

EXHIBIT LIST

NO.	DESCRIPTION	DATE
1	Letter to EMS & Animal Services	12/30/22
2	Response to Letter	1/10/23
3	Follow-up letter	1/20/23

Hernando County Clerk of Circuit Court  
Audit Services Department  
Follow-Up Audit Report  
of  
EMS & Animal Services Drug Inventory Controls Audit  
December 30, 2022

The purpose of this report is to provide management with information regarding the results of the audit. The audit was conducted by the Audit Services Department on December 30, 2022. The audit was conducted in accordance with the Florida State Auditor's Office's (FSO) Audit Manual, Chapter 200, and the Florida State Auditor's Office's (FSO) Audit Manual, Chapter 200, and the Florida State Auditor's Office's (FSO) Audit Manual, Chapter 200.

During the audit, the auditor observed that the EMS & Animal Services Department's drug inventory controls were not in compliance with the Florida State Auditor's Office's (FSO) Audit Manual, Chapter 200, and the Florida State Auditor's Office's (FSO) Audit Manual, Chapter 200. The auditor observed that the EMS & Animal Services Department's drug inventory controls were not in compliance with the Florida State Auditor's Office's (FSO) Audit Manual, Chapter 200, and the Florida State Auditor's Office's (FSO) Audit Manual, Chapter 200.

The auditor also observed that the EMS & Animal Services Department's drug inventory controls were not in compliance with the Florida State Auditor's Office's (FSO) Audit Manual, Chapter 200, and the Florida State Auditor's Office's (FSO) Audit Manual, Chapter 200. The auditor observed that the EMS & Animal Services Department's drug inventory controls were not in compliance with the Florida State Auditor's Office's (FSO) Audit Manual, Chapter 200, and the Florida State Auditor's Office's (FSO) Audit Manual, Chapter 200.


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ATTACHMENT: EMS & Animal Services Drug Inventory Controls Audit Report - 12/30/22

## MANAGEMENT LETTER

**TO:** Jeffrey Rogers, County Administrator

**VIA:** The Honorable Douglas A. Chorvat, Jr.

**FROM:** Elizabeth Hogan, CIA, CFE, Director of Audit Services 

**DATE:** December 30, 2022

**SUBJECT:** Follow-Up Audit of EMS & Animal Services Drug Inventory Controls

In accordance with the Audit Services Department's Audit Project Schedule, the internal audit team conducted a follow-up audit of the EMS & Animal Services Drug Inventory Controls Audit. Based on testing, observations, and communications with key personnel, the audit team produced the attached report for your review. A copy of this report has been forwarded to the Board of County Commission as an agenda "correspondence to note" item.

The purpose of this report is to furnish management with independent, objective analyses, recommendations, counsel, and information concerning the activities reviewed. The audit report is a tool to help management discern and implement specific improvements. It is not an appraisal or rating of management.

Although the internal audit team exercised due professional care in the performance of this follow-up audit, this should not be construed to mean that unreported noncompliance or irregularities do not exist. The deterrence of fraud and/or employee abuse is the responsibility of management. Audit procedures alone, even when carried out with professional care, do not guarantee that fraud or abuse will be detected.

The courtesies and cooperation extended by the employees of the Hernando County Fire and Emergency Services (HCFES) and Animal Services departments during the audit were sincerely appreciated.

If you have any questions, concerns, or need additional information in regard to the above or the attached report, please do not hesitate to contact Audit Services at (352) 540-6235, or just stop by our offices in Room 300C.

**ATTACHMENT: EMS & Animal Services Drug Inventory Controls Follow-Up Audit Report**

**Copy:** Paul Hasenmeier, Public Safety Director/Fire Chief  
Patrick Taylor, Deputy Fire Chief  
Chris Linsbeck, Community Services Director  
James Terry, Animal Services Manager

**Copy: Board of County Commissioners**

Chairman John Allocco  
Commissioner Jerry Campbell  
Commissioner Steve Champion  
Commissioner Brian Hawkins  
Commissioner Elizabeth Narverud

**Copy: Audit Services Planning & Priorities Committee**

The Honorable Douglas A. Chorvat, Jr., Clerk of the Circuit Court and Comptroller  
Joshua Stringfellow, CPA, Director of Financial Services  
Jon Jouben, County Attorney  
Jeffrey Rogers, County Administrator  
Tobey Phillips, Deputy County Administrator  
Toni Brady, Director, Office of Management & Budget/Chief Procurement Officer  
Jeff Wolf, CPA, Senior Audit Manager, MSL P.A.  
William Blend, CPA, CFE Shareholder, MSL P.A.

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## Executive Summary

The Audit Services Department (ASD) conducted a follow-up audit of the EMS & Animal Services Drug Inventory Controls Audit dated April 17, 2019. The purpose of this follow-up audit was to determine the status of the previous recommendations for improvement and management's corrective actions.

The purpose of the original EMS & Animal Services Drug Inventory Controls Audit was to provide management with some level of assurance that the internal controls for drug inventories were adequate.

To assess the status of previous recommendations, the ASD interviewed management and staff members, performed limited testing, and observed the security of both departments.

Of the seven recommendations in the original audit report, ASD determined that three recommendations were implemented; three recommendations were partially implemented; and one recommendation was not implemented.

The three recommendations that were implemented pertained to the following Opportunities of Improvement:

- Document PAR values for non-controlled medications within the Logistics Department's warehouse
- Implement proper segregation of duties for the ordering, receiving, and counting of medication, such that no one person participates in all three activities
- Limit access to the Logistics Department's warehouse

The three recommendations that were partially implemented pertained to the following Opportunities for Improvement:

- Implement software to accurately track medical supply inventory (Hernando County Fire and Emergency Services)

Communications with Logistics staff and observation of the system set up has determined that the software implementation is in process and expected to be completed by the end of year.

- Review Controlled Substance logs for accuracy and completeness, and reconcile entries to a completed Accountability Form

The review of recordkeeping and PAR quantities determined that directives were given to staff on proper medication recordkeeping. Even though a directive was issued, of the 7 engines/units reviewed, 57% of the Controlled Substance Logs and/or Accountability Forms were inaccurate or incomplete.

- Implement periodic reviews of Engine and Rescue Units' inventory of medications for adherence to PAR quantities of non-controlled substances by all paramedics and EMTs

The review of PAR levels determined that of the 7 engines/units reviewed, 57% of the Controlled Substance Logs had PAR levels above the required PAR quantities.

The one recommendation that was not implemented was for the following Opportunity for Improvement:

- Implement software to accurately track medical supply inventory (Animal Services)

The review determined that the Animal Services Department has not implemented software to maintain medical supply inventory electronically. However, the procedures in place complied with United States Drug Enforcement Administration (DEA) requirements.

ASD commends management for the full implementation of recommended improvements, and we encourage management to fully implement all recommendations.

Audit Comment No.	Audit Services Recommendation	Management Responses	Implementation Status				
			Implemented	Acceptable Alternative	Partially Implemented	Not Implemented	No Longer Applicable
1	The ASD recommends that Public Safety, now known as HCFES, and Animal Services implement software to accurately track the medical supply inventory and to enhance the internal control environment by reducing the risk of undetected theft or loss, unexpected shortages, and unnecessary purchases of items already on hand. Budgetary conditions should be reviewed and assessed for the costs associated with this implementation.	<p>HCFES Logistics has collaborated with Tech Services and procured an additional module with Asset Works (Currently being utilized by Fleet Management) to provide us with a web-based inventory management system. Implementation is expected this year.</p> <p>Hernando County Animal Services agrees that having an electronic method of inventory tracking would be a great addition to the manual forms required by the Drug Enforcement Administration. HCAS is currently moving toward changing our primary records management system to PetPoint which has modules for this task. Dr. Julie has already begun training staff which was a great step forward. HCAS is confident the recommendations for electronic tracking of controlled substances will be implemented this year. Because we already have PetPoint we will not have to purchase a new records management system.</p>			<p>✓ (HCFES)</p>	<p>✓ (Animal Services)</p>	

Audit Comment No.	Audit Services Recommendation	Management Responses	Implementation Status				
			Implemented	Acceptable Alternative	Partially Implemented	Not Implemented	No Longer Applicable
2	The ASD recommends that HCFES management review proper medication recordkeeping procedures with staff and implement reviews of each unit's Accountability Forms to their Controlled Substance Logs.	The Division Chief of Operations has drafted an operational memo along with a mandated review of our medication policy for all field personnel. This directive reiterates the importance of accurate inventory control as well as accurate medication logs in real-time.			✓		
3	The ASD recommends that management periodically review Engine and Rescue Unit's non-controlled medications for adherence to the established PAR quantities.	HCFES has implemented protocols for personnel to provide input on PAR levels for Rescues and Engines. These suggestions or recommendations are vetted through HCFES administration committee. All inconsistencies in PAR levels on units has been corrected.			✓		
4	The ASD recommends that management formally document the PAR values for non-controlled medications within the Logistics Warehouse.	HCFES Logistics had already amended its inventory control sheets to include PAR levels.	✓				
5	The ASD recommends HCFES separate the duties of ordering, receiving, and counting medication. If staffing level constraints prevent the ability to properly segregate these duties, then management should implement adequate mitigating controls such as review of all	Accounts payable will assume the duties of ordering medication and medical supplies instead of Logistics. Once Logistics counts the inventory, Accounts Payables will place orders to replenish the stock. Logistics will	✓				



Audit Comment No.	Audit Services Recommendation	Management Responses	Implementation Status				
			Implemented	Acceptable Alternative	Partially Implemented	Not Implemented	No Longer Applicable
	orders and random inventory verifications.	receive the order and verify all is received. Another person in Accounts Payable will process the invoice for payment.					
6	To establish inventory accountability and reduce the possibility of inventory shrinkage, the ASD recommends that HCFES management limit access to the Logistics Department's Warehouse to only those indicated in the Medication Policy.	With authorization from HCFES administration the Logistics Department has changed the locks on the entry doors to the inventory area, providing access to the Deputy Fire Chief, Battalion Chiefs, the Logistics Manager, the Logistics Coordinator and the Logistics Technician.	✓				

**Acknowledgement**

Fieldwork was performed by: Vicky Sizemore, Internal Auditor *WS*

This report was reviewed and authorized by Douglas A. Chorvat, Jr., Clerk of Circuit Court and Comptroller.

*D. Chorvat, Jr.*  
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Douglas A. Chorvat, Jr.

*12/30/2022*  
\_\_\_\_\_  
Date

## BACKGROUND INFORMATION

Over the past few years, both the Hernando County Fire Rescue and the Animal Services Departments have undergone changes. On July 1, 2020, Hernando County Fire Rescue consolidated with County Emergency Management to become an all-hazards emergency service provider and was renamed Hernando County Fire and Emergency Services (HCFES). In 2021, the Animal Services Department welcomed a new Veterinarian to continue their mission to rescue, rehome, and reunite stray or abused animals.

To accomplish their missions to provide quality medical care to the citizens of Hernando County or to the animals in their custody, both the HCFES Department and the Hernando County Animal Services Department purchase and maintain medical supply inventories including controlled substances.

According to eFinance Plus, the County's financial system, in FY 2021/2022, HCFES spent \$522,341 and Animal Services spent \$90,289 on medical operating supplies. For HCFES, the expenditure for medical operating supplies accounts for approximately 6% of the actual operating expenditures. For Animal Services, the expenditure for medical operating supplies accounts for approximately 26% of the actual operating expenditures.

## OBJECTIVE

The purpose of this follow-up audit of the EMS & Animal Services Drug Inventory Controls Audit was to assess the status of previous recommendations for improvement.

The purpose of the original audit was to provide management with some level of assurance that the internal controls for drug inventories were adequate.

## SCOPE

To determine the current status of the previous recommendations, ASD interviewed management and staff members, performed limited testing, and observed the security of both departments to assess the actual actions taken by management to implement operational improvements.

Opportunity for Improvement	Description	Page Reference
1	Implement software to accurately track medical supply inventory	13-14
2	Review Controlled Substance Logs for accuracy and completeness, and reconcile entries to a completed Accountability Form	15-16
3	Implement periodic reviews of Engine and Rescue Units' inventory of medications for adherence to PAR quantities of non-controlled substances by all paramedics and EMTs	17
4	Document PAR values for non-controlled medications within the Logistics warehouse	18
5	Implement proper segregation of duties for the ordering, receiving, and counting of medication, such that no one person participates in all three activities	19
6	Limit access to the Logistics Department's warehouse	20

Discussion Points  
Status of Recommendations

This section reports the follow-up actions taken by management regarding the Opportunities for Improvement reported in the EMS and Animal Services Drug Inventory Controls Audit dated April 17, 2019. The audit comments and recommendations contained herein are those of the original audit, followed by the current status of the Opportunity for Improvement.

**Discussion Point 1: Inventory Software – HCFES and Animal Services**

According to the Government Accountability Office (GAO) Executive Guide Best Practices in Achieving Consistent, Accurate Physical Counts of Inventory and Related Property, "Managing the acquisition, production, storage, and distribution of inventory is critical to controlling cost, operational efficiency, and mission readiness."

**1. Opportunity for Improvement: Implement software to accurately track medical supply inventory**

Currently, both HCFES and Animal Services are manually tracking their inventory levels. This manual process presents the risk that errors and/or losses may go undetected. A computer-based system would streamline accountability audits, and further supplement the handwritten logs required by the Drug Enforcement Administration.

**Recommendation:** The ASD recommends that HCFES and Animal Services implement software to accurately track the medical supply inventory and to enhance the internal control environment by reducing the risk of undetected theft or loss, unexpected shortages, and unnecessary purchases of items already on hand. Budgetary conditions should be reviewed and assessed for the costs associated with this implementation.

**Management Response:** (HCFES)

**HCFES, Logistics has collaborated with Tech Services and procured an additional module with Asset Works (Currently being utilized by Fleet Management) to provide us with a web-based inventory management system. Implementation is expected this year.**

**Status (HCFES): Partially Implemented**

Communications with Logistics staff and observation of the system set up has determined that the software implementation is in process and expected to be completed by the end of year.

**Updated Management Response:**

As of 12/16/2022 – Logistics Division has designated a "Inventory Manager", latest update is that the full inventory and implementation of "Asset Works" stands at 80-85% complete. There has been some delay due to the adaptation of the system databases to handle "soft inventory", however, Logistics and IT are working together to resolve the issues. 100% completion is expected by 2022Q4 or 2023Q1. In the interim, a monthly perpetual inventory has been implemented for the narcotics storage room. Weekly and monthly, a "running inventory" is performed utilizing a "2-person confirmation" to ensure that no

one person is responsible for the inventory and to provide a check and balance.

**Implementation Date: Currently being implemented.**

**Management Response:** (Animal Services)

**Hernando County Animal Services agrees that having an electronic method of inventory tracking would be a great addition to the manual forms required by the Drug Enforcement Administration. HCAS is currently moving toward changing our primary records management system to PetPoint which has modules for this task. Dr. Julie has already begun training staff which was a great step forward. HCAS is confident the recommendations for electronic tracking of controlled substances will be implemented this year. Because we already have PetPoint we will not have to purchase a new records management system.**

**Status (Animal Services): Not Implemented**

The review determined that the Animal Services Department has not implemented software to maintain medical supply inventory electronically. However, the procedures in place complied with United States Drug Enforcement Administration (DEA) requirements.

**Updated Management Response:**

Since our initial review response HCAS management has learned the capabilities of drug tracking utilizing Pet-Point. We discovered that the program does not offer an actual inventory module. You can document drug use in an individual animal's record; however, there is no master drug log program that would then deduct the used amount from a master list. The paper drug logs currently used are required by the Drug Enforcement Agency and meet all requirements. HCAS drug control practices and drug procedures have been audited by the Florida Department of Health, the Department of Business and Professional Regulations, and the Drug Enforcement Administration and found in compliance with each.

It is important to note that HCAS does not have controlled substances outside of our facility; therefore, we do not have the same challenges as an organization with a substantial distribution network. Based on our volume, structure, and years of successful audits, management and the staff veterinarian do not find sufficient benefit in changing to an electronic system.

## **Discussion Point 2: Recordkeeping Controlled Medications – HCFES**

According to the Florida Administrative Code & Florida Administrative Register 64J-1.021 (Security of Medications), HCFES' operating procedures regarding the security and recordkeeping of medications are authorized by HCFES' Medical Director and consistent with specifications outlined by the U.S. DEA Title 21 and Florida Statutes Chapters 499 and 893.

Code of Federal Regulations (CFR) state that "Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location."<sup>1</sup>

Inventory of controlled substances carried on all fire engine and rescue units are recorded at each shift change on the unit's monthly Controlled Substance Vehicle Log. Any used, expired, or broken/tampered drugs are recorded on an Accountability Form which is then exchanged to the station's Battalion Chief (BC) for a replacement vial upon the BC's verification of usage on a properly documented Patient Care Record.

### **2. Opportunity for Improvement: Review Controlled Substance logs for accuracy and completeness, and reconcile entries to a completed Accountability Form**

ASD's observations noted that all controlled medications were properly stored and safeguarded. Review of the required logs and forms, however, disclosed a couple of lapses in recordkeeping.

ASD's review of the Controlled Substance Logs for the Fire Stations selected for testing disclosed one instance in which the log incorrectly reflected an increase in Versed. In addition, this log also indicated that for the time period reviewed, the daily inventory was taken at 0800 each day; however, when ASD was at the Fire Station staff members indicated that the inventory had occurred at 0730.

In addition, ASD traced Controlled Substance Log entries to the completed Accountability Form. One out of the eighteen entries reviewed did not have a completed Accountability Form.

**Recommendation:** The ASD recommends that HCFES management review proper medication recordkeeping procedures with staff and implement reviews of each unit's Accountability Forms to their Controlled Substance Logs.

#### **Management Response:**

The Division Chief of Operations has drafted an operational memo along with a mandated review of our medication policy for all field personnel. This directive reiterates the importance of accurate inventory control as well as accurate medication logs in real-time.

#### **Status: Partially Implemented**

The review of recordkeeping and PAR quantities determined that directives were given to staff on proper medication recordkeeping. Even though a

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<sup>1</sup> <https://www.ecfr.gov/current/title-21/chapter-II/part-1304/subject-group-ECFR9944e94ba5f1eb0/section-1304.11>

directive was issued, of the 7 engines/units reviewed, 57% of the Controlled Substance Logs and/or Accountability Forms were inaccurate or incomplete.

**Updated Management Response:**

As with discussion point #1, the completion of full electronic inventory for both controlled and non-controlled inventory is 80-85% complete. Along with the continued transition to electronic inventory control for the warehouse, they are completing inventory itemization for all fire stations and apparatus to ensure that they remain at PAR.

**Implementation Date:**

**Currently being implemented.**



### **Discussion Point 3: Periodic Automatic Replenishment (PAR) Quantities – HCFES**

Medications and fluids used by HCFES for treating patients are obtained under the Medical Director's Medical License. The Medical Director authorizes the inventory levels that are to be carried on each ambulance and/or engine. The inventory levels are referred to as PAR. PAR quantities are established to ensure medications/fluids are on-hand to provide the best possible care while also minimizing the cost of wasting expired medications.

The PAR level for both controlled and non-controlled medications are documented on the logs used by HCFES personnel. HCFES personnel perform an inventory at each shift change. For non-controlled supplies, HCFES personnel perform an inventory on a weekly basis.

When medications/fluids fall below the PAR level, field personnel request replenishment(s) of controlled medications through the Battalion Chiefs and request replenishment(s) of non-controlled medications through the Captains. To obtain replenishment of controlled medications, HCFES paramedics must complete an Accountability Form which documents when the medication was administered. The administration of the medications is also included in the Patient Care Report in the IMAGETREND system.

#### **3. Opportunity for Improvement: Implement periodic reviews of Engine and Rescue Units' inventory of medications for adherence to PAR quantities of non-controlled substances by all paramedics and EMTs**

Based on the results of ASD's inventory observations, there were no discrepancies in the amounts of the counts observed.

However, during some inventory observation cases, the quantity of non-controlled substances on Public Safety engines and rescue units exceeded PAR quantities. Exceeding the established PAR levels could result in overspending.

**Recommendation:** The ASD recommends that management periodically review Engine and Rescue Units' non-controlled medications for adherence to the established PAR quantities.

#### **Management Response:**

**HCFES has implemented protocols for personnel to provide input on PAR levels for Rescues and Engines. These suggestions/recommendations are vetted through HCFES administration and the committee. All inconsistencies in PAR levels on units has been corrected.**

#### **Status: Partially Implemented**

The review of PAR levels determined that of the 7 engines/units reviewed, 57% of the Controlled Substance Logs had PAR levels above the required PAR quantities.

#### **Updated Management Response:**

Along with the continued transition to electronic inventory control for the warehouse, they are completing inventory itemization for all fire stations and apparatus to ensure that they remain at PAR. At the time of submission, all PAR sheets as submitted to Logistics are accounted for and correct.

**Implementation Date: Currently being implemented.**

**4. Opportunity for Improvement: Document PAR values for non-controlled medications within the Logistics warehouse**

PAR values for non-controlled medications within the Logistics Warehouse are not in writing and are known only to the Logistics Coordinator.

**Recommendation:** The ASD recommends that management formally document the PAR values for non-controlled medications within the Logistics Warehouse.

**Management Response:**

**HCFES Logistics had already amended its inventory control sheets to include PAR levels.**

**Status: Implemented**

#### Discussion Point 4: Segregation of Duties – HCFES

According to the American Institute of Certified Public Accountants (AICPA), "Segregation of Duties (SOD) is a basic building block of sustainable risk management and internal controls for a business. The principle of SOD is based on shared responsibilities of a key process that disperses the critical functions of that process to more than one person or department. Without this separation of key processes, fraud and error risks are far less manageable."<sup>2</sup>

Logistics personnel are comprised of the Logistics Manager, the Logistics Coordinator, and the Logistics Technician. With a wide range of field duties among the fire stations belonging to the Logistics Department, the Logistics Coordinator is often the individual to order medications and supplies, verify the order upon receiving the items, and perform the weekly inventory of the stock room.

**5. Opportunity for Improvement: Implement proper segregation of duties for the ordering, receiving, and counting of medication, such that no one person participates in all three activities**

The Logistics Coordinator performs all three duties of ordering, receiving, and counting medication for the Logistics warehouse. When one person participates in all three phases, there is an opportunity for fraudulent activity.

**Recommendation:** The ASD recommends that Public Safety separate the duties of ordering, receiving, and counting medication. If staffing level constraints prevent the ability to properly segregate these duties, then management should implement adequate mitigating controls such as review of all orders and random inventory verifications.

**Management Response:**

**Accounts payable will assume the duties of ordering medication and medical supplies instead of Logistics. Once Logistics counts the inventory, Accounts Payables will place orders to replenish the stock. Logistics will receive the order and verify all is received. Another person in Accounts Payable will process the invoice for payment.**

**Status: Implemented**

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<sup>2</sup> <https://www.aicpa.org/interestareas/informationtechnology/resources/value-strategy-through-segregation-of-duties.html>

## **Discussion Point 5: Logistics Department's Warehouse Security – HCFES**

The Logistics Department Warehouse located at HCFES Headquarters is accessible by keypad or by physical key. According to Florida Statute 499.0121 (Storage and handling of prescription drugs; recordkeeping), "Entry into areas where prescription drugs are held must be limited to authorized personnel."

HCFES' Medication Policy lists authorized personnel as the Medical Director, HCFES Administrative Chiefs, Battalion Chiefs, Logistics Manager, Logistics Coordinator, Logistics Personnel, and the Quality Assurance Coordinator(s).

In addition to compliance with Florida Statute, HCFES must comply with the Code of Federal Regulations (CFR). Per the CFR, "The controlled substances storage areas shall be accessible only to an absolute minimum number of specifically authorized employees."<sup>3</sup>

### **6. Opportunity for Improvement: Limit access to the Logistics Department's Warehouse**

Based on ASD's observation, the Logistics Department's area used for the storage of controlled substances appears to be adequate and in compliance with regulations.

However, discussions with HCFES personnel disclosed that access to the Logistics Department's area that is used for the storage of non-controlled substances included personnel not specifically listed in HCFES' Medication Policy such as, administration staff, captain medics, and any other staff member who may have obtained the keypad code. This access allows them to obtain non-controlled medications directly from the Logistics Department's inventory.

**Recommendation:** To establish inventory accountability and reduce the possibility of inventory shrinkage, the ASD recommends that HCFES management limit access to the Logistics Department's Warehouse to only those indicated in the Medication Policy.

#### **Management Response:**

**With authorization from HCFES administration the Logistics department has changed the locks on the entry doors to the inventory area, providing access to the Deputy Fire Chief, Battalion Chiefs, the Logistics Manager, the Logistics Coordinator and the Logistics Technician.**

**Status: Implemented**

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<sup>3</sup> <https://www.ecfr.gov/current/title-21/chapter-II/part-1301/subject-group-ECFRa7ff8142033a7a2/section-1301.72>