



**STATE OF
OHIO**
BOARD OF PHARMACY



Guidance Document

What Provisional Dispensary Licensees Can Expect During an Inspection

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**Ohio Medical Marijuana Control Program
What Provisional Dispensary Licensees Can Expect During an Inspection**

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I. Document Purpose, Audience and Topics Covered

A. Document Purpose

This reference document is designed to provide an overview to Provisional Dispensary Licensees (PDLs) regarding what to expect during both Pre-inspections and Final inspections. Its objectives are to:

- Provide guidance to PDLs—though not all inclusive;
- Clarify compliance requirements for the award of a certificate of operation;
- Ensure accurate representation of application responses and approved variances.

B. Intended Audience

The intended audience for this document includes individuals employed by or acting on behalf of a PDL.

C. Topics Covered

The topics covered in this guidance document include:

- When to schedule pre-inspections and final inspections
- What PDLs can expect during an inspection

II. Applicable Rules and Definitions

PDLs are advised to review and understand Division 3796:6 of the Ohio Administrative Code, which includes the following Chapters:

Definitions	Chapter 3796:6-1
Licensing	Chapter 3796:6-2
Operations	Chapter 3796:6-3
Enforcement	Chapter 3796:6-4
Fees	Chapter 3796:6-5

PDLs are also advised to understand [Division 3796:8](#) of the Ohio Administrative Code, which sets forth the products that may be accepted from cultivators and processors.

III. During an Inspection (Pre/Final)

Pre-inspections should only be requested once the PDL can demonstrate adherence to what was submitted in its dispensary application. Prior to scheduling a pre-inspection, dispensaries need to complete compliance tasks assigned by State Board of Pharmacy personnel and consider the status of the following requirements:

1. Designated representative is selected, licensed and identified in eLicense;
2. Marketing and advertising materials, training materials, labels, logos and DBAs have been submitted for review and approved;
3. All structural and time variances have been submitted and reached resolution;
4. Surety bond is filed and a copy is on file with the Board;
5. Registration with the Ohio Business Gateway is completed and PDL is registered for employer withholding as well as sales tax;
6. Foundational training for all requisite staff is completed;
7. METRC system preparedness (including online training) is completed; and
8. Prepared to complete point-of-sale testing during pre-inspection.



A pre-inspection is intended to identify outstanding issues, the remediation of which may serve as evidence of compliance with applicable statutes and rules. A pre-inspection can be scheduled but will not be executed without completing all the above-referenced tasks. A final inspection will not be scheduled without evidence of compliance with the applicable statutes and rules.

For a PDL to be prepared for METRC / OARRS point-of-sale (POS) testing (or “end-to-end testing”), the following needs to occur:

1. Designated Representative and POS vendor review the Data Submitter Guide available on the Licensee Resources Page;
2. Designated Representative completes online METRC and Appriss training;
3. Designated Representative contacts METRC helpdesk to get credentials issued for METRC production environment;
4. Designated Representative generates and provides provisional dispensary API to their chosen POS vendor;
5. PDL establishes supporting data (Room Setup);
6. PDL creates a PMP Clearinghouse account (APPRISS);
7. PDL or POS vendor can add sFTP access to PMP clearinghouse account and configures sFTP submission destination.

During end-to-end testing, a PDL must confirm:

1. Test package is received and accepted by the PDL;
2. POS retrieves package data from METRC;
3. PDL transfers the package to established room;
4. PDL confirms that that the POS can identify the METRC Product ID from the test package;
5. Test Patient data is manually entered into the POS for the transaction;
6. Test DEA number for Dispensary & CTR Physician entered in POS (use DEA number OH1111119 for test purposes only);
7. PDL posts sale of test Item to METRC via POS and prints sales receipt;
8. POS transmits transaction data to PMP Clearinghouse or DR undertakes manual submission process; and
9. PDL verifies the sale with adjustment to the test package inventory in METRC.

Upon successful completion of the end-to-end testing, a PDL must:

1. Discontinue test data in METRC (Rooms);
2. PDL adjusts the test package to zero with a “State Ordered Destruction” reason;
3. PDL finishes the package;
4. PDL runs initial End of Day Report;
5. PDL voids the sale in POS;and
6. PDL runs revised End of Day Report.



Additional items to be reviewed / tested during inspections include:

- External signage compliance
- Landscaping compliance
- External trash security
- Security lighting
- Vault compliance
- Delivery / Receiving protocol
- Destruction area
- Security of doors and locks
- Authorized access to facility protocol
- Access logs and protocol (e.g. who has alarm code(s) and key)
- Video surveillance and alarm systems
- Internal signage (e.g. Do Not Enter, Edible Marijuana Warning placard, and MMCP Helpline)
- Temperature controlled spaces and cleanliness
- Opaque, non-identifiable bags
- Recordkeeping
- Employee Training Records
- Positive ID

After receiving notice of a satisfactory final inspection from the State of Ohio Board of Pharmacy, the PDL is required to remit payment of the two-year certificate of operation fee before the PDL's certificate of operation will be activated.

A dispensary may begin receiving and dispensing medical marijuana only after receipt of a medical marijuana dispensary certificate of operation issued by the State of Ohio Board of Pharmacy. **A Dispensary does not have an active Certificate of Operation until notified in writing by the State of Ohio Board of Pharmacy's Licensing Department.** Although payment has been submitted, and the license tile may show "Active" when logged into the eLicense.ohio.gov account, this does NOT mean that the Certificate of Operation has been issued. When the Certificate of Operation is issued, the Primary Contact and Designated Representative will be notified by e-mail, with the Certificate of Operation attached.



IV. Agent Territories and Contact Information

The State Board of Pharmacy encourages all PDLs to contact their respective Agent with any questions regarding Pre-inspections and Final inspections.

