

VIRTUAL CONVENTION 2021



Nov. 12-14

Surviving a DEA Visit

Sponsored by: Kolibry, LLC



Presenters



Kelley Detweiler



Andy Eiseman



A veterinarian's take on surviving a DEA visit...



Dr. Peter Weinstein

- University of Illinois (DVM)
- Cornell University (undergrad)
- SCVMA Executive Director
- 2021 NAVC Speaker of the Year
- Subject matter expert and acclaimed author on veterinary practice management, operational systems, regulatory dynamics, team-building and leadership



Objectives

DEA Visits

Required Records

Drug Security

Surviving the Visit



DEA Visits

Why the DEA Visits

The DEA routinely conducts audits and inspections at facilities registered to work with controlled substances.

As a practitioner, you can typically expect an inspection **every three years** to determine if you are compliant with applicable laws. The DEA may also perform an audit if they believe something illegal may be taking place.



Triggers

The DEA conducts facility site visits to determine your compliance with the Controlled Substances Act (CSA).

DEA audits or inspections can be triggered for a variety of reasons, such as:

- To investigate a tip received regarding compliance issues/poor practices
- To investigate deviations in ordering patterns
- Random inspections to ensure compliance.

According to Title 21 Code of Federal Regulations and the Controlled Substances Act, Section 880, DEA registrants can be randomly checked at any time to investigate how controlled substances are received, managed, distributed, and stored, including:

- Inspection, copying and verifying correctness of records, reports or other documents required to be kept or made
- Inspection of all finished and unfinished controlled substances
- A physical inventory of all controlled substances at the premises

The risk is real.

Inspections conducted by the DEA are typically unannounced.

Hefty civil fines are being levied against non-compliant individuals and businesses across the healthcare industry, **including veterinary practices**. It's not uncommon for fines to exceed \$1 million, not including the risk of having your DEA registration revoked and the negative fallout from publicity.

\$15,691

Maximum Federal fine per infraction.

\$8.9 billion

Average federal fines levied per year.

DEA

\$466,540

Average fine levied per case.

Source: DEA (2003-09). With increased inspections and a 45% increase in the average fine, it is estimated that these numbers may actually be 25% or more higher in recent years.



Audits v. Inspections

Inspections: DEA inspections are conducted by DEA diversion investigators who are assigned to various field offices across the U.S. and are generally part of the DEA's Diversion Control Program.

Audits: A DEA Audit begins when **DEA Form 82** (Notice of Inspection of Controlled Premises) or an Administrative Inspection Warrant is presented to a DEA registrant prior to the inspection.

Consequences

DEA inspections and audits are routine; however, they can lead to criminal prosecution and administrative action against your DEA registration if violations are discovered.



A blurred photograph of a hospital hallway. In the background, a person is walking away from the camera. The hallway has several windows and doors. The lighting is bright, and the overall scene is out of focus.

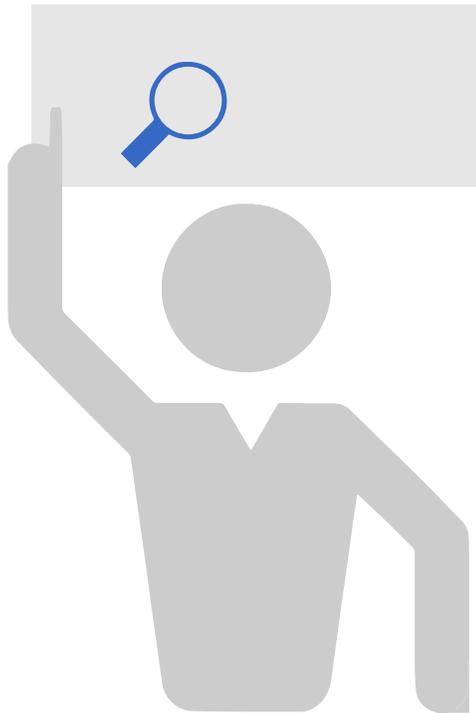
Surviving the Visit

When the DEA arrives



- Immediately inform the DEA registrant
- Request credentials, photo identification, and obtain their contact information (business card)
- Ask for the reason for the visit
- Be courteous and polite

What **not** to do



Argue	Surrender	Over-Share
NEVER attempt to argue with the DEA.	NEVER surrender your registration if you are asked to voluntarily.	NEVER volunteer information. Answer questions with a "yes" "no" or "I'll find out" when asked.

Verification

When the DEA arrives, the investigator must state their **purpose**, provide **credentials** and present **written notice** of the inspection authority.

Once verified, you may give permission for the investigation or refuse it.

Consent

It is generally in your best interest to consent to the DEA's investigation. However, there are legitimate reasons for an investigation to be denied such as:

- The investigation is not during normal business hours
- No one is available to speak about the facility's operations.

If reasonable circumstances exist to prevent a DEA investigation, you may request that the investigation be conducted at another time.



Refusal

If you refuse the investigation, the DEA can go to a judge or magistrate and ask for an **Administrative Inspection Warrant**. This legal ability to force an investigation is authorized by the inspection clause in the Controlled Substances Act.

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Magistrate Judge Brian A. Tsuchida

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

IN THE MATTER OF:	NO. ADMINISTRATIVE WARRANT FOR ENTRY AND INSPECTION PURSUANT TO 21 U.S.C. § 880 [EX PARTE]
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WARRANT FOR INSPECTION

TO: Kari Hemp, Diversion Investigator, and any other authorized Diversion Investigator or Special Agent of the Drug Enforcement Administration of the United States Department of Justice.

ADMINISTRATIVE WARRANT
PAGE - 1

UNITED STATES ATTORNEY
700 Stewart Street, Suite 5220
Seattle, Washington 98101-1271
(206) 533-7970

DEA Warrants & Notices of Inspection

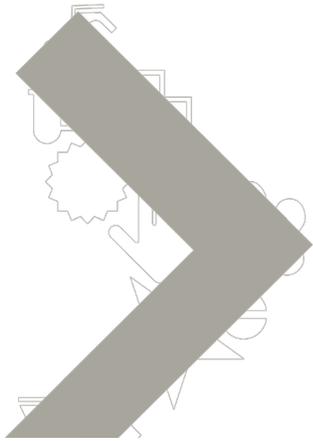
(DEA Form 82)

Unlike searches for criminal proceedings, the DEA does not require a search warrant to conduct a DEA inspection to determine compliance with the CSA. However, if the DEA is participating in a criminal investigation with other agencies, it must have a search warrant to search a practice/clinic.



Informed Consent

If a DEA Form 82 is presented, the DEA registrant must give informed consent before the DEA audit or inspection may begin. Informed consent is a written statement by the registrant stating that:



- They have been informed of the constitutional right not to have an administrative inspection;
- Anything of incriminating nature can be used against the registrant in a criminal prosecution, and
- They voluntarily consent.

Informed Consent Exclusions

In some cases, the DEA does not need informed consent to conduct a DEA inspection without an Administrative Search Warrant. An Administrative Warrant is not required for:



- establishments applying for initial DEA registration;
- inspection of books and records pursuant to an administrative subpoena issued by the DEA's subpoena power; or
- administrative inspections where there is an imminent danger to the public health or safety, and where the opportunity to apply for a warrant is lacking.

Administrative Inspection Warrants

If the DEA registrant refuses to give informed consent to the DEA audit, the DEA must obtain an Administrative Inspection Warrant from the U.S. Federal District Court. Unlike a Search Warrant, an Administrative Inspection Warrant does not require the DEA to show probable cause. Rather, to obtain an administrative search warrant, the DEA is required to describe the nature and extent of the inspection and any items that they wish to seize. Courts routinely grant Administrative Search Warrants.



Administrative Search Warrants

If the DEA presents an Administrative Search Warrant to conduct a DEA audit or inspection, **the registrant must comply**. Refusal to comply is grounds for arrest. If you receive a DEA administrative search warrant, you should contact your attorney or a compliance expert immediately to help protect you, your practice and your DEA registration.



When the inspection starts



- Once the inspection starts, all personnel in the facility should be informed of the DEA's presence.
- All personnel should follow established procedures for DEA inspections and all interactions with the investigators should remain courteous and professional.
- Provide the DEA with a space where they can work undisturbed.

Scope of Inspection

The DEA does not have the authority to inspect everything within your facility. Specifically, the DEA may not inspect:

- Sales data
- Financial information
- pricing





Required Records

Be prepared to provide the following records upon request

- State controlled substance license and DEA registration
- Most recent inventory (e.g., initial, biennial)
- Authorized personnel log, employee screening statements
- Policies and procedures regarding controlled substances
- Current usage logs
- Disposal records
- Access to controlled substance storage cabinet or safe
- Purchasing records (i.e., invoices, packing slips, DEA Form 222s), with Schedule I – II records separated from Schedule III – V
- Waste or breakage-spillage reports (DEA Form 41)
- Theft/significant loss reports (DEA Form 106)



Your ready & retrievable file

Your initial and biennial inventories are part of the required records that must be **available onsite for inspection** by the DEA immediately upon request at the location matching your DEA registration. These records must be should be maintained in what we refer to as a **“readily retrievable” file**.



Records



Contents of your readily retrievable file

- Initial inventory
- Biennial inventory
- DEA registration & state licenses/certifications
- Executed and unexecuted DEA Form-222s (or electronic equivalent)
- Power of Attorney forms
- Receipts and/or invoices for schedules III-V controlled substances
- Records of controlled substances distributed (i.e., sales to other registrants, returns to vendors, distributions to reverse distributors)
- Records of controlled substances dispensed
- Reports of Theft or Significant Loss (DEA Form-106), if applicable
- Inventory of Drugs Surrendered for Disposal (DEA Form-41), if applicable
- Records of any transfers of controlled substances
- Authorized Personnel list

Separating records

Make sure that your schedule II records are kept separate from schedule III-V and non-controlled substance records.



Logbooks

The DEA will review your usage logbooks to ensure that all controlled substances are **consistently, accurately** and **legibly** recorded and that any discrepancies are appropriately identified, investigated, resolved and reported (as applicable).





Drug Security

During a DEA visit the effectiveness of the controls in place at your facility will be evaluated as they relate to the prevention of drug diversion.



Physical security

The DEA will evaluate your facility's physical security to ensure that controlled substances are being properly safeguarded; including storage, security systems and access control.



Secure Storage

Controlled substance storage will be evaluated to ensure compliance with the requirements set forth in CFR §1301.72.

Additionally, remember that schedule II controlled substances must be kept separated from schedule III-V's as well as all expired and non-federally controlled substances within storage.



Access Control

§1301.72(d)

The controlled substances storage areas shall be accessible only to an absolute minimum number of specifically authorized employees. When it is necessary for employee maintenance personnel, nonemployee maintenance personnel, business guests, or visitors to be present in or pass-through controlled substances storage areas, the registrant shall provide for adequate observation of the area by an employee specifically authorized in writing



Authorized Users



- Individuals must be properly authorized via Power of Attorney by the DEA registrant.
- An Authorized user List **must be** created and maintained and a copy should be retained as part of your readily retrievable file.



Diversion risks

- Improper wasting/disposal
- Inaccurate logging systems
- Lack of Power of Attorney (“POA”)
- Lack of SOP’s
- Lack of background checks
- Inadequate storage
- Outdated video surveillance



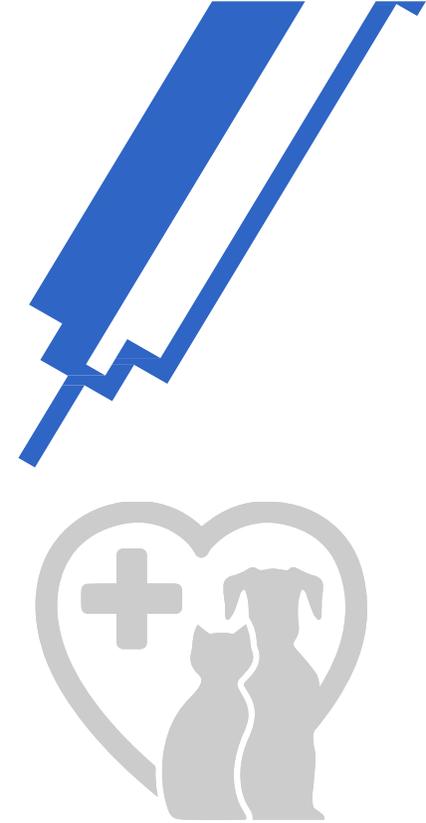
Employee Security

The DEA will evaluate employee hiring and onboarding processes to assess if your facility is doing its due diligence to prevent drug diversion by properly vetting employees as well as ensuring that individuals working with controlled substances are properly educated and trained. This includes:

- Background checks
- drug screening
- Employee screening statements
- Controlled substance education and training during onboarding

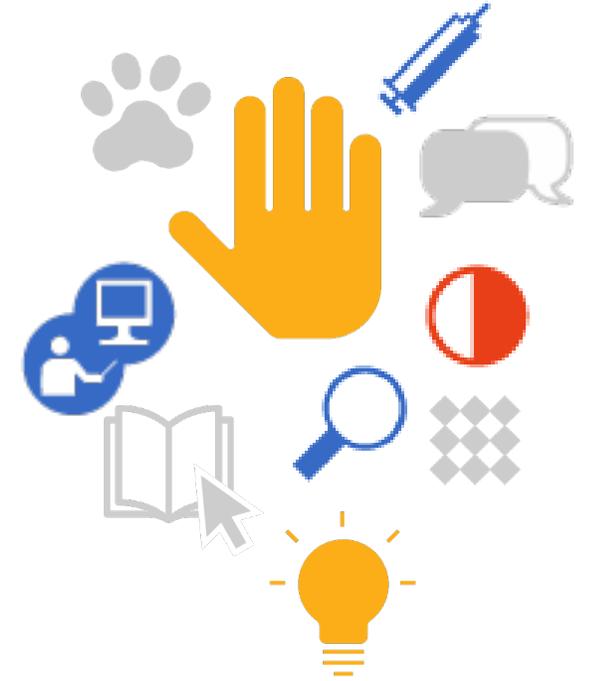
Wasting

Diversion often takes place during the wasting process when excess drugs are not fully expelled and properly wasted rendering them "non-retrievable". The DEA will assess wasting processes, including management of expired controlled substances awaiting destruction.



Expired Drugs

Expired controlled substances awaiting destruction **must be securely stored** and included in counts with the rest of controlled substance inventory until the time of disposal. If expired controlled substances are stored with active controlled substance inventory they must also be clearly separated out in storage.



DEA Investigations

A DEA visit is typically what starts the investigation process. The DEA may also request an interview with you to attempt to gather more information. If they have probable cause to believe that you have not been complying with the CSA, you may also receive an Administrative Search Warrant for your facility.





Divulging Information

NOTE: Any information offered to the DEA may be used against you in an administrative or criminal proceeding.

Contact your attorney before speaking with the DEA to ensure that your rights are protected, and that the DEA does not exceed the scope of their powers.

Noncompliance Audit Reports



Following a DEA audit, if noncompliance is found, the DEA will issue an audit report detailing issues considered noncompliant with the CSA.



If noncompliance is found, the DEA may refer the matter to the Department of Justice (DOJ) for criminal prosecution and/or take administrative action against your DEA registration.



Conclusion

Taking a **proactive approach** to controlled substance compliance significantly increases your chances of surviving a DEA Inspection. Compliance is an **ongoing process** that requires dedication but if you invest the time now it will pay you back in dividends down the road. **Don't wait until it's too late.**



We've got news!



Kolibry has partnered with renowned veterinarian,
Dr. Peter Weinstein, in Simple Solutions 4 Vets!

Simple Solutions is compliance company designed for veterinarians, led by a veterinarian and team of experts driven to provide better compliance solutions to the veterinary industry. Services are designed to help **simplify processes** and allow veterinarians to prioritize what's important so that at the end of the day you feel **supported, safe** and **satisfied** rather than overwhelmed, frustrated and overworked.

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Questions:

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