

SECURITY & ACCESS FOR CONTROLLED DRUGS

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Physical Security

Because of their abuse potential, controlled substances must be afforded additional security to prevent them from being diverted from legitimate medical use to illicit use. The Controlled Substance Act (CSA) requires the owner of the substances to make a reasonable attempt to keep them secured from unauthorized persons, both internally and externally.

Requiring double locks to secure controlled substances is a common myth in the veterinary profession; this is not a bad idea, but it is not a requirement. The physical security requirements of the CSA afford the practitioner a wide degree of latitude when setting up a secure storage location. The CSA states **"controlled substances must be kept in a securely locked, substantially constructed cabinet or safe."**ⁱ This includes all schedules of controlled substances and applies to all drugs present in the facility.

There is no single specific definition of "substantially constructed" but any safe or container that is used must provide a reasonable deterrent from theft. It must be "tough enough" to provide protection from moderate, forceful attack. For free-standing containers, there is no size or weight requirements for a controlled substance safe, however, it must be large enough to prevent easy dislocation and removal of the entire container.

To balance accessibility and security, we believe a combination-style lock is a better choice than a key style for the working supply of controlled substances in a veterinary practice. And the new generation of fingerprint locks provide the most flexibility possible; some even keep a record of each time the safe was opened and by whom!

For drugs that need to be refrigerated after mixing, the CSA doesn't provide an exemption to the security rules. Those drugs must be secured to deter theft from pilfering. Lockable refrigerator inserts are readily available from numerous internet sourcesⁱⁱ.

The CSA requires every registrant possessing controlled substances to "provide effective controls and procedures to guard against theft and diversion of controlled substances." For that reason, all practices must institute policies that are aimed at preventing theft or diversion by employees. Some simple controls that the registrant should employ include:

- limiting access to the absolute necessary people needed for operations,
- regular review of purchasing and use records by someone other than the normal inventory clerk,

- regular comparison of log entries to medical records to verify accuracy and to spot fake entries, and
- unannounced, random inventory checks.

Recording security cameras are not specifically required by the CSA or regulations, but they are strongly suggested as part of the overall security plan. A strategically placed camera overlooking the safe or cabinet will not only provide evidence in the event of a theft, but its mere presence will also act as a deterrent.

The security requirements for controlled substances apply to mobile operations just as they apply to fixed facilities. Vehicles that store controlled substances for operations must have a substantially constructed, adequately secured container or safe. Simply keeping the drugs in a box or bag and locking the vehicle's doors or the vet box is not adequate. In most cases, a portable gun safe type container that is bolted to the vet box is the best solution. The types with a push-button lock are more practical than ones with a keyed lock. The safe or container must be locked when unsupervised.

Granting Staff Access

The Controlled Substance Act (CSA) does not dictate how many people may be granted access to the controlled substance safe in a veterinary hospital. That decision is normally up to the registrant who owns the drugs. Tennessee does not add any additional limitations on the registrant's authority to grant access.

Although the DEA doesn't set a specific limit on the number of people with access, they do require each registrant to keep that number to the absolute minimum necessary for operations. In smaller practices, this is self-limiting, but in larger organizations, decisions must be made. Even in human medical care environments, it's common practice to restrict controlled substance access to just one or two people per shift to prevent many of the problems associated with "too many hands." Furthermore, experience has shown that recordkeeping errors increase significantly when more than a couple of people have physical access to the drugs!

The regulation does limit access to controlled substances to people who meet certain criteria, so there is an implied requirement to screen agents determine eligibility. The level and detail of that screening should be commensurate with the person's access.

For employees with limited access to drugs, such as receptionists who merely hand over packaged drugs to the client upon discharge, or the technician who is able to access a limited supply of injectable drugs for in-house administration but not access to the bulk supply, a basic screening could consist of having them complete a written questionnaire certifying to meet required security criteria. This is from the DEA's web site:

"It is the position of DEA that the obtaining of certain information by non-practitioners is vital to fairly assess the likelihood of an employee committing

a drug security breach. The DEA feels the need to know this information is a matter of business necessity, essential to overall controlled substances security. In this regard, it is believed that conviction of crimes and unauthorized use of controlled substances are activities that are proper subjects for inquiry as part of a registrant's screening program. It is, therefore, assumed that the following questions will become a part of a registrant's comprehensive employee screening program:

Question: Within the past five years, have you been convicted of a felony, or within the past two years, of any misdemeanor or are you presently charged with committing a criminal offense? (Do not include traffic violations, juvenile offenses or military convictions, except by general court-martial.) If the answer is yes, furnish details of conviction, offense, location, date and sentence.

Question: In the past three years, have you ever knowingly used any narcotics, amphetamines or barbiturates, other than those prescribed to you by a physician? If the answer is yes, furnish details."ⁱⁱⁱ

"Question: Have you at any time had an application for registration with the DEA denied, had a DEA registration revoked or have you ever surrendered a DEA registration for cause? If the answer is yes, furnish details of situation including the date. For purposes of this question, the term "for cause" means surrender in lieu of, or as a consequence of, any federal or state administrative, civil or criminal action resulting from an investigation of the individual's handling of controlled substances."

The written screening form must be a separate document apart from the employment application or any other form and must include a statement that providing any false information or omission of information will jeopardize that person's qualification for employment in an area where controlled substance access is part of the job description.

For staff members with extensive access to the drugs and the ordering process, it's prudent for the registrant to conduct a more thorough screening. Generally, a local police background check for drug-related convictions in addition to the written questionnaire mentioned earlier, would be prudent for staff members with extensive access to controlled substances. Prior to conducting such a background check, be sure to check your state laws regarding employee background checks...most require a specific form that must be signed by the employee acknowledging and authorizing the check. Of course, if an employee refuses to grant permission for a background check, it's well within the rights (and maybe even an obligation) of the registrant to prohibit access to controlled substances by that employee. Of course, be sure to keep the results of any such background check confidential and available only to managers with a need to know that information.

Summary

The responsibilities of a DEA registrant include protecting the drugs from unauthorized diversion. The procedures one must take include those necessary to prevent theft by break-ins, but also theft from internal sources!

ⁱ Title 21 Code of Federal Regulations, Section 1301.75

ⁱⁱ www.gohcl.com and search for "refrigerator locks"

ⁱⁱⁱ Title 21, Code of Federal Regulations, Section 1301.90