A ☐ (d) Manufacturer;

Yes ☐ No ☐ N/A ☐ (e) Name, address, and telephone number of the original dispensing pharmacy;

Yes ☐ No ☐ N/A ☐ (f) Prescription number for the original dispensing pharmacy;

Yes ☐ No ☐ N/A ☐ (g) Quantity packaged;

Yes ☐ No ☐ N/A ☐ (h) Expiration date as assigned by the original dispensing pharmacy;

Yes ☐ No ☐ N/A ☐ (i) Date of packaging;

Yes ☐ No ☐ N/A ☐ (j) Name of pharmacy technician who performed packing function;

Yes ☐ No ☐ N/A ☐ (k) Name and initials of verifying licensed pharmacist; and

Yes ☐ No ☐ N/A ☐ (l) Name of the patient.

Comments:_____

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18. CONSULTANT SERVICES

Yes ☐ No ☐ There are written policies for and documentation of timely medication review by consulting pharmacists at all sites.

19. DELIVERY SERVICES

Yes ☐ No ☐ There are policies for and documentation of timely delivery of medications to all sites.

Yes ☐ No ☐ There are policies for and documentation of timely delivery of controlled dangerous substances to all sites.

Inspectors Comments:

Inspector Signature_____

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

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

FINAL 1/05/2015

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	_____	(G) = (F-E) or (E-F)
		Excess Shortage

INVOICE REVIEW

CII:

_____
_____
_____

CIII - CV:

_____
_____

PRESCRIPTION REVIEW

CII #
DATE

COMMENTS:

_____
_____
_____
_____

CIII - CV #
DATE

COMMENTS:

_____
_____
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_____