

***Gameday Ready: Strategies for Controlled
Substance Oversight, Continuous Audit
Readiness, and Inspection Response That
Win Every Time***

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Pharmacy Forward: Advancing Practice for a
Healthier Tomorrow!

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Disclosure Statement

- Jaime McDermott has no relevant financial relationship(s) with ineligible companies to disclose.
and
- None of the planners for this activity have relevant financial relationships with ineligible companies to disclose.





Learning Objectives

At the completion of this activity, the participant will be able to:

1. **Identify Key Regulatory Bodies and Their Audit Focus Areas**
2. **Describe Best Practices for Maintaining Continuous Audit Readiness**
3. **Outline an Effective Inspection Response Plan**
4. **Discuss Internal Compliance Monitoring and Self-Audit Capabilities**

Assessment Question #1



What may trigger a DEA Inspection?



- A. Past violations or corrective actions
- B. Complaints
- C. ARCOS outliers
- D. All of the above



Assessment Question #2



What is one best practice for maintaining continuous audit readiness in a pharmacy setting?



- A. Conducting internal audits only after receiving an inspection notice.
- B. Storing controlled substance records off-site for convenience.
- C. Implementing routine inventory reconciliation and staff training.
- D. Waiting for regulatory updates before updating SOPs.



Assessment Question #3



What is a key component of an effective inspection response plan?



- A. Allowing any available staff member to lead the inspection.
- B. Preparing a designated inspection binder or FAQ and communication protocol.
- C. Avoiding documentation during the inspection to reduce liability.
- D. Postponing the inspection until leadership is available.



Assessment Question #4



What is the primary purpose of internal monitoring?













- A. Punishment
- B. Risk mitigation and improvement
- C. Reducing workload
- D. Avoiding inspections



Key Regulatory Bodies and Their Audit Focus Areas

MATRIX OF REGULATORY AGENCIES AND THEIR AUDIT FOCUS AREAS

	 Security	 Recordkeeping	 Licensing	 Billing	 Documentation
 DEA	✓	✓	✓	✓	✓
 STATE BOARDS PHARMACY	✓	✓	✓		✓
 FDA	✓	✓	✓	✓	✓
 CMS/ MEDICAID AUDITORS	✓	✓	✓		✓
 NABP	✓	✓	✓	✓	✓

Key factors

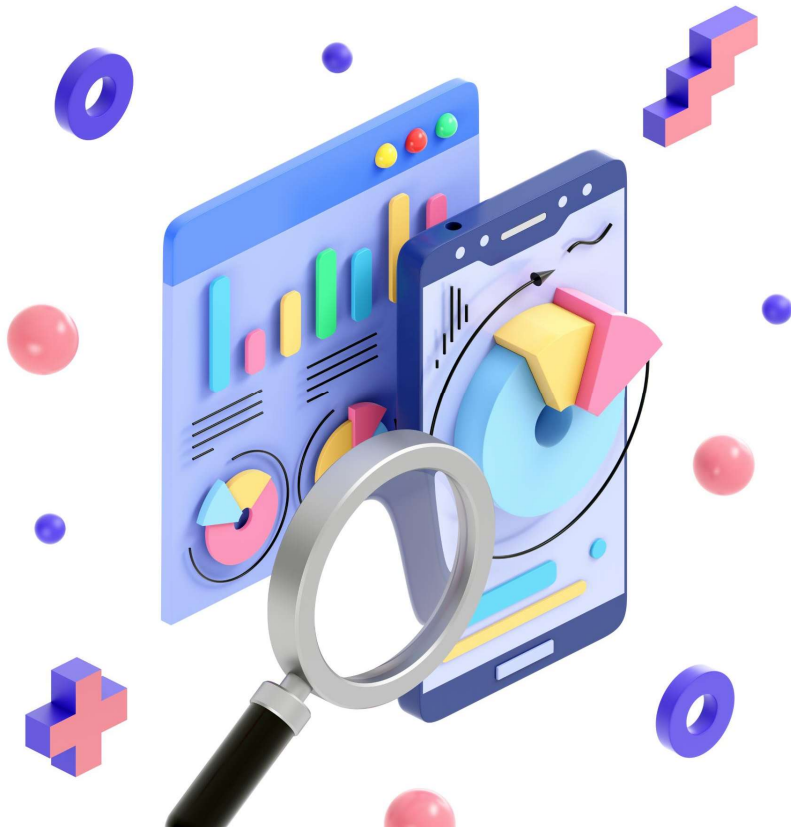
- Your practice setting
 - Hospital, Community, Mail Order
 - Compounding
- Your location

Other possible agencies

- State Controlled Substance Authority
 - May be Board of Pharmacy or separate entity
- Accrediting bodies:
 - NABP
 - Joint Commission
 - URAC
- Payors



Common Inspection Triggers



Routine Inspections

- Workplan

Data Anomalies

- ARCOS outliers
- PDMP reporting

Past Violations or Corrective Actions

Employee Complaints

- Complaints or reports from employees about unethical practices can prompt audits to investigate the claims.

Referrals from Other Agencies

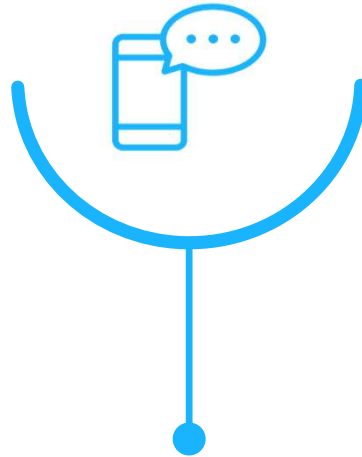
- MCOs, PBMs, CMS
- State Medicaid Fraud Units (MFU)



Your Inspection Game Time Goals



**Expect an
Inspection**



**Prepare
for an
Inspection**



**Manage the
Inspection**



DEA Inspections

Elements of an Inspection



LICENSING



RECORDS AND
INVENTORIES



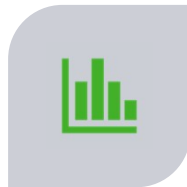
SECURITY



DRUG DISPOSAL/
DESTRUCTION



MEDICAL
RECORDS



REPORTING

Primary purpose is to ensure compliance with the Controlled Substance Act – ensuring a **closed system of distribution**



On-Site Inspection

Authority to Inspect – DEA Entry to Facility

- Notice of Inspection (DEA Form 82)
- Administrative Inspection Warrant
- Criminal Search Warrant

U.S. DEPARTMENT OF JUSTICE DRUG ENFORCEMENT ADMINISTRATION	
NOTICE OF INSPECTION OF CONTROLLED PREMISES	
<small>DEA USE ONLY</small>	
<small>FILE NUMBER</small>	
<small>NAME OF INDIVIDUAL</small>	<small>TITLE</small>
<small>NAME OF CONTROLLED PREMISES</small>	<small>DEA REGISTRATION NO.</small>
<small>NUMBER AND STREET</small>	<small>DATE</small>
<small>CITY AND STATE</small>	<small>ZIP CODE</small> <small>TIME (Initial inspection)</small>
STATEMENT OF RIGHTS	
<small>1. You have a constitutional right not to have an administrative inspection made without an administrative inspection warrant.</small>	
<small>2. You have the right to refuse to consent to this inspection.</small>	
<small>3. Anything of an incriminating nature which may be found may be seized and used against you in a criminal prosecution.</small>	
<small>4. You shall be presented with a copy of this Notice of Inspection.</small>	
<small>5. You may withdraw your consent at any time during the course of the inspection.</small>	



Inspection Components

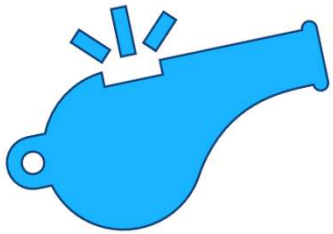
Commonly Requested Items

- List of Employees with CS Access (name, title)
- Copies of licenses/certificates (state/federal)
- Facility floor plan
- CS Required Records
 - Receipts (222s, invoices, CSOS)
 - POA to order CII
 - Dispensing/Distribution Records
 - Records of Returns/Transfers
 - Records of Destruction (DEA Form 41)
 - Theft/Loss Reports (DEA Form 106)
 - Most recent biennial inventory
- Alarm Company Contract
- List of Suppliers – name, address, DEA#
- Corporate Structure/Information – Articles of Incorporation
- Background Check / Drug Screening Information
- Dispensing Metrics (i.e. % of CS scripts)
- Accountability Audit
 - Count certain CS on hand
 - Review receipts, dispensing records for the audit period
 - Calculate any differences



Penalties on the Field

Common Inspection Findings



The best teams don't argue the call — they go back to the plan, fix the discipline issues that caused the flag in the first place.

Improper execution of DEA 222 Forms	Lack of required inventories	Not properly reconciling	Alarm system not checked
POAs and lack of revocations	CS Accountability Audit	Take back of CS	Not notifying DEA of theft/loss
	CSOS login and CSOS recordkeeping	Lack of complete and accurate records	



The Game Plan

Best Practices for Continuous Audit Readiness



DEA Readiness Binder or Job Aid



Recordkeeping System



Regular Checks and Monitoring



Robust Security Measures



Train Staff at Hire and Continuously



Playbook Essentials

Readiness Binder / Job Aid



**Maintain a DEA
Readiness Binder
or Job Aid**

- Current Organization Chart
- List of Corporate Officers
- Current Power of Attorney forms
- Copy of Current DEA and State Registrations/Licenses/Permits
- Copy of CMEA Certificate
- DEA Point of Contact
- Authorized Access List
- Latest Biennial Inventory
- Most Recent Destruction Document
- Approved Supplier List
- Site Map and Facility Floor Plans with security placements
- Name/Contact for Alarm Monitoring and Background Check Companies
- Year End Reports



Playbook Essentials

Effective Recordkeeping Systems

Maintaining accurate and organized records ensures easy access to critical information during audits.

Recordkeeping Readiness

Implement SOP / Recordkeeping System for Required Records

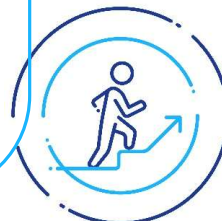
- Maintain SOPs for required records that define what, where, when, who, how long
- Keep all CS records in a single, easily accessible location
- Maintain access controls to records

Perpetual Inventory Systems

Checks and Balances/ Redundancies

Regular Reconciliation Processes

Folder Label	Folder Contents
1. 2025: Controlled Drug Inventories Reference: DEA SOP #501.6	<ul style="list-style-type: none"> o Annual DEA-required controlled drug inventory o Initial inventory for new pharmacies o Required inventory for new pharmacy manager/pharmacist-in-charge (PIC) o Required inventory for acquisitions o Required inventories for controlled drug schedule changes o Other inventories as required by state regulations
2. Power of Attorney (current and revoked) Reference: DEA SOP #501.3	<ul style="list-style-type: none"> o Active Powers of Attorney (POAs) for pharmacists, including Pharmacy Practice Coordinator (PPC), authorized to execute DEA 222 order forms o POAs revoked within the previous 3 years <ul style="list-style-type: none"> • Should include original POA and executed revocation
3. Unexecuted DEA Official Order Forms (DEA Form 222) and Order Form Log Reference: DEA SOP #501.3	<ul style="list-style-type: none"> o Current Order Form Log (a new log is attached, if necessary) o Unexecuted DEA Form 222s, maintained in numerical order by Order Form serial number
4. 2025: CII- Cancelled and Executed DEA Official Order Forms (DEA Form 222) w/ invoices or inventory paperwork attached (folders 4a & 4b) *2 Folders included*	<ul style="list-style-type: none"> o All contents listed below should be maintained in chronological order. May label additional overflow folders 4c, 4d, and so on, if necessary. o CII Purchases (DEA SOP #501.5): Cardinal Invoices (for CSOS) or Executed DEA 222 forms with Cardinal invoice that are appropriately stamped, signed and dated



Defense Wins Games

Robust Security Measures

Implementing robust physical controls, access logs, and alarm systems is crucial for safeguarding assets. These security measures help prevent unauthorized access and potential breaches, adding a layer of protection that supports audit readiness.



Robust Physical Controls

Physical controls, like barriers and surveillance, form the first line of defense.

Integrated Alarm Systems

Central alarm systems and testing protocols

Detailed Access Controls

- Define who/how/what/when
- Utilize access logs
- Automated
- Track exceptions



Run the Drills. Fix the Gaps.

Implement Regular Checks

Conduct frequent internal reviews and checks to ensure all processes are compliant and up-to-date with audit standards.

Inventory Spot-Checks & Cycle Counts

Perform weekly spot-checks focusing on high-risk drugs like CII opioids to promptly identify and address any discrepancies. System driven = improved compliance.

Prompt Discrepancy Investigation

Review manual adjustments regularly and promptly investigate and document any inventory discrepancies to promote accountability and reduce regulatory risks

Documentation and Recordkeeping Checks

Verify all controlled substance records (invoices, dispensing logs, inventory counts) are complete and retrievable. Review for timely entries, accurate dates, and proper segregation of CII vs. CIII–CV records.

Mock Audits

Conduct unannounced internal “mock inspections” to test readiness. Ensure staff can locate key documents (e.g., DEA registration, inventories, Form 222s). Debrief and document outcomes and track action items.



Training Camp Essentials

Ongoing training and audits foster a culture of compliance and continuous audit readiness, ensuring staff are always prepared



Well-defined, standard Policies and Procedures (SOPs)

- Include in new hire training for all applicable associates
- Post SOPs and associated QRG, FAQs, Exhibits, etc. for associates to easily access

Annual Compliance Training

- Regular compliance training
- Diversion Awareness
- Micro learning opportunities
- Drives culture of accountability and vigilance

Pre-Inspection Readiness

- Draft detailed SOPs for responding to regulatory inspections – include in training
- Educate Staff - Readiness Binder or Quick Reference Guide
- Understand your Company policies – what information is in scope vs what isn't



It's Game Time! Are You Ready?



- Decide in advance who will greet the DEA investigators
- Provide a clean and orderly work-space for the investigators
- Ask for a list of documents requested
- Leverage centralized reporting systems
- Make copies of any documents provided
- Conduct a parallel desk audit
- If DEA removes any documents, ask for a receipt
- Maintain a detailed record of all inspection activities and responses to ensure accuracy and accountability during and after the inspection



Post-Game Review

Closing Discussion, Debrief, and Corrective Action Follow-Up

Closing Discussion with DEA

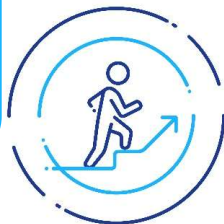
- ✓ Summary of the inspection
- ✓ Clarify discrepancies
- ✓ Make recommendations
- ✓ Ask questions

Post-Inspection Follow-up

- ✓ Review and summarize inspection results
- ✓ Conduct a debrief with all relevant personnel to review the outcomes of the inspection and discuss findings.

Corrective Action

- ✓ Address any findings - implement necessary internal investigations or corrective actions and document the outcomes.
- ✓ Follow up diligently to ensure all corrective measures have been completed satisfactorily and effectively.



Defensive Coordinator/Film Room

Internal Monitoring

This helps ensure compliance with policies, identify areas for improvement, and mitigate risks

Setting the Standards: Your Defensive Playbook

- Establish clear rules of the game – benchmarks, and guidelines ensure organization activities align with policies and objective
 - ✓ Policies/procedures
 - ✓ Risk Metrics
 - ✓ Monitoring Protocols and Workplans
- Define expectations – everyone knows the play, their position and what success looks like

Continuous Observation: Film Room

- Ongoing monitoring = film review and sideline observation
 - Inventory data
 - Dispensing data
 - Self Audits
- Identify misses, gaps, trends and risk early – not after the game is over
- Build Redundancy

Report Findings: Make Halftime Adjustments

- Document and communicate findings objectively – coaching, not personal criticism
- Use standardized reporting tools, like what regulators expect to see
- Turn observations into corrective plays, training, or process changes
- Adjust the game plan before the next drive, not after the final whistle

Strong teams don't wait for penalties to fix their defense – they monitor, adjust and improve continuously



Check the Scoreboard

Self Audit Essentials

Self-audits aren't about penalties — they're about knowing the score and fixing the gaps before the next whistle.

Why Self Audits Matter:

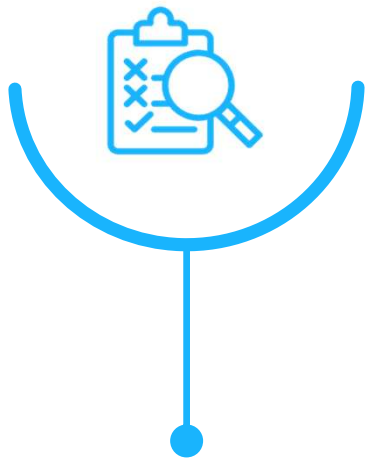
- ✓ Assess an organization's own processes and operations
- ✓ Identify strengths and gaps before inspectors do
- ✓ Improve operational efficiency, not just compliance
- ✓ Turn data into insight using analytics and audit tools

What Strong Teams Do

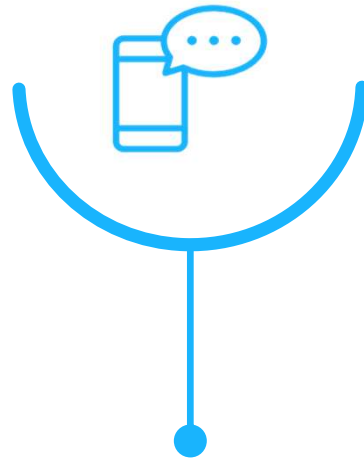
- ✓ Evaluate performance consistently and objectively
- ✓ Track results, trends, and repeat issues over time
- ✓ Use software to document findings and measure improvement



Your Inspection Game Time Goals



Expect an Inspection



Prepare for an Inspection



Manage the Inspection



Assessment Question #1



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