



CITY OF SAN ANTONIO

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March 5, 2012

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SUBJECT: Audit Report of Animal Care Services Drug Inventory Management

Mayor and Council Members:

We are pleased to send you the audit report of Animal Care Services Drug Inventory Management. This audit began in September 2011 and concluded with an exit meeting with department management in January 2012. Management's verbatim response is included in Appendix B of the report. Animal Care Services should be commended for their cooperation and assistance during this audit.

The Office of the City Auditor is available to discuss this report with you individually at your convenience.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Kevin W. Barthold".

Kevin W. Barthold, CPA, CIA, CISA
City Auditor
City of San Antonio

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CITY OF SAN ANTONIO
OFFICE OF THE CITY AUDITOR



Audit of Animal Care Services

Drug Inventory Management

Project No. AU12-001

March 5, 2012

Kevin W. Barthold, CPA, CIA, CISA
City Auditor

Executive Summary

As part of our annual Audit Plan, we conducted an audit of the Animal Care Services' drug inventory management. The audit objectives, conclusions, and recommendations follow:

Is Animal Care Services adequately managing its drug inventory?

No, management has not implemented adequate controls to ensure drug inventory is appropriately managed.

We found that Animal Care Services (ACS):

- Does not have written policies and procedures in place related to the management of drug inventory. For example, management has not implemented a contingency plan to ensure daily operations continue in the absence of a veterinarian licensed by the Drug Enforcement Administration (DEA). Additionally, management has not established formal authorization levels for drug purchases.
- Is not in full compliance with state and federal regulations over controlled substances. For example, we observed unauthorized access to controlled substances. Additionally, we found that a complete and accurate record of controlled substances does not exist.
- Has not implemented a formal due diligence process or developed written contracts for relief veterinarians. For example, management does not verify that relief veterinarians have a current medical license and, where applicable, a current DEA license. Additionally, management does not require background checks to ensure relief veterinarians have not been convicted of any drug-related felonies.

We recommend that Animal Care Services management:

- Establish written policies and procedures for all processes related to the management of drug inventory, including purchasing, storing, transferring, administering, and disposing of drugs. Policies and procedures should provide ACS personnel with sufficient guidance to ensure compliance with state and federal regulations over controlled substances and help ACS management obtain proper oversight of drug purchasing and usage.

- Comply in full with state and federal regulations over controlled substances. Management should establish standard log book structures and formats to ensure controlled substances are accurately tracked when received, transferred, administered, and/or disposed. In addition, log book standardization will help ensure that inventory records are in compliance with the applicable authoritative regulations.
- Establish a formal due diligence process for relief veterinarians that will ensure their licenses are current and they are authorized to handle controlled substances per state and federal regulations. The due diligence process should also include a criminal background check. In addition, management should establish written contracts with each relief veterinarian.

Animal Care Services management's verbatim response is provided at Appendix B on page 9.

Other Matters

We determined that Chameleon, ACS' point-of-sale system also used for tracking animal treatments, is being under-utilized. For example, the system can generate reports showing drug consumption over time, which could be compared to purchases or inventory records, thus helping management determine efficiency of drug usage and detect potential loss, waste, or abuse. However, ACS personnel do not consistently record dosages administered to animals in the system; therefore, reporting data is incomplete and unusable for such purposes. We recommend that management work with appropriate personnel to explore Chameleon's reporting potential and require ACS personnel to record data that would be necessary to produce useful management reports, such as dosages of controlled substances administered to animals each day.

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Background

Animal Care Services (ACS) is responsible for the enforcement of Chapter 5 of the City's Animal Code to ensure public health and safety. The department offers services intended to promote responsible pet ownership through community outreach, animal placement programs, legislation, and enforcement. The department's mission is as follows:

“Encourage responsible pet ownership by promoting and protecting the health, safety and welfare of the residents and animals of Bexar County through education, enforcement and community partnership.”

ACS' FY 2011 adopted budget was \$8.6 million, and the 2012 budget increased to \$9.4 million. Total drug expense for the 2011 fiscal year was \$341,669, which comprised about 4% of the 2011 budget.

ACS maintains an inventory of drugs used for spay/neuter surgeries, vaccinations, and euthanasia. Some of these drugs are classified as controlled substances and are regulated by the DEA and the Texas Department of Public Safety. Regulations require ACS to maintain log books for controlled substances at each location in which they are stored or administered to animals. For example, ACS personnel use a primary log to record amounts of controlled substances received from vendors and stored in the main drug inventory safe. Any substances dispensed to other locations from the main safe are logged out of the primary log book and into a secondary log book kept at the receiving location. Dosages administered to individual animals are recorded in the log book at the location in which the animal was treated.

Audit Scope and Methodology

The audit scope includes fiscal year 2011 (October 2010 through September 2011) and the months in which fieldwork was conducted (October 2011 through mid-December 2011).

To obtain an understanding of operations related to drug management, we interviewed ACS staff and management who worked at the administrative office, clinic, kennels, and euthanasia-by-injection (EBI) buildings at the Highway 151 location. We also interviewed external veterinarians who are paid by the City for services provided on behalf of ACS. These individuals are referred to as “relief veterinarians.” Finally, we interviewed ACS management and Human Resources personnel to obtain an understanding of due diligence procedures for selecting and contracting relief veterinarians.

To establish testing criteria, we reviewed the Texas Health and Safety Codes 481 and 483, as well as Codified Federal Regulations *Title 21 – Food and Drugs, Chapter II, Drug Enforcement Administration* (the “Controlled Substances Act”). Additionally, we reviewed the *Practitioner’s Manual, An Informational Outline of the Controlled Substances Act, 2006 Edition*¹. Finally, since ACS did not have written policies and procedures related to drug inventory management, we interviewed ACS management and staff to obtain an understanding of expectations and informal procedures related to drug inventory management.

During the course of the audit, we observed ACS personnel conduct a full physical count of drug inventory kept at the Highway 151 location. To validate inventory count results, we selected a haphazard sample of 25 items from ACS inventory sheets to verify actual inventory quantities and also selected 25 physical items from inventory stock to verify they were accurately counted per ACS inventory sheets. We used the final inventory count results to verify that drug inventory on-hand was accurately reflected in SAP, the City’s financial reporting system, for the 2011 fiscal year.

We obtained log books for controlled substances to determine general reasonableness and compliance with state and federal regulations (e.g. looked for mathematical errors, unusual patterns, signs of removed pages, etc.). We then judgmentally selected two controlled substances used at ACS, based on potential for abuse and quantity used, and analyzed corresponding log books to ensure they accurately and completely reflected quantities received, dispensed, administered, and/or disposed. We also verified that the current balances recorded in the respective logs accurately reflected physical inventory on-hand. Finally, we selected a sample of 25 entries from EBI sedation and euthanasia log books, and another 25 from the Clinic sedation log book, to verify that dosages administered to individual animals were correctly entered into Chameleon.

We obtained all available purchase requisitions, invoices, and other supporting documentation for controlled substance orders placed during the audit period, which comprised 25 orders. To determine whether we received documentation for all orders, we identified all controlled substance shipments received per veterinarians’ log book entries made during the audit period and determined whether fiscal staff provided invoices corresponding to each log book entry. We reviewed supporting documentation to determine whether ACS veterinarians or appropriate levels of management approved purchase order requests prior to purchase orders being processed and to ensure that fiscal personnel filed documentation required by federal regulations with controlled substance orders.

We conducted this audit from the end of September 2011 through mid-December 2011 in accordance with generally accepted government auditing standards.

¹ The Practitioner’s Manual is published by the Drug Enforcement Administration, Office of Diversion Control, to assist practitioners (including veterinarians) in their understanding of the Federal Controlled Substances Act and its regulations.

Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our audit results and conclusions based on audit objectives. We believe that the evidence obtained provides a reasonable basis for our audit results and conclusions based on audit objectives. This audit included tests of management controls that we considered necessary under the circumstances.

Audit Results and Recommendations

A. No Written Policies and Procedures

Animal Care Services does not have written policies and procedures over drug inventory management processes. Instead, operations are dependent on the subjective direction of management. Formal policies and procedures help ensure compliance with applicable state and federal regulations and promote accountability for individuals whose job functions involve drug inventory. Without formal policies and procedure, employees' actions become inconsistent, leaving drug inventory stock and records vulnerable to errors, misuse, abuse, and/or theft.

Recommendation

ACS Management should establish written policies and procedures for all processes related to the management of drug inventory, including purchasing, storing, transferring, administering, and disposing of drugs. ACS should use regulations as the basis for developing policies and procedures related to controlled substances. Management should require all personnel, including relief veterinarians, who work with physical drug inventory and corresponding records to formally acknowledge that they read, understood, and agreed to comply with the policies and procedures.

B. Violations of State and Federal Regulations for Controlled Substances

B.1 Auditors found evidence that unauthorized personnel accessed and used controlled substances. Although these drugs were appropriately used for daily operations and extraction of the drugs was accurately logged, the individuals who accessed them were explicitly prohibited from doing so by the DEA-licensed veterinarian, who was on leave at the time. Section 1301.22(b) of the Controlled Substance Act indicates that, if a practitioner clearly prohibits access to controlled substances acquired under his/her DEA license, such access would violate DEA regulations. Management did not have a contingency plan in place for such occasions and, therefore, was unable to continue daily operations without violating regulations. Violation of regulations may result in the City losing its DEA license, preventing ACS from acquiring controlled substances necessary for daily operations.

B.2 Log books did not provide a complete or accurate record of controlled substance inventory as required by section 1304 of the Controlled Substances

Act. For instance, while primary log books indicated quantities dispensed to secondary locations, secondary log books often did not have entries showing those quantities were received. Additionally, we could not clearly trace quantities dispensed from the primary log to corresponding logs for sedation drugs. In these cases, sedation drugs were a combination of more than one substance, but log book entries did not clearly indicate proportions of each substance per bottle received. Management did not establish standards for log book structure or format and had not conducted regular reasonableness checks on log books to ensure consistency, completeness, and accuracy. Log books are, therefore, ineffective controls, leaving controlled substances more vulnerable to loss or theft without detection.

B.3 Controlled substance inventory records, including log books, invoices, cycle count records, and other supporting documentation, were not in full compliance with DEA regulations. For example, we examined 18 log books kept at various locations and identified a number of issues, including evidence of missing pages and calculation errors. Additionally, four logs were kept in a spiral notebook and another in a three-ring binder, rather than a bound book as required by the DEA. None of the log books had consistently-numbered pages.

ACS personnel were unable to provide all log books, invoices, and other supporting documentation we requested for controlled substance inventory. Additionally, we found that records for some drugs were mingled with other records. Section 1304 of the Controlled Substance Act requires records of all controlled substances to be readily retrievable, and records for specific substances to be segregated from other records. Management had not provided formal guidelines for record-keeping of controlled substance inventory. Violations of regulations could result in the loss of ACS' license to acquire and use controlled substances and, therefore, permanently disrupt daily operations and prevent ACS from fulfilling its mission.

Recommendations

B.1 Management should establish a contingency plan for unplanned absences of the DEA-licensed veterinarian who is responsible for controlled substances at ACS. Such a plan should provide means to authorize appropriate personnel to access controlled substances necessary to continue with daily operations during the veterinarian's absence. Management should ensure that the contingency plan is in line with applicable state and federal regulations.

B.2 Management should work with veterinarians, supervisors, and other appropriate staff to develop standard log book structures that are in line with state and federal regulations and provide a clear, complete, and accurate account of all controlled substance transfers, usage, and disposal. Management should also implement a clear policy requiring veterinarians and/or supervisors to regularly review log books for consistency, accuracy, and completeness.

Regular reviews should include verification of current inventory balances in logs according to physical inventory on-hand. Reviews and inventory verifications should be documented in the log books.

B.3 In conjunction with recommendation **A**, management should develop clear guidelines to ensure record-keeping of controlled substances is in line with applicable regulations. Management should also provide training opportunities to personnel responsible for drug inventory records to ensure they are familiar with and understand applicable regulations.

C. No Contracts or Due Diligence for Relief Veterinarians

C.1 Animal Care Services paid eleven different relief veterinarians to provide services on the City's behalf, such as spay or neuter surgeries and vaccinations, between October 2010 and October 2011. ACS management had not established a written contract with any of these veterinarians for their time and services. However, according to ACS management, the department is currently working with Legal to produce a contract template that will be used for all current and future relief veterinarians. Without written contracts, ACS may not be able to hold relief veterinarians accountable for their work, potentially leaving ACS solely liable for any malpractice performed by veterinarians.

C.2 Management has not established formal due diligence procedures for selecting relief veterinarians, such as verification of medical and DEA licenses or conducting criminal background checks. Section 1301.76 of the Controlled Substances Act requires ACS to conduct a criminal background check of any individual who has access to controlled substances to verify that he/she has never been convicted of a drug-related felony. Allowing a convicted felon to access controlled substances directly violates federal regulations. Verifying medical and, if applicable, DEA licenses would mitigate the risk of contracting an individual who has been convicted of drug-related felonies or involved in any other malpractice.

Recommendations

C.1 Management should continue working with Legal to generate formal contracts with each current and future relief veterinarian. In the meantime, management should ensure that the contract for the relief veterinarian currently responsible for controlled substances explicitly establishes accountability for complying with applicable state and federal regulations.

C.2 Management should establish policies and procedures that require completion of formal due diligence procedures prior to allowing relief veterinarians to conduct services on behalf of ACS. Due diligence procedures should include a criminal background check and verification of medical and, if

applicable, DEA licenses. ACS should coordinate these efforts with other City departments, such as Human Resources and San Antonio Police, as appropriate.

D. Chameleon Features Not Used for Management Reporting

We determined that Chameleon, a point-of-sale system with features for tracking animal treatments, is being under-utilized. For example, the system can generate reports showing drug consumption over time, which could be compared to purchases or inventory records, thus helping management determine efficiency of drug usage and detect potential loss, waste, or abuse. However, ACS personnel do not consistently record dosages administered to animals in the system; therefore, reporting data is incomplete and unusable for such purposes.

Recommendation

Management should work with appropriate personnel to explore Chameleon's reporting potential and require ACS personnel to record data that would be necessary to produce useful management reports, such as dosages of controlled substances administered to animals each day.

Appendix A – Staff Acknowledgement

Andre C. DeLeon, CPA, Audit Manager
Bruce Coleman, CIA, Auditor in Charge
Claudia Peña, CFE, Auditor

Appendix B – Management Response



CITY OF SAN ANTONIO

SAN ANTONIO TEXAS 78283-3966

February 24, 2012

Kevin W. Barthold, CPA, CIA, CISA
 City Auditor
 San Antonio, Texas

RE: Management’s Corrective Action Plan for the Audit of Animal Care Services – Drug Inventory Management

Animal Care Services (ACS) Department has reviewed the audit report and has developed the Corrective Action Plans below corresponding to report recommendations.

Recommendation					
#	Description	Audit Report Page	Accept, Partially Accept, Decline	Responsible Person's Name/Title	Completion Date
A	<p>Written Policies and Procedures ACS management should establish written polices and procedures for all processes related to the management of drug inventory, including purchasing, storing, transferring, administering, and disposing of drugs. ACS should use regulations as the basis for developing policies and procedures related to controlled substances. Management should require all personnel, including relief veterinarians, who work with physical drug inventory and corresponding records to formally acknowledge that they read, understood, and agreed to comply with the policies and procedures.</p>	4	Accept	Dr. Marilyn Gotbeter, ACS Veterinarian	July 1, 2012
<p>Action plan: ACS is currently working on writing its policies and procedures that would ensure ACS is managing its drug inventory in compliance with the state and federal regulations. Once finalized (July 1, 2012), ACS will ensure that all personnel (including any relief veterinarians) who work with physical drug inventory and corresponding records formally acknowledge that they read, understand, and agree to comply with the policy and procedures outlined. This formal acknowledgement will be included in the individuals' personnel record or contract file. The Clinic Manager (and or designee) will also maintain a copy of all acknowledgement forms and ensure they are up-to-date.</p>					

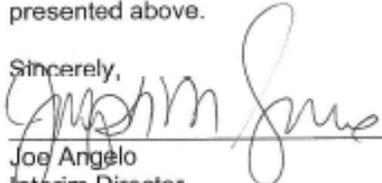
Recommendation					
#	Description	Audit Report Page	Accept, Partially Accept, Decline	Responsible Person's Name/Title	Completion Date
B	<p>Compliance with Regulations</p> <p>Management should establish a contingency plan for unplanned absences of the DEA-licensed veterinarian who is responsible for controlled substances at ACS. Such a plan should provide means to authorize appropriate personnel to access controlled substances necessary to continue with daily operations during the veterinarian's absence. Management should ensure that the contingency plan is in line with applicable state and federal regulations.</p> <p>Management should work with veterinarians, supervisors, and other appropriate staff to develop standard log book structures that are in line with state and federal regulations and provide a clear, complete, and accurate account of all controlled substance transfers, usage, and disposal. Management should also implement a clear policy requiring veterinarians and/or supervisors to regularly review log books for consistency, accuracy, and completeness. Regular reviews should include verification of current inventory balances in logs according to physical inventory on-hand. Reviews and inventory verifications should be documented in the log books.</p> <p>In conjunction with recommendation A, management should develop clear guidelines to ensure record-keeping of controlled substances is in line with applicable regulations. Management should also provide training opportunities to personnel responsible for drug inventory records to ensure they are familiar with and understand applicable regulations.</p>	5	Accept	Dr. Marilyn Gotbeter, ACS Veterinarian	July 1, 2012

Recommendation					
#	Description	Audit Report Page	Accept, Partially Accept, Decline	Responsible Person's Name/Title	Completion Date
	<p>Action plan: As part of the development of new policies and procedures, ACS will establish a contingency plan for unplanned absences of the DEA-licensed veterinarian. This policy/procedure will be finalized by July 1, 2012 and will be in compliance with known state and federal regulations.</p> <p>ACS is in the process of making changes to our log books and structure to be in compliance with state and federal regulations. We have replaced all non-compliant log books with bound books that have consistently-numbered pages. ACS has purchased stamps that will be used to standardize the existing structure and format of the drug books. ACS is also in the process of establishing formalized policies and procedures outlining the management of drug log books to include standardizing log book structures and formatting. New policies will also include departmental audit expectations and procedures.</p> <p>Once the policies and procedures are finalized, the Chief Vet (or acting vet) will ensure that all applicable employees are properly taught and understand what they must do to remain in compliance with established policies. Following the vet's training, all applicable employees and relief vets will formally acknowledge that they understand and agree to comply with the policy and procedures outlined. This formal acknowledgement will be included in the individuals' personnel record or contract file. The Clinic Manager (and or designee) will also maintain a copy of all acknowledgement forms and ensure compliance.</p>				
C	<p>Due Diligence for Relief Vets Management should continue working with Legal to generate formal contracts with each current and future relief veterinarian. In the meantime, management should ensure that the contract for relief veterinarian currently responsible for controlled substances explicitly establishes accountability for complying with applicable state and federal regulations.</p> <p>Management should establish policies and procedures that require completion of formal due diligence procedures prior to allowing relief veterinarians to conduct services on behalf of ACS. Due diligence procedures should include a criminal background check and verification of medical and, if applicable, DEA licenses. ACS should coordinate these efforts with other City departments, such as Human Resources and San Antonio Police, as appropriate.</p>	6	Accept	Joe Angelo, Interim Director	July 1, 2012

Recommendation					
#	Description	Audit Report Page	Accept, Partially Accept, Decline	Responsible Person's Name/Title	Completion Date
	<p>Action plan: Effective March 1, 2012, all contract vets who provide vet services for ACS will have an established contract with ACS outlining their assigned duties. ACS will also maintain a record showing all contract relief vets have a current medical license, a DEA license, and have passed a background check. These records will be provided to ACS prior to the contract vet conducting business for ACS.</p> <p>ACS will formalize its policies and procedures in regards to the usage of relief veterinarians and due diligence procedures. These new polices will be included in the formal policies and procedures that will be finalized July 1, 2012.</p>				
D	<p>Inventory Reporting Tool Management should work with appropriate personnel to explore Chameleon's reporting potential and require ACS personnel to record data that would be necessary to produce useful management reports, such as dosages of controlled substances administered to animals each day.</p>	7	Accept	Christine Garnett, Interim Clinic Manager & Heber Lefgren, Assistant to the Director	October 1, 2012
	<p>Action plan: ACS will ask ITSD to update Chameleon to include all medication that is currently being utilized by ACS and manually record all drugs received and dispensed. ACS will formalize this request and, if agreeable by ITSD, will make the required changes by October 1, 2012.</p> <p>ACS is currently not using Chameleon to its full capacity for tracking inventory and/or treatments. This is in part due to the fact that Chameleon is not linked to the City's fiscal system (SAP). ACS will submit a request to ITSD that a business case be created to look at the costs associated with linking Chameleon to SAP. This request will be submitted by March 15, 2012.</p>				

We are committed to addressing the recommendations in the audit report and the plan of actions presented above.

Sincerely,



 Joe Angelo
 Interim Director
 Animal Care Services

2/28/12

 Date



 Erik Walsh
 Deputy City Manager
 Office of the City Manager

2/28/12

 Date