CANNON BUILDING
861 SILVER LAKE BLVD., SUITE 203
DOVER, DELAWARE 19904-2467

STATE OF DELAWARE

BOARD OF PHARMACY

TELEPHONE: (302) 744-4500
FAX: (302) 739-2711
WEBSITE: DPR.DELAWARE.GOV
EMAIL: customerservice.dpr@state.de.us

COMMUNITY PHARMACY PHARMACIST-IN-CHARGE SELF-INSPECTION REPORT INSTRUCTIONS

Purpose of the Self-Inspection Report

The Pharmacist-in-Charge (PIC) and all pharmacists on duty are responsible for ensuring that their pharmacies comply with all state and federal laws governing pharmacy practice. The primary purpose of this form is to guide you through a self-inspection that will help you identify and correct areas of non-compliance with state and federal law. Board inspectors will also use the completed form to evaluate the pharmacy's level of compliance.

When a Board inspector identifies an area of deficiency, he or she may issue a Deficiency Notice. The PIC is required to respond in writing. Identifying and correcting an area of non-compliance *before* the Board inspection can eliminate the Deficiency Notice. *Note that neither the self-inspection nor Board inspection evaluates your compliance with all the laws and rules of the practice of pharmacy.*

When conducting your self-inspection, it is important to take the time to review the relevant sections of law and regulations and then to personally verify that your pharmacy is in compliance. Avoid *assuming* that your pharmacy is compliant even if "that's the way it has been for years." Note that not having (or not being able to readily retrieve) required documents and records is a common deficiency cited during unannounced inspections. Maintain all such documents in a well-organized manner, such as a binder, and accurately describe the location(s) of the required documents on your *Self-Inspection Report*, if the required documents are readily available to the inspectors, even when you are not present during the inspection, you can reduce your chance of receiving a Deficiency Notice in this area.

If you have questions during your self-inspection, you may contact an inspector by emailing customerservice.dpr@state.de.us or call (302) 744-4500.

When to Complete Self-Inspection Report

The PIC of a Delaware-licensed community pharmacy must complete this *Self-Inspection Report*:

- within 30 days of your first being designated as PIC, ***and***
- by February 1 of each year while you continue as the PIC.

Section 3.1.2.7 of the Board's Rules and Regulations describes this requirement. Failure to complete the *Self-Inspection Report* when required, as explained above, may result in disciplinary action.

Completing and Retaining the Report

☐ Complete all items on the self-inspection report form.

- The form provided online is fillable and savable on your computer. It is suggested that you print the form and complete it by hand as you inspect the various aspects of your pharmacy. You may then transcribe your responses to the fillable form.
- Carefully confirm whether or not you are compliant and mark the appropriate box to the right of each item. If you have any deficiencies please correct them and explain what measures you took and the date of correction next to the question.

☐ Review the report with your staff pharmacists, technicians and interns.

☐ ***INFORM ALL PHARMACISTS AND PHARMACY STAFF WHERE THE SELF INSPECTION FORM IS LOCATED. THE STAFF MUST BE ABLE TO LOCATE THIS FORM AT THE TIME OF ANY BOARD OF PHARMACY INSPECTION***

☐ ***Print out and Sign*** the completed report form.

☐ Retain the completed and signed printout of the form on-site at the pharmacy so that it is immediately available for inspection at all times, even if you are not present when an unannounced inspection occurs.

- Retaining a copy of the completed form on your computer is ***not*** sufficient.
- ***Do not mail the completed form to the Pharmacy Board office.***

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COMMUNITY PHARMACY PHARMACIST-IN-CHARGE SELF-INSPECTION REPORT

Date PIC Self-Inspection was performed: _____ /_____ /_____

PHARMACY INFORMATION

Name of Pharmacy (as shown on license): _____

Delaware Pharmacy License Number: A3 - _____ Controlled Substances Registration PH - _____

DEA Registration #: _____

Location Address: _____
Street (*No PO Boxes*)

_____ _____ _____
City State Zip

Phone: _____ Fax: _____ Email: _____

Enter hours of operation:

	PHARMACY DEPARTMENT HOURS	STORE HOURS
Weekdays	_____ AM to _____ PM	_____ AM to _____ PM
Saturday	_____ AM to _____ PM	_____ AM to _____ PM
Sunday	_____ AM to _____ PM	_____ AM to _____ PM
Holidays	_____ AM to _____ PM	_____ AM to _____ PM

1. PHARMACY PERSONNEL INFORMATION

PIC Name (as shown on license) _____ Pharmacist License No A1 - _____

Enter date (month/day/year) that you became PIC for this pharmacy: _____

List all other registered pharmacists who will be dispensing at the Pharmacy.

FULL NAME	LICENSE NUMBER
	A1-_____
	A1-_____
	A1-_____
	A1-_____
	A1-_____
	A1-_____

List all support personnel including pharmacy technicians, pharmacy interns, and pharmacy students and any certificate number, if available.

FULL NAME	CERTIFICATE NUMBER

PHARMACY PERSONNEL INFORMATION, Continued

INSPECTION QUESTION		CORRECTIVE ACTION/DATE
Are all supportive personnel under immediate supervision of a pharmacist (24 *Del. C.*§2507)?	**Yes** ☐ **No** ☐	
Do the pharmacy technicians perform only tasks permitted by Section 19.2 of the Pharmacy Rules and Regulations?	**Yes** ☐ **No** ☐	
Is the schedule for technical support available during all pharmacy operation hours as described by Section 3.8 of the Pharmacy Rules and Regulations?	**Yes** ☐ **No** ☐	

2. RECORDS, REFERENCE MATERIALS AND OTHER DOCUMENTS

List where each of the following items is located inside the pharmacy. ***Be as specific as possible (e.g., "file cabinet drawer").***

RECORD	LOCATION
Current Delaware laws, regulations and alerts (if not electronic):	
PIC Self-Inspection Reports for last three years	
Biennial controlled substance inventory	
Schedule II-V invoices for last three years	
Completed CII order forms (DEA form 222) for last three years	
Current CPR cards and immunization certification documents	
Support personnel training manual and documentation of training	

3. REFERENCE MATERIALS

INSPECTION QUESTION		CORRECTIVE ACTION/DATE
Are reference materials current and available in either hard copy or electronic form ?	**Yes** ☐ **No** ☐	
Do the reference materials include all of the following as required by the sections of the Pharmacy Rules and Regulations shown?		
• Provide information on the therapeutic use, dosing, pharmacology, adverse effects, and interactions of drugs dispensed to patient (Section 3.3.2.1)?	**Yes** ☐ **No** ☐	
• Provide information helpful in the counseling of patients on the use of drugs dispensed (Section 3.3.2.2)?	**Yes** ☐ **No** ☐	
• Enable the pharmacist to properly compound medicines within accepted standards of pharmacy practice (Section 3.3.2.3)?	**Yes** ☐ **No** ☐	
• Include a list of therapeutic equivalents for drugs dispensed (Section 3.3.2.4)?	**Yes** ☐ **No** ☐	
• Include current Delaware and federal laws and regulations governing pharmacy and controlled substances (Section 3.3.2.5)?	**Yes** ☐ **No** ☐	
• Provide any other information necessary to the safe and effective practice of pharmacy for the specific practice setting (Section 3.3.2.6)?	**Yes** ☐ **No** ☐	

4. PHARMACY POLICIES & PROCEDURES

In addition to location, list policy number and page where each of the following is found.

POLICY/PROCEDURE	LOCATION	POLICY NUMBER & PAGE
Dispensing of pharmaceuticals		
Monitoring & removing recalled, outdated drugs		
Automated dispensing systems		
Delegation for authority when PIC is not available		
Compounding		
Vaccinations		
Quality assurance		
Long term care		

5. LICENSES & PERMITS

INSPECTION QUESTION		CORRECTIVE ACTION/DATE
Have you verified that all wholesalers from which you purchase medication are licensed/registered in Delaware? Enter names and license/ registration numbers of primary and secondary wholesalers: Primary: _____ _____ Secondary: _____ _____	Yes ☐ No ☐	
Are all pharmacists, technicians and interns aware that they should report arrests, convictions and suspected and known violations to the Board?	Yes ☐ No ☐	
Are each of the following items posted, displayed or plainly visible?		
• Current Federal and State Registrations/permits?	Yes ☐ No ☐	
• Current licenses of the pharmacists that practice at this location?	Yes ☐ No ☐	
• Sign with the name of pharmacist on duty and name of the PIC?	Yes ☐ No ☐	
• Sign stating that medication errors may be reported to Board of Pharmacy?	Yes ☐ No ☐	
• Sign stating that patient can request lot and expiration date of medication at the time Rx is filled?	Yes ☐ No ☐	

6. PHYSICAL FACILITIES Section 3.4 of the Pharmacy Rules and Regulations

INSPECTION QUESTION		CORRECTIVE ACTION/DATE
Does the pharmacy have sufficient size, space, sanitation, and environmental control for adequate distribution, dispensing, and storage of drugs and devices including a sink with hot and cold water, shelves, refrigerator/freezer, narcotic cabinets and safes and counter areas which are adequate to avoid crowding?	Yes ☐ No ☐	
Is the temperature monitored and maintained (keep logs for refrigerator and freezer)?		
• Room temp maintained at (58°-77°F)	Yes ☐ No ☐	
• Refrigerator temperature maintained (36°- 46°F)	Yes ☐ No ☐	
• Freezer temperature maintained at (-13°-14°F)	Yes ☐ No ☐	
• Are logs present for all areas listed above (room temp/refrigerator/freezer) with an area to document corrective action if a temperature is out of range	Yes ☐ No ☐	
• Are refrigerator temperatures checked twice a day if the refrigerator contains vaccines as per CDC requirements?	Yes ☐ No ☐ N/A ☐	
Is the pharmacy area, kept clean and free of clutter (including refrigerator, sink, counting trays, automated dispensing machines, floors, etc.)?	Yes ☐ No ☐	
Does the pharmacy have all the required equipment and is the equipment in good working order?	Yes ☐ No ☐	
Is there adequate key control (24 *Del. C.*§2533)?		
• Is the key in possession of the pharmacist only?	Yes ☐ No ☐	
• Does the procedure for storage and documentation of the use of a spare key prevent authorized access?	Yes ☐ No ☐	
• Describe the procedure used when floater obtains key: _____ _____		
Do the building standards and security meet the requirements of Sections 3.5 and 3.6 of the Pharmacy Rules and Regulations?		
• Is a minimum of nine square feet partitioned area available for counseling?	Yes ☐ No ☐	
• Is the counseling area set apart by 5-foot dividers on two sides?	Yes ☐ No ☐	
• When the prescription department and front store hours are different, is a floor-to-ceiling physical barrier used?	Yes ☐ No ☐ N/A ☐	
• Is the "No professional services rendered" sign posted when the prescription department is closed?	Yes ☐ No ☐ N/A ☐	
• Are filled prescriptions stored only in the department or a secured storage area?	Yes ☐ No ☐	

7. PATIENT COUNSELING Section 5.2 of the Pharmacy Rules and Regulations

. INSPECTION QUESTION		CORRECTIVE ACTION/DATE
How is a new prescription identified as requiring counseling for new and refill? _____ _____		
Is a patient's refusal/acceptance of counseling documented? Describe type of record kept:_____	**Yes** ☐ **No** ☐	
Does the record indicate who made the offer to counsel?	**Yes** ☐ **No** ☐	
Does the record indicate who counseled the patient?	**Yes** ☐ **No** ☐	
Is written information also provided?	**Yes** ☐ **No** ☐	
Is counseling conducted in a confidential manner?	**Yes** ☐ **No** ☐	
Are the following included with all prescriptions that are delivered to the patient? • Written information about the prescription? • Phone number and hours that a pharmacist is available to answer questions?	 **Yes** ☐ **No** ☐ **Yes** ☐ **No** ☐	

8. COMPOUNDING PHARMACY Section 5.1.6 of the Pharmacy Rules and Regulations

INSPECTION QUESTION		CORRECTIVE ACTION/DATE
Is all compounding (NOT including reconstituting antibiotics) performed only by the R.Ph.?	**Yes** ☐ **No** ☐	
• **If NO**, is a log maintained showing the identity of the compounding person?	**Yes** ☐ **No** ☐	
• Is a log maintained, per FDA, that lists all of the ingredients and product information used in the compound (manufacturer, lot number, manufacturers expiration date, quantities used)?	**Yes** ☐ **No** ☐	
If compounding is done by support personnel, does the R.Ph. check each step?	**Yes** ☐ **No** ☐ **N/A** ☐	
Is the pharmacy performing sterile compounding?	**Yes** ☐ **No** ☐	

9. REPACKING PHARMACY Section 6.3 of the Pharmacy Rules and Regulations

INSPECTION QUESTION		CORRECTIVE ACTION/DATE
Is the pharmacy performing re-packing? **If NO,** skip to section **10. DISPENSING PHARMACY**.	**Yes** ☐ **No** ☐	
When repackaging is done, does the log show the date repacked, the control number, the expiration date, the name and strength of the drug, and the person who prepared it?	**Yes** ☐ **No** ☐	
If not repacked by a pharmacist, is there notation of the pharmacist's check?	**Yes** ☐ **No** ☐	

10. DISPENSING PHARMACY Section 5.0 of the Pharmacy Rules and Regulations

INSPECTION QUESTION		CORRECTIVE ACTION/DATE
Are automatic counting devices used in the pharmacy? • **If NO, SKIP TO THE NEXT QUESTION in <u>this</u> section.** • **If YES, does each cell contain the following:**	 **Yes** ☐ **No** ☐	
a. Name of the drug?	**Yes** ☐ **No** ☐	
b. Manufacturer's name and NDC?	**Yes** ☐ **No** ☐	
c. Date filled?	**Yes** ☐ **No** ☐	
d. Batch/lot number and expiration date of the batch/lot?	**Yes** ☐ **No** ☐	
Are all prescriptions maintained for a period of three years?	**Yes** ☐ **No** ☐	
When a generic drug is dispensed, is the manufacturer or distributor noted on the original prescription and the label?	**Yes** ☐ **No** ☐	
Are the initials of the filling/refilling pharmacist noted on the prescription and/or computer record?	**Yes** ☐ **No** ☐	

11. PATIENT PROFILES Section 5.1.10 of the Pharmacy Rules and Regulations

INSPECTION QUESTION	CORRECTIVE ACTION/DATE
What type of profile do you use? ☐ **Manual** ☐ **Computerized**	
Are profiles checked prior to dispensing new and refill prescriptions? **Yes** ☐ **No** ☐ • **If NO**, explain when profiles are checked: _____ _____	
Check what you record on profile: ☐ **Refills** ☐ **Prescriptions Only** ☐ **Both Refills and Prescription**	
Who performs the data entry (Rx, profile)? ☐ **R.Ph.** ☐ **Support Personnel**	
Are profiles kept for at least one year from date of last entry in profile? **Yes** ☐ **No** ☐	
Do profiles include the following information? a. Patient last and first name, address, phone number? **Yes** ☐ **No** ☐ b. Patient age or DOB? **Yes** ☐ **No** ☐ c. Prescriber's name and, for controlled substances, DEA #? **Yes** ☐ **No** ☐ d. Original dispense date, prescription number, number of refills? **Yes** ☐ **No** ☐ e. Allergy information and chronic diseases? **Yes** ☐ **No** ☐ f. If the answer to allergies and/or chronic diseases is "none," is "none" shown on the patient profile? **Yes** ☐ **No** ☐ g. Documentation of any information the patient refused to provide? **Yes** ☐ **No** ☐ h. Initials of dispensing pharmacist? **Yes** ☐ **No** ☐ i. Documentation of patient's refusal or acceptance of counseling? **Yes** ☐ **No** ☐ j. Pharmacist comments related to OTC use? **Yes** ☐ **No** ☐	

12. COMPUTER SYSTEMS Section 5.1.12 of the Pharmacy Rules and Regulations

INSPECTION QUESTION	CORRECTIVE ACTION/DATE
Who is authorized to enter data into the computer system? _____	
What is the method of entry for each authorized person (e.g., individual access code, general access code)? _____	
Would another pharmacist or support person be able to enter prescription? **Yes** ☐ **No** ☐	
If there is a general access code, can the person who entered the data be identified? **Yes** ☐ **No** ☐	
Is computer used for other store functions? **Yes** ☐ **No** ☐	
Does data entry of patient profiles comply with regulation? **Yes** ☐ **No** ☐	
Does data entry of prescription information comply with regulation? **Yes** ☐ **No** ☐	
Does data entered identify the responsible pharmacist(s) for each step in the dispensing process? **Yes** ☐ **No** ☐	
Does data entered remain online for at least one year from last entry? **Yes** ☐ **No** ☐	
Is data entered from one through three years ago available within five days? **Yes** ☐ **No** ☐	
If pharmacy records of the distribution, receipt, and dispensing of controlled substances are maintained centrally, is a copy of the letter notifying the DEA available? **Yes** ☐ **No** ☐	

13. BACKUP RECORD KEEPING Section 5.1.12.5 of the Pharmacy Rules and Regulations

INSPECTION QUESTION	CORRECTIVE ACTION/DATE
Is there a back-up record-keeping system available if your computer is inoperative? **Yes** ☐ **No** ☐	
Does this back-up record-keeping system ensure that all renewals are authorized? **Yes** ☐ **No** ☐	
Does this back-up record-keeping system give you the ability to enter prescriptions dispensed and renewed while the computer is inoperative? **Yes** ☐ **No** ☐	

14. CONTAINERS

INSPECTION QUESTION		CORRECTIVE ACTION/DATE
Are medications dispensed in containers which comply with USP requirements?	**Yes** ☐ **No** ☐	
Are child-resistant containers used?	**Yes** ☐ **No** ☐	
Is permission to use regular containers (no safety cap) documented?	**Yes** ☐ **No** ☐	

15. LABELING *24 Del C. §2522*

INSPECTION QUESTION		CORRECTIVE ACTION/DATE
Do prescription labels show the following?		
• Prescription number?	**Yes** ☐ **No** ☐	
• Patient name?	**Yes** ☐ **No** ☐	
• Specific directions (no "as directed" prescriptions)?	**Yes** ☐ **No** ☐	
• Drug name and strength?	**Yes** ☐ **No** ☐	
• Prescriber name?	**Yes** ☐ **No** ☐	
• Date of dispensing?	**Yes** ☐ **No** ☐	
• Appropriate auxiliary labels?	**Yes** ☐ **No** ☐	
• Name and address of the dispensing pharmacy?	**Yes** ☐ **No** ☐	

16. PRESCRIPTON TRANSFERS/ EXCHANGE OF VALID NON-CONTROLLED PRESCRIPTIONS BETWEEN PHARMACIES Section 5.1.11 of the Pharmacy Rules and Regulations

INSPECTION QUESTION		CORRECTIVE ACTION/DATE
Do verbal requests for a prescription transfer meet all of the following:		
• Request comes from a registered pharmacist or pharmacy intern or student under the direct supervision of a pharmacist ?	**Yes** ☐ **No** ☐	
• Prescription is immediately reduced to writing and contains the information required on a written prescription as per Section 5?	**Yes** ☐ **No** ☐	
• First and last name of the of the pharmacist transmitting the information is documented on the copied prescription ?	**Yes** ☐ **No** ☐	
• Prescription used for refills is clearly identified as a COPY?	**Yes** ☐ **No** ☐	
• Copy or transfer shows date and file number of the original prescription and indicates the name and address of the pharmacy providing the copy?	**Yes** ☐ **No** ☐	
• Copy shows the last date of dispensing?	**Yes** ☐ **No** ☐	
• Actual number of refills remaining are indicated?	**Yes** ☐ **No** ☐	
• Notation indicating a copy was given and refills are no longer valid is placed on either the original prescription or the patient profile?	**Yes** ☐ **No** ☐	

17. IMMUNIZATIONS Section 14.0 of the Pharmacy Rules and Regulations

INSPECTION QUESTION		CORRECTIVE ACTION/DATE
Is the pharmacy immunizing? • **If NO,** skip to section **18. CONTROLLED SUBSTANCES**.	**Yes** ☐ **No** ☐	
Is proof available onsite that each immunizing pharmacist meets the educational requirements, including a current CPR certification, two hours of continuing education on immunization and a completed certification of immunization?	**Yes** ☐ **No** ☐	
Has the immunizing pharmacist(s) submitted their educational requirements and CPR certification to the Board of Pharmacy so they are licensed as an Immunizing Pharmacists?	**Yes** ☐ **No** ☐	
Is there a Policy and Procedure manual on immunization?	**Yes** ☐ **No** ☐	
Are prescriptions or the physician-approved protocol current and available for inspection?	**Yes** ☐ **No** ☐	
Are all immunization patients counseled and given written information?	**Yes** ☐ **No** ☐	
Are signed copies of patient immunization consent forms retained?	**Yes** ☐ **No** ☐	

IMMUNIZATIONS Section 14.0 of the Pharmacy Rules and Regulations, Continued

INSPECTION QUESTION		CORRECTIVE ACTION/DATE
Does documentation of each injection include the following?		
• Patient name, address, phone number?	Yes ☐ No ☐	
• Patient DOB and gender?	Yes ☐ No ☐	
• Name of medication administered, lot and expiration date?	Yes ☐ No ☐	
• Administration site, dose, date of order and date of administration?	Yes ☐ No ☐	
• Prescriber name?	Yes ☐ No ☐	
• Name of pharmacist administering the injection?	Yes ☐ No ☐	
Is all documentation retained for at least three years?	Yes ☐ No ☐	
Is documentation of vaccinations reported to the Division of Public Health Immunization Registry as required?	Yes ☐ No ☐	

18. CONTROLLED SUBSTANCES 21 CFR 1300-1306

INSPECTION QUESTION		CORRECTIVE ACTION/DATE
Are U.S. Official Order Form-Schedule II (DEA Form 222) (21 CFR 1305) and un-negotiated forms secure?	Yes ☐ No ☐	
Are the DEA Form 222s properly executed and retained for at least two years (21 CFR 1305.12)?	Yes ☐ No ☐	
Regarding invoices of controlled substances (21 CFR 1304.04 f 1, 2):		
• Are Schedule II order forms and invoices filed separately?	Yes ☐ No ☐	
• Are Schedule III – V invoices signed and dated upon receipt and filed separately from other invoices?	Yes ☐ No ☐	
• Are all invoices retained for at least two years?	Yes ☐ No ☐	
Regarding controlled substances that are returned for disposal (21 CFR 1307.21):		
• Are the drugs returned for disposal via the reverse distributor?	Yes ☐ No ☐	
• Are DEA Form 41 filed properly and retained for two years?	Yes ☐ No ☐	
Has there been any loss of controlled substances since the last review?	Yes ☐ No ☐	
• **If YES**, did you complete and submit a report of theft/loss of controlled substances to the Board and DEA (21 CFR 1301.76(b))?	Yes ☐ No ☐	
Was a biennial inventory of controlled substances completed (21 CFR 1304.11c)?	Yes ☐ No ☐	
• **If YES, enter DATE COMPLETED:** _____		
Did the Pharmacist-in-Charge (PIC) change after the last self-inspection?	Yes ☐ No ☐	
• **If YES,** answer these questions:		
a. PIC Start Date: _____	Yes ☐ No ☐	
b. Was the Pharmacy Board notified about the PIC change within ten days and was a copy of the notification retained onsite?	Yes ☐ No ☐	
c. Did the departing and incoming PICs do a complete inventory of controlled substances, submit it to the Office of Controlled Substances and retain a copy onsite?	Yes ☐ No ☐	
Do prescriptions for controlled substances contain each of the following:		
• Patient's name and address?	Yes ☐ No ☐	
• Prescriber's name, address, phone number, and DEA #**?**	Yes ☐ No ☐	
• Date of issue?	Yes ☐ No ☐	
• Drug name, strength and quantity?	Yes ☐ No ☐	
• Specific directions?	Yes ☐ No ☐	

CONTROLLED SUBSTANCES 21 CFR 1300-1306, Continued

INSPECTION QUESTION		CORRECTIVE ACTION/DATE
Does the prescriber verify all verbal prescriptions for controlled substances?	**Yes** ☐ **No** ☐	
Regarding Schedule II prescriptions:		
• Filled separately from other prescriptions?	**Yes** ☐ **No** ☐	
• Filled within seven days of issue in a quantity of not more than 100 or a 31-day supply, whichever is greater?	**Yes** ☐ **No** ☐	
• Properly cancelled and signed by the filling pharmacist ?	**Yes** ☐ **No** ☐	
• Not partially filled unless noted on the prescription that the patient is in a long-term care facility ("LTCF") or is "terminally ill" and not exceeding 60 days from issue?	**Yes** ☐ **No** ☐	
• Listed in a perpetual inventory to audit on-hand quantities for accuracy? (Not a requirement)?	**Yes** ☐ **No** ☐ **N/A** ☐	
Are OTC sales of pseudoephedrine products recorded and checked on line?	**Yes** ☐ **No** ☐	
Are pseudoephedrine products reported to The National Data Base?	**Yes** ☐ **No** ☐	
Is this pharmacy distributing controlled substances to other registrants including pharmacies, hospitals and practitioners?	**Yes** ☐ **No** ☐	
• **If YES, answer these questions:**		
a. Are the Schedule II controlled substances distributed via DEA Form 222?	**Yes** ☐ **No** ☐	
b. Are the Schedule III-V controlled substances distributed via invoice?	**Yes** ☐ **No** ☐	

19. CONTROLLED SUBSTANCES AUDIT

Complete a controlled substances audit for THREE (3) drugs as directed by the Board. The table at right shows the recommended drugs for the PIC to audit. If you do not dispense *any* of the drugs on the list, choose three drugs (CII) that you frequently dispense.

AUDIT PERIOD	RECOMMENDED DRUGS
2016	**Choose *three of the following drugs*:** • Oxycodone 10 mg tabs or capsules • Oxycodone 5 mg/Acetaminophen 325 mg • Methadone 10 mg • Hydrocodone 5 mg/325 mg • Oxycodone CR (controlled release) 20 mg tabs • Fentanyl patches 25 micrograms

Complete the following table and calculate the percentage discrepancy as shown. ***Submit a report to the Board within 30 days to explain a discrepancy greater than 0.2% for Schedule II medications.***

AUDIT PERIOD *(must be a minimum of three months):*	
FROM DATE OF LAST BIENNIAL INVENTORY: _____	**TO DATE OF DRUG AUDIT: _____**

Audit three drugs that were dispensed during the audit period. It is NOT ACCEPTABLE to choose drugs that were not purchased or dispensed during the audit period and then reporting "zero" sales.

NAMES OF DRUGS AUDITED	LAST INVENTORY	PURCHASES SINCE INVENTORY	SALES SINCE INVENTORY	CALCULATED AMOUNT (=Last Inventory PLUS (+) Purchases , then subtract (-) Sales)	CURRENT INVENTORY	DISCREPANCY (subtract Current Inventory (-) from Calculated Amount)	% DISCREPANCY (divide Discrepancy by sum of Last Inventory and Purchases, then multiply by 100)
Sample	*300*	*700*	*600*	*400*	*350*	*50*	*5%*

IF YOU HAVE CONCERNS ABOUT THE AUDIT, CONTACT THE OFFICE OF CONTROLLED SUBSTANCES FOR CLARIFICATION.

CERTIFICATION

Delaware law holds the pharmacist-in-charge responsible for ensuring pharmacy compliance with all state and federal laws governing the practice of pharmacy. Failure to do so may result in fines and/or actions against the pharmacy and/or pharmacist license.

I, _____, Delaware Pharmacist license # A1 - _____, hereby certify that I have completed the self-inspection of this pharmacy of which I am pharmacist-in-charge. I understand that all responses are subject to verification by the Board of Pharmacy and/or the Office of Controlled Substances. I further state under penalty of perjury that the information contained in this self-inspection form is true and correct to the best of my knowledge and belief.

Signature of Pharmacist-in-Charge: _____ Date: _____