INTERNAL AUDIT OFFICE

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MARCH 1, 2017

FIRE DEPARTMENT

CONTROLLED SUBSTANCES AUDIT

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City of Riviera Beach Internal Audit Office

"Promoting honest, efficient, effective, and fully accountable city government."

FIRE DEPARTMENT CONTROLLED SUBSTANCES AUDIT

Audit # IAO0516-03FD March 2017

Mr. Danny Jones
Interim City Manager
600 West Blue Heron Blvd.
Riviera Beach, Florida 33404

March 1, 2017

Re: Audit of the Fire Department Controlled Substances Inventory (IAO0516-03FD)

Enclosed is the audit report for the Fire Department, approved as part of the Annual Audit Plan. The Fire Department is responsible for safeguarding, securing, and accounting for the controlled substances (narcotics) used on emergency medical calls. The audit included: a) reviewing compliance to Department policy, procedure, and statutory requirements, b) evaluating internal controls, and c) evaluating the efficiency of inventory control activities.

The Department's current Standard Operating Procedures (SOP) address three areas of the Controlled Substances Inventory Process: a) Security of medications, fluids, and controlled substances (SOP EMS-1), b) Replacement of controlled substances (SOP EMS-2), and c) Missing or broken containers of controlled substances (SOP EMS-3). Despite the well-intentioned content of these procedures, there exists several places where the Department should adopt additional procedures (internal controls), including the development of a transparent audit trail from ordering and storage, to usage and disposal.

The audit did uncover several significant deficiencies in the way the Department orders, stores, and disposes controlled substances inventory. Improvements to internal controls related to management oversight, separation of duties, and inventory reconciliations are recommended. Department Management has indicated that this report will provide valuable insight into policy and procedure updates to be developed in 2016/17 as part of its integration of newly purchased storage and distribution equipment.

If you need additional information or have any questions, please contact me at (561) 845-3470.

Sincerely,

William Brown

William Brown, CIA, CGAP
Internal Auditor, City of Riviera Beach
wbrown@rivierabch.com

City of Riviera Beach Internal Audit Office

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FIRE DEPARTMENT CONTROLLED SUBSTANCES AUDIT

Executive Summary

Audit # IAO0516-03FD

March 2017

Purpose

During the City's Annual Risk Assessment process, the Riviera Beach Fire Department (FD) submitted Controlled Substances Inventory as the Department's number one candidate for audit. The Internal Audit Office (IAO) evaluated the internal controls associated with: a) ordering, b) receiving & storage, c) security, d) management, and e) disposal of controlled substances.

Highlights

The Fire Department has developed standard operating procedures (SOPs) outlining specific roles and responsibilities for complying with State of Florida statutes governing Controlled Substances (CS). The critical operating procedures listed below were not consistently followed:

- Requiring dual controls to access CS inventory
- Ordering CS in a size and at a frequency to: a) prevent inventory from reaching zero, b) not exceed the capacity of the department's storage lock box, and c) prevent CS from "expiring on the shelf"
- Utilizing the Station 87 main inventory lock box as the only approved place to store CS inventory (aside from CS stored on EMS/ALS vehicles)
- Requiring disposal forms be completed at the time CS are disposed (including signatures by witnesses)

In addition to the non-compliance issues stated above, several internal control deficiencies were observed, including:

a) Lack of a transparent and easily monitored audit trail: from ordering and storage, to usage and disposal. Currently, the Department does not have a robust ability to reconcile CS ordered to CS stored to CS administered or disposed.

b) Separation of Duty conflicts for order/receipt, and access/storage activities.

(*Continued on next page*)

Management Response

The City of Riviera Beach Fire Department (FD) agrees with the findings and recommendations of the audit. The Fire Department responses follow each of the report's recommendations. The full Department response can be found in the report's appendix.

Recommendations

To address non-compliance with standard operating procedures, the Fire Department should:

1. Create and monitor a strategic Controlled Substances (CS) ordering and stocking policy using the following inputs:
   - CS historical usage records
   - The capacity of authorized storage space
   - CS expected shelf life
   - Vendor required minimum order sizes
   - Narcotics container size
2. Create and monitor a strategic CS ordering and stocking policy to prevent stock-outs. Develop a contingency SOP for "rig swaps" *if* main inventory levels go to zero.
3. Use only secure, authorized areas to store Controlled Substances.

To address internal control deficiencies, the Department should:

4. Ensure a proper separation of duties exists throughout the Controlled Substances Inventory Process.
5. Monitor access to CS to ensure that dual controls are followed.

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FIRE DEPARTMENT CONTROLLED SUBSTANCES AUDIT

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March 2017

Highlights (*Continued from previous page*)

c) Ineffective management oversight to ensure standard operating procedures are being followed.

Department Management appears committed to address the findings contained within this audit report. Following the discussion of preliminary findings, the Fire Department immediately began updating SOPs, and correcting internal control deficiencies. The Fire Department has purchased and received new storage and distribution equipment. The UCAPIT storage unit is a storage and dispensing machine ("vending machine type") with biometric transaction identification, increased storage capacity, and inventory software that is expected to yield advanced reporting capabilities.

The accompanying audit report is intended to assist the Fire Department in both establishing and maintaining internal controls used to promote honest, efficient, effective, and accountable inventory control. The Internal Audit Office commends the department on steps already undertaken, and for the commitment to take further steps to address the deficiencies documented.

Recommendations (*Continued from previous page*)

6. Reconcile Controlled Substances (CS) Inventory records periodically. All purchased CS should be tracked and monitored from purchase through EMS usage and/or disposal.

7. Ensure that all required historical records are kept secure and easily retrieved for review.

   Seek a legal determination on record retention, then proceed with destroying all records past the required retention period.

To improve the efficiency of CS inventory activities, the Department should:

8. Develop procedures allowing CS to be restocked immediately following EMS use in the field.

9. Investigate elimination of the hardcopy log book, or find ways to keep it in better physical condition.

10. Investigate ways to make the daily inventory process more efficient.

11. Investigate "right sized" container sizes for CS.

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Background

During the City's Annual Risk Assessment process, the City of Riviera Beach Fire Department (FD) submitted the Controlled Substances Inventory (CS) as the Department's candidate for audit. The subsequent risk rating by the City Manager's Office placed the audit onto the Annual Audit Plan. The City of Riviera Beach Fire Department (FD) has developed and implemented Standard Operating Procedures (SOPs) for narcotics used on emergency calls. Narcotics used by EMS and ALS Paramedics are Morphine, Valium, and Versed, collectively referred to as "Controlled Substances."

The Fire Department is charged with keeping Class II and IV narcotics securely stored and safeguarded against theft and fraudulent use. From Florida Code[1], Rule: 64J-1.021, each ALS shall provide:

"Security procedures which include the provider's method of ensuring against theft, tampering with or contamination of controlled substances, medications, and fluids and the identities and position titles of employees who have access to controlled substances."

The Department currently uses three narcotics classified by the DEA as Class II and Class IV controlled substances: Valium (Class IV), Morphine (Class II), and Versed (Class IV).

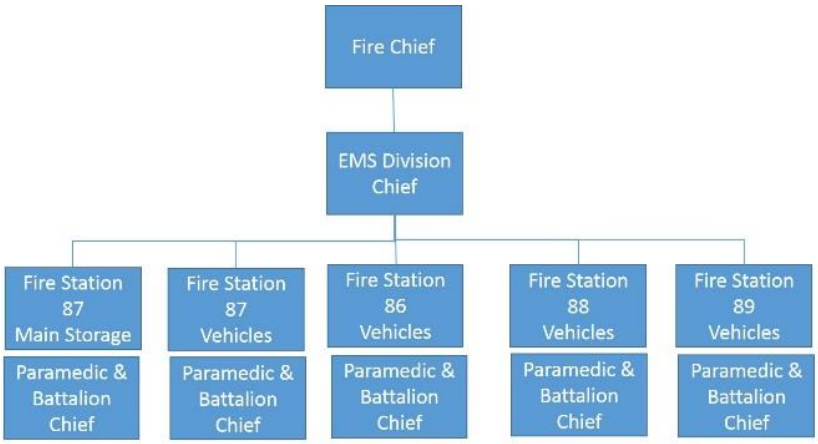
DEA Controlled Substances Categories

CI	High potential for abuse. No medical value
CII	High potential for abuse. Use may lead to severe physical or psychological dependence. • Includes Morphine
CIII	Potential for abuse less than CI and CII. Use may lead to low to moderate physical dependence or high psychological dependence.
CIV	Low potential for abuse relative to CIII. Use may lead to limited physical or psychological dependence. • Includes Midazolam (Versed) and Diazepam (Valium)
CV	Low potential for abuse relative to CIV. Use may lead to limited physical or psychological dependence, less than CIV.

The Department's main controlled substances inventory is located at Fire Station 87, but each rescue vehicle authorized to carry controlled substances is issued a small amount (typically up to two of each controlled substance).

[1] Florida Administrative Code & Florida Administrative Register, Department of Health; Division of Emergency Preparedness and Community Support; Chapter: Emergency Medical Services; Rule: 64J-1.021 Security of Medications.

Fire Department Controlled Substances Inventory Participants

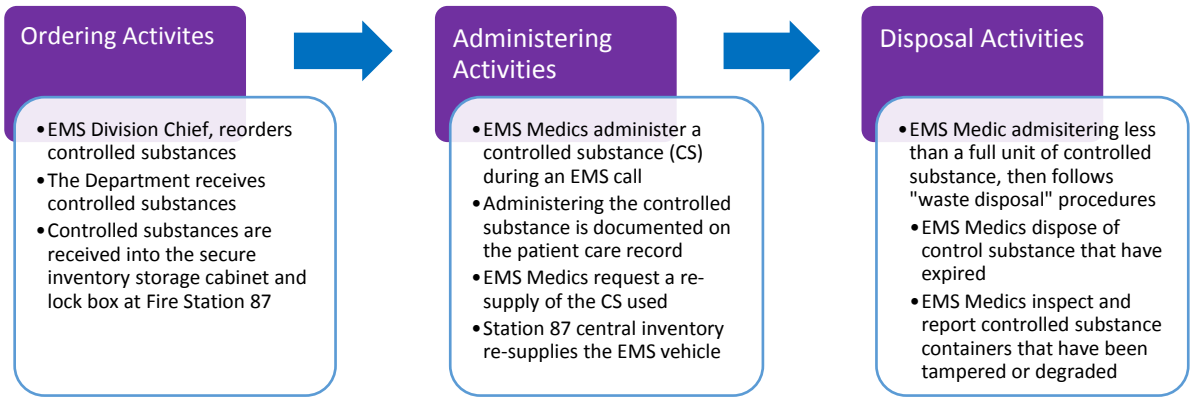


The audit of Controlled Substances inventory included reviewing internal controls intended to secure narcotics from theft, fraudulent use, or mismanagement. The management of the Fire Department is responsible for ensuring: a) the reliability and integrity of records and b) compliance with applicable Statutes, Department Policy & Procedures. Fire Department management is responsible for implementing internal controls that secure and safeguard the controlled substances inventory, this includes ensuring:

- The integrity of records – order, inventory, usage, and disposal records must be accurate
- Controlled substances are held secure and safeguarded throughout the receiving, storage, administering (during an EMS call), and disposal activities (for expired, tampered, etc.)

The following flowchart illustrates the Controlled Substances Inventory Cycle.

Flowchart 1: Controlled Substances Inventory Cycle



Fire Department Controlled Substances Roles & Responsibilities

Medical Director - For the purposes of Emergency Medical Services, the medical director shall be the registrant and the EMTs will be acting as his agent in administering controlled substances to patients. The medical director will be treating the EMS agency for which he provides oversight as his practice. As such, he is allowed to maintain an inventory of controlled substance for the administration to patients in the usual course of business once registered with the DEA.

Fire Chief (Department Director) - Sets control substance inventory policy, establishes and implements internal controls to ensure the reliability and integrity of inventory information and the security of controlled substances.

EMS Division Chief – Provides day-to-day oversight of the controlled substances inventory. Ensures internal controls are in place and functioning as intended (including staff adherence to policies, procedures, and statutes). The EMS Chief initiates and receives orders for controlled substances (orders are authorized by the City's Medical Director) and is provided access to the controlled substances inventory as stipulated in the Departments Standard Operation Procedures (SOPs).

Station 87 Battalion Chief – Responsible for the day-to-day security of the controlled substances inventory (along with the Station 87 Paramedic). Is responsible for one half of the dual access control designed to safeguard the controlled substances inventory in the 2-key Lucite storage container (Battalion Chiefs keep the "red key" to the Lucite lock box in their possession).

All Station Battalion Chiefs – Responsible for signing the daily inventory log signifying that the Medics and Station Captains have recorded all required information in the inventory log.

Station 87 Paramedic – Performs a daily inventory of controlled substances, recording counts in an inventory log book. Is responsible for the second half of the dual access control to the controlled substances Lucite storage container (the Station 87 Paramedic keeps the "blue key" to the Lucite lock box in their possession).

All Station Paramedics – By Department SOP (policy), in compliance with Florida State Statute, "only State licensed paramedics, on-duty Battalion Chief, EMS Division Chief, or Medical Director shall have access to Controlled Substances."[2] At shift-change the on-coming Medic, and the Medic whose shift is ending, together perform an inventory of controlled substances for narcotics stored in the med-box of each EMS vehicle - recording counts in an inventory log. Following the administration of a controlled substance, the Medic is responsible for documenting the use of the controlled substance – this may include the waste/disposal of partial amounts of CS not administered.

Station Captains – Responsible for signing the daily inventory log signifying that the Medics have recorded all required information in the inventory log.

Department Administrative Assistant / Department Accounting Specialist – signs for controlled substances mail orders when the EMS Division Chief is not available to do so.

Department Accounting Specialist – Creates Purchase Requisitions for Controlled Substances.

[2] City of Riviera Beach Fire Department SOP EMS-1: Security of medications, fluids, and controlled substances; SOP EMS-2: Replacement of Controlled Substances; SOP EMS-3: Missing or broken containers of controlled substances

Controlled Substances Inventory Supplier

The Fire Department orders controlled substances from an approved vendor, formerly the Palm Beach County HealthCare District (HCD), and currently Cardinal Health, LLC. After placing an order with the Palm Beach County Healthcare District, the Department received a fax "ready for pick up" and the Fire Department's EMS Division Chief then traveled to the HCD to personally pick up controlled substance orders. The EMS Division Chief received a DEA form as a receipt with both a supplier's signature releasing the order to City of Riviera Beach and the EMS Division Chief signature acknowledging receipt and transfer of accountability to the Department. With the new vendor Cardinal Health, the controlled substances order is mailed directly to Fire Station 87 – the main storage location. Ordering and receiving documentation is primarily held at the vendor with some information accessible through City Financial Management System (FMS) records.

- The vendor's records include the DEA Form listing: quantity ordered, filled, ordered by, filled by, picked up by signature (transferring control to Fire Department staff), and associated dates.
- The vendor also tracks when the controlled substance was removed from their inventory system and the associated cost.
- Receipt into Fire Department inventory is documented through the Fire Department's main inventory log book.
- The City's Financial Management System (FMS) tracks payments to vendors through FMS expenditure accounts, with supporting documentation such as Purchase Orders, Purchase Requisition, etc.

Controlled Substances Inventory – Main Storage at Fire Station 87

The main storage area for Controlled Substances inventory is at Station 87 inside a locked store room, inside a locked Supply Cabinet, inside a 2-key, dual access controlled Lucite lock box. The Station 87 Medic unlocks the store room door and props the door open when someone is in the Supply Room obtaining supplies. When supplies have been obtained, the Medic is responsible for closing and locking the door to the Supply Room. Inside the Supply room, there are shelves containing various Department supplies. Also contained in the Supply Room is a single-keyed, locking cabinet. Inside the **locking supply cabinet**, a two-keyed, **Lucite lock box** houses the controlled substances inventory (Morphine, Valium Versed). The controlled substances security box is bolted to the supply cabinet.

Controlled Substances Inventory, Med-Box on EMS Vehicles

The Fire Department's four Emergency Medical Services (EMS) rescue vehicles, and two Advance Life Support (ALS) engines stock limited amounts of controlled substances for use on emergency calls. The EMS and ALS vehicles stock up to two each of Valium, Versed, and Morphine. The controlled substances are stored in a locked, mobile container, known as the "med-box." The med-box is stored in a locking exterior compartment of the EMS/ALS vehicle.

The med-box also contains non-controlled substances, and a separate locked Lucite security container (lock box) for controlled substances. The Lucite container has a separate lock, and only the on-duty Paramedic assigned to the vehicle has the key – the key ring is transferred to the Paramedic coming on-duty at change of shift. Fire Department procedures dictate that the med-box remains in the locked exterior of the EMS/ALS vehicle until it is needed on a call.

The Fire Department utilizes an **inventory log book** with the following characteristics: a) hard cover, b) consecutively numbered page, c) numbered lined pages, and d) handwritten column headings indicating required information for each day. Information required for each inventory log, on each day is as follows:

Daily Information Recorded in Controlled Substances Inventory Log Books		
EMS **Vehicle** Log Book Columns		Main **Supply Cabinet** Log Book Columns
Date action taken (either inventory count or removal from inventory)		Entry Line, sequentially numbered
Time action taken		Date & Time
Count prior to the action		Lot Number & Count prior to action
Controlled Substance Name		Note: The sheet heading contains the controlled substances name
Count after action taken		Lot Number & Count after the action
Expiration date		Action taken (either inventory count or removal from inventory)
Off-shift Paramedic name		OCA # (7 digit "case or EMS trip number)
Off-shift Paramedic number		Unit number (EMS vehicle number)
Off-shift Paramedic signature		Paramedic signature
On-shift Paramedic Name		Paramedic ID number
On-shift Paramedic number		Battalion Chief signature
On-shift Paramedic signature		Battalion Chief ID#
Captain signature		
Captain/Battalion Chief Signature and ID number		

Audit Scope & Audit Objectives

Prior to developing the audit scope and audit objectives, the Internal Audit Office (IAO) performed a risk assessment of the controlled substances inventory. With the risk assessment, the IAO:

- Identified risks associated with the ordering/receiving of controlled substances
- Identified risks associated with the access/security of controlled substances
- Identified risks associated with the waste/disposal of controlled substances
- Identified the controls established by management to prevent, detect, eliminate or minimize risks
- Documented inherent risks associated with current internal controls

The scope and audit objectives address the results of the risk assessment. The Internal Audit Office (IAO), along with the Fire Department (FD), developed the scope and objectives of the audit.

The scope is the boundary of the audit, directly tied to the audit objectives. The scope defines the: a) subject matter that the internal auditor will evaluate, assess and report on, b) period of time reviewed, and c) locations that will be included.

The scope of this audit included an examination of current internal controls employed to secure and safeguard the Department's controlled substances inventory. The controlled substances (CS) inventory areas audited included:

1) Ordering – including safety stock calculation and stock out analysis
2) Receiving controlled substances into the Department
3) Storing inventory into a secure location
4) Recording daily inventory - including recording the expiration dates
5) Administering (use) and resupply of CS inventory.

The scope included an examination of compliance to statutory requirements[3] and to Department Policy & Procedure. The audit covered the period from May 2014 through June 2016[4]. The audit period was established to cover a period of inventory practices / records adequate to achieve the audit objectives.

The objectives for this audit were:

Objective 1: Determine whether controlled substances are recorded, stored, and secured in compliance with established Fire Department Policy & Procedures, laws and "industry" practices.

Objective 2: Determine whether controlled substance procedures and practices adequately control risks during the following activities: ordering, receiving and storing (safeguarding) inventory, dispensing, conducting physical inventories, reconciling / accounting for use, etc.

Objective 3: Determine the efficiency of the current inventory control system.

Methodology

This audit was conducted in accordance with generally accepted government auditing standards. Those standards require that the Internal Audit Office (IAO) plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on the audit objectives. The IAO believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on the audit objectives.

The methodology developed for this audit included an assessment of internal controls placed by management to provide: a) inventory management in compliance with Department Standard Operating Procedures, b) security of controlled substances from theft, fraudulent use, and mismanagement, and c) compliance with applicable laws and regulations. The IAO seeks to provide reasonable assurance that internal controls are operating as management intends. The preventive and detective controls evaluated included those in place for: ordering, receiving, stocking, storing, distributing, dispensing, disposing and reconciling controlled substances inventory.

[3] Florida State Statutes Chapter 499 and 893, and Chapter 64E-2 Florida Administrative Code

[4] Federal Drug Enforcement Agency regulations require controlled substances records be kept for two years.

During the audit planning stages, the Internal Audit Office (IAO) reviewed documents pertinent to the audit objectives, including: a) the Fire Department's supplied Standard Operating Procedures[5], b) Station 87 Main Supply Cabinet Controlled Substances Inventory Log Book, c) Stations 86, 87, 88, 89 EMS/ALS Vehicle Controlled Substances Inventory Log Books, d) Florida State Statutes governing controlled substances, e) controlled substances vendor-supplied DEA forms for controlled substances (DEA#PP0082406), f) controlled substances vendor inventory records, and g) City of Riviera Beach Financial Management System (FMS) expenditure records and supporting documentation (purchase requisitions, purchase orders, and authorizations).

Following a review of pertinent resources, the Internal Audit Office (IAO), along with the Fire Chief (Fire Department Director), established **criteria** to use in evaluating the controlled substances inventory. The IAO used interviews, observations, inventory records, data analysis, and various testing methods to document the current **condition** of the Fire Department's Controlled Substances Inventory. The resulting gaps between criteria ("what is desired") and condition ("what actually exists") yielded the **findings** and **recommendations** contained within this report.

To accomplish the agreed upon audit objectives, IAO performed the following:

- Obtained documentation related to current controlled substances inventory ordering, receiving, stocking, storing, distributing, dispensing, disposing and reconciling.
- Reviewed internal controls through interviews, observation and examination of documents.
- Met with appropriate staff to discuss existing procedures and practices.
- Performed site visits at Fire Stations.
- Observed physical security in place at controlled substances inventory areas.
- Sampled Department controlled substances records[6].
- Reviewed supporting documentation.
- Analyzed Chain of Custody, and other process documentation for completeness, and accuracy.
- Reviewed the physical and system security intended to control unauthorized access to controlled substances inventory and inventory records.
- Researched best practices and compared results with the current Department policy, procedures, and practices of the current cash handling process.
- Reviewed FMS expenditure accounts verifying controlled substances financial activity.
- Reviewed the Department's controlled substances inventory log at each Fire Station.

The IAO conducted a variety of testing to gain an understanding of the Fire Department's Controlled Substances Inventory, including:

- Tested controlled substances inventory records for compliance to: a) statutory requirements and b) Department Policy & Procedures
- Observed staff practices for compliance with procedures and other internal controls

[5] City of Riviera Beach Fire Department SOP EMS-1: Security of medications, fluids, and controlled substances; SOP EMS-2: Replacement of Controlled Substances; SOP EMS-3: Missing or broken containers of controlled substances

[6] Judgmental sampling was used, detail findings contained in audit work papers documents sample sizes used. In some cases a lack of complete records impacted possible sample size.

- Traced controlled substances ordering records to inventory log re-stocking records
- Vouched FMS expenditure documentation to Department ordering and receiving records
- Analyzed effectiveness of internal controls to secure and safeguard controlled substances
- Identified inherent risks and possible impacts to the City
- Reviewed the audit trail/Chain of Custody documentation for controlled substances inventory
- Evaluated the accuracy of current controlled substances inventory

The audit's systematic approach enabled the IAO to fully achieve the audit objectives, including assessing the risk that abuse or illegal acts could occur and go undetected, or that unintentional errors could otherwise impede the department's ability to efficiently and effectively store Controlled Substances.

The audit steps specifically associated with **Audit Objective 1** ("determine compliance") included the following:

1) Established the audit criteria for securing and safeguarding controlled substances inventory, and then sampled and tested the compliance to each (including statute, policy and procedure). For example, the Department shared policy and procedure documents (in the form of Standard Operating Procedures – SOPs[7]), as well as Florida Statutes[8], laws, and governing agencies[9] that pertain to controlled substances inventory. Each area was tested to determine compliance to the audit criteria.

2) Wherever the Department does not meet the established criteria: a) document the possible impact and, b) recommend ways that the Department can meet the agreed upon criteria.

The audit steps associated with **Audit Objective 2** ("control risk") included testing the effectiveness of internal controls wherever controlled substances are handled or secured. This included the following:

1) Identify internal controls in place to prevent or detect deviations from policy and procedure

2) Evaluate the effectiveness of internal controls designed to prevent and/or detect errors, theft or fraud. This included evaluating:

    - Chain of Custody / Separation of Duties controls
    - Accuracy and completeness of inventory documentation, for example: determining whether information required in the Inventory Log Book is complete; determining if Inventory Log Book records for the audit period are available for review
    - Reconciling information from different sources, for example: determining whether the 30 units ordered and picked up (documented on the Purchase Requisition and DEA form), are placed into inventory (documented in the Inventory Log Book),
    - Physical security controls, for example determining whether video camera monitoring of the main supply cabinet has been effective

[7] City of Riviera Beach Fire Department SOP EMS-1: Security of medications, fluids, and controlled substances; SOP EMS-2: Replacement of Controlled Substances; SOP EMS-3: Missing or broken containers of controlled substances

[8] Florida State Statutes Chapter 499 and 893, and Chapter 64E-2 Florida Administrative Code

[9] US Department of Justice, Drug Enforcement Administration, Diversion Control Division, Title 21 Code of Federal Regulations, Part 1300

3) Observed and compared staff practices, with recognized inventory system best practices[10].

4) Documented inherent risks of current controls and assessed the potential impacts to the City.

The audit steps associated with **Audit Objective 3** ("efficiency of the inventory control system") included a high-level review of process efficiency, including ordering, receiving, and stocking methods. The efficiency of staff roles in moving, administering, securing, and safeguarding controlled substances inventory was also evaluated.

As defined by Government Auditing Standards, the Riviera Beach Internal Audit Office (IAO) is free from organizational impairments to independence. We report directly to, and are accountable to, the City Manager. Organizationally, the IAO is outside the staff or line management function of the units that we audit. We report the results of our audits to the City Manager, the Auditee, and the City Council. Audit Reports are available to the public.

Findings and Recommendations

The Internal Audit Office (IAO) performs audit work as an independent, outside observer for the purpose of providing assurance that internal controls are in place and functioning as intended, to mitigate risk. Management's internal controls promote honest, efficient, effective, and accountable operations. The following findings and recommendations have been developed in an impartial manner, based on sufficient and appropriate evidence, free from personal or organizational impairment. A response to each recommendation was provided by the Fire Chief, who serves as the Department Director. Selected text from the Department response is provided following each recommendation. The full Fire Department response is included in the Appendix of this report.

The Internal Audit Office (IAO) evaluated each area contained herein by first establishing evaluation *criteria* with the Fire Department, then through interviews, observations, data analysis, and various testing methods, the IAO documented the current *condition* of the Department's Controlled Substances inventory. The IAO's conclusions about the current condition have resulted in the findings and recommendations presented in this section of the report. A **Finding** statement is supported by: a) the **Criteria** used to evaluate the area, b) the **Condition** found to exist during the audit, c) the **Recommendations** to improve the audited area**,** and d) the Fire Department's **Management Response**.

[10] Inventory Management software: Checkmate EMS Inventory Management. http://dynamic-systemsinc.com/software/inventory-management/

Audit Criteria

The Fire Department's Controlled Substances Inventory is secured and safeguarded by Department-defined internal controls. The IAO uses the Department's internal controls as audit criteria.

- **Preventive Controls**: These internal controls include Policy & Procedure / Standard Operating Procedures (SOPs) / Locks and Keys, etc. These controls prevent fraud, theft, staff errors, mismanagement, etc.
    - SOPs specify that dual access controls will be used to access the controlled substances storage lock box (2 people, each with a separate key, each person witnessing the actions of the other).
    - SOPs dictate that controlled substance inventory at all Fire Stations be counted: a) at the beginning of each shift, at the same time, by both the off-going and the on-coming shift Paramedic, and b) whenever the Station 87 main inventory is used to replenish controlled substances that have been administered (used) on EMS calls – restocking the EMS/ALS vehicles.
    - SOPs specify the information to be recorded in the controlled substances inventory log books at each station (CS quantity, lot number, authorization signatures, etc.).
    - Controlled substances inventory is secured under lock and key – locked supply room, locked supply cabinet, two lock Lucite lock box.

- **Detective Controls**: These internal controls include Policy & Procedure / Standard Operating Controls (SOPs) and strategically located surveillance cameras. These controls detect fraud, theft, staff errors, mismanagement, etc.
    - SOPs dictate that EMS Paramedics examine the containers of controlled substances to detect tampering and whether the CS is past its expiration date
    - Surveillance cameras record the activities at storage areas; Department management has the ability to review video to detect whether staff is complying with SOPs
    - SOPs/management expectations dictate that Battalion Chiefs detect whether information on daily inventory logs have been completed

In general, internal controls should protect the controlled substances inventory from theft, misuse, mismanagement, or other fraudulent use; internal controls include:

- Limiting inventory access to those responsible and accountable for its security or use
- Creating an audit trail (identifying staff that access, administer, or dispose of controlled substances)
- Monitoring and reconciling controlled substances inventory records
- Separation of Duties – no one person should be responsible for activities whereby the person could commit theft or fraud and be able to cover it up
- Keeping controlled substances secure throughout its use by the Fire Department

- Documenting transfer of custody of controlled substances when it leaves one person's accountability and is transferred to another person's custody

In order to achieve the Audit's objectives, the IAO determined whether the current internal controls have the ability to:

- Ensure the controlled substances inventory is accurately documented
- Prevent and/or detect staff errors, theft, or fraud
- Secure and safeguard controlled substances inventory

Condition

In general, the following condition was observed:

- Orders of controlled substances (CS) sometimes exceeded the quantity indicated in Department SOPs – see Finding 1
- Reordering practices have allowed the controlled substances inventory to be completely depleted on multiple occasions – see Finding 2
- Controlled substances are not always stored in the department-authorized, secure, inventory location – see Finding 3
- Some existing internal controls are ineffective, because they are not effectively monitored. Risk for fraud, theft, and misuse exists in identified inventory activities – see Finding 4 & 5
- Reconciling the amount of controlled substances ordered to the amount inventoried is not performed – see Finding 6
- Controlled substances inventory log records (from the main Station 87 storage cabinet) are incomplete – see Finding 7
- Several controlled substances inventory activities could be made more efficient – Finding 8

Report Structure

First, a general **Finding Statement** is provided; the Finding is supported by the **Audit Criteria** used in developing the Finding (the criteria is what was expected to be in place based upon Department Policy & Procedures / SOPs, statutes, or inventory control industry best practices).

Following the description of the audit criteria used, the **General Condition** found by the Internal Audit Office (IAO) is documented. The condition leads to the Finding.

Next, the IAO draws conclusions from the condition, and describes the resulting **impact to the Department**.

1. Finding: The Department sometimes orders controlled substances in quantities exceeding what is indicated in the Department's Standard Operating Procedures (SOPs).

The Internal Audit Office (IAO) tested for compliance to the Department's Standard Operating Procedures (SOPs). Although the Department was found to be in general compliance with the majority of SOPs, the IAO noted that Controlled Substances (CS) were ordered in quantities exceeding the amounts indicated in the SOPs. The following paragraphs document the non-compliance observed, and the corresponding risks to the Department.

1. Audit Criteria/SOP: The Department supplied the Internal Audit Office with Standard Operating Procedures (SOPs) to be used as audit criteria. **SOP EMS-1**[11], is silent on specifics of ordering and order quantities; however it clearly states, "*A maximum of twenty Valium and twenty (20) Morphine may be maintained within the Medical Supply Room lock box at any given time."* This would indicate that an *order quantity* of 20 or less would be required in order to maintain *no more than* "A maximum of twenty…"

1. Condition, Non-Compliance: Of the eleven documented purchase orders of controlled substances reviewed by the IAO, 3 (27%) exceeded the order quantity specified in the Department's **SOP EMS-**1. For example: ordering, receiving, and inventory records indicate that Valium was purchased in an amount of 30 syringes, and Morphine was purchased in amounts of 50 and 25 vials – all exceeding the criteria of "*a maximum of 20…maintained…at any given time*."

Impact/Risk: The Department acknowledged the preceding condition resulted in quantities-on-hand that exceeded the capacity of the authorized storage area (Lucite lock box). Based on documented order quantities, the Department stored quantities greater than the "*twenty Valium and twenty (20) Morphine*" specified in the SOP. This practice presents several risks to the Department, including:

a) Exceeding the authorized storage capacity, which could result in quantities being stored in less secure areas,
b) Added difficulty in "managing" CS distribution (including difficulty in determining which CS inventory to distribute first based on expiration dates),
c) More time consuming to take daily inventory (with more inventory and/or if two storage locations are used versus one).

Audit Objective 1:

Determine whether controlled substances are recorded, stored, and secured in compliance with established Fire Department Policy & Procedures, laws and "industry" practices.

[11] City of Riviera Beach Fire Department SOP EMS-1: Security of medications, fluids, and controlled substances

1. Recommendation: The Department should use the following inputs to determine an ideal amount of controlled substances inventory to order and stock.

- The historical annual use of each controlled substance, from the IAO's analysis:
    - Valium = 39 syringes per year
    - Versed = 12 vials per year
    - Morphine = 32 vials per year
- The storage capacity of the new UCAPIT storage/dispensing equipment
- The shelf life / expiration dates of controlled substances received from the vendor
- The minimum order size from the City's controlled substances vendor

1. Management Response: The Department agrees. Quantities that the medications come supplied in are a static number, i.e. Valium generally comes supplied in boxes of 5 vials and Morphine generally comes in boxes of 25. Vendors do not open these boxes and distribute quantities to meet a need that our Department may actually have.

For example, if we have an actual need of 12 Morphine vials we would have no choice but to accept the delivery that exceeded our needs by 13 vials simply because of how the vendors dispense product…a remedy in hindsight would have been to adjust the par levels in the policy to reflect this practice. We also had to make contingency planning to allow for overstocking by design in the event of a manufacturer backorder. These backorders had the potential to cause us, and in some instances did, to drop to a par level of 0 in restock. Again, we acknowledge that formally adjusting the portion of the policy that addressed par levels would have been prudent.

Prior to the commencement of this audit, plans were well under way for implementing an automated dispensing solution with the ability to track data on usage, dispensing and trends. Since September 2016, we have been fully operational with our UCAPIT medication dispensing machine which not only tracks usage and dispensing data, but also sends electronic reports by email when a product is near replacement levels. It should be noted that the usage data found within the IAO's report will assist greatly in setting par levels in our new policies, and ordering practices.

Inventory Flow Analysis

Based on a review of the Health Care District of Palm Beach County's DEA Form (#PP0082406)[1] and compared with the Station 87 main storage location Inventory Log Book[1], the IAO ***observed discrepancies*** *including:*

a) instances where a larger quantity of controlled substances was received from the Health Care District, than was placed into the secure inventory at Station (87), and

b) where inventory was received into inventory without a corresponding order/purchase (presumably from a "secret" storage area).

Fire Rescue is currently tracking our ordering intervals for our Controlled Substances and we expect a final implementation of this completed process within the next 90-120 days (by July 2017).

2. Finding: The Department has stored controlled substances in an area other than what is authorized by SOPs.

The IAO tested for compliance to controlled substances Standard Operating Procedures (SOPs). Although the Department was found to be in general compliance with the majority of SOPs, it was discovered that controlled substances were stored in an area not authorized by policy.

2. Audit Criteria/SOP: The Department's SOP establishes criteria for controlled substances storage:

"SOP EMS-1: Security of medication fluids, and controlled substances; section: Medical Supply Storage Areas, "*Controlled Substances (Morphine and assorted benzodiazepines (Valium, Versed and Ativan) not assigned to a rescue vehicle shall be stored within the lock box in the EMS Supply Closet at Station (87).*"

2. Condition, Non-Compliance: The Internal Audit Office (IAO) reviewed DEA forms, Purchase Orders, FMS Accounts, and vendor order records to obtain evidence of the amount of CS "coming into" the Fire Department. The amount ordered/picked-up by the Department was compared with the amount that was placed into inventory (documented in the Station 87 Inventory Log Book). The analysis showed that **58% of the time**, the amount of controlled substances restocked to inventory was an amount *less than what was ordered* and picked up **(not everything ordered was placed immediately into the Department's secured, authorized storage area,** which is the Station 87 Supply Cabinet and Lucite lock box).

Department Action: Following an investigation by the Fire Chief, an undocumented, alternative storage location was discovered. The alternative storage location was in a locking file cabinet in the EMS Division Chief's office.

The EMS Division Chief expressed that a locked file cabinet and the lock on his office door, where both keys remained in his possession, was sufficient security for the controlled substances. The sufficiency of this security is addressed in Finding's 4 & 5; however, from a compliance perspective, the IAO concludes that maintaining a secret[12], unauthorized storage area is in conflict with the Department's stated Standard Operating Procedure which authorizes only one Station 87 storage area – the supply room/cabinet/Lucite lock box.

New Inventory Storage & Dispensing Equipment

During the audit, the Department purchased a new inventory storage and dispensing equipment (UCAPIT) that is both hardware (dispenser) and software (inventory reporting, biometric access controls, and audit trail).

The Department indicated that the UCAPIT inventory control, dispensing machine will lead to a significant policy shift towards inventory control and monitoring. UCAPIT will replace the storage cabinet, Lucite container, and the Inventory Log Book.

The Department indicated that the UCAPIT dispenser has an ability to maintain a higher volume of controlled substances, with increased security and inventory reporting.

[12] IAO interviews indicated that the Department Director (Fire Chief), Deputy Chief, and staff participants in the CS inventory process had no knowledge of the unauthorized storage area, making the EMS Division Chief the only one who knew, hence "secret."

Impact/Risk: The unauthorized storage area does not comply with the Department's Standard Operating Procedures. The impact of the noncompliance is that controlled substances are stored in a less secure, unauthorized storage area, bypassing several internal controls designed to secure and safeguard controlled substances (CS) inventory (see Finding 4).

When controlled substances are stored outside the authorized security system designed by the Fire Department:

- There is a *significant* risk that fraud or theft *could* occur, and not be detected.
- It becomes more difficult to adhere to First In (first purchased), First Out (first distributed), also referred to as "FIFO" inventory stock rotations, designed to use inventory prior to its expiration date.
- It becomes more difficult to: a) track inventory, and b) reconcile amounts ordered with amounts stored, with amounts administered and disposed.

The IAO concludes that using an undocumented, unauthorized storage location bypassed preventive and detective controls specified in the Department's SOPs.

2. Recommendation: The Department should use only secure, authorized storage locations for controlled substances inventory.

2. Management Response: The Department agrees. During the audit period we completed our planned purchase of our UCAPIT machine which in addition to biometric screening with data storage and reporting also provided us with the obviously much-needed ability to maintain a higher volume of controlled substances and enhanced security. Implementation of this recommendation is complete.

3. Finding: The Department's inventory management practices have allowed the main controlled substances inventory to reach zero several times.

3. Audit Criteria/SOP: The Department's SOPs are silent on what inventory level should prompt a controlled substances (CS) re-order. SOPs are equally silent on the roles and responsibilities of staff related to the ordering, receipt, and order verification of controlled substances. However, the SOP EMS-1 does mention the desire to, "*allow sufficient lead-time for replacement during the month and to ensure adequate stock levels for reordering*." However, management and staff indicated that the Department has instituted practices designed to prevent the main storage area at Station 87 from running out of CS inventory.

3. Condition, Non-Compliance: Despite the stated procedures and ordering practices aimed at preventing stock-outs, the Department reached zero inventory levels four times during the audit period. One possible effect of a poorly managed inventory system is running out of inventory. During the audit period, the IAO observed the following at the main storage area (Station 87):

- On 5/3/2015, Valium inventory went to zero for a total of 5 days.

- On 9/2/2015, Versed inventory went to zero for a total of 12 days.
- Morphine inventory went to zero two times for a total of 21 days during the audit period.

On these occasions, controlled substances (CS) inventory was at zero for a combined thirty-eight days (*for an average of 9 days each occurrence)*. During these periods of zero inventory, EMS/ALS vehicles still maintained a limited supply (up to 2 containers of each narcotic per emergency vehicle), still, a significant operational and reputational risk existed.

Impact/Risk: The Department's ordering practices resulted in noncompliance to the Department's intent to "*allow sufficient lead-time for replacement during the month and to ensure adequate stock levels for reordering*." When the main inventory reaches zero, the impact of the noncompliance is that EMS/ALS vehicles cannot be resupplied after administering a CS on an emergency call.

The four documented instances of zero inventory leads the **IAO to conclude that the current safety-stock (PAR levels) and ordering practices are not functioning as the Department intended: in a way that prevents stock-outs.**

Department Action: The IAO shared preliminary findings and risks with the Department Director, the Fire Chief. The Department proactively responded to these findings while the audit was in progress. The Department acknowledged occasions where, due to a variety of reasons, the main supply of controlled substances has reached zero. The Department committed to changes in current procedures and inventory monitoring, including: a) changes in documentation of inventory and b) communicating reorder requirements well in advance of situations that could result in zero inventory.

The newly purchased UCAPIT storage and dispensing equipment has increased storage capacity which should help; however, the inventory quantities must be effectively managed to prevent larger quantities of controlled substances from reaching expiration dates.

Additionally, the Department indicated that it would adjust policy and procedure to incorporate first in, first out (FIFO) inventory controls – controlled substances with the closest expiration date will be used first. The expected benefit of FIFO is that the occurrence of controlled substances reaching their expiration date should be reduced.

3A. Recommendation: The Department should adopt an inventory management strategy that will eliminate stock outs (inventory reaching zero). The Department should establish order quantities of controlled substances based on factors such as: a) demand or EMS use, b) the capacity of the department's storage lock box, c) vendor required order sizes, and d) preventing controlled substances from expiring "on the shelf."

The strategy should be monitored by reporting dates when the reorder point is reached and when the order is placed, and then received. **The results of the strategy should be reported and reviewed** on an annual basis, including: number of stock outs (when zero inventory is reached). Whenever inventory reaches zero, it should be reported with an explanation and corrective action plan.

3B. Recommendation: When a controlled substance inventory level reaches zero, Department Policy should address how a "rig swap" takes place and who authorizes it. If an EMS vehicle cannot resupply its inventory from the Station 87 main storage area, then a rig swap might occur - when one EMS vehicle

"borrows" from another. During a rig swap, the Paramedic should record information such as: the vehicle numbers involved in the swap and other required inventory log information.

3A. and 3B. Management Response: The Department agrees. While we acknowledge our restock par levels did in fact reach zero; we also experienced mitigating circumstances, primarily manufacturer backorder having played a significant role in these circumstances. Moving forward, the acquisition of the UCAPIT dispensing machine has allowed us to increase par levels due to significant upgrade in storage area and equally give real-time par level information upon harvesting of data on their server. The machine possesses software which can be programmed for enhanced, automated scheduling of par and expiration date notifications. Fire Rescue has fully addressed these recommendations by tracking our ordering and stocking intervals and as such, we consider these recommendations implemented.

4. Finding: Internal Control deficiencies, including Separation of Duties (SoD) conflicts, were observed in the ordering, receiving, storage, and access to controlled substances.

Separation of Duties (SoD)

4. Audit Criteria: The Internal Audit Office (IAO) analyzed whether appropriate Separation of Duty (SoD) controls were in place and effective. SoD is a preventive control whose purpose is to prevent incompatible duties from being performed by any one individual. An incompatible duty, or activity, is one where a perpetrator can commit fraud in one activity and conceal it when performing another activity. For example, if the same person: a) authorizes a purchase, b) receives it, c) verifies the order, d) takes custody of, and e) has access to record keeping, then that person has too many incompatible duties - because there is significant risk that the person *could* alter records to conceal fraud. With proper Separation of Duties, it is expected that at least one individual involved in the process, will discover and identify staff errors, theft, or fraud.

The more negotiable the asset (the easier it can be turned into money), the greater the need for proper **Separation of Duties**, especially when dealing with cash, negotiable checks, and inventories.

4. Condition: Separation of Duties conflicts were observed in the ordering, receiving, and storage of controlled substances. Staff and management interviews confirmed that the EMS Division Chief is responsible for: a) specifying amounts of controlled substances to order, b) receiving or picking up the order[13] – verifying the correctness of the order, c) inspecting the containers of ordered units, d) and transporting to the authorized and secure Station 87 main storage area. Additionally, during the course of the audit, the IAO discovered that the EMS Division Chief used a locking cabinet in his office to store CS inventory "overflow" from the primary storage area – this constituted a further SoD conflict.

Ideally, the staff person recording inventory activity and triggering a reorder, is independent of the person ordering controlled substances, who in turn, is independent of the person receiving the order and verifying its completeness, who then is independent of the person restocking the inventory.

[13] During the course of the audit, the vendor for controlled substances changed, and this process step changed to "controlled substances are delivered through the mail to the EMS Division Chief (packages can be "signed for" by office staff)."

Impact/Risk: The Department's utilization of an unauthorized storage location resulted in significant deficiencies: a) not only was it not officially authorized (via SOP), it was not widely known to exist, b) it did not offer the same degree of security as the authorized inventory location, and c) it presented a significant Separation of Duties conflict in that the EMS Division Chief, ordered, received and stored the controlled substances the EMS Chief had the ability to commit theft or fraudulent use of controlled substances and to cover it up.

Department Action: The Separation of Duties conflict was recognized by the Department and the EMS Division Chief took the following steps to rectify the practice:

- Removed all controlled substances stored in the EMS Office (at the time of discovery, 25 vials of Morphine) and placed them into the secure, authorized, main storage area at Station 87.
- The Department indicated that this practice has ended, and should not be necessary with the increased storage capacity once the UCAPIT equipment is installed.
- Separation of Duties controls will be a focus as the Department works to create new SOPs to address cited deficiencies.

4. Recommendation: The Department should evaluate all current roles and responsibilities performed as part of the Controlled Substances Inventory Process. No one person, regardless of management level, should have sole, unfettered access to the main Controlled Substances inventory at Station 87. A proper Separation of Duties should exist throughout the controlled substances inventory process. Controlled Substances Inventory records should be reconciled periodically.

4. Management Response: The Department agrees. The IAO preliminary findings have already had a positive impact in the construct of our new Comprehensive Medication policies. We further agree that the SoD will allow for an evening out of workload. During the audit cycle we also signed an agreement with Cardinal Health which ensures a near paperless system of ordering and confirmation of order.

Fire Rescue is currently under a trial period of new policies aimed at clearly defining roles and responsibilities regarding access and distribution as well as accountability for all Controlled Substances. We expect a final implementation of this recommendation within the next 90-120 days (July 2017).

5. Finding: Internal Control deficiencies were found in the Dual Access Controls established by management to safeguard controlled substances.

Dual Access Controls

The Department has instituted dual access controls, which requires two people be present whenever controlled substances are accessed. The purpose of dual access controls (or dual "authorization" controls, such as requiring two signatures to verify inventory counts) is to prevent one person from being alone with, or having complete control over, the Department's narcotics (controlled substances). Without dual controls, it is easier for someone to commit and cover up errors, fraud, misuse, theft, etc.

The IAO analyzed four dual access (or dual authorization) controls as part of this audit. Each of these four controls is addressed separately in the following sections.

5A. Dual Access Control: **Station 87 Main Authorized Storage, 2 key Lucite Lock Box**

5A. Audit Criteria/SOP: The Fire Department's SOP addresses dual access to the Department's controlled substances main Station 87 inventory storage. The Station 87 Paramedic accesses Controlled Substances (CS) stored in the Lucite lock box whenever: a) the daily inventory is conducted, b) expiration dates are checked, c) controlled substances ordered from a vendor are added to the main storage, d) EMS/ALS vehicles are restocked after administering controlled substances on a call, and e) controlled substances have reached their expiration and must be disposed.

The preventive controls at the main inventory include: a) keyed entry into the Supply Room, b) keyed entry into the Supply Cabinet, and c) dual keyed access into the Lucite lock box that stores the controlled substances inventory. The SOP states the requirements of the dual access as follows:

SOP EMS-1:[14] "*Only the on-duty Station 1 assigned Paramedic, EMS Division Chief and on-duty Battalion Chief* ***shall replace and witness the replacement*** *of controlled substances via a* ***2 key system*** *from the controlled substance lock box.*"

SOP EMS-2:[15] "*Only the on-duty Battalion Chief, Station (87) Paramedic or EMS Division Chief shall replace and/or witness the replacement of Controlled Substances via a 2 key system from the Controlled Substance lock box*."

Internal Audit Office (IAO) note: The audit criteria established by **SOP EMS-1 and SOP EMS-2** is that two of the three specified staff, with two different keys, should be present during the replacement of controlled substances – as when controlled substance inventory are restocked from the vendor.

SOP EMS-2: "*6. Station (87) Paramedic and Battalion Chief shall then open the lock box with their respective keys in the presence of the paramedic who administered the Controlled Substance.*"

"*8. Station (87) Paramedic and Battalion Chief shall then lock Controlled Substance lock box*."

"(*Note: At no time shall the Division Chief or EMS Captain pass their respective keys) or delegate their responsibilities to any other personnel to complete the replacement procedure*.)"

Internal Audit Office (IAO) note: The audit criteria established by "**SOP EMS-2: 6. and 8.**"is that: a) both the Battalion Chief and Paramedic have separate keys, b) both the Battalion Chief and Paramedic should be present and unlock the lock box, c) keys should not be shared, and d) the Paramedic requesting the controlled substance should witness the removal of the correct amount of controlled substance to resupply the EMS/ALS vehicle.

[14] City of Riviera Beach Fire Department SOP EMS-1: Security of medications, fluids, and controlled substances

[15] City of Riviera Beach Fire Department SOP EMS-2: Replacement of Controlled Substances

5A. Condition: In September 2015, the Department installed **surveillance video cameras** at: a) the Station 87 main controlled substances storage room, b) Fire Station equipment storage areas, and c) Fire Station service bays. Based on observations and analysis of Supply Cabinet Inventory Logs, it appears that the two-key, dual access control is not always followed – for example a Medic using 2 keys (his own and the Battalion Chief's key), was observed to be the sole person entering the Lucite lock box containing controlled substances inventory. Observations included only one Paramedic, with both his assigned key and the Battalion Chief's key, entering the Lucite lock box.

Impact/Risk: Controlled substances are highly regulated, with well-established safeguarding protocols; when actual practices do not conform to well-defined procedures (SOPs), the risk for theft, fraudulent use, or mismanagement is significantly increased. The dual access control at the Station 87 main controlled substances, inventory storage (2-key system: Battalion Chief and Paramedic) is an internal control designed to prevent one person from having sole access to the controlled substances inventory. The risk for theft or fraudulent misuse increases significantly when one person is allowed access to both keys of a 2-key control system. **In IAO concludes that: a) Individuals have sole access to the controlled substances inventory, and b) management has not effectively monitored staff to ensure access controls are followed (such as the 2 key, 2 person dual-access control).**

Audit Objective 2:

Determine whether controlled substances procedures and practices adequately control risks during the following activities:
a) ordering,
b) receiving and storing inventory,
c) distributing,
d) conducting physical inventories, and
e) reconciling / accounting for use or disposal

Department Action: The Department responded to these findings while the audit was in progress. The initiatives involved: a) auditing the current controlled substances inventory, and b) emphasizing the importance of the current dual-access controls to Paramedics and Battalion Chiefs, c) monitoring the adherence to dual-access controls by reviewing recorded video of the controlled substances location, and d) training on the new UCAPIT storage and dispensing equipment.

5A. Recommendation: The IAO applauds the Department on its quick action as described above. An important element of the action taken will be to properly document the monitoring procedures being implemented - this includes recording dates and times monitored, and the outcome or result of the monitoring (or training). In short, the IAO recommends:

- Dual access controls for the Station 87 main controlled substances inventory should be: a) followed by staff and station management and, b) monitored by Department management -reviewing surveillance video (and by reviewing UCAPIT transaction reports, once implemented)

- The surveillance video should be held for a much longer period than the current 30 days, for a period that allows the Department adequate time to use the video for the monitoring purposes described above.

5A. Management Response: The Department agrees. The Departments UCAPIT dispensing machine has completely changed both our policy and procedure in the accounting for, access, distribution and disposal of Controlled Substances. Additionally, the new policy will reflect that accounting is constant through database monitoring; access by 2 persons by mandatory electronic finger scan, is strictly limited to

Medical Director approved Paramedics or Medics in Charge (MIC). These new policies and procedures were reviewed by all personnel and implemented with periodic review over a 4 week period. We consider this recommendation implemented.

5B. Dual Access Control: **EMS/ALS Vehicle Storage (Med-Box)**

5B. Audit Criteria/SOP: The EMS/ALS vehicles are equipped with a locking medical box ("med-box") that stores a limited supply of controlled substances to be administered on EMS calls. The med-box contains up to 2 of each controlled substance. At each shift change, the off-shift and the on-shift paramedic meet to count and inspect the med-box controlled substances inventory, and to "hand-off control" of the med-box keys. The inventory is recorded in the EMS/ALS vehicle's Inventory Log Book - both Medics sign the Inventory Log Book. From SOP EMS-1:

"*A complete inventory of all Controlled Substances and medications stored on the rescue vehicles will be performed in a face to face meeting between the on-coming and the off-going paramedic whenever there is a change, of any length of time, for the assigned paramedic of the active rescue unit. This will include daily routine shift changes and periodic changes during the shift for whatever reason.*"

5B. Condition: The IAO interviewed Department Paramedics, they indicated that, sometimes this "transfer of custody" does not occur as stipulated in the SOP. No definitive evidence was uncovered to determine the degree that SOPs are followed. The only record of the hand-off is the Inventory Log Book, and although it has the signatures of both the off-going medic and the on-coming medic, whether the inventory is counted, inspected, and transferred in a "face-to-face" meeting is not able to be determined from the written record.

Impact/Risk: One purpose for documenting transfer of custody is that the person accepting control becomes clearly accountable for any tampering, or misuse occurring while the CS is in his/her custody. When the transfer does not take place as noted in the SOP, the intent of dual access control is bypassed – if the on-shift Medic takes control from the off-shift Medic without verifying the controlled substance inventory in the med-box, and later discovers something inappropriate with the inventory, the on-shift Medic who accepted control (and responsibility) will deflect blame to the off-shift medic, and vice-versa. Management will be caught in the middle, it will be very difficult to assign accountability, because management does not enforce a clear, documented hand-off between the two Medics. If both Paramedics participate in the inventory inspection at shift change, and sign for transfer of control in each other's presence, the accountability would be squarely with the on-shift Paramedic.

5B. Recommendation: The controlled substances inventory is a highly liquid asset – easily converted to cash, and one that contributes directly to the public health and well-being of citizens in need, it should be thought of as a valuable resource. With this in mind, Policy & Procedures should address accountability *and* consequences (similar to those specified in cash handling policy and procedures). The Department should monitor compliance, and reinforce the importance of following the procedure. Paramedic shifts should overlap with enough time to complete the transfer of the controlled substances med-box. Video surveillance from Station bay cameras, or other monitoring, is recommended.

5B. Management Response: The Department agrees. The Department has implemented a new daily Controlled Substances Log and Transaction Log books on each ALS Unit to address the observed deficiencies. The new numbered lockout tags (seals) affixed to locking Plexiglas Controlled Substances boxes will provide efficient med box security – if the seal has not been broken, there is no need to physically inspect the contents. These new policies and procedures were trained on with follow up training over a 4 week period. Follow up confirmation will be conducted to ensure compliance. We consider this recommendation implemented.

5C. Dual Access Control: **Restocking EMS/ALS Vehicles**

5C. Audit Criteria/SOP: After a controlled substance is administered on an emergency call, the EMS/ALS vehicle returns to the Station 87 main storage to be resupplied. The dual access controls in place for restocking EMS/ALS vehicles are stipulated in the Department's SOP as follows:

SOP EMS-2: Replacement of Controlled Substances,

"*6. The on-duty Division Chief shall open supply closet in which Controlled Substances lock box is contained."*

"*7. EMS Captain and Division Chief shall then open the lock box with their respective keys in the presence of the paramedic who administered the Controlled Substance."*

"9. EMS Captain shall then lock Controlled substances lock box in the presence of Division Chief and paramedic."

"10. EMS Captain and the paramedic who administered the Controlled Substance shall then log the replaced Controlled Substance into the rescue vehicles Controlled Substances log. Note: At no time shall the Division Chief or EMS Captain pass their respective key(s) or delegate their responsibilities to any other personnel to complete the replacement procedure.)"

5C. Condition: Observations from the Station 87 main storage room indicates that, in conflict with SOPs, the Station 87 Paramedic, *sometimes* with the Paramedic being resupplied, opens the supply cabinet and accesses the CS in the lock box. The IAO could not determine whether the replenishment to the rescue vehicle is witnessed by the Station 87 EMS Captain and whether the vehicle log book is also signed at that time. Interviews with Department Paramedics indicated that the vehicle Inventory Log Book remains at the remote Fire Station as a convenience for the Captain/Battalion Chief to sign, and does not stay in the rescue vehicle, as indicated in the SOP.

Impact/Risk: The Department's cited SOP appears to state that the resupply of CS to the rescue vehicle should be under dual controls from the time it leaves the Station 87 main storage room, supply cabinet lock box to the time it is secured in the rescue vehicles Lucite lock box (inside the med-box). If this does not happen, or if it is not monitored to assure it happens, then there is a risk of fraud from the time the CS is handed to the Medic in the Station 87 Supply room to the time it is secured in the rescue vehicles med-box, at some later time.

5C. Recommendation: The Department should ensure that the transfer of controlled substances from the Station 87 main inventory storage room to the EMS/ALS vehicle Lucite lock box is witnessed, as described in the SOP, by the Station 87 Captain.

As stipulated in Policy and Procedures, the transfer of Controlled Substances (CS) from Captain to EMS/ALS vehicle Paramedic should periodically be monitored using the Fire station's bay cameras. The video from surveillance cameras should be retained for a time period aligned to the Department's monitoring frequency.

Because the controlled substances inventory is a highly convertible asset, and one that contributes directly to the public health and well-being of the citizenry, it should be thought of as an extremely valuable resource. With this in mind, Policy & Procedures should address accountability and consequences (similar to those specified in cash handling Policy & Procedures).

5C. Management Response: The Department agrees. Fire Rescue was under a policy review and revision process as we were in the time frame of the audit. As such we have modified policy to reflect 2 items that we now operate with. We have taken possession of the UCAPIT Machine which now allows for any Medical Director approved, on-duty MIC to participate in a 2 person access to controlled substances for replacement via finger-scan on the machine itself. These events are captured on the UCAPIT Machines database.

Additionally, because of our video monitoring capabilities, we have the ability to identify whom is entering the room and for what purposes. Fire Rescue has fully addressed this recommendation by amending our policies to come into alignment with the tracking capabilities of the UCAPIT Machine and consider this recommendation implemented.

5D. Dual Access Control: **Disposal of Partially Administered Controlled Substances**

5D. Audit Criteria/SOP: Controlled Substances (CS) that are only **partially administered** during an emergency call results in "leftover." The CS leftover, or "remainder," must be properly disposed and documented. If a CS is only partially administered, the remainder must be disposed in front of an authorized witness (usually a doctor or nurse). Witnessing and documenting the disposal of CS are internal controls designed to prevent the theft of CS "leftover."

For example, the EMS/ALS vehicle stocks controlled substances in 10 ml vials, if the Paramedic only administers a 5 ml dose, and the patient responds favorably to the first dose, a second dose may not be required. In this scenario, the Medic must then dispose of the remaining 5 ml of unused controlled substance in front of a witness. The Paramedic and the witness must sign a disposal form witnessing that the Control Substance "remainder" was properly disposed. The disposal form is then "electronically attached" to the patient case report (the report documenting the emergency call).

The Department's SOPs specifically address the disposal of leftover controlled substances from use on an emergency call:

SOP EMS-1: "*In the event there is unused Controlled Substance leftover after administration, a drug disposal form is to be filled out, witnessed and attached to the run report*."

SOP EMS-2: "*2. The paramedic shall dispose of the remainder of Controlled Substance in the presence of Emergency Room RN or Physician and shall properly complete the "Controlled Substance" disposal form which shall be forwarded with the final EMS report*."

Paramedics are required to record the date and time they administered the CS and the incident number. The paramedic must also provide their signature and a description of the event, show a subtraction in the Inventory Log Book and the resulting inventory level. When a controlled substance is "wasted," (when leftover CS is disposed) the paramedic must record the amount of the drug used, the amount destroyed, the method of destruction, and the signature of the paramedic and a witness.

5D. Condition: Prior to August 2015, the Paramedic completed a hardcopy form (Patient Case Report - PCR) that was manually entered into a database software – EMSpro. Since that time, Paramedics enter the details of the emergency call directly into an electronic tablet (SafetyPad) with Electronic Patient Care Report (ePCR) software. The ePCR software creates an electronic record of the EMS call – a database of information is created.

At first glance, the use of e-tablets to create an electronic database appears to be a cutting edge capability; however, the IAO requested access to the database to perform simple queries, for example, "list all cases where controlled substances were used, by date, by EMS vehicle or by EMS Paramedic." The Department was unable to generate this type of basic report. Instead, the Department offered to print out individual reports by report (case) number. **The Department's e-record capability (ePCR) is essentially the same as filing a hard copy report in a file cabinet,** then accessing the information on each individual report, one report at a time.

A limited sampling of Drug Disposal forms indicated inconsistencies related to when and how the drug disposal forms are completed: a) some case reports indicated that a partial use had taken place, but did not have disposal forms completed, and then b) some case reports indicated CS had been fully administered (ie. no leftover), yet a drug disposal form was filled out.

Impact/Risk: The IAO concludes that **disposal forms are not consistently filled out**, **not fully monitored or checked against the case report** (the Electronic Patient Care Report (EPCR)), all of which **greatly diminishes the forms use as an internal control** preventing or detecting fraud, misuse, or theft.

Department Action: The Department responded to these findings while the audit was in progress. The Department acknowledged shortcomings related to current drug disposal documentation. The Department indicated that reminder alerts within the Medic's SafetyPAD ePCR (electronic patient care report) would: a) remind the Medics to immediately complete automated disposal documentation, and b) send programming alerts to the EMS Administrator to review and ensure the disposal policy was followed. The Department committed to biweekly testing and auditing of this procedure to ensure compliance.

5D. Recommendation: The Department should take steps to better manage the disposal of controlled substances that are "leftover" following an emergency call. Possible activities to perform include:

- Actively monitor whether Disposal forms are being completed as intended based on SOPs.

- Currently this is a manual process, which would require (as the IAO was forced to do) staff to review individual PCR reports printed from the ePCR database.

- Contract with Craig Prusansky, or other provider, to train Department staff on how Crystal Reports can interact with the SafetyPad ePCR database to pull in data that allows an efficient way to monitor the information filled out on ePCR reports.

    - The IAO contacted the Palm Beach County Fire Rescue District Captain, Rescue Division and EMS Quality Manager, Craig Prusansky. He is well-versed in the capabilities of the SafetyPAD ePCR software database capabilities. He indicated that the City of Riviera Beach was not fully utilizing the capability of the ePCR software. He indicated that database reports could be generated that would list PCR fields of all reports within a data range.

      For example, instead of: a) looking at individual call/case reports (not knowing whether a narcotic was administered or not) and b) manually recording the amount of narcotic administered versus wasted, staff could pull <u>all</u> data fields into a matrix for just cases where CS was administered, and then review data fields to verify consistency and accuracy of data, including disposal of "leftover." The Department should be able to quickly audit the ePCR dB to determine whether disposal fields are completed as required and whether the data makes sense, for example: if 5 ml of CS is administered, verify that the remaining 5 ml is listed on the disposal form.

      If this is correct, then the Department could use the ePCR database to monitor whether patient and case fields are completed as required, for example whether disposal forms have been completed where the ePCR indicates a narcotic was used. Captain Prusansky indicated that the ePCR database could be manipulated via Crystal Reports. He indicated that would welcome be available to train the City's Fire Department staff on how to use Crystal Reports and the ePCR database.

      Contact Captain Prusansky at:

      Office: 561.616.6908
      Cell: 561.398.6638
      Email: cprusans@pbcgov.org

5D. Management Response: The Department agrees. In situations that necessitate the administration of CS, we now have both mandatory data fields within each patient care report, (ePCR) and real-time notification of the use of a CS on a call by using an alerting feature whereby the Division Chief of EMS receives an automated email from ePCR software that a CS was administered on a given call. Database queries within the SafetyPAD ePCR software for CS usage have been built to identify usage and associated trends. The aforementioned CS Transaction Log will follow the patient into the Emergency room where a "witness to waste" is acknowledged by the hospital staffer, RN or higher level, within both the ePCR and Transaction log book. Fire Rescue has fully addressed this recommendation by amending our ePCR Patient Care Reporting system. We consider this recommendation implemented.

5E. Dual Access Control: **Disposal of "Expired" Controlled Substances**

5E. Audit Criteria/SOP: Controlled Substances are checked daily for expiration dates. The Department has established SOPs for removing a controlled substance prior to its expiration date. From SOP EMS-1:

"*On the first day of each month: Each Station Captain shall ensure that the inventory …is examined for deterioration and its expiration date. Any item, which has exceeded its expiration date…shall be removed from stock immediately, quarantined and replaced. Any item, which will expire in the upcoming month, shall be targeted for replacement. The Station 1 (87) Paramedic shall ensure adequate stock levels and lead time foe replacing and maintain proper stock levels*."

Additionally, from SOP EMS-1:

"*All items that are deteriorated, outdated,…shall be removed from stock, noted within the appropriate log, and given to the Station 1 (87) Paramedic for quarantine and disposal*."

"*Any item, which has exceeded its expiration date or deteriorated beyond functional usage shall be removed from stock immediately and replaced (do not use expired drugs)*."

The Department's SOPs are silent on the procedures, roles and responsibilities for actually disposing of controlled substances that reach their expiration date. The IAO adopted the same audit criteria as used for disposal of controlled substances that had been partially administered – a disposal form and a witness to the disposal.

When paramedics find expired drugs, either at the Main controlled substance storage at Station 87 or on the EMS/ALS vehicles at remote Fire Stations, they record the occurrence in the Controlled Substance Inventory Log Book. The expiring CS is removed from the storage area and is taken to Station 87, given "to the Station 1 (87) Paramedic for quarantine and disposal" and to obtain a replacement.

5E. Condition: The IAO reviewed Inventory Log Books noting: a) dates when expired controlled substances were removed, b) the type of narcotic, and c) the amount of narcotic expired. The IAO provided the Department with a "removed from inventory" list of twenty-nine instances where controlled substances were removed due to expiration (67 inventory units – in some instances more than one unit was removed). The IAO requested the disposal documentation for each CS (see the Appendix for the list of expired drugs provided to the Department). The Department responded that the controlled substances were removed and disposed, but disposal forms were not completed.

From Station 87 main inventory log book records (supported by remote Fire Station log book records), the IAO documented the amount of controlled substances removed from inventory due to expiration dates being reached. The IAO then compared the amount of controlled substances purchased to the amount that was disposed prior to being administered on emergency calls (ie. "expired on the shelf"). The results are listed below.

- 130 Valium inventory units were ordered during the audit period
  - 21 Valium (16% of total Valium) were disposed because of expiration dates
- 50 Versed inventory units were ordered during the audit period
  - 37 Versed (74% of total Versed) were disposed because of expiration dates
- 75 Morphine inventory units were ordered during the audit period

- 9 Morphine (12% of total Morphine) were disposed because of expiration dates

The percentage of controlled substances expiring "on the shelf" appears high, indicating an inefficient use of resources. The percentage of Versed units expiring is significantly greater than the other two narcotics. It is difficult to determine what role order quantities and the use of an unauthorized storage area played in this condition, but both could have contributed.

Impact/Risk: The risk of not documenting and monitoring the disposal of expiring narcotics is that the Department cannot be certain that the CS were properly disposed. The Department's policy and procedures specify how to dispose of partially administered narcotics, but not expiring narcotics – this may send a message that the Department does not care about what happens to expiring narcotics, this coupled with not monitoring the "disposal documentation" of controlled substances, can increase the risk of fraud, misuse, or theft.

Department Action: When this was brought to the attention of Department management, the Department acknowledged shortcomings related to current drug disposal documentation. The Department indicated that the CS should have been disposed of immediately - with the Battalion Chief present, and disposal forms completed and forwarded to the EMS Office. This had not occurred. The Department is taking the following steps to correct the observed deficiency:

- Disposal policies for narcotics exceeding their expiration dates are being created
- Training will be scheduled on a department-wide basis to ensure understanding of disposal policy and procedures

Disposal forms were completed retroactively based on the information recorded in the Inventory Log Books. Going forward the Department committed to documenting the disposal of expiring narcotics utilizing: a) dual authorizations (witnessing) and b) a disposal form.

5E. Recommendation: The Department should develop SOPs for the disposal of controlled substances reaching their expiration date. The disposal SOP should include dual authorization and witnessing controls same or similar to those existing for partially administered controlled substances. Examples of possible safeguards to employ include:

- If expired controlled substances are to be quarantined in an area prior to disposal, mark the controlled substances container in marker with the word "expired."
- If expired controlled substances are to be quarantined, properly secure the controlled substances with equal/better security to that of the regular controlled substances (CS) inventory.
- If expired controlled substances are to be quarantined, verify that the CS container has not been tampered with prior to disposal.
- The Department should: a) document the removal of expiring CS inventory, b) analyze why it has expired "on the shelf," for example: Were order quantities too large? Has demand or EMS use decreased? Did the vendor supply CS with short expiration dates? and c) take action to prevent the situation in the future.
- Whenever possible, dispose of controlled substances in an area where the disposal can be captured on video surveillance, and then periodically monitored for adherence to SOPs.
- At the time of disposal, verify that the lot number being disposed matches the lot number of the narcotics (from the Inventory Log Book) removed due to expiration.

5E. Management Response: The Department agrees. For the disposal of CS which expire "on the shelf," the department is seeking assistance from the Police Department in an effort to follow an established model currently in use by several local Fire Departments. There is currently a "quarantine area" within the UCAPIT machine where controlled substances shall be placed and "logged in" until they can be retrieved for proper disposal and documentation by 2 Medics in Charge (MIC).

Fire Rescue is exploring an option that incorporates agreements with either the Police Department or the Sheriff's Office for destroying the expired product. We will implement the improvement by July 1st 2017.

6. Finding: The Department's inventory records lack the accuracy, consistency, and completeness to account for all controlled substances purchased during the audit period.

6. Audit Criteria/Audit Trail: Based on management and staff interviews, the expected flow of controlled substances (CS) through the Department is graphically displayed below. Thorough and complete records are crucial for an effective audit trail. An effective audit trail will document that: "the amount of CS ordered and picked up," was actually "placed into inventory," and "the amount of controlled substances invoiced and paid matches what was ordered."

Purchasing and Inventory Storage

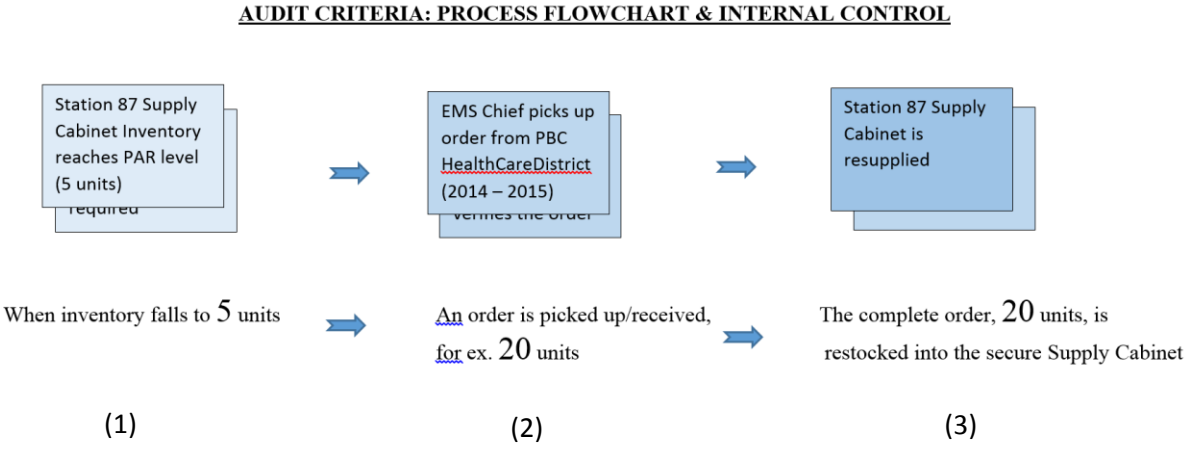
The Internal Audit Office (IAO) created **Flowchart 2** to display the anticipated flow of controlled substances (CS) when:

1) Inventory reaches a level that triggers a reorder (the "PAR level"), to the point where

2) Controlled substances are ordered, and then

3) CS are placed into inventory

Flowchart 2: Controlled Substances Re-Order to Stock Cycle



In a sophisticated inventory control system, the amount of inventory ordered should:

- Align with storage capacity
- Be timely, so as to prevent stock-outs (preventing zero inventory scenarios)
- Align with usage (demand)

Maintaining accurate written records establishes an effective audit trail. An effective audit trail is paramount to establishing accountability in the controlled substances inventory process. The Fire Department has established several means of documentation meant to create an acceptable audit trail. The IAO's detail analysis of existing audit trail records can be found in the Appendix.

6. Condition/Audit Trail: Fire Department management has established documentation requirements designed to ensure an accurate and complete audit trail. For each controlled substance (CS), the **purchase requisition** and **purchase order** displays the date, amount and type of controlled substance "ordered." The **DEA form** lists the date and amount of controlled substance obtained from the vendor. From Flowchart 2, the amount of CS ordered should match the amount obtained from (or delivered) from the vendor. The **Inventory Log Book** then documents the day and the amount of CS placed into inventory, this should correspond closely with the amount and date obtained from the vendor.

The IAO attempted to vouch the amount added to the Main Inventory Storage (the Station 87 Supply Cabinet lock box) with the amount obtained from the vendor (DEA form), and then vouched that to the CS ordered – which is listed on the Purchase Requisition and Purchase Order.

<u>Purchases Do Not Match Inventory Entries</u>

The IAO documented the dates and amounts of all Controlled Substances ordered/received and placed into inventory during the audit period. Then the IAO verified ordering records through the vendor's records and the City's Financial Management System. The IAO also cross-referenced the Station 87 main storage restocking records (Inventory Log Book) with the usage recorded in EMS/ALS vehicles Inventory Log Books.

Based on the analysis of provided records, the amount of Controlled Substances purchased/received could not be 100% matched to amounts placed into inventory. The matter was referred back to the Fire Department. The Department could not produce records reconciling these differences, but indicated moving forward the UCAPIT machine will have significant impact on the Department's ability to have definitive accountability of all CS transactions.

The IAO concludes that the Department does not effectively monitor audit trail documents. An example of this is the quantity of controlled substances that are ordered and picked-up was not compared with the amount added to the Station 87 main inventory storage area. If this audit trail had been actively monitored, an unauthorized storage location would have been discovered prior to this audit being conducted.

Impact/Risk: If an audit trail is not: a) accurate, b) complete, c) consistently documented, and d) monitored, the risk for staff errors, fraud, theft or misuse significantly increases. When the CS order records are not monitored against receiving, inventory, and usage records, coupled with activity records

that are sometimes incomplete, an important internal control is lost: the ability to equate the amount ordered - with the amount received – with the amount placed into inventory.

Department Action: The Department acknowledged inconsistencies and occasional lapses in documenting inventory. The Department indicated that the Station 87 inventory logs would be replaced by the newly purchased UCAPIT equipment which records access into the inventory dispenser through thumbprint recognition. Prior to the arrival of the new equipment, the Department indicated that increased monitoring would be put in place to ensure staff's compliance with current responsibilities and requirements.

The UCAPIT equipment is expected to track and report: access ID, access time, number of controlled substances removed, etc. As such, the Department indicated that log books and daily counting of the Station 87 main inventory will no longer be needed. The Department indicated that once policies and procedures are revised (incorporating the UCAPIT equipment), department staff would be trained on the revisions, and on the type of monitoring that would be conducted.

6. Recommendation: The Department should identify the most effective audit trail to: a) monitor compliance to SOPs, and b) safeguard controlled substances. An effective audit trail safeguards the controlled substances, but also protects staff from unwarranted suspicion, and from the temptation that comes with "thinking that: errors, fraud or misuse" won't be detected. The department should consider implementing activities, and developing resources, such as:

- Transaction reporting
- Exception reporting
- Periodic staff training

Initially, report information and report monitoring can be obtained from a variety of sources (purchase orders, purchase requisitions, inventory logs (or UCAPIT reports), ePCRs, vendor invoices, DEA forms, receiving and inspection documents, but the goal should be to migrate this type of reporting/monitoring capability into the City's Information Technology Master Plan. As such, the Department should keep the IT Department involved in current and future information reporting and monitoring initiatives.

6. Management Response: The Department agrees. Our new Policy and the procedure, found within it, will reflect that an audit trail can more effectively be executed from ordering to receipt, storage and dispensing by using a combination of UCAPIT inventory software, electronic computer filing of same in dedicated files, database queries of SafetyPAD and constant reinforcement training regarding our processes.

Fire Rescue is currently working under a draft policy and procedure that includes data harvesting from UCAPITs database and information being stored electronically in files from order forms and receipts to ePCR data tracking. We expect a final implementation of this recommendation to address the finding by July 1st 2017.

7. Finding: The Department has not retained all historical records required by the Drug Enforcement Agency (DEA).

The IAO reviewed log books at each Fire Station for content, consistency, and physical condition. This was followed by a review of information from historical log books – inventory logs that have been "completed" and are now retained as required by record retention statutes/ordinances.

7. Criteria/Record Retention: The IAO's research turned up three record keeping requirements specific to controlled substances. The first from Florida Administrative Code (FAC) Chapter 64E-2 Emergency Medical Services Controlled Substance states:

"*Any records maintained by the provider as required by these rules shall be accessible to authorized representatives of the department and shall be* ***retained for a period of at least 5 years*** *except as otherwise specified in this rule*."[16]

The second from Florida Statutes, 499 Florida Drug and Cosmetic Act, states the following:

"*Inventories and records must be made available for inspection and photocopying by authorized federal, state, or local officials* ***for a period of 2 years*** *following disposition of the drugs* ***or 3 years*** *after the creation of the records, whichever period is longer.*"[17]

The third from the US Department of Justice, Drug Enforcement Administration, states the following:

"…every inventory and other records required to be kept under this part must be kept by the registrant and be available, **for at least 2 years** from the date of such inventory or records, for inspection and copying by authorized employees of the Administration."[18]

Note: Florida state retention regulations may require these records to be kept for a longer period of time.

7. Condition/Missing Records: The historical records were requested and reviewed by the IAO. The IAOs general impression was that inventory log books are not treated and maintained in a professional manner. Log Books were found to be in a ragged condition - the binding of some Log Books were observed to be broken to the point of separating from the book.

Historical records (past Inventory Log Books) were, for the most part, completed in a satisfactory manner; however, a full review of Station 87 main inventory log books found periods where historical inventory records are missing. The inventory records for the following days were missing:

- *Valium inventory logs:* *8/6/2014 to 9/2/2014*
- *Morphine inventory logs:* *8/6/2014 to 9/2/2014*
- *Versed inventory logs:* *8/6/2014 to 3/4/2015*

Department Action: The Department responded to these findings while the audit was in progress. The department indicated that the Valium and Morphine records and the first 30 days of missing Versed

[16] FAC CHAPTER 64E-2 EMERGENCY MEDICAL SERVICES, 64E-2.013 Records and Reports (1).

[17] Florida Statute 499.0121 (6) Recordkeeping, 5. (b)

[18] Title 21 Code of Federal Regulations, Part 1304 – Records and Reports of Registrants, General Information, 1304.04 Maintenance of records and inventories.

records are attributed to a "transitional period" when a new inventory log form was being created and implemented. The five months of missing Versed records were attributed to a misplaced log book – the inventory log book was unable to be located during the audit.

7A. Recommendation: The Department should develop protocols to keep required historical records safe and secure. These records should be easily retrieved for inspection. The Department should migrate from a paper, hardcopy records system to one that is database centered. The storage of historical records should be integrated into the City's Information Technology Master Plan. As such, the Department should keep the IT Department involved in current and future records retention initiatives.

7A. Management Response: The Department agrees. As we have migrated to utilizing electronic ordering and filing of all associated documents, electronic record keeping will be more robust and database centered in its reflection of all CS transactions. We will also continue to engage with the City's IT Department to ensure we are always operating as efficiently and completely as we can be.

Fire Rescue is currently working under a draft policy and procedure that includes creating a database complete with ordering information being stored in electronic files. These files will include order forms and receipts as well as ePCR data tracking. We expect a final implementation of this recommendation to address the finding by July 1st 2017.

7B. Recommendation/EMS Inventory Management:
The Fire Department should investigate migrating from paper records to database records that are easily stored, retrieved, and audited. The Department should work with the City's IT Department to explore custom or "off-the-shelf" EMS inventory system software options, such as CheckMate EMS Inventory Management. This should include researching the use of bar codes (or RFID) on each inventory unit of CS (some software utilizes the vendors existing bar codes). The IAO performed research into Fire Department / EMS inventory software, the research summary can be found in the Appendix of this report.

7B. Management Response: The Department agrees. As we have migrated to utilizing electronic ordering and filing of all associated documents, electronic record keeping will be more robust and database centered in its reflection of all CS transactions. We will also continue to engage with the City's IT Department to ensure we are always operating as efficiently and completely as we can be.

Fire Rescue is currently working under a draft policy and procedure that includes creating a database complete with ordering information being stored in electronic files. We continue to search for enhanced solutions but believe the UCAPIT tracking will significantly enhance our inventory tracking capabilities. We will reassess after the maturation of the capabilities of the UCAPIT program its usefulness in resolving the stated inventory concerns. We expect a final implementation of this recommendation to address the finding by September 1st, 2017.

8. Finding: There are opportunities for improving the efficiency of some Controlled Substances inventory activities.

During the course of the audit, the Internal Audit Office (IAO) noted opportunities where changes in process, policy, procedure, or automation may improve the efficiency of inventory activities.

8A. Criteria: Station 87 Paramedic (in charge) Roles & Responsibilities

Based on current Department SOPs, The **Station 87 Paramedic** serves a dual role:

- First, the Paramedic is responsible for accessing the main controlled substances storage area, the Station 87 Supply Closet/cabinet/Lucite lock box:
    - This includes taking daily inventory of controlled and uncontrolled substances.
    - This includes restocking the cabinet with items from vendors, including controlled substances.
    - This includes restocking narcotics to EMS/ALS vehicles that have administered controlled substances during emergency calls.
- Secondly, the Paramedic also serves on the Station 87 EMS vehicle:
    - This includes securing the med-box in a locked compartment on the EMS vehicle.
    - This includes going on emergency calls as the Paramedic assigned to the Station 87 EMS vehicle.

> **Audit Objective 3:**
>
> Determine the efficiency of the current inventory control system.

8A. Condition: When the Station 87 Paramedic is away on an emergency call, other EMS/ALS vehicles cannot get replacement inventory. If the rescue vehicles assigned to the other 3 fire stations have an emergency call overlapping a Station 87 call, it's possible that a rescue vehicle from another station will have to wait some time and operate with fewer than recommended narcotics on board until the Station 87 Paramedic returns. Although this may be considered a minor efficiency issue, ideally, when a rescue vehicle needs a resupply of controlled substances, it should not have to wait on the EMS 87 vehicle to complete its emergency call.

8A. Recommendation: The Department should investigate a change in roles and responsibilities (utilizing the capability of the new UCAPIT dispenser) to eliminate the restocking constraint identified above that the EMS 87 Paramedic must be present to restock other EMS/ALS vehicles.

8B. Criteria/SOP: Inventory Log Book

The Fire Department has developed Standard Operating Procedures (SOPs) to address the type of daily information to be recorded in the Inventory Log Book, and the roles and responsibilities of staff.

From SOP EMS-1:

"*A Daily Drug Inventory shall be performed for all medications and a separate written log shall be maintained for all Controlled Substances. The Controlled Substances log at each location will include:*

- *Consecutively and permanently numbered pages*
- *Specific unit number*
- *Time of the inventory***"**

From SOP EMS-2:

"7. The following information shall be logged into the supply closet Controlled Substance log book:

- *Date of action*
- *Time of action*
- *Specific unit number"*

Additionally, from SOP EMS-1:

"*Each entry will be made on consecutive lines and on consecutive pages in the logbook. Whenever a missing logbook, missing page, or missing dated entry is discovered, the paramedic will immediately notify the Station Captain and the on-duty Division Chief for remedy*."

8B. Condition/Inventory Log Records: The IAO interviewed Department staff and management and conducted a judgmental sampling of the documents referenced above. The following condition of Inventory Log Books was found to exist:

Inventory Log Book (activity: "count inventory"):

- For the overwhelming number of days reviewed, all required information was found to be completed, although infrequent omissions were observed, for example: days completely left blank (not inventoried), missing Battalion Chief or Captain signatures, incorrect lot numbers recorded, etc.

- The IAO observed that some entry pages where the time the inventory was conducted was required, and completed; while other times during the audit period the time was not a required field, so minor inconsistencies such as this exist.

The current use of hard copy, bound **Inventory Log Books** seems outdated. The log book entries are sometimes illegible, sometimes missing information, on rare occasions, missing entire days, often the books become deteriorated, and most importantly, the majority of day's entries just mirror the previous days – so there exists a redundancy (and perhaps monotony!) of entering the same inventory data day after day.

Additionally, physical hardcopy log books can be misplaced such as the case with the 2014 Versed log book, mentioned in Finding 7.

Inventory Log Book entries by the Paramedic must currently be "verified" via the Fire Station Captain and the Battalion Chief signatures. This entails: a) locating the log, b) reviewing that entries have been made and c) signing the log. The Captain and the Battalion Chief's signatures seem to have limited value,

because the signatures are not verifying the inventory data, they are simply checking to make sure entries have been made.

8B. Recommendation: The Department should look into ways to eliminate the hardcopy Inventory Log Book. The UCAPIT software capabilities should be fully utilized to "track" controlled substances inventory at the Station 87 main inventory storage area. The City's IT Department should be solicited to develop/guide the Department on efficiency improvements such as:

1) The new UCAPIT storage/dispensing equipment should have the software capability to "manage controlled substances inventory" by tracking and reporting the following type of information:

    - Date of all inventory transactions
    - Recording the types and amounts of controlled substances that go into and out of inventory
    - Recording the staff involved in each inventory transaction
    - Recording the purpose or reason for the inventory transaction (perhaps using built in codes)
    - The lot number of the controlled substance dispensed
    - The expiration of the controlled substance dispensed
    - The EMS/ALS vehicle where the controlled substance will be inventoried (restocked)
    - Reporting / providing "on-screen" access to Department management. Department management should be able to view inventory and easily report information by inventory transaction, by date, by controlled substance, by EMS rescue vehicle, etc.
    - Software should be programmed to automatically alert designated staff that controlled substances should be reordered

    In a sophisticated just-in-time inventory system, the City's software would communicate the order directly to the vendor (with the Department copied via email), the vendor then fills the order and sends the predetermined order size to the designated Department staff, who then verifies the amount received.

    Result/Benefit: Ideally, the UCAPIT dispensing equipment would allow the current practice of the Captain's and Battalion Chief's signatures to be replaced by biometric access data to the narcotics inventory. Biometric access, such as a thumb print, should allow access for a limited time, perhaps 15 seconds, so that only access while the person is present will be allowed.

    Result/Benefit: This could enable the Inventory Log Books at the main controlled substances storage area to be eliminated.

2) The Department should investigate whether the tracking and reporting capabilities of the new UCAPIT equipment, along with fully utilizing the capabilities of the ePCR software, and the

eTablets, can replace both the Station 87 main storage area Inventory Log Books, as well as, the EMS/ALS vehicle logs.
The Inventory Log Book is used to record:

- How much of each controlled substance exists in inventory,
- The lot numbers and expiration dates of inventory,
- Inventory transaction information: the date inventory is used, the amount of inventory used, and which EMS/ALS vehicle used the inventory.

The Inventory Log Books are a record of where the Department's controlled substances inventory resides, although it cannot be accessed from a central area – one must physically go to each Fire Station. In a moderately sophisticated inventory management system, the system inventory – where each controlled substance resides, should be located in a central database, where only periodic inventory audits need to take place, not daily – although daily inventory information resides in a database available to review or report at any time.

During the course of the audit, the Internal Auditor and the EMS Division Chief discussed the capabilities of using ePCR software and the e-Tablets currently used to document emergency call data, to also record inventory. At the time, it seemed possible. The City's IT Department should be solicited to develop/guide the Department on efficiency improvements such as:

Ideally, the Department could investigate whether current or future e-tablet software could also be used to electronically record daily inventory – much like the dual authorization e-form used to document disposal of partially used vials of controlled substances. Currently, the Medic and the witnessing nurse or doctor electronically sign and date the disposal of the controlled substance – all performed on an electronic form.

The Department should work with the City's IT Department to explore custom or "off-the-shelf" EMS inventory system software options, such as CheckMate EMS Inventory Management – this should include researching the use of bar codes on each inventory unit of CS (some software even utilizes the vendors existing bar codes).

Result/Benefit: A benefit of using an electronic method is that a real-time date stamp can be auto-filled on the e-form, making it harder to manipulate the date and time of the inventory or use of the controlled substance.

Result/Benefit: Likewise, if inventory has not changed from the previous day (which is the majority of the time) a "same as" function can be used to duplicate the previous day's inventory.

Result/Benefit: When inventory information resides on a robust database, the information can be viewed by whoever Department management designates, every time the inventory is accessed, used or disposed, the details of the occurrence can be reported and distributed.

8C. Criteria/Physical Inventory Inspections: Currently, per Department SOPs, Paramedics conduct physical inspections of the CS inventory in their control (at the main CS storage, and on EMS/ALS vehicles). The Paramedics are required to inspect CS for tampering, expiration dates, number of CS containers, etc. This information is then manually written in the Inventory Log Book.

8C. Recommendation: The Department should investigate the use of physical security controls that would eliminate the need for Paramedics to physically inspect controlled substances *every day*, for example, perhaps by utilizing numbered/sequenced "evidence security tape" or other tagging method placed across the Lucite lock box opening – if the seal has not been broken, if the tape number is the same as the previous day, the controlled substances within the lock box are the same as the previous day's entry, perhaps just record the safety seal number to ensure there has been no entry since the last count/inspection. This change in procedure would eliminate the need to: day after day, record the identical inventory entry, as the day before.

Result/Benefit: There may not be a need to perform the face-to-face physical inventory "changeover" between EMS/ALS Paramedics - with both the off-going and the on-coming paramedic physically inspecting the CS from the Lucite lock box. Likewise, the current procedure of recording the same information sometimes week after week, may not be required – indeed, information errors were observed even in the current procedure.

8D. Condition: When an emergency call requires a controlled substance to be administered, the Paramedic may not administer the entire volume of the narcotic. For example, from a 10 ml vial, perhaps only 5 ml are administered. If the "effect" of the first 5 ml is adequate, then the remaining 5 ml in the vial would not be administered. Instead the "remainder" would be disposed of by the Paramedic, following the Department's SOP: a) a disposal form is required to be completed, and b) a "witness" must attest that the disposal is proper, etc.

Impact/Risk: Determining the frequency of where "half" of a controlled substance is administered and "half" is wasted/disposed was outside the scope of the audit; however, anecdotal evidence (based on the number of disposal forms reviewed) seems to indicate that this happens more than occasionally.

A *possible impact/result* of performing an analysis would be that the Department may find that it wastes a significant amount of controlled substances - based on the narcotics container size currently purchased and the amounts of controlled substances Paramedics typically administer. If this is proven to be the case, the Department may be able to purchase controlled substances in a more efficient size, i.e. a size that would dramatically reduce the amount of controlled substances that are wasted.

Interviews with Department Paramedics indicated that the current vial size (10 ml vials) corresponds to "old guidelines" that established a protocol where the first dose to a patient was a 5 ml dose, then additional treatments would be at a 5 ml if needed. However, the Paramedic interviewed indicated that new guidelines recommend administering an initial 2 ml dose, followed by doses in increments of 2 ml. If this practice is implemented, then the possibility of wasting even a higher percentage of a 10 ml vial becomes a possible outcome. Verification of the new guideline was outside the scope of the audit, but if verified by the Department, then CS container size should be a topic of discussion when drafting new CS Policy, Procedures and operating guidelines.

8D. Recommendation: The IAO contacted the former and current controlled substances vendor to inquire into whether different container sizes of controlled substances exist for purchase. The two vendors (Palm Beach County Health Care District, and Cardinal Health) reported that controlled substances are available in the following container sizes:

- Versed is available in 1 ml and 2 ml syringe, and in a 1 ml, 2 ml, 5 ml, and 10 ml vial
- Morphine comes in a 1 ml syringe and 1 ml, 10 ml, 20 ml vial or ampule
- Valium comes in a 2 ml syringe and a 10ml vial

The Department should explore whether CS container size changes would result in a more efficient use of CS – reducing amounts of CS currently wasted, and reducing the time the Paramedic takes to waste / get witness signatures, etc. Any change in container size should be aligned with the size of the CS lock box.

Result/Benefit: The Department should align its CS container size to its administering protocols with a "right-sized" controlled substance container. The objective would be less narcotic is wasted - it becomes a more efficient use of the purchased narcotic. An additional benefit of fewer instances of wasting / disposing is that it decreases the opportunity for misuse, fraud or theft of the leftover CS.

8A-D. Management Response: The Department agrees. We have undergone many changes and enhancements during the audit period to reflect that we take this extremely seriously. In previous responses we have identified that we have migrated to the UCAPIT dispensing machine and installed security cameras in sensitive locations. We created a more logical workflow and workload distribution by policy and become more familiar with the capabilities of the software within the SafetyPAD ePCR system.

We have also built out more logic-based and easy to follow and utilize log books, electronic filing of orders, invoices and field use of CS. We have also committed to vigilantly pursue opportunities for constant improvement to our Policies, Procedures and Practices.

Appendix

1. Fire Department's Management Response to Audit Findings & Recommendations (Complete)…page 40
2. Laws, Statutes, Ordinances Governing Controlled Substances…page 45 (Governing the City of Riviera Beach Emergency Medical Services)

499.001	Florida Drug and Cosmetic Act
CHAPTER 64E-2	Florida Administrative Code
CHAPTER 983	Florida Statute
Title 21, Part 1300	Code of Federal Regulation
DEA Form 106	Theft or Loss of Controlled Substances

3. EMS Inventory Systems Control…page 72
4. Controlled Substances Inventory Security Systems…page 75

Fire Department's Management Response

CITY OF RIVIERA BEACH

600 West Blue Heron Blvd. RIVIERA BEACH, FLORIDA 33404
(561) 845-4104 FAX (561) 845-4137

Fire Rescue

To: William Brown, Internal Auditor

From: Reginald K. Duren, Fire Chief

Date: March 7, 2017

Re: Fire Rescue Controlled Substance Audit

1. Finding: The Department sometimes orders controlled substances in quantities exceeding what is indicated in the Department's Standard Operating Procedures (SOPs).

   Management Response- Agree: Quantities that the medications come supplied in are a static number, i.e. Valium generally comes supplied in boxes of 5 vials and Morphine generally comes in boxes of 25. Vendors do not open these boxes and distribute quantities to meet a need that our Department may actually have.

   For example if we have an actual need of 12 Morphine vials we would have no choice but to accept the delivery that exceeded our needs by 13 vials simply because of how the vendors dispense product. We do recognize the challenges we had in these numbers versus actual usage, a remedy in hindsight would have been to adjust the par levels in the policy to reflect this practice. We also had to make contingency planning to allow for overstocking by design in the event of a manufacturer backorder. These backorders had the potential to cause us, and in some instances did, to drop to a par level of 0 in restock. Again, we acknowledge that formally adjusting the portion of the policy that addressed par levels would have been prudent.

   Prior to the commencement of this audit, plans were well under way for implementing an automated dispensing solution with the ability to track data on usage, dispensing and trends. Since September 2016, we have been fully operational with our UCAPIT medication dispensing machine which not only tracks usage and dispensing data, but also sends electronic reports by email when a product is near replacement levels. It should be noted that the usage data found within the IAO's report will assist greatly in setting par levels in our new policies and ordering practices. Fire Rescue is currently tracking our ordering intervals for our Controlled Substances and we expect a final implementation of this completed process within the next 90-120 days.

2. Finding: The Department has stored controlled substances in an area other than what is authorized by SOPs.

   Management Response- Agree: During the audit period we completed our planned purchase of our UCAPIT machine which in addition to biometric screening with data storage and reporting also provided us with the obviously much-needed ability to maintain a higher volume of controlled substances and enhanced security.

   Fire Rescue is currently and will continue to store all Controlled Substances in the UCAPIT Machine as it has the capacity to store all of the Controlled Substances we will need to acquire. Implementation of this recommendation is complete.

3. Finding: The Department's inventory management practices have allowed the main controlled substances inventory to reach zero several times.

   Management Response 3A & 3B- Agree: While we acknowledge our restock par levels did in fact reach zero; we also experienced mitigating circumstances, primarily manufacturer backorder having played a significant role in these circumstances. Moving forward, the acquisition of the UCAPIT dispensing machine has allowed us to increase par levels due to significant upgrade in storage area and equally give real-time par level information upon harvesting of data on their server. The machine possesses software which can be programmed for enhanced, automated scheduling of par and expiration date notifications. Additionally, the revision of the Log Books now in service on our ALS Vehicles and increased field level surveillance should also lead to better tracking of their par levels and expiration date notifications.

   3A. Fire Rescue has fully addressed this recommendation by tracking our ordering and stocking intervals and as such, we consider this recommendation implemented.

   3B. Fire Rescue has fully addressed this recommendation by tracking our ordering and stocking intervals and as such, we consider this recommendation implemented.

4. Finding: Internal Control deficiencies, including Separation of Duties (SoD) conflicts, were observed in the ordering, receiving, storage, and access to controlled substances.

   Management Response – Agree: The IAO preliminary findings have already had a positive impact in the construct of our new Comprehensive Medication policies. We further agree that the SoD will allow for an evening out of workload. During the audit cycle we also signed an agreement with Cardinal Health which ensures a near paperless system of ordering and confirmation of order.

   Fire Rescue is currently under a trial period of new policies aimed at clearly defining roles and responsibilities regarding access and distribution as well as accountability for all Controlled Substances. We expect a final implementation of this recommendation within the next 90-120 days.

5. Finding: Internal Control deficiencies were found in the Dual Access Controls established by management to safeguard controlled substances.

   A. **Management Response – Agree:** The Departments UCAPIT dispensing machine has completely changed both our policy and procedure in the accounting for, access, distribution and disposal of Controlled Substances. Additionally, the new policy will reflect that accounting is constant through database monitoring; access by 2 persons by mandatory electronic finger scan, is strictly limited to Medical Director approved Paramedics or Medics in Charge (MIC). These new policies and procedures were reviewed by all personnel and implemented with periodic review over a 4 week period.

      Fire Rescue has fully addressed this recommendation by installing the UCAPIT Machine as well as a review and adjustment of policy. We consider this recommendation implemented.

      Dual Access Control: EMS/ALS Vehicle Storage (Med-Box)

   B. **Management Response – Agree:** The Department agrees. The Department has implemented a new daily Controlled Substances Log and Transaction Log books on each ALS Unit to address the observed deficiencies. The new numbered lockout tags (seals) affixed to locking Plexiglas Controlled Substances boxes will provide efficient med box security – if the seal has not been broken, there is no need to physically inspect the contents. These new policies and procedures were trained on with follow up training over a 4 week period. Follow up confirmation will be conducted to ensure compliance.

      Fire Rescue has fully addressed this recommendation by implementing a new log book system and lock out tags for boxes the Controlled Substances are contained in. We consider this recommendation implemented.

      Dual Access Control: Restocking EMS/ALS Vehicles

   C. **Management Response – Agree:** Fire Rescue was under a policy review and revision process as we were in the time frame of the audit. As such we have modified policy to reflect 2 items that we now operate with. We have taken possession of the UCAPIT Machine which now allows for any Medical Director approved, on-duty MIC to participate in a 2 person access to controlled substances for replacement via finger-scan on the machine itself. These events are captured on the UCAPIT Machines database. We have been operating with this system and video camera review since October of 2016 without any untoward events occurring.

      Additionally, because of our video monitoring capabilities, we have the ability to identify whom is entering the room and for what purposes. As such, the MIC assigned to Station 87 is also capable of gaining entry to the room for the Paramedic in need of replacing a Controlled Substance which also serves the need for a 2 MIC approved retrieval process.

Fire Rescue has fully addressed this recommendation by amending our policies to come into alignment with the tracking capabilities of the UCAPIT Machine and consider this recommendation implemented.

Dual Access Control: Disposal of Partially Administered Controlled Substances

D. **Management Response - Agree:** In situations that necessitate the administration of CS, we now have both mandatory data fields within each patient care report, (ePCR) and real-time notification of the use of a CS on a call by using an alerting feature whereby the Division Chief of EMS receives an automated email from ePCR software that a CS was administered on a given call. Database queries within the SafetyPAD ePCR software for CS usage have been built to identify usage and associated trends. The aforementioned CS Transaction Log will follow the patient into the Emergency room where a "witness to waste" is acknowledged by the hospital staffer, RN or higher level, within both the ePCR and Transaction log book.

Fire Rescue has fully addressed this recommendation by amending our ePCR Patient Care Reporting system. We consider this recommendation implemented.

Dual Access Control: Disposal of "Expired" Controlled Substances

E. **Management Response – Agree:** For the disposal of CS which expire "on the shelf," the department is seeking assistance from the Police Department in an effort to follow an established model currently in use by several local Fire Departments. There is currently a "quarantine area" within the UCAPIT machine where controlled substances shall be placed and "logged in" until they can be retrieved for proper disposal and documentation by 2 MIC's.

Fire Rescue is exploring an option that incorporates agreements with either the Police Department or the Sheriff's Office which would allow us to pass possession to them for destroying the expired product within the next 90 days. Following our determination of the best way to address the finding, we will implement the improvement by July 1st 2017.

6. Finding: The Department's inventory records lack the accuracy, consistency, and completeness to account for all controlled substances purchased during the audit period.

Management Response – Agree: Our new Policy and the procedure found within it will reflect that an audit trail can more effectively be executed from ordering to receipt, storage and dispensing by using a combination of UCAPIT inventory software, electronic computer filing of same in dedicated files, database queries of SafetyPAD and constant reinforcement training regarding our processes.

Fire Rescue is currently working under a draft policy and procedure that includes data harvesting from UCAPITs database and information being stored electronically in files from order forms and receipts to ePCR data tracking. We expect a final implementation of this recommendation to address the finding by July 1st 2017.

7. Finding: The Department has not retained all historical records required by the Drug Enforcement Agency (DEA).

   Management Response – Agree: As we have migrated to utilizing electronic ordering and filing of all associated documents, electronic record keeping will be more robust and database centered in its reflection of all CS transactions. We will also continue to engage with the City's IT Department to ensure we are always operating as efficiently and completely as we can be.

   7A. Fire Rescue is currently working under a draft policy and procedure that includes creating a database complete with ordering information being stored in electronic files. These files will include order forms and receipts as well as ePCR data tracking. We expect a final implementation of this recommendation to address the finding by July 1st 2017.

   7B. Fire Rescue is currently working under a draft policy and procedure that includes creating a database complete with ordering information being stored in electronic files. We continue to search for enhanced solutions but believe the UCAPIT tracking will significantly enhance our inventory tracking capabilities. We will reassess after the maturation of the capabilities of the UCAPIT program its usefulness in resolving the stated inventory concerns. We expect a final implementation of this recommendation to address the finding by September 1st, 2017.

8. Finding: There are opportunities for improving the efficiency of some Controlled Substances inventory activities.

   Management Response – Agree: We have undergone many changes and enhancements during the audit period to reflect that we take this extremely seriously. In previous responses we have identified that we have migrated to the UCAPIT dispensing machine and installed security cameras in sensitive locations. We created a more logical workflow and workload distribution by policy and become more familiar with the capabilities of the software within the SafetyPAD ePCR system.

   We have also built out more logic-based and easy to follow and utilize log books, electronic filing of orders, invoices and field use of CS. We have also committed to vigilantly pursue opportunities for constant improvement to our Policies, Procedures and Practices.

Laws, Statutes, Ordinances Governing Controlled Substances

(Governing the City of Riviera Beach Emergency Medical Services)

499.001 Florida Drug and Cosmetic Act; short title.

(Selected Text)

PART I

DRUGS; DEVICES; COSMETICS;
HOUSEHOLD PRODUCTS

499.0051 Criminal acts.—

(1) FAILURE TO MAINTAIN OR DELIVER TRANSACTION HISTORY, TRANSACTION INFORMATION, OR TRANSACTION STATEMENT.—

(a) A person engaged in the distribution of prescription drugs who fails to deliver to another person a complete and accurate transaction history, transaction information, or transaction statement concerning a prescription drug or contraband prescription drug, as required by this chapter and rules adopted under this chapter, before, or simultaneous with, the transfer of the prescription drug or contraband prescription drug to another person commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(c) Any person who knowingly destroys, alters, conceals, or fails to maintain a complete and accurate transaction history, transaction information, or transaction statement concerning any prescription drug or contraband prescription drug, as required by this chapter and rules adopted under this chapter, in his or her possession commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(2) KNOWING FORGERY OF TRANSACTION HISTORY, TRANSACTION INFORMATION, OR TRANSACTION STATEMENT.—A person who knowingly forges, counterfeits, or falsely creates any transaction history, transaction information, or transaction statement; who falsely represents any factual matter contained on any transaction history, transaction information, or transaction statement; or who knowingly omits to record material information required to be recorded in a transaction history, transaction information, or transaction statement, commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(4) KNOWING SALE OR TRANSFER OF PRESCRIPTION DRUG TO UNAUTHORIZED PERSON.—A person who knowingly sells or transfers to a person not authorized to purchase or possess prescription drugs, under the law of the jurisdiction in which the person receives the drug, a prescription drug in a wholesale distribution transaction commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(11) ADULTERATED AND MISBRANDED DRUGS; FALSE ADVERTISEMENT; FAILURE TO MAINTAIN RECORDS RELATING TO DRUGS.—Any person who violates any of the following provisions commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083; but, if the violation is committed after a conviction of such person under this subsection has become final, such person commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083, or as otherwise provided in this part:

(h) The failure to maintain records related to a drug as required by this part and rules adopted under this part, except for transaction histories, transaction information, or transaction statements, invoices, or shipping documents related to prescription drugs.
(i) The possession of any drug in violation of this part, except if the violation relates to a deficiency in transaction histories, transaction information, or transaction statements.

(12) REFUSAL TO ALLOW INSPECTION; SELLING, PURCHASING, OR TRADING DRUG SAMPLES; FAILURE TO MAINTAIN RECORDS RELATING TO PRESCRIPTION DRUGS.—Any person who violates any of the following provisions commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, or as otherwise provided in this part:
(a) The refusal or constructive refusal to allow:
1. The department to enter or inspect an establishment in which drugs are manufactured, processed, repackaged, sold, brokered, or held;
2. Inspection of any record of that establishment;

16) **CONTROLLED SUBSTANCE DISTRIBUTION**.—Any person who engages in the wholesale distribution of prescription drugs and who knowingly distributes controlled substances in violation of s. 499.0121(14) commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. In addition to any other fine that may be imposed, a person convicted of such a violation may be sentenced to pay a fine that does not exceed three times the gross monetary value gained from such violation, plus court costs and the reasonable costs of investigation and prosecution.

Chapter 499 DRUG, COSMETIC, AND HOUSEHOLD PRODUCTS (Entire Chapter)

SECTION 0121
Storage and handling of prescription drugs recordkeeping.
499.0121 Storage and handling of prescription drugs; recordkeeping.—The department shall adopt rules to implement this section as necessary to protect the public health, safety, and welfare. Such rules shall include, but not be limited to, requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records.
(1) ESTABLISHMENTS.—An establishment at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed must:
(a) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;
(b) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;
(c) Have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;
(d) Be maintained in a clean and orderly condition; and
(e) Be free from infestation by insects, rodents, birds, or vermin of any kind.
(2) SECURITY.—
(a) An establishment that is used for wholesale drug distribution must be secure from unauthorized entry.
1. Access from outside the premises must be kept to a minimum and be well-controlled.
2. The outside perimeter of the premises must be well-lighted.
3. Entry into areas where prescription drugs are held must be limited to authorized personnel.
(b) An establishment that is used for wholesale drug distribution must be equipped with:
1. An alarm system to detect entry after hours; however, the department may exempt by rule establishments that only hold a permit as prescription drug wholesale distributor-brokers and establishments that only handle medical oxygen; and

2. A security system that will provide suitable protection against theft and diversion. When appropriate, the security system must provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.
(c) Any vehicle that contains prescription drugs must be secure from unauthorized access to the prescription drugs in the vehicle.
(3) STORAGE.—All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the official compendium.
(a) If no storage requirements are established for a prescription drug, the drug may be held at "controlled" room temperature, as defined in the official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.
(b) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, or logs must be used to document proper storage of prescription drugs.
(c) The recordkeeping requirements in subsection (6) must be followed for all stored prescription drugs.
(4) EXAMINATION OF MATERIALS AND RECORDS.—
(a) Upon receipt, each outside shipping container must be visually examined for identity and to prevent the acceptance of contaminated prescription drugs that are otherwise unfit for distribution. This examination must be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.
(b) Each outgoing shipment must be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have expired or been damaged in storage or held under improper conditions.
(c) The recordkeeping requirements in subsection (6) must be followed for all incoming and outgoing prescription drugs.
(d) Upon receipt, a wholesale distributor must review records required under this section for the acquisition of prescription drugs for accuracy and completeness, considering the total facts and circumstances surrounding the transactions and the wholesale distributors involved. This includes authenticating each transaction listed on a pedigree paper, as defined in s. 499.003(37).
(5) RETURNED, DAMAGED, OR OUTDATED PRESCRIPTION DRUGS.—
(a)1. Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated must be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier. A quarantine section must be separate and apart from other sections where prescription drugs are stored so that prescription drugs in this section are not confused with usable prescription drugs.
2. Prescription drugs must be examined at least every 12 months, and drugs for which the expiration date has passed must be removed and quarantined.
(b) Any prescription drugs of which the immediate or sealed outer containers or sealed secondary containers have been opened or used must be identified as such and must be quarantined and physically separated from other prescription drugs until they are destroyed or returned to the supplier.
(c) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the drug must be destroyed or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale distributor must consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the conditions of the drug and its container, carton, or labeling, as a result of storage or shipping.
(d) The recordkeeping requirements in subsection (6) must be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs.
(6) RECORDKEEPING.—The department shall adopt rules that require keeping such records of prescription drugs as are necessary for the protection of the public health.
(a) Wholesale distributors must establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These records must provide a complete audit trail from receipt to sale or other disposition, be readily retrievable for inspection, and include, at a minimum, the following information:

1. The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;
2. The name, principal address, and state license permit or registration number of the person authorized to purchase prescription drugs;
3. The name, strength, dosage form, and quantity of the drugs received and distributed or disposed of;
4. The dates of receipt and distribution or other disposition of the drugs; and
5. Any financial documentation supporting the transaction.

(b) Inventories and records must be made available for inspection and photocopying by authorized federal, state, or local officials for a period of 2 years following disposition of the drugs or 3 years after the creation of the records, whichever period is longer.

(c) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means must be readily available for authorized inspection during the retention period. Records that are kept at a central location outside of this state and that are not electronically retrievable must be made available for inspection within 2 working days after a request by an authorized official of a federal, state, or local law enforcement agency. Records that are maintained at a central location within this state must be maintained at an establishment that is permitted pursuant to this part and must be readily available.

(d) Each manufacturer or repackager of medical devices, over-the-counter drugs, or cosmetics must maintain records that include the name and principal address of the seller or transferor of the product, the address of the location from which the product was shipped, the date of the transaction, the name and quantity of the product involved, and the name and principal address of the person who purchased the product.

(e) When pedigree papers are required by this part, a wholesale distributor must maintain the pedigree papers separate and distinct from other records required under this part.

(7) PRESCRIPTION DRUG PURCHASE LIST.—Each wholesale distributor, except for a manufacturer, shall annually provide the department with a written list of all wholesale distributors and manufacturers from whom the wholesale distributor purchases prescription drugs. A wholesale distributor, except a manufacturer, shall notify the department not later than 10 days after any change to either list. Such portions of the information required pursuant to this subsection which are a trade secret, as defined in s. 812.081, shall be maintained by the department as trade secret information is required to be maintained under s. 499.051.

(8) WRITTEN POLICIES AND PROCEDURES.—Wholesale distributors must establish, maintain, and adhere to written policies and procedures, which must be followed for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesale distributors must include in their written policies and procedures:

(a) A procedure whereby the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement, if the deviation is temporary and appropriate.

(b) A procedure to be followed for handling recalls and withdrawals of prescription drugs. Such procedure must be adequate to deal with recalls and withdrawals due to:

1. Any action initiated at the request of the Food and Drug Administration or any other federal, state, or local law enforcement or other government agency, including the department.
2. Any voluntary action by the manufacturer or repackager to remove defective or potentially defective drugs from the market; or
3. Any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design.

(c) A procedure to ensure that wholesale distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility if a strike, fire, flood, or other natural disaster, or a local, state, or national emergency, occurs.

(d) A procedure to ensure that any outdated prescription drugs are segregated from other drugs and returned to the manufacturer or repackager or destroyed. This procedure must provide for written documentation of the disposition of outdated prescription drugs. This documentation must be maintained for 2 years after disposition of the outdated drugs.

(9) RESPONSIBLE PERSONS.—Wholesale distributors must establish and maintain lists of officers, directors, managers, designated representatives, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.
(10) COMPLIANCE WITH FEDERAL, STATE, AND LOCAL LAW.—A wholesale distributor must operate in compliance with applicable federal, state, and local laws and regulations.
(a) A wholesale distributor must allow the department and authorized federal, state, and local officials to enter and inspect its premises and delivery vehicles, and to audit its records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.
(b) A wholesale distributor that deals in controlled substances must register with the Drug Enforcement Administration and must comply with all applicable state, local, and federal laws. A wholesale distributor that distributes any substance controlled under chapter 893 must notify the department when registering with the Drug Enforcement Administration pursuant to that chapter and must provide the department with its DEA number.
(11) SALVAGING AND REPROCESSING.—A wholesale distributor is subject to any applicable federal, state, or local laws or regulations that relate to prescription drug product salvaging or reprocessing.
(12) SHIPPING AND TRANSPORTATION.—The person responsible for shipment and transportation of a prescription drug in a wholesale distribution may use a common carrier; its own vehicle or employee acting within the scope of employment if authorized under s. 499.03 for the possession of prescription drugs in this state; or, in the case of a prescription drug intended for domestic distribution, an independent contractor who must be the agent of the authorized seller or recipient responsible for shipping and transportation as set forth in a written contract between the parties. A person selling a prescription drug for export must obtain documentation, such as a validated airway bill, bill of lading, or other appropriate documentation that the prescription drug was exported. A person responsible for shipping or transporting prescription drugs is not required to maintain documentation from a common carrier that the designated recipient received the prescription drugs; however, the person must obtain such documentation from the common carrier and make it available to the department upon request of the department.
(13) DUE DILIGENCE OF SUPPLIERS.—Prior to purchasing any prescription drugs from another wholesale distributor, a prescription drug wholesale distributor, an out-of-state prescription drug wholesale distributor, or a prescription drug repackager must:

(a) Enter an agreement with the selling wholesale distributor by which the selling wholesale distributor will indemnify the purchasing wholesale distributor for any loss caused to the purchasing wholesale distributor related to the purchase of drugs from the selling wholesale distributor which are determined to be counterfeit or to have been distributed in violation of any federal or state law governing the distribution of drugs.
(b) Determine that the selling wholesale distributor has insurance coverage of not less than the greater of 1 percent of the amount of total dollar volume of the prescription drug sales reported to the department under s. 499.012(8)(g) or $500,000; however the coverage need not exceed $2 million.
(c) Obtain information from the selling wholesale distributor, including the length of time the selling wholesale distributor has been licensed in this state, a copy of the selling wholesale distributor's licenses or permits, and background information concerning the ownership of the selling wholesale distributor, including the experience of the wholesale distributor in the wholesale distribution of prescription drugs.
(d) Verify that the selling wholesale distributor's Florida permit is valid.
(e) Inspect the selling wholesale distributor's licensed establishment to document that it has a policies and procedures manual relating to the distribution of drugs, the appropriate temperature controlled environment for drugs requiring temperature control, an alarm system, appropriate access restrictions, and procedures to ensure that records related to the wholesale distribution of prescription drugs are maintained as required by law:
1. Before purchasing any drug from the wholesale distributor, and at least once each subsequent year; or
2. Before purchasing any drug from the wholesale distributor, and each subsequent year obtain a complete copy of the most recent inspection report for the establishment which was prepared by the department or the regulatory authority responsible for wholesale distributors in the state in which the establishment is located.
(14) DISTRIBUTION REPORTING.—Each prescription drug wholesale distributor, out-of-state prescription drug wholesale distributor, retail pharmacy drug wholesale distributor, manufacturer, or repackager that engages in the wholesale distribution of controlled substances as defined in s. 893.02 shall submit a report to the department of

its receipts and distributions of controlled substances listed in Schedule II, Schedule III, Schedule IV, or Schedule V as provided in s. 893.03. Wholesale distributor facilities located within this state shall report all transactions involving controlled substances, and wholesale distributor facilities located outside this state shall report all distributions to entities located in this state. If the prescription drug wholesale distributor, out-of-state prescription drug wholesale distributor, retail pharmacy drug wholesale distributor, manufacturer, or repackager does not have any controlled substance distributions for the month, a report shall be sent indicating that no distributions occurred in the period. The report shall be submitted monthly by the 20th of the next month, in the electronic format used for controlled substance reporting to the Automation of Reports and Consolidated Orders System division of the federal Drug Enforcement Administration. Submission of electronic data must be made in a secured Internet environment that allows for manual or automated transmission. Upon successful transmission, an acknowledgment page must be displayed to confirm receipt. The report must contain the following information:
(a) The federal Drug Enforcement Administration registration number of the wholesale distributing location.
(b) The federal Drug Enforcement Administration registration number of the entity to which the drugs are distributed or from which the drugs are received.
(c) The transaction code that indicates the type of transaction.
(d) The National Drug Code identifier of the product and the quantity distributed or received.
(e) The Drug Enforcement Administration Form 222 number or Controlled Substance Ordering System Identifier on all Schedule II transactions.
(f) The date of the transaction.

The department must share the reported data with the Department of Law Enforcement and local law enforcement agencies upon request and must monitor purchasing to identify purchasing levels that are inconsistent with the purchasing entity's clinical needs. The Department of Law Enforcement shall investigate purchases at levels that are inconsistent with the purchasing entity's clinical needs to determine whether violations of chapter 893 have occurred.

(15) DUE DILIGENCE OF PURCHASERS.—
(a) Each prescription drug wholesale distributor, out-of-state prescription drug wholesale distributor, and retail pharmacy drug wholesale distributor must establish and maintain policies and procedures to credential physicians licensed under chapter 458, chapter 459, chapter 461, or chapter 466 and pharmacies that purchase or otherwise receive from the wholesale distributor controlled substances listed in Schedule II or Schedule III as provided in s. 893.03. The prescription drug wholesale distributor, out-of-state prescription drug wholesale distributor, or retail pharmacy drug wholesale distributor shall maintain records of such credentialing and make the records available to the department upon request. Such credentialing must, at a minimum, include:
1. A determination of the clinical nature of the receiving entity, including any specialty practice area.
2. A review of the receiving entity's history of Schedule II and Schedule III controlled substance purchasing from the wholesale distributor.
3. A determination that the receiving entity's Schedule II and Schedule III controlled substance purchasing history, if any, is consistent with and reasonable for that entity's clinical business needs.
(b) A wholesale distributor must take reasonable measures to identify its customers, understand the normal and expected transactions conducted by those customers, and identify those transactions that are suspicious in nature. A wholesale distributor must establish internal policies and procedures for identifying suspicious orders and preventing suspicious transactions. A wholesale distributor must assess orders for greater than 5,000 unit doses of any one controlled substance in any one month to determine whether the purchase is reasonable. In making such assessments, a wholesale distributor may consider the purchasing entity's clinical business needs, location, and population served, in addition to other factors established in the distributor's policies and procedures. A wholesale distributor must report to the department any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of the law. The wholesale distributor shall maintain records that document the report submitted to the department in compliance with this paragraph.
(c) A wholesale distributor may not distribute controlled substances to an entity if any criminal history record check for any person associated with that entity shows that the person has been convicted of, or entered a plea of

guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction related to controlled substances, the practice of pharmacy, or the dispensing of medicinal drugs.

(d) The department shall assess national data from the Automation of Reports and Consolidated Orders System of the federal Drug Enforcement Administration, excluding Florida data, and identify the national average of grams of hydrocodone, morphine, oxycodone, and methadone distributed per pharmacy registrant per month in the most recent year for which data is available. The department shall report the average for each of these drugs to the Governor, the President of the Senate, and the Speaker of the House of Representatives by November 1, 2011. The department shall assess the data reported pursuant to subsection (14) and identify the statewide average of grams of each benzodiazepine distributed per community pharmacy per month. The department shall report the average for each benzodiazepine to the Governor, the President of the Senate, and the Speaker of the House of Representatives by November 1, 2011.

History.—s. 16, ch. 92-69; s. 32, ch. 98-151; ss. 38, 40, ch. 2000-242; ss. 15, 16, 18, ch. 2003-155; s. 86, ch. 2004-5; s. 4, ch. 2004-328; s. 10, ch. 2004-387; s. 3, ch. 2005-248; s. 5, ch. 2006-310; s. 17, ch. 2007-6; s. 13, ch. 2008-207; s. 62, ch. 2009-21; s. 3, ch. 2009-221; s. 40, ch. 2010-161; s. 18, ch. 2011-141.

Note.—Paragraph (6)(d) former s. 499.013(4).

Florida Administrative Code & Florida Administrative Register

Department of Health;
Division of Emergency Preparedness and Community Support;
Chapter: Emergency Medical Services

CHAPTER 64E-2
EMERGENCY MEDICAL SERVICES

64E-2.013 Records and Reports.

(1) Each provider shall be responsible for supervising, preparing, filing and maintaining records and for submitting reports to the department as requested. All records shall be handled in such a manner as to ensure reasonable safety from water and fire damage and to be safeguarded from unauthorized use. Any records maintained by the provider as required by these rules shall be accessible to authorized representatives of the department and shall be retained for a period of at least 5 years except as otherwise specified in this rule. Each provider shall maintain the following administrative records:

(a) Vehicle registration, copy of past department inspection reports, proof of current vehicle permit, and proof of current insurance coverage.

(b) Personnel records for each employee, to include date of employment, training records, employee application, documentation of current certification, and confirmation that each driver is in compliance with Section 401.281, F.S.

(c) Copy of up-to-date department approved TTPs.

(2) Each EMS provider shall ensure that an accurate and complete patient care record was prepared for each instance in which a patient was transported to a hospital. The transporting EMS provider shall have the complete and accurate patient care record as defined in subsection 64E-2.001(17), F.A.C., and required in Rule 64E-2.013, F.A.C., available upon request within 24 hours of the time the vehicle was originally dispatched in response to the request for emergency medical assistance.

(3) The accurate and complete patient care record shall include all known information listed below and the known information defined under subsection 64E-2.001(15), F.A.C.;

(a) Date of call;

(b) Time of call;

(c) The service name;

(d) Incident ID number;

(e) Lead crew signature or identification number;

(f) Service name for any other licensed service providing care;

(g) Name for first responder agency;

(h) The patient’s full name or unique identification number if the name is unknown;

(i) The patient's age;

(j) Patient assessment information (e.g., airway, breathing, circulation, pupils, skin and vitals) taken on scene and en route with times taken for vitals;

(k) The initial vitals taken by a non-transport service before the arrival of the transport unit;

(l) The patient's medical history, current medications; allergies, and chief complaint;

(m) Interventions attempted (e.g., airway, breathing, circulation, and secondary interventions); and

(n) Medication(s) administered including the time, medication, dose and route.

(4) Non-transporting vehicle personnel shall provide information pertinent to the patient's identification, patient assessment and care provided to the patient to the transporting vehicle personnel at the time the responsibility of the patient is transferred to the transporting service.

(5) Transporting vehicle personnel shall provide recorded information to the receiving hospital personnel at the time the patient is transferred that contains all known pertinent incident, patient identification and patient care information.

(6) Each EMS provider shall maintain a copy of the patient care record as defined in subsection 64E-2.001(17), F.A.C., for a period of at least 5 years. This copy is considered to be the copy of record, shall contain an original signature by the lead crew member or an identification number assigned to the lead crew member and is certifiable as a true copy.

(7) Each licensed EMS provider is responsible for quality review for completeness and accuracy of their own patient care records.

(8) Medication errors and reactions en route shall be reported to the physician who ordered the medication, the receiving physician, and the ALS medical director.

(9) Each provider shall maintain a written plan, available for review by the department, for the proper handling, storage, and disposal of biohazardous wastes in accordance with Chapter 64E-16, F.A.C.

(10) Each provider shall return his license to the department within 15 calendar days after a change of name or ownership of the service or upon permanently ceasing to provide service.

(11) Each air ambulance provider shall maintain documentation describing the service rendered to the patient and cost as part of the patient's record in accordance with Section 401.251(4)(c), F.S.

(12) A fixed wing air ambulance provider shall have an air medical crew member document the cabin altitude hourly. The cabin pressure shall be documented on the patient care record.

(13) Each provider shall document and submit to the department, the information contained on DH Form 1304, May 02, "EMS Aggregate Prehospital Report and Provider Profile Information Form", which is incorporated by reference and available from the department as defined and required in DHP 150-445, May 02, "Department of Health, Bureau of Emergency Medical Services (EMS) Instruction Manual for the: EMS Aggregate Pre-hospital and Provider Profile Information Form (DH 1304)", which is incorporated by reference and available from the department.

(a) Reports shall be submitted in accordance with the format and time frame specified in DHP 150-445. Reports received after the due date(s) specified in DHP 150-445 or not in the format specified in DHP 150-445, may not be included in reports published by the department.

(b) The non-transporting unit is responsible for providing critical treatment and intervention information as

defined in DHP 150-445 to the transporting unit at the time that the responsibility for the patient's care is transferred to the transporting unit. The transporting unit is required to include counts of all known critical treatments and interventions that were administered or attempted to be administered to the patient prior to their arrival as defined and required in DHP 150-445 as part of their required quarterly submission of DH Form 1304 to the department.

Specific Authority 381.0011, 395.405, 401.30, 401.35 FS. Law Implemented 381.001, 381.0205, 395.401-.405, 401.23, 401.25, 401.27, 401.30, 401.35, 401.411 FS. History–New 11-29-82, Amended 4-26-84, 3-11-85, Formerly 10D-66.60, Amended 11-2-86, 4-12-88, 8-3-88, 12-10-92, 11-30-93, 12-10-95, 1-26-97, Formerly 10D-66.060, Amended 7-14-99, 2-20-00, 4-15-01, 11-3-02, 10-24-05.

64E-2.037 Security of Medications.

(1) Each ALS and air ambulance provider shall develop, implement, maintain, and have available for review by the department written operating procedures approved and signed by the medical director for procuring, storing, handling, dispensing, and disposal of all controlled substances, medications, and fluids.

(a) These procedures must address the provider's method for meeting applicable state and federal requirements.

(b) Security procedures which include the provider's method of ensuring against theft, tampering with or contamination of controlled substances, medications, and fluids and the identities and position titles of employees who have access to controlled substances.

(c) The amount of each controlled substance, authorized by the medical director, to be in on-site storage.

(d) Documentation procedure for the distribution, disposal, and re-supply of controlled substances, medications, and fluids maintained on site. This procedure shall address on-site and shift change inventory procedures for all controlled substances stocked by the provider and identify a record keeping procedure, which includes inventory schedules for stocking of medical supplies and reporting and resolving any discrepancy found during an inventory.

(2) All operating procedures related to controlled substances, medications, and fluids shall be consistent with and meet the minimum federal requirements specified by the United States Department of Justice, Drug Enforcement Administration in Title 21, Code of Federal Regulations, Food and Drugs, Part 1300 to END, Chapter II, April 1, 2000, and minimum state requirements specified in Chapters 499 and 893, F.S., and rules adopted there under.

Specific Authority 401.26, 401.35 FS. Law Implemented 401.25, 401.26, 401.35(1) FS. History–New 9-3-00, Amended 11-24-02.

Rule: 64J-1.004 Medical Direction.

(1) Each ALS, BLS or air ambulance provider shall maintain on file for inspection and copying by the department its current contract for a medical director by which it employs or independently contracts with a physician qualified pursuant to this section to be its medical director.

(2) There is no standard format for a medical director's contract, however, in drafting such an instrument, the following provisions may be addressed:

(a) Name and relationship of the contracting parties.

(b) A list of contracted services inclusive of medical direction, administrative responsibilities, professional membership, basic and advanced life support review responsibilities, and reporting requirements.

(c) Monetary consideration inclusive of fees, expenses, reimbursement, fringe benefits, clerical assistance and office space.

(d) Termination clause.

(e) Renewal clause.

(f) Provision for liability coverage.

(g) Effective dates of the contract.

(3) Qualifications:

(a) A medical director shall be a Florida licensed M.D. or D.O.

(b) In addition to all other provisions applicable to medical directors in this rule, an air ambulance medical director shall be knowledgeable of the aeromedical requirements of patients and shall evaluate each patient in person or by written protocol prior to each interfacility transfer flight for the purpose of determining that the aircraft, flight and medical crew, and equipment meet the patient's needs.

(c) A medical director shall be board certified and active in a broad-based clinical medical specialty with demonstrated experience in prehospital care and hold an ACLS certificate or equivalent as determined in Chapter 64J-1.022, F.A.C. Prehospital care experience shall be documented by the provider.

(d) A medical director shall demonstrate and have available for review by the department documentation of active participation in a regional or statewide physician group involved in prehospital care.

(4) Duties and Responsibilities of the Medical Director.

(a) Develop medically correct standing orders or protocols which permit specified ALS and BLS procedures when communication cannot be established with a supervising physician or when any delay in patient care would potentially threaten the life or health of the patient. The medical director shall issue standing orders and protocols to the provider to ensure that the provider transports each of its patients to facilities that offer a type and level of care appropriate to the patient's medical condition if available within the service region. The medical director or his appointee shall provide continuous 24-hour-per-day, 7-day-per-week medical direction which shall include in addition to the development of protocols and standing orders, direction to personnel of the provider as to availability of medical direction "off-line" service to resolve problems, system conflicts, and provide services in an emergency as that term is defined by Section 252.34(3), F.S.

(b) Develop and implement a patient care quality assurance system to assess the medical performance of paramedics and EMTs. The medical director shall audit the performance of system personnel by use of a quality assurance program to include but not be limited to a prompt review of patient care records, direct observation, and comparison of performance standards for drugs, equipment, system protocols and procedures. The medical director shall be responsible for participating in quality assurance programs developed by the department.

(c) With the exception of BLS medical directors each ALS or air ambulance service medical director shall possess proof of current registration as a medical director, either individually or through a hospital, with the U.S. Department of Justice, DEA, to provide controlled substances to an EMS provider. DEA registration shall include each address at which controlled substances are stored. Proof of such registration shall be maintained on file with each ALS or air ambulance provider and shall be readily available for inspection.

(d) Ensure and certify that security procedures of the EMS provider for medications, fluids and controlled substances are in compliance with Chapters 499 and 893, F.S., and Chapter 64F-12, F.A.C.

(e) Create, authorize and ensure adherence to, detailed written operating procedures regarding all aspects of the handling of medications, fluids and controlled substances by the provider.

64J-1.021 Security of Medications.

(1) Each ALS and air ambulance provider shall develop, implement, maintain, and have available for review by the department written operating procedures approved and signed by the medical director for procuring, storing, handling, dispensing, and disposal of all controlled substances, medications, and fluids.

(a) These procedures must address the provider's method for meeting applicable state and federal requirements.

(b) Security procedures which include the provider's method of ensuring against theft, tampering with or contamination of controlled substances, medications, and fluids and the identities and position titles of employees who have access to controlled substances.

(c) The amount of each controlled substance, authorized by the medical director, to be in on-site storage.

(d) Documentation procedure for the distribution, disposal, and re-supply of controlled substances, medications, and fluids maintained on site. This procedure shall address on-site and shift change inventory procedures for all controlled substances stocked by the provider and identify a record keeping procedure, which includes inventory schedules for stocking of medical supplies and reporting and resolving any discrepancy found during an inventory.

(2) All operating procedures related to controlled substances, medications, and fluids shall be consistent with and meet the minimum federal requirements specified by the United States Department of Justice, Drug Enforcement Administration in Title 21, Code of Federal Regulations, Food and Drugs, Part 1300 to END, Chapter II, April 1, 2000, and minimum state requirements specified in Chapters 499 and 893, F.S., and rules adopted there under.

Florida Statute
CHAPTER 893
DRUG ABUSE PREVENTION AND CONTROL

893.07 Records.—

(1) Every person who engages in the manufacture, compounding, mixing, cultivating, growing, or by any other process producing or preparing, or in the dispensing, importation, or, as a wholesaler, distribution, of controlled substances shall:

(a) On January 1, 1974, or as soon thereafter as any person first engages in such activity, and every second year thereafter, make a complete and accurate record of all stocks of controlled substances on hand. The inventory may be prepared on the regular physical inventory date which is nearest to, and does not vary by more than 6 months from, the biennial date that would otherwise apply. As additional substances are designated for control under this chapter, they shall be inventoried as provided for in this subsection.

(b) On and after January 1, 1974, maintain, on a current basis, a complete and accurate record of each substance manufactured, received, sold, delivered, or otherwise disposed of by him or her, except that this subsection shall not require the maintenance of a perpetual inventory.

Compliance with the provisions of federal law pertaining to the keeping of records of controlled substances shall be deemed a compliance with the requirements of this subsection.

(2) The record of controlled substances received shall in every case show:

(a) The date of receipt.

(b) The name and address of the person from whom received.

(c) The kind and quantity of controlled substances received.

(3) The record of all controlled substances sold, administered, dispensed, or otherwise disposed of shall show:

(a) The date of selling, administering, or dispensing.

(b) The correct name and address of the person to whom or for whose use, or the owner and species of animal for which, sold, administered, or dispensed.

(c) The kind and quantity of controlled substances sold, administered, or dispensed.

(4) Every inventory or record required by this chapter, including prescription records, shall be maintained:

(a) Separately from all other records of the registrant, or

(b) Alternatively, in the case of Schedule III, IV, or V controlled substances, in such form that information required by this chapter is readily retrievable from the ordinary business records of the registrant.

In either case, the records described in this subsection shall be kept and made available for a period of at least 2 years for inspection and copying by law enforcement officers whose duty it is to enforce the laws of this state relating to controlled substances. Law enforcement officers are not required to obtain a subpoena, court order, or search warrant in order to obtain access to or copies of such records.

(5) Each person described in subsection (1) shall:

(a) Maintain a record which shall contain a detailed list of controlled substances lost, destroyed, or stolen, if any; the kind and quantity of such controlled substances; and the date of the discovering of such loss, destruction, or theft.

(b) In the event of the discovery of the theft or significant loss of controlled substances, report such theft or significant loss to the sheriff of that county within 24 hours after discovery. A person who fails to report a theft or significant loss of a substance listed in s. 893.03(3), (4), or (5) within 24 hours after discovery as required in this paragraph commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083. A person who fails to report a theft or significant loss of a substance listed in s. 893.03(2) within 24 hours after discovery as required in this paragraph commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

History.—s. 7, ch. 73-331; s. 1439, ch. 97-102; s. 25, ch. 2011-141.

US Department of Justice
Drug Enforcement Administration
Diversion Control Division

Title 21 Code of Federal Regulations, Part 1300

Title 21 CFR 1301.22

The Medical Director – EMS Relationship

All practitioners that will manufacture, distribute, or dispense controlled substances are required to register with the DEA. The requirement of registration is waived for any agent or employee of a person who is registered to engage in any group of independent activities, if such agent or employee is acting in the usual course of his/her business or employment (Title 21 CFR 1301.22). **For the purposes of Emergency Medical Services, the medical director shall be the registrant and the EMTs will be acting as his agent in administering controlled substances to patients. The medical director will be treating the EMS agency for which he provides oversight as his practice.** As such, he is allowed to maintain an inventory of controlled substance for the administration to patients in the usual course of business once registered with the DEA.

Recordkeeping (Title 21 CFR Section 1301.71)

Records for Schedule II Controlled Substances must be maintained separately from all other records. Records for Schedules III-V do not need to be separate, but they must be readily retrievable from all ordinary records.

Inventory counting must be done at least once every 2 years and a complete and accurate written, typewritten, or printed record must document controlled substances on hand.

The administration of all controlled substances must be documented to include patient name, patient address, date of administration, name of controlled substance, amount administered, and the initials of the person administering the controlled substance.

Per Federal DEA regulations, all records shall be kept for two (2) years. Florida state retention regulations may require these records to be kept for a longer period of time.

PART 1304 — RECORDS AND REPORTS OF REGISTRANTS

GENERAL INFORMATION

Section 1304.01 Scope of Part 1304.

Section 1304.02 Definitions.

Section 1304.03 Persons required to keep records and file reports.

Section 1304.04 Maintenance of records and inventories.

(a) Except as provided in paragraphs (a)(1) and (a)(2) of this section, every inventory and other records required to be kept under this part must be kept by the registrant and be available, for at least 2 years from the date of such inventory or records, for inspection and copying by authorized employees of the Administration.

(1) Financial and shipping records (such as invoices and packing slips but not executed order forms subject to §§1305.17 and 1305.27 of this chapter) may be kept at a central location, rather than at the registered location, if the registrant has notified the Administration of his intention to keep central records. Written notification must be submitted by registered or certified mail, return receipt requested, in triplicate, to the Special Agent in Charge of the Administration in the area in which the registrant is located. Unless the registrant is informed by the Special Agent in Charge that permission to keep central records is denied, the registrant may maintain central records commencing 14 days after receipt of his notification by the Special Agent in Charge. All notifications must include the following:

i) The nature of the records to be kept centrally.

(ii) The exact location where the records will be kept.

(iii) The name, address, DEA registration number and type of DEA registration of the registrant whose records are being maintained centrally.

(iv) Whether central records will be maintained in a manual, or computer readable, form.

(2) A registered retail pharmacy that possesses additional registrations for automated dispensing systems at long term care facilities may keep all records required by this part for those additional registered sites at the retail pharmacy or other approved central location.

(3) A collector that is authorized to maintain a collection receptacle at a long-term care facility shall keep all records required by this part relating to those collection receptacles at the registered location, or other approved central location.

(b) All registrants that are authorized to maintain a central recordkeeping system under paragraph (a) of this section shall be subject to the following conditions:

(1) The records to be maintained at the central record location shall not include executed order forms and inventories, which shall be maintained at each registered location.

(2) If the records are kept on microfilm, computer media or in any form requiring special equipment to render the records easily readable, the registrant shall provide access to such equipment with the records. If any code system is used (other than pricing information), a key to the code shall be provided to make the records understandable.

(3) The registrant agrees to deliver all or any part of such records to the registered location within two business days upon receipt of a written request from the Administration for such records, and if the Administration chooses to do so in lieu of requiring delivery of such records to the registered location, to allow authorized employees of the Administration to inspect such records at the central location upon request by such employees without a warrant of any kind.

(4) In the event that a registrant fails to comply with these conditions, the Special Agent in Charge may cancel such central recordkeeping authorization, and all other central recordkeeping authorizations held by the registrant without a hearing or other procedures. In the event of a cancellation of central recordkeeping authorizations under this paragraph the registrant shall, within the time specified by the Special Agent in Charge, comply with the requirements of this section that all records be kept at the registered location.

(c) Registrants need not notify the Special Agent in Charge or obtain central recordkeeping approval in order to maintain records on an in-house computer system.

(d) ARCOS participants who desire authorization to report from other than their registered locations must obtain a separate central reporting identifier. Request for central reporting identifiers will be submitted to the ARCOS Unit. See the Table of DEA Mailing Addresses in Sec. 1321.01 of this chapter for the current mailing address.

(e) All central recordkeeping permits previously issued by the Administration expired September 30, 1980.

(f) Each registered manufacturer, distributor, importer, exporter, narcotic treatment program and compounder for narcotic treatment program shall maintain inventories and records of controlled substances as follows:

(1) Inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all of the records of the registrant; and

(2) Inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant.

(g) Each registered individual practitioner required to keep records and institutional practitioner shall maintain inventories and records of controlled substances in the manner prescribed in paragraph (f) of this section.

(h) Each registered pharmacy shall maintain the inventories and records of controlled substances as follows:

(1) Inventories and records of all controlled substances listed in Schedule I and II shall be maintained separately from all other records of the pharmacy.

(2) Paper prescriptions for Schedule II controlled substances shall be maintained at the registered location in a separate prescription file.

(3) Inventories and records of Schedules III, IV, and V controlled substances shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy.

(4) Paper prescriptions for Schedules III, IV, and V controlled substances shall be maintained at the registered location either in a separate prescription file for Schedules III, IV, and V controlled substances only or in such form that they are readily retrievable from the other prescription records of the pharmacy. Prescriptions will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is stamped in red ink in the lower right corner with the letter "C" no less than 1 inch high and filed either in the prescription file for controlled substances listed in Schedules I and II or in the usual consecutively numbered prescription file for non-controlled substances. However, if a pharmacy employs a computer application for prescriptions that permits identification by prescription number and retrieval of original documents by prescriber name, patient's name, drug dispensed, and date filled, then the requirement to mark the hard copy prescription with a red "C" is waived.

(5) Records of electronic prescriptions for controlled substances shall be maintained in an application that meets the requirements of part 1311 of this chapter. The computers on which the records are maintained may be located at another location, but the records must be readily retrievable at the registered location if requested by the Administration or other law enforcement agent. The electronic application must be capable of printing out or transferring the records in a format that is readily understandable to an Administration or other law enforcement agent at the registered location. Electronic copies of prescription records must be sortable by prescriber name, patient name, drug dispensed, and date filled.

(Authority: 21 U.S.C. 821 and 871(b); 28 CFR 0.100)

[36 FR 7790, Apr. 24, 1971, as amended at 36 FR 13386, July 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 39 FR 37985, Oct. 25, 1974; 45 FR 44266, July 1, 1980; 47 FR 41735, Sept. 22, 1982; 51 FR

5320, Feb. 13, 1986; 62 FR 13959, Mar. 24, 1997; 70 FR 25466, May 13, 2005; 75 FR 10677, Mar. 9, 2010; 75 FR 16306, Mar. 31, 2010; 79 FR 53562, Sept. 9, 2014]

Section 1304.05 Records of authorized central fill pharmacies and retail pharmacies.

Section 1304.06 Records and reports for electronic prescriptions.

INVENTORY REQUIREMENTS

Section 1304.11 Inventory requirements.

(a) *General requirements.* 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. An inventory taken by use of an oral recording device must be promptly transcribed. Controlled substances shall be deemed to be "on hand" if they are in the possession of or under the control of the registrant, including substances returned by a customer, ordered by a customer but not yet invoiced, stored in a warehouse on behalf of the registrant, and substances in the possession of employees of the registrant and intended for distribution as complimentary samples. A separate inventory shall be made for each registered location and each independent activity registered, except as provided in paragraph (e)(4) of this section. In the event controlled substances in the possession or under the control of the registrant are stored at a location for which he/she is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. The inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.

(b) *Initial inventory date.* Every person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he/she first engages in the manufacture, distribution, or dispensing of controlled substances, in accordance with paragraph (e) of this section as applicable. In the event a person commences business with no controlled substances on hand, he/she shall record this fact as the initial inventory.

(c) *Biennial inventory date.* After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.

(d) *Inventory date for newly controlled substances.* On the effective date of a rule by the Administrator pursuant to §§1308.45, 1308.46, or 1308.47 of this chapter adding a substance to any schedule of controlled substances, which substance was, immediately prior to that date, not listed on any such schedule, every registrant required to keep records who possesses that substance shall take an inventory of all stocks of the substance on hand. Thereafter, such substance shall be included in each inventory made by the registrant pursuant to paragraph (c) of this section.

(e) *Inventories of manufacturers, distributors, registrants that reverse distribute, importers, exporters, chemical analysts, dispensers, researchers, and collectors.* Each person registered or authorized (by §§1301.13, 1307.11, 1307.13, or part 1317 of this chapter) to manufacture, distribute, reverse distribute, dispense, import, export, conduct research or chemical analysis with controlled substances, or collect controlled substances from ultimate users, and required to keep records pursuant to §1304.03 shall include in the inventory the information listed below.

(1) *Inventories of manufacturers.* Each person registered or authorized to manufacture controlled substances shall include the following information in the inventory:

(i) For each controlled substance in bulk form to be used in (or capable of use in) the manufacture of the same or other controlled or non-controlled substances in finished form, the inventory shall include:

(A) The name of the substance and

(B) The total quantity of the substance to the nearest metric unit weight consistent with unit size.

(ii) For each controlled substance in the process of manufacture on the inventory date, the inventory shall include:

(A) The name of the substance;

(B) The quantity of the substance in each batch and/or stage of manufacture, identified by the batch number or other appropriate identifying number; and

(C) The physical form which the substance is to take upon completion of the manufacturing process (e.g., granulations, tablets, capsules, or solutions), identified by the batch number or other appropriate identifying number, and if possible the finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number or volume thereof.

(iii) For each controlled substance in finished form the inventory shall include:

(A) The name of the substance;

(B) Each finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);

(C) The number of units or volume of each finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial); and

(D) The number of commercial containers of each such finished form (e.g. four 100-tablet bottles or six 3-milliliter vials).

(iv) For each controlled substance not included in paragraphs (e)(1) (i), (ii) or (iii) of this section (e.g., damaged, defective or impure substances awaiting disposal, substances held for quality control purposes, or substances maintained for extemporaneous compoundings) the inventories shall include:

(A) The name of the substance;

(B) The total quantity of the substance to the nearest metric unit weight or the total number of units of finished form; and

(C) The reason for the substance being maintained by the registrant and whether such substance is capable of use in the manufacture of any controlled substance in finished form.

(2) *Inventories of distributors.* Each person registered or authorized to distribute controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1)(iii) and (iv) of this section.

(3) *Inventories of registrants that reverse distribute.* Each person registered or authorized to reverse distribute controlled substances shall include in the inventory, the following information:

(i) The name of the substance, and

(ii) The total quantity of the substance:

(A) For controlled substances in bulk form, to the nearest metric unit weight consistent with unit size;

(B) For each controlled substance in finished form: Each finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter); the number of units or volume of each finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial); and the number of commercial containers of each such finished form (e.g., four 100-tablet bottles or six 3-milliliter vials); and

(C) For controlled substances in a commercial container, carton, crate, drum, or other receptacle that has been opened: If the substance is listed in Schedule I or II, make an exact count or measure of the contents; or if the substance is listed in Schedule III, IV, or V, make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case an exact count of the contents shall be made; or

(iii) For controlled substances acquired from collectors and law enforcement: The number and size (e.g., five 10-gallon liners, etc.) of sealed inner liners on hand, or

(iv) For controlled substances acquired from law enforcement: the number of sealed mail-back packages on hand.

(4) *Inventories of importers and exporters.* Each person registered or authorized to import or export controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1) (iii) and (iv) of this section. Each such person who is also registered as a manufacturer or as a distributor shall include in his/her inventory as an importer or exporter only those stocks of controlled substances that are actually separated from his stocks as a manufacturer or as a distributor (e.g., in transit or in storage for shipment).

(5) *Inventories of chemical analysts.* Each person registered or authorized to conduct chemical analysis with controlled substances shall include in his inventory the same information required of manufacturers pursuant to paragraphs (e)(1) (iii) and (iv) of this section as to substances which have been manufactured, imported, or received by such person. If less than 1 kilogram of any controlled substance (other than a hallucinogenic controlled substance listed in Schedule I), or less than 20 grams of a hallucinogenic substance listed in Schedule I (other than lysergic acid diethylamide), or less than 0.5 gram of lysergic acid diethylamide, is on hand at the time of inventory, that substance need not be included in the inventory. Laboratories of the Administration may possess up to 150 grams of any hallucinogenic substance in Schedule I without regard to a need for an inventory of those substances. No inventory is required of known or suspected controlled substances received as evidentiary materials for analysis.

(6) *Inventories of dispensers and researchers.* Each person registered or authorized to dispense or conduct research with controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1)(iii) and (iv) of this section. In determining the number of units of each finished form of a controlled substance in a commercial container that has been opened, the dispenser or researcher shall do as follows:

(i) If the substance is listed in Schedules I or II, make an exact count or measure of the contents; or

(ii) If the substance is listed in Schedule III, IV, or V, make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case he/she must make an exact count of the contents.

(7) *Inventories of collectors.* Each registrant authorized to collect controlled substances from ultimate users shall include in the inventory the following information:

(i) For registrants authorized to collect through a mail-back program, the record shall include the following information about each unused mail-back package and each returned mail-back package on hand awaiting destruction:

(A) The date of the inventory;

(B) The number of mail-back packages; and

(C) The unique identification number of each package on hand, whether unused or awaiting destruction.

(ii) For registrants authorized to collect through a collection receptacle, the record shall include the following information about each unused inner liner on hand and each sealed inner liner on hand awaiting destruction:

(A) The date of the inventory;

(B) The number and size of inner liners (e.g., five 10-gallon liners, etc.);

(C) The unique identification number of each inner liner.

[62 FR 13959, Mar. 24, 1997, as amended at 68 FR 41228, July 11, 2003; 79 FR 53562, Sept. 9, 2014]

CONTINUING RECORDS

Section 1304.21 General requirements for continuing records.

(a) Every registrant required to keep records pursuant to §1304.03 shall maintain, on a current basis, a complete and accurate record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of by him/her, and each inner liner, sealed inner liner, and unused and returned mail-back package, except that no registrant shall be required to maintain a perpetual inventory.

(b) Separate records shall be maintained by a registrant for each registered location except as provided in Sec. 1304.04(a). In the event controlled substances are in the possession or under the control of a registrant at a location for which he is not registered, the substances shall be included in the records of the registered location to which they are subject to control or to which the person possessing the substance is responsible.

(c) Separate records shall be maintained by a registrant for each independent activity and collection activity for which he/she is registered or authorized, except as provided in §1304.22(d).

(d) In recording dates of receipt, importation, distribution, exportation, other transfers, or destruction, the date on which the controlled substances are actually received, imported, distributed, exported, otherwise transferred, or destroyed shall be used as the date of receipt, importation, distribution, exportation, transfer, or destruction (e.g., invoices, packing slips, or DEA Form 41).

(e) *Record of destruction.* In addition to any other recordkeeping requirements, any registered person that destroys a controlled substance pursuant to §1317.95(d), or causes the destruction of a controlled substance pursuant to §1317.95(c), shall maintain a record of destruction on a DEA Form 41. The records shall be complete and accurate, and include the name and signature of the two employees who witnessed the destruction. Except, destruction of a controlled substance dispensed by a practitioner for immediate administration at the practitioner's registered location, when the substance is not fully exhausted (e.g., some of the substance remains in a vial, tube, or syringe after administration but cannot or may not be further utilized), shall be properly recorded in accordance with §1304.22(c), and such record need not be maintained on a DEA Form 41.

[36 FR 7792, Apr. 24, 1971, as amended at 36 FR 13386, July 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, as amended at 62 FR 13960, Mar. 24, 1997; 79 FR 53563, Sept. 9, 2014]

Section 1304.22 Records for manufacturers, distributors, dispensers, researchers, importers, exporters, registrants that reverse distribute, and collectors.

Section 1304.23 Records for chemical analysts.

Section 1304.24 Records for maintenance treatment programs and detoxification treatment programs.

Section 1304.25 Records for treatment programs that compound narcotics for treatment programs and other locations.

Sec. 1304.26 Additional recordkeeping requirements applicable to drug products containing gamma-hydroxybutyric acid.

Disposal (Title 21 CFR Section 1307.21)

Subpart A — Disposal of Controlled Substances by Registrants

Controlled substances that are expired or need to be removed from inventory for any reason cannot be wasted. You need to request permission from the DEA to dispose of any controlled substance. The registrant shall submit DEA Form 41 at least 14 days in advance of the proposed disposal. The preferred method of disposal is to utilize a reverse distributor (a DEA registered disposal firm.) Other methods need further approval from the DEA District Office.

2) Access

a) Access to controlled substances shall be limited to crew members authorized to utilize the medications in the course of usual patient care and those responsible for inventory.

b) Access shall be limited to only those personnel necessary to maintain inventory and utilize the medication during patient care.

c) All access shall occur in the presence of two personnel.

3) Documentation

a) Every use of controlled substance shall be documented in the patient care record as well as on an inventory sheet

b) Every access to the controlled substances whether for shift change count and examination or during restocking shall be documented with a beginning and ending count

c) All documentation shall have two signatures

d) All documents shall be securely stored for a minimum of five (5) years.

e) A service needs to determine if the patient care record or if the inventory sheet will be the primary record for the DEA. For CII substances, these records need to be maintained separately from all

other records and the record must have all required information (patient name, address, controlled substance, amount administered, date administered, initials of person administering substance)

4) Use

a) After use of a controlled substance the following shall be documented:

(1) Medication used

(2) Amount used

(3) Amount wasted

(4) Patient name

(5) Patient address

(6) Date given

(7) Time given

(8) Initials of person(s) administering

b) Any amount of a controlled substance that is wasted should be witnessed by at least two people and recorded.

c) After use, the entire stock of controlled substance that was accessed shall be counted by two personnel and counts documented.

6) Daily accountability

a) At the start of every shift, all controlled substances shall be examined for evidence of tampering, expiration dates, and count.

i) Counts shall be verified against the last count.

ii) Any discrepancy or evidence of tampering shall be reported immediately.

iii) Theft or loss of a controlled substance needs to be reported to the DEA within 1 business day and a DEA Form 106, Report of Theft or Loss, needs to be completed and submitted.

iv) Any controlled substance that appears to have been tampered with shall be secured for DEA investigation, and the DEA shall be notified within 1 business day.

8) Facility Storage

a) Replacement inventory should be stored in a locked cabinet or locked refrigerator.

b) Access should be limited to necessary personnel.

9) Facility Replacement

a) After receiving replacement inventory, the following should be verified by two people:

(1) Medication

(2) Amount

(3) Date received

(4) Current count

(5) Inspection of entire inventory for tampering and expiration dates

b) If the replacement inventory was damaged or appears to be tampered with during shipment a service supervisor should be notified immediately and proper DEA notification shall be made.

DISPOSAL OF CONTROLLED SUBSTANCES

Section 1307.21 Procedure for disposing of controlled substances.

(a) Any person in possession of any controlled substance and desiring or required to dispose of such substance may request assistance from the Special Agent in Charge of the Administration in the area in which the person is located for authority and instructions to dispose of such substance. The request should be made as follows:

(1) If the person is a registrant, he/she shall list the controlled substance or substances which he/she desires to dispose of on DEA Form 41,and submit three copies of that form to the Special Agent in Charge in his/her area; or

(2) If the person is not a registrant, he/she shall submit to the Special Agent in Charge a letter stating:

(i) The name and address of the person;

(ii) The name and quantity of each controlled substance to be disposed of;

(iii) How the applicant obtained the substance, if known;, and

(iv) The name, address, and registration number, if known, of the person who possessed the controlled substances prior to the applicant, if known.

(b) The Special Agent in Charge shall authorize and instruct the applicant to dispose of the controlled substance in one of the following manners:

(1) By transfer to person registered under the Act and authorized to possess the substance;

(2) By delivery to an agent of the Administration or to the nearest office of the Administration;

(3) By destruction in the presence of an agent of the Administration or other authorized person; or

(4) By such other means as the Special Agent in Charge may determine to assure that the substance does not become available to unauthorized persons.

(c) **In the event that a registrant is required regularly to dispose of controlled substances, the Special Agent in Charge may authorize the registrant to dispose of such substances, in accordance with paragraph (b) of this section, without prior approval of the Administration in each instance, on the condition that the registrant keep records of such disposals and file periodic reports with the Special Agent in Charge summarizing the disposals made by the registrant.** In granting such authority, the Special Agent in Charge may place such conditions as he deems proper on the disposal of controlled substances, including the method of disposal and the frequency and detail, of reports;

(d) This section shall not be construed as affecting or altering in any way the disposal of controlled substances through procedures provided in laws and regulations adopted by any State.

Access

a) Access to controlled substances shall be limited to crew members authorized to utilize the medications in the course of usual patient care and those responsible for inventory.

b) Access shall be limited to only those personnel necessary to maintain inventory and utilize the medication during patient care.

c) All access shall occur in the presence of two personnel.

Documentation

a) Every use of controlled substance shall be documented in the patient care record as well as on an inventory sheet

b) Every access to the controlled substances whether for shift change count and examination or during restocking shall be documented with a beginning and ending count

c) All documentation shall have two signatures

d) All documents shall be securely stored for a minimum of five (5) years.

e) A service needs to determine if the patient care record or if the inventory sheet will be the primary record for the DEA. For CII substances, these records need to be maintained separately from all other records and the record must have all required information (patient name, address, controlled substance, amount administered, date administered, initials of person administering substance)

Use

a) After use of a controlled substance the following shall be documented:

(1) Medication used

(2) Amount used

(3) Amount wasted

(4) Patient name

(5) Patient address

(6) Date given

(7) Time given

(8) Initials of person(s) administering

b) Any amount of a controlled substance that is wasted should be witnessed by at least two people and recorded.

c) After use, the entire stock of controlled substance that was accessed shall be counted by two personnel and counts documented.

Daily accountability

a) At the start of every shift, all controlled substances shall be examined for evidence of tampering, expiration dates, and count.

i) Counts shall be verified against the last count.

ii) Any discrepancy or evidence of tampering shall be reported immediately.

iii) Theft or loss of a controlled substance needs to be reported to the DEA within 1 business day and a DEA Form 106, Report of Theft or Loss, needs to be completed and submitted.

iv) Any controlled substance that appears to have been tampered with shall be secured for DEA investigation, and the DEA shall be notified within 1 business day.

Facility Replacement

a) After receiving replacement inventory, the following should be verified by two people:

(1) Medication

(2) Amount

(3) Date received

(4) Current count

(5) Inspection of entire inventory for tampering and expiration dates

b) If the replacement inventory was damaged or appears to be tampered with during shipment a service supervisor should be notified immediately and proper DEA notification shall be made.

If any records (including unexecuted DEA-222, Official Order Forms) are stored at a location other than the registered location, DEA must be notified in writing.

Subpart A — Disposal of Controlled Substances by Registrants

1317.01 Scope.

1317.05 Registrant disposal.

1317.10 Registrant return or recall.

1317.15 Reverse distributor registration requirements and authorized activities.

§1317.01 Scope.

This part sets forth the rules for the delivery, collection, and destruction of damaged, expired, returned, recalled, unused, or otherwise unwanted controlled substances that are lawfully possessed by registrants (subpart A) and non-registrants (subpart B). The purpose of such rules is to provide prompt, safe, and effective disposal methods while providing effective controls against the diversion of controlled substances.

Theft or Loss of Controlled Substances - DEA Form 106

IMPORTANT NOTICE: Only those persons registered with DEA to handle controlled substances may utilize this form.

Federal regulations require that registrants notify the DEA Field Division Office in their area, in writing, of the theft or significant loss of any controlled substance within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in their area, DEA Form 106, "Report of Theft or Loss of Controlled Substances" regarding the theft or loss. (21 C.F.R. § 1301.76(b))

DEA controlled substance registrants are strongly encouraged to complete and submit the DEA Form 106 online. In addition to being more convenient, completing the form online results in fewer errors. A link to the online DEA Form 106 is provided below.

In order to better track controlled substances reported as lost or stolen, DEA has incorporated use of the National Drug Code (NDC) number in the DEA Form 106. The NDC number identifies the manufacturer, product, dosage form, and package size. Entry of the NDC number will prompt the system to auto-populate additional fields such as the name of the product, dosage form, dosage strength, and quantity per container.

If a registrant does not have internet access, a paper copy of the DEA-106 form can be requested by writing to:

Drug Enforcement Administration
Attn: Regulatory Section/ODG
8701 Morrissette Drive
Springfield, VA 22152

For more information regarding reporting theft or loss of controlled substances, see the Federal Register Notice – "Reports by Registrants of Theft or Significant Loss of Controlled Substances."

DEA Form106

Data will be entered through a **secure connection** to the online application system. **Your web browser must support 128-bit encryption.**

If you have questions regarding the electronic submission of the DEA Form-106, please contact **DEA Call Center 1-800-882-9539**.

Privacy Act Information for DEA Form 106

Authority: Section 301 of the Controlled Substances Act of 1970 (PL-513).

Purpose: Report theft or loss of Controlled Substances.

Routine Uses: The Controlled Substances Act authorizes the production of special reports required for statistical and analytical purposes. Disclosures of information from this system are made to the following categories of users for the purposes stated:

1. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.
2. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.

Effect: Failure to report theft or loss of controlled substances may result in penalties under Section 402 and 403 of the Controlled Substances Act.

Under the Paperwork Reduction Act, a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Records Management Section, Drug Enforcement Administration, Washington, D.C. 20537; and to the Office of Management and Budget, Washington, D.C. 20503.

Inventory Systems Control (IAO Research)

EMS Inventory Systems Control

Inventory Control Objective: At any time, Riviera Beach Fire Department (FD) should be able to know and locate any controlled substances (CS) lot number ordered and stored – this means by lot number and unique identifier (bar code or RFID) the FD should know where each CS is stored, and when it is used or disposed. The staff that uses or disposes of CS should also be identified and recorded/reported. Use and/disposal dates and times should be recorded.

Best business practices dictate that all inventories should be tracked in a proper inventory system to ensure that assets are properly recorded and safeguarded. To this end, the IAO has conducted precursory research into the following inventory products. This research is not intended to be expansive or all-inconclusive, but to serve as a "jumping off point" for the Department to pursue.

Controlled Substances Inventory Security Systems

Cyberlock Security for Controlled Substances

Resource: Clark County EMS, Las Vegas, NV

Reference

http://www.emsworld.com/press_release/10418039/clark-county-fire-department-uses-cyberlock-to-manage-narcotics

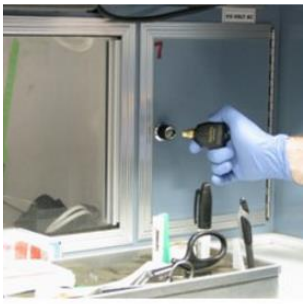
- The CyberLock system's electronic locks and keys record openings and unauthorized entry attempts. The audit report allows the department to confirm that the responsible person is taking inventory, checking drug expiration dates, and ensuring that the drugs have not been tampered with. Each narcotic safe has to be inventoried daily, in the morning during shift-change. If a safe has been opened any other time of the day, it must correspond with an emergency call.

http://www.emsworld.com/article/10373625/tracking-and-controlling-access-to-controlled-substances

http://www.cyberlock.com/

Tracking and Controlling Access to Controlled Substances

BY ANDY HILVERDA ON JUL 21, 2010



Jeff Reagor, Clark County Fire Department EMS Supervisor, says, "We were required to have a system of checks and balances in place that would provide an accounting of the handling of all controlled substances. Our narcotics needed to be safely secured in each of our ALS engines and rescue vehicles."

After researching available products, Reagor shares the department's reasons for choosing CyberLock, "With CyberLock, we could gain tight key control and the ability to track how many times and when our narcotic safes were being opened. We saw this as a good way to have accountability with our narcotics handling."

Reagor continues, "Deputy Chief Russ Cameron, Chief of the department's Fire and EMS Training Program, obtained the funding for the CyberLock system and, in May 2008, we began installing CyberLocks on our narcotic safes. We worked closely with A&B Security, a Las Vegas access control and security company. A&B Security is the department's supplier of narcotic safes. Their people came on site and gave us the support we required to install and manage the CyberLock system."

Each time the Clark County FD gets a new rescue unit, mechanics install a narcotic safe onboard. The safe is secured in the unit with titanium hardware and fitted with a CyberLock in a matter of minutes. The unit number, a unit identifier and the fire station it is assigned to are entered into the CyberLock system software before delivering the rescue unit to the appropriate fire station. Extra electronic keys are stored in a secured centralized location so a key can be activated whenever the department receives a new rescue unit.

To date, Clark County has installed CyberLocks on safes in the fire stations themselves, on rescue unit safes and on safes in engine company vehicles. The department also has a reserve fleet that consists of five rescue vehicles, eight engines and two ladder trucks. Each of these is equipped with a narcotic safe that has been fitted with a CyberLock.

Reagor comments, "In the event we need to use one of the reserve fleet vehicles, the CyberLock software allows us to quickly program an electronic key on-the-fly to access that particular unit's safe."

When a rescue vehicle is taken out of service, involved in an accident, or disabled in some manner, the narcotics are immediately removed from that unit's safe and placed in the fire station safe until the department receives a replacement rescue unit.

The City was able to easily interface the CyberLock software with Clark County's computer network. The integration of the two systems went smoothly and they work together seamlessly. The CyberLock software runs on each fire station's office computer.

Reagor states, "The electronic locks and keys record openings and unauthorized attempts to enter, so at any time an EMS supervisor can pull up a log of events in the software and see when a narcotic safe has been opened and by whom. The audit report the CyberLock software provides is of utmost importance to us."

EMS Coordinator Troy Tuke oversees all Clark County's EMS operations including the audit process for the department's controlled substances. Each EMS supervisor is responsible for managing the CyberLock System for their assigned platoon. One key is issued for each rescue unit that has a paramedic onboard, and one individual is assigned responsibility for that key. **The EMS supervisor can look at the audit report from the safe lock and the key to see if that responsible individual is checking drug expiration dates, taking inventory of the drugs, and insuring that the drugs have not been tampered with. This must be done during shift-changes in the morning of each day. If the EMS supervisor sees that a safe has been opened any other time of the day, it must correspond with an emergency call during that time.** If there is a discrepancy, the EMS supervisor would immediately report this to the EMS Coordinator for further action.

If an electronic key is lost, the EMS supervisor can go into the system and deactivate the key so it will no longer open that particular narcotic safe. A new key can then be assigned to that rescue unit. If someone tries to open a safe that their key is not authorized to access, the safe's lock will not open and their key will alarm. Also, there will be a record of that person's key being denied entry to that safe.

Reagor says, "If a safe should be opened at a time there is no emergency call, it would raise a red flag and have to be investigated. We would know who has possession of the key."

The CyberLock software generates a monthly report of narcotic safe and electronic key activity from all department units. If a certain individual is not compliant, the department takes aggressive steps to make sure they do conform by checking the drugs they are responsible for.

Reagor summarizes, "We are always looking for effective solutions that allow us to expand and improve our services to the people who live in or visit our communities. Implementing CyberLock to more efficiently manage the handling of our controlled substances has been a great decision for us. As the Las Vegas area grows and the need for services and protection increases, Clark County Fire Department is poised to meet those needs."

Andy Hilverda is Vice President of Videx, Inc., a company that designs and manufactures CyberLock access control products that are shipped worldwide from their headquarters located in Corvallis, Oregon. Hilverda can be reached at 541/758-0521 and sales@videx.com. For more information, visit www.videx.com.

Controlled Substances Inventory Security Systems

Checkmate Inventory Control Software from Dynamic- Systems, Inc.

http://dynamic-systemsinc.com/wp-content/uploads/2014/09/CheckMate-StockRoom-Rev-14.pdf

I. Flexible Features of CheckMate EMS Inventory Management:

- Track Inventory by Location (Stockroom, Truck, Ambulance)
- Set Min/Max by Location
- Track Items by Lot Number
- Record and Track Expiration Dates
- Multiple units of measure (case; ounces; each)
- Multiplier available (receive by the case but issue by the bottle)
- Keep Audit Trail of Usage by Location
- Print Replenishment Reports by Location
- Use Vendor UPC or Print Laser Labels from Check-Mate

II. Benefits of CheckMate EMS Inventory Management

- Fast, Accurate Replenishment of Trucks & Ambulances
- Never throw away expired items again!
- Use Manufacturers' item numbers & barcodes—no need to re-label
- Comply with controlled substance requirements with lot & expiration date tracking
- Attach MSDS documents to inventory records
- Cycle count or full inventory count - fast & accurate
- First year unlimited support included in purchase price