



PREPARING FOR A DEA INSPECTION

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SO YOU'RE HAVING A DEA AUDIT!



ENHANCE PROFITABILITY, STREAMLINE OPERATIONS, AND IMPROVE THE QUALITY OF PATIENT CARE



INSPECTION GOALS

- Expect an Inspection.
- Prepare for an Inspection.
- Manage the Inspection.





FEDERAL REGULATION OF CONTROLLED SUBSTANCES

- The Controlled Substances Act provides authority for the regulation of controlled substances by the DEA.
- DEA regulations promulgated based on CSA.
- DEA is primarily a **law enforcement agency** but is also a **regulatory agency** overseeing legitimate controlled substances and companies.
- The Diversion Control Division, with oversight of 1.8 million registrants, is the regulatory branch within DEA that carries out this function.



CSA CONTROL MECHANISMS



CSA and Regulations





CORRESPONDING RESPONSIBILITY

- A prescription must be issued by a DEA registered prescriber for a legitimate medical purpose in the usual course of practice.
- A pharmacist has a “corresponding responsibility” to ensure the same standards are in place when the prescription is filled.
- Title 21 Code of Federal Regulations 1306.04(a).
- “The person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.”



[Population Summary](#) • [Registrants by State](#) • [Registrants by Bus. Act.](#) • [Chemical Handlers](#) • [Qualifying Practitioners by State](#)

Registrant Population - Summary

Total Registrants

You must select a cycle and click the "View" button to insure you are viewing accurate figures for the selected cycle.

SELECT CYCLE:

12 - 2018

Retail Level (RL) Registrants	1,777,256	*Chemical Handlers	957
Wholesale Level (WL) Registrants	17,150		
TOTAL	1,794,406		

* Chemical Handler Registrants are not included in Controlled Substances Act Registrant Totals
[View Active Chemical Handler Registrant Statistics](#)

71,536

RETAIL LEVEL		WHOLESALE LEVEL	
Retail Pharmacy	71,536	Manufacturer	578
Hospital/Clinic	18,081	Distributor	899
Practitioner	1,303,105	Researcher	11,875
Teaching Institute	258	Analytical Labs	1,520
Mid-Level Practitioner	384,276	Importer	269
		Exporter	271



DEA AUTHORITY TO INSPECT





DEA AUTHORITY TO INSPECT



PURPOSE

- “To inspect, copy, and verify the correctness of records, reports, or other documents required to be kept or made under the Act and regulations promulgated under the Act, including but not limited to . . .”
 - Biennial Inventory
 - Order Forms
 - Prescriptions
 - Distribution records
 - Receipts
 - Finished & Unfinished CS
 - Reports
 - Conduct Inventory



DEA FORM - 82, NOTICE OF INSPECTION

- Considered informed, voluntary written consent.
- Constitutional right not to have an inspection without an administrative inspection warrant.
- Right to refuse and/or withdraw consent at any time.
- Anything incriminating may be seized and used in a criminal proceeding.
- Copy or form must be issued to pharmacist.



U.S. DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

**NOTICE OF INSPECTION
OF CONTROLLED PREMISES**

DEA USE ONLY
FILE NUMBER

NAME OF INDIVIDUAL		TITLE
NAME OF CONTROLLED PREMISES		DEA REGISTRATION NO.
NUMBER AND STREET		DATE
CITY AND STATE	ZIP CODE	TIME (initial inspection)

STATEMENT OF RIGHTS

1. You have a constitutional right not to have an administrative inspection made without an administrative inspection warrant.
2. You have the right to refuse to consent to this inspection.
3. Anything of an incriminating nature which may be found may be seized and used against you in a criminal prosecution.
4. You shall be presented with a copy of this Notice of Inspection.
5. You may withdraw your consent at any time during the course of the inspection.

ACKNOWLEDGMENT AND CONSENT

I, _____, have been advised of the above Statement of Rights
(Name)
by DEA _____, who
(Title and Name)

has identified himself/herself to me with his/her credentials and presented me with this Notice of Inspection containing a copy of sections 302(f) and 510(a), (b) and (c) of the Controlled Substances Act (21 U.S.C. 822(f) and 21 U.S.C. 880(a), (b) and (c)), printed hereon, * authorizing an inspection of the above-described controlled premises. I hereby acknowledge receipt of this Notice of inspection. In addition, I hereby certify that I am the _____

(President) (Manager) (Owner)

for the premises described in this Notice of Inspection; that I have read the foregoing and understand its contents; that I have authority to act in this matter and have signed this Notice of Inspection pursuant to my authority.

I understand what my rights are concerning inspection. No threats or promises have been made to me and no pressure of any kind has been used against me. I voluntarily give consent for inspection of these controlled premises.

(Signature)

(Date)

WITNESSES:

(signed) _____
(date)

(signed) _____
(date)

* See Reverse



ADMINISTRATIVE INSPECTION WARRANT

- Issued by a Federal Judge/Magistrate.
- Pursuant to an Affidavit – Probable Cause.
- Consent not required.
- Must be served during normal business hours only at a DEA registered location (controlled premise).
- A copy of the Inspection Warrant must be left at the pharmacy.
- Limited in scope to records/reports required under the Act and regulations.



ADMINISTRATIVE INSPECTION WARRANT

Typical Probable Cause

- The pharmacy has not been previously inspected by DEA.
- ARCOS data.
- Theft or Significant Loss reports.
- Suspicious Order Monitoring report.
- Pharmacy board complaint.



SEARCH WARRANT

- Must be issued by a Federal Judge/Magistrate.
- Pursuant to an Affidavit – Probable Cause.
- Consent not required.
- May be served at any time (day or night) or location specified on the warrant.
- A copy of the Search Warrant must be left at the pharmacy.
- No limit to items that may be seized as proof of criminal activity as specified in the warrant.



SEARCH WARRANT

Typical Probable Cause

- Confidential informant information of criminal activity.
- Arrest of employee for theft of controlled substances.
- Undercover “buys” of controlled substances.
- Other illegal criminal activity.



WHAT TO EXPECT ONSITE

- Two Inspectors (usually, but may be more) will present themselves unannounced.
 - Both DEA or DEA with a state person.
- Identify themselves, present credentials and state the purpose of the visit.
- Serve a copy of the inspection authority.
- Obtain authorization signature (if required).



WHAT TO EXPECT ONSITE

- Conduct a physical count of selected controlled substances.
- Ask for the location of certain records.
- Review and seize records (if authorized by inspection authority).
- May take up to four hours (on average) onsite.



WHAT WILL DEA REVIEW/EXAMINE?

- | |
|--|
| • DEA Certificate of Registration & State Permits |
| • Power of Attorney Form(s) – Registration and C II Orders |
| • Executed DEA Forms 222 / CSOS records |
| • Supplier invoices |
| • Records of return (including disposal) |
| • Distributions to other registrants |
| • Controlled substance prescriptions, C II and C III - V |

Not an exhaustive list



WHAT WILL DEA REVIEW/EXAMINE?

- | |
|---|
| • Prescription refill records |
| • Daily computer dispensing print-outs |
| • Biennial inventory |
| • Security/Storage of controlled substances |
| • Reports of theft or significant loss (DEA Form 106) |



THE ACCOUNTABILITY AUDIT

- Creates a “balance sheet” of controlled substance activity.
- Uses an opening and closing inventory.
 - Opening inventory is last Biennial or other physical inventory.
 - Closing inventory is physical count of controlled substances on hand by investigators.
- Total of opening inventory and all receipts should equal the total of closing inventory and all distributions.
- What deviation is acceptable?





SAMPLE DEA COMPUTATION CHART

DEA Registrant
123 Main Street
Anytown, USA

1	2	3	4	5	6	7	8	9
Name & Strength of Drug	Initial Inv. as of 6/30/17 COB +	Total Purchased =	Total Accountable for Col 2 + Col 3	Closing Inv. as of 6/20/18 OOB Count on Hand	Sales Prescription & Log	Total Can Account For Col 5 + Col 6	Difference Over = (+) Short = (-) Col 7 - Col 4	Percent Difference Col 8 / Col 4
Oxycodone 15 mg tabs	240	1000	1240	152	1088	1240	0	0.00%
Oxycodone 30 mg tabs	12	200	212	67	145	212	0	0.00%
			0					
Hydrocodone 10/325 tablets UD	148	700	848	68	780	848	0	0.00%
Hydrocodone 10/325 tablets	2750	33500	36250	1187	35063	36250	0	0.00%
Hydrocodone 10/500 tablets UD	678	500	1178	685	493	1178	0	0.00%
Hydrocodone 10/500 tablets	250	4500	4750	768	3982	4750	0	0.00%
Alprazolam 2 mg tablets	150	500	650	52	598	650	0	0.00%



ACTUAL AUDIT RESULTS

Drug	NDC #	Difference	Percent
Oxycodone 5/325 mg tabs	00406-0512-01	0	0
Oxycodone 30 mg tabs	00228-2879-11	0	0
Opana ER 20 mg tabs	63481-0816-60	0	0
Opana ER 5 mg tabs	63481-0907-70	0	0
Morphine ER 60 mg tabs	00406-8380-01	0	0
Hydrocodone 10/325 mg tabs	00406-0367-01	+55	+3.51%
Hydrocodone 10/325 mg tabs	00591-0853-01	-28	-4.00%
Hydrocodone 7.5 /500 mg tabs	00406-0358-01	0	0
Hydrocodone 7.5 /750 mg tabs	00406-0360-05	+27	+1.40%
Alprazolam 2 mg tabs	00781-1089-05	+6	+0.020%
Alprazolam 1 mg tabs	00603-2129-21	-11	-2.88%



POTENTIAL DEA ADVERSE ACTIONS

Letter of Admonition

- Lowest level of Administrative Action.
- Letter outlines violations and provides regulatory references.
- Requests written response within 30 days.

Administrative Hearing

- Informal hearing.
- Legal representation at discretion of registrant.
- Held at Local DEA office.
- Results in a Memorandum of Agreement.



POTENTIAL DEA ADVERSE ACTIONS

Order to Show Cause

- May be immediate suspension (imminent danger) or traditional.
- Seeks to revoke or deny DEA registration.
- Notice and opportunity for administrative hearing.
- Memorandum of Agreement

Civil Fines

- Refuse or negligently fail to keep records/reports.
- Up to \$10,000 or \$25,000 per count.
- Potential significant totals.



POTENTIAL DEA ADVERSE ACTIONS

Criminal Prosecution

- Illegal distribution
- Knowing and intentionally furnishing false records.
- Prison sentence dependent on sentencing guidelines.



RECENT DEA PHARMACY EXAMPLE ACTIONS*

(ADMINISTRATIVE)

Health Fit Pharmacy	<ul style="list-style-type: none">• Order to Show Cause - Revocation.• No state license.• May 2018.
Zion Clinic Pharmacy	<ul style="list-style-type: none">• Order to Show Cause - Revocation• Multiple causes.• March 2018.
Trinity Pharmacy II	<ul style="list-style-type: none">• Order to Show Cause - Revocation• Multiple causes.• February 2018.

*Public Information available in the Federal Register



RECENT DEA PHARMACY EXAMPLE ACTIONS*

(CIVIL)

Confederated
Salish and
Kootenai Tribes
Pharmacy

- Failed to maintain complete and accurate records.
- \$95,520 civil fine.
- November 2018.

P & S Pharmacy

- Failed to maintain complete and accurate records.
- \$100,000 civil fine.
- April 2018.

Hillcrest
Pharmacy

- Failed to maintain complete and accurate records.
- \$147,500 civil fine.
- June 2014.

*As available by internet search