



AUDIT REPORT



DATE

November 20, 2020

NO.

2020-007

2nd FOLLOW-UP FIRE EMS CONTROLLED SUBSTANCES
(ORIGINAL REPORT NO. 2017-003 ISSUED AUGUST 17, 2017)
(FOLLOW-UP REPORT NO. 2019-006 ISSUED APRIL 5, 2019)

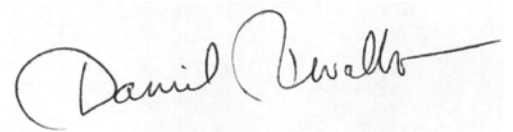
INTERNAL AUDIT DIVISION
ROGER D. EATON
CLERK OF THE CIRCUIT COURT AND COUNTY COMPTROLLER
CHARLOTTE COUNTY FLORIDA

Honorable Roger D. Eaton
Charlotte County Clerk of the Circuit Court and Comptroller
350 East Marion Avenue
Punta Gorda, Florida 33950

We have completed a second follow-up audit of Fire EMS Controlled Substances (Follow-Up Report No. 2019-006 issued April 5, 2019). The purpose of this follow-up was to ensure comments and recommendations of the original follow-up were adequately addressed. We performed expanded testing on identified areas of concern.

The report details the original audit comments, recommendations, and follows up on original and follow-up responses provided. Follow-up was accomplished thru inquiries and observations of evidence. Management responses have been included and immediately follow this audit report.

Respectfully submitted,

A handwritten signature in black ink that reads "Daniel Revallo". The signature is written in a cursive style with a long horizontal stroke extending to the right.

Daniel Revallo
Internal Audit Director

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EXECUTIVE SUMMARY

The Internal Audit Division completed a second, follow-up audit of the Charlotte County Fire and Emergency Medical Services (EMS) procedures for dispensing controlled substances as needed for emergency medical procedures.

This second, follow-up audit considered the “Comments, Recommendations, and Follow-up Results” reported within the *Follow-up Fire EMS Controlled Substances Audit Report No. 2019-006*. Internal Audit evaluated responses documented and subsequent corrective actions taken or delegated by the respondent. Internal Audit also considered the updated Medical Director’s Policies and Procedures, Section 1.20 “Controlled Substance Accountability” (“CSA”) (Version 1.3, 05-2019), and obtained third-party confirmation from vendors.

This audit report will conclude our second, follow-up, as it pertains to Fire EMS Controlled Substances. The status of corrective action will either be:

OPEN – Corrective action has not been taken to adequately address the initial, follow-up audit comment.

OPEN/PARTIALLY COMPLETED – Corrective action has begun but has not adequately addressed the initial, follow-up audit comment.

CLOSED – Corrective action has been taken to adequately address the initial, follow-up audit comment.

OTHER COMMENTS – Additional issues identified during follow-up audit procedures.

Follow-up Audit Comments and Status of Corrective Actions

OPEN

- Two of the controlled substances administered by Fire EMS are not being tested for as part of the drug testing process.

OPEN/PARTIALLY COMPLETED

- “Stock Decrease” is inconsistently used to record controlled substance usage or waste.
- Battalion’s Chief’s initials were not always present for a stock increase or decrease.
- Central storage of controlled substances is not maintained in accordance with internal controls.
- Fire EMS does not follow *Audit Procedures* outlined in Medical Director’s Policies and Procedures.

CLOSED

- Rescue vehicle controlled substance inventories were not replenished prior to starting a new controlled substance accountability log book.
- Transaction receipts are not consistent to account for what controlled substances are received.

OTHER COMMENTS

- Additional log completion matters related to distribution, disposal, and re-supply activities were identified.
- The Quality Improvement (QI) Coordinator/EMS audits did not occur.
- There are no storage levels (maximum and minimum) established by policy for Central Storage, and Battalion storage levels exceeded the maximum allowed per policy.
- Controlled substances were procured using a pCard of staff other than the Deputy Chief of Training or his designee, and DEA Forms 222 were not used in sequential order.

The following is a summary of our recommendations:

1. **We recommended** Management ensure consistent and proper use of the “Stock Decrease” column in the controlled substance logs.
2. **We recommended** Management ensure that Battalion Chiefs consistently initial stock transactions involving Central Storage inventories.
 - **We additionally recommend** that Fire EMS management enforce consistent and proper use of all CSA log columns.
3. Recommendation was implemented.
 - **We additionally recommend** that parameters be established and policy be updated to include approved controlled substance storage levels (maximum and minimum) for Central Storage.
4. **We recommended** Management ensure proper security over central storage of controlled substances.
 - **We additionally recommend** that management implement dual-control procedures over all Central Storage activities, including receipt, storage access, transfers out, etc.
5. **We recommended** Management ensure the drug testing process includes all of the controlled substances administered by Fire EMS.
 - **We additionally recommend** that management continue to assess applicable risks and evaluate the appropriateness of acceptance, at least annually.
6. Recommendation was implemented.
 - **We additionally recommend** that the Medical Director's Policies and Procedures be followed and procurements for controlled substances be made only by the Deputy Chief of Training or his designee only.
 - **We additionally recommend** that best practices be followed and DEA Forms 222 be used in sequential order.
7. **We recommended** management adhere to these audit procedures and use them to help avoid and correct the situations that gave origin to the first three findings.
 - **We additionally recommend** that management adhere to defined audit procedures and document completion accordingly.

BACKGROUND

Advanced Life Support (ALS) and Basic Life Support (BLS) responses are provided to meet the emergency medical needs of Charlotte County citizens.

Only ALS vehicles are equipped with controlled substances. All sixteen (16) rescue units are designated as ALS, and eleven (11) engines are equipped to provide ALS.

Delivery of emergency medical services requires using a variety of medical supplies and medications, including controlled substances. Controlled substances are classified according to their potential for abuse, accepted medical use, and probability for causing physical or psychological dependency. Based on these factors, the drugs are ranked by the Federal Drug Enforcement Agency in one of five schedules.

Fire EMS uses four (4) controlled substances, ranked per Florida Statute 893, Drug Abuse Prevention and Control: Morphine (Schedule II), Versed/Midazolam (Schedule IV), Ketamine (Schedule III), and Fentanyl (Schedule II).

A substance in Schedule II has a high potential for abuse and has a currently accepted but severely restricted medical use in treatment in the United States. Abuse of the substance in this schedule may lead to severe psychological or physical dependence.

A substance in Schedule III has a potential for abuse less than the substances contained in Schedules I and II and has a currently accepted medical use in treatment in the United States. Abuse of the substance in this schedule may lead to moderate or low physical dependence or high psychological dependence or, in the case of anabolic steroids, may lead to physical damage.

A substance in Schedule IV has a low potential for abuse relative to the substances in schedule III and has a currently accepted medical use for treatment in the United States. Abuse of the substance may lead to limited physical or psychological dependence relative to the substances in Schedule III.

Chapters 499 and 893 of the Florida Statutes govern, and Section 64J-1 of the Florida Administrative Code provides for, the rules and regulations for emergency medical services related to the purchase, inventory, and dispensing of controlled substances. These Statute chapters and sections give specific direction related to the requisite audit trail for controlled substance transactions.

Controlled substance accountability (CSA) logs are used to track inventory, usage and responsibility of controlled substances. Daily inventories are recorded along with usage, waste and transfer of controlled substances.

CSA logs were initially wire bound and recently replaced with a glue bound option, as pages over time would rip and tear out. The glue bound option, however, was unable to withstand Florida's heat and humidity. As a result, Fire/EMS reverted back to the wire bound CSA logs.

AUDIT OBJECTIVES

The purpose of this second, follow-up audit was to determine whether Charlotte County Fire EMS adequately and timely applied corrective actions reported within the *Follow-up Fire EMS Controlled Substances Audit Report No. 2019-006*.

SCOPE AND METHODOLOGY

To perform this second, follow-up audit, we inquired of Fire EMS management regarding the status of corrective actions. To test corrective actions, where applicable, we examined a sample of controlled substance activity logs for compliance with the Medical Director's Policies and Procedures, Section 1.20 "Controlled Substance Accountability" (Version 1.3, 05-2019).

Due to COVID-19 restrictions, Internal Audit sampled only complete logs, versus in-use logs, which are onboard active, ALS units. The sample selection made was based on both auditor judgment and availability. Internal Audit sampled eight (8) logs, which consisted of ALS rescue units and engines, a Battalion unit, and Central Storage.

In addition, Internal Audit reviewed all controlled substance procurement activity and related support, including (but not limited to) transaction receipts, purchase confirmations and vendor invoices, packing slips and shipping confirmations, pCard statements, and stock additions to Central Storage.

Procedures performed considered controlled substance activities for the period of October 1, 2018 through June 30, 2020.

ADDITIONAL PROCEDURES

In addition to the second, follow-up audit procedures performed and documented above, Internal Audit performed the following -

- Obtained third-party confirmation from BoundTree Medical, Henry Schein, and Emergency Medical Products (a "sister company" of BoundTree Medical) for the controlled substances purchased (October 1, 2018 through June 30, 2020).
- Performed a surprise audit of Central Storage stock on June 30, 2020.

Both procedures were performed without exception.

COMMENTS, RECOMMENDATIONS AND FOLLOW-UP AUDIT RESULTS

1. **"Stock Decrease" is inconsistently used to record controlled substance usage or waste.**

We recommended Management ensure consistent and proper use of the "Stock Decrease" column in the controlled substance logs.

Initial Follow-up Response: The definition of “Stock Decrease” was strengthened as our response stated, but this audit has identified opportunities to improve our communication and training. We also have created training videos that are being deployed through our internet training provider that will further explain all processes and lines in the book. This will allow all entries to be consistent and correct. This is being deployed to all personnel now.

Status of Corrective Action: Open/Partially Completed

Auditor Comments: Follow-up procedures performed, determined that the “Stock Decrease” column continues to be used improperly for drugs administered and/or wasted, etc. In most cases identified (15 of 18 cases), the “Stock Decrease” and the “Drug/mg Admin” columns were used simultaneously.

Other Comments: Additional log completion matters related to distribution, disposal, and re-supply activities noted during follow-up procedures include the following:

- There were several instances where notes and/or documentation of amounts were not specified. The "Notes" column *generally* does not contain the required details, as defined by policy.
- There were three (3) instances where "Witness Print" or "Witness Signature" were not present for "Drug/mg Wasted", as required by policy.
- There was one (1) instance where the stock reduction recorded (250 mcg. Fentanyl) did not agree to the combined mcg. amounts recorded for "Drug/mg Admin" and "Drug/mg Waste". There was 50 mcg. of Fentanyl unaccounted for.

Improper use of columns can lead to inconsistencies and confusion regarding the disposition of a drug, and create opportunity for fraud, waste and/or abuse, etc. **Refer also to item no. 2.**

2. Battalion’s Chief’s initials were not always present for a stock increase or decrease.

We recommended Management ensure that Battalion Chiefs consistently initial stock transactions involving Central Storage inventories.

Initial Follow-up Response: We’ve strengthened the definitions as our original response stated, but this audit identified that the frequency of book audits was not practical. As a result, we have now put into place that the Battalion log books are being audited every 4 weeks by the Deputy Chief of EMS and the QI Coordinator/EMS.

Status of Corrective Action: Open/Partially Completed

Auditor Comments: Follow-up procedures identified eight (8) entries where there were no documented Battalion’s Chief’s initials for stock changes. An additional eight (8) entries included initials for non-stock increases or decreases in error.

Improper use of columns can lead to inconsistencies and confusion regarding the disposition of a drug, and create opportunity for fraud, waste and/or abuse, etc.

We additionally recommend that Fire EMS management enforce consistent and proper use of all CSA log columns. Fire EMS management should consider the need for additional staff training and/or disciplinary actions for continued error. To ensure proper record keeping of controlled substances from “Cradle to Grave,” all columns need to be understood, and management should enforce proper completion.

Other Comments: Management audit procedures, including the QI Coordinator/EMS responsibilities noted by Fire EMS management in the initial follow-up response, did not occur as intended. ***The performance of management’s audit procedures are further discussed in item no. 7.***

3. Rescue vehicle controlled substance inventories were not replenished prior to starting a new control substance accountability log book.

We recommended Management ensure narcotic inventories are filled to maximum levels prior to starting new controlled substance accountability log books.

Initial Follow-up Response: We concur that this issue has been closed. Additionally, a new page was placed into the book warning of the last page, this provides a reminder that this procedure needs to occur before the book is completed.

Status of Corrective Action: Closed

Auditor Comments: We observed the “reminder” page noted by Fire EMS management, as well as replenishment activities for each controlled substance log reviewed during audit procedures, except for Central Storage.

Other Comments: There are no storage levels (maximum and minimum) established by policy for Central Storage. No established parameters could lead to inadequate or excessive amounts maintained on hand, and a higher potential for fraud, waste, and/or misuse, etc. Excessive amounts maintained can also trickle downward, impacting the Field Storage (Battalion) levels.

As an example, the Battalion log reviewed exceeded the maximum storage limits on both Morphine and Fentanyl. The number of vials on hand at final entry were 34 and 50, respectively. In addition, on hand amounts for each controlled substance throughout the log were generally over the established policy limits, and at times, doubled the maximum quantities allowed. Maximum levels per policy is 25 vials of each type of controlled substance.

We additionally recommend that parameters be established and policy be updated to include approved controlled substance storage levels (maximum and minimum) for Central Storage. Consideration should be given to anticipated needs (use trends) and the frequency of drug expiration, etc. Routine audits should also consider on-hand amounts compared to established limits.

4. Central storage of controlled substances is not maintained in accordance with internal controls.

We recommended Management ensure proper security over central storage of controlled substances.

Initial Follow-up Response: We concur that this issue is closed. Additionally, Central Storage has been relocated to the Deputy Chief of EMS’ office to allow for more consistent delivery and disbursement.

Status of Corrective Action: Open/Partially Completed

Auditor Comments: We observed that Central Storage has been relocated. However, relocation to the Deputy Chief of EMS' office creates an internal control weakness, due to a lack of segregation of duties. Control over both the authorization to procure and the custody functions for controlled substances, creates a greater opportunity for fraud, waste and/or misuse, etc. When segregation of duties are not practical, dual-control procedures become essential to adequately safeguard and protect from fraud, waste and/or misuse, etc.

We additionally recommend that management implement dual-control procedures over all Central Storage activities, including receipt, storage access, transfers out, etc. Evidence of dual-control should be maintained within the Central Storage CSA Log when stock changes are made, through witness signature or initials, etc.

5. Two of the controlled substances administered by Fire EMS are not being tested for as part of the drug testing process.

We recommended Management ensure the drug testing process includes all of the controlled substances administered by Fire EMS.

Initial Follow-up Response: Currently the testing for two of the controlled substances is not commonly done in the prehospital setting. There is no process for the local testing of these controlled substances. Additionally, Charlotte County Fire & EMS performs random drug testing, as well as reasonable suspicion testing for all employees. Management accepts the risk, as we are testing to the extent possible, and compensating controls are in place to identify cases of reasonable suspicion.

Status of Corrective Action: Open

Auditor Comments: Follow-up procedures included inquiry of the Deputy Chief of EMS, noting that no changes have been made.

We additionally recommend that management continue to assess applicable risks and evaluate the appropriateness of acceptance, at least annually.

6. Transaction receipts are not consistent to account for what controlled substances are received.

We recommended Management ensure cardholder activity agrees with the itemized procurement card receipt and itemized vendor sales receipt.

Initial Follow-up Response: We have modified the ordering since the audit. The distributor extended a line of credit for our orders without permission from us and were not billing us upon shipment of our orders. These created discrepancies with the timeline of our billing records. We have placed ourselves on point of sale billing and this will fix that issue. We also are maintaining records of all orders, packing slips, and invoices in a file for review for future audits. There is no guarantee on the availability of stock when the distributor receives an order, this can cause a shipping/billing delay from time of order. By maintaining documentation on site, we will have accurate support of what is reflected in the log books.

Status of Corrective Action: Closed

Auditor Comments: Internal Audit reviewed controlled substance procurement activity, noting that adequate support is maintained within a well-organized folder. Support maintained included (but was not limited to) transaction receipts, purchase confirmations and vendor invoices, packing slips and shipping confirmations, and pCard statements, etc. Procurements noted for the audit period were acquired through pCard credit, verified to supportive documentation, traced into Central Storage, and recorded to the general ledger, etc.

Other Comments: Detailed tests found one transaction for the procurement of controlled substances that was procured using a pCard of staff other than the Deputy Chief of Training or his designee. In addition, DEA Forms 222 were not used in sequential order.

The Medical Director's Policies and Procedures Section 1.20 "Controlled Substance Accountability" Version 1.3 (05-2019) states "Controlled Substances shall be procured by the Deputy Chief of Training or his/her designee only." As such, it is reasonably expected that his pCard be used.

The observations noted may enable unauthorized and/or unintended charges to go undetected or unquestioned, etc.

We additionally recommend that the Medical Director's Policies and Procedures be followed and procurements for controlled substances be made only by the Deputy Chief of Training or his designee only. Errors should be identified, documented and corrected with the vendor.

We additionally recommend that best practices be followed and DEA Forms 222 be used in sequential order.

7. Fire EMS does not follow Audit Procedures outlined in Medical Director's Policies and Procedures.

We recommended management adhere to these audit procedures and use them to help avoid and correct the situations that gave origin to the first three findings.

Initial Follow-up Response: Charlotte County Fire & EMS realizes that all processes require appropriate and thorough documentation. We are taking all the audit findings very serious and will continue to look for ways to improve and create the best processes possible. Due to the nature of our business at certain times, some processes could not be followed, therefore we have removed some unnecessary steps that were repetitive in nature. We will constantly monitor and adjust procedures as necessary. The Medical Directors policies have been modified for efficiencies and improvements that were recommended by the audit.

Status of Corrective Actions: Open/Partially Completed

Auditor Comments: While the Medical Director's policies and procedures were modified, the performance of Audit Procedures remains an area for improvement. In addition, Internal Audit couldn't easily differentiate between an audit and a correction, as both are initialed in the same manner and location, etc.

We additionally recommend that management adhere to defined audit procedures and document completion accordingly. Routine audits, as defined by policy, should be performed to confirm on-hand stock amounts as well as consider entries for proper completion, etc. Initials of supervisory review puts the onus of accuracy on the supervisor. Evidence of review should be clearly documented and distinguishable from corrections made.

ACKNOWLEDGEMENT

We would like to thank Charlotte County Fire and Emergency Medical Services (EMS) for their assistance and cooperation in the completion of this audit.

Audit performed by:
Misti Payette
Internal Auditor
Charlotte County Clerk of Court and Comptroller



Date: November 2, 2020

To: Dan Revallo, Director of Internal Audit, Charlotte County Clerk's Office

From: Michael Davis, Deputy Chief Charlotte County Fire & EMS

CC: Bill Van Helden, Director of Public Safety

Re: Charlotte County Fire & EMS Narcotics Audit

Recently, the narcotics system in place at Charlotte County Fire & EMS was audited by your office. Misti Payette upon arrival was given the autonomy to perform this audit as required. The controls and security of our narcotics system is very important as we must meet federal standards and best practices. Orlando Solarte handled himself very professionally throughout this process and the collaborative efforts of your office is greatly appreciated. Here is our response to your findings.

1. "Stock Decrease" is inconsistently used to record controlled substance usage or waste.

We recommended Management ensure consistent and proper use of the "Stock Decrease" column in the controlled substance logs.

As of the follow-up audit some occurrences were by employees that are no longer employed. We are attempting to strengthen this by transitioning to an electronic process for controlled substances. These inconsistencies would immediately flag upper management. This immediate notification will allow for both notification of an issue and our ability to address it right then. If training is warranted it can be provided at the time of the error or progressive discipline could occur. We anticipate the introduction of the electronic system in the next 2-3 weeks (soft opening with dual entry). In the meantime, we will be pushing out another clarification email to all Fire-EMS to reinforce the correct procedure for this line speaking directly to a stock increase/decrease occurs with a Battalion Chief, while an administration is not a stock decrease. We will also enforce the notes section and witness requirements.



2. Battalion's Chief's initials were not always present for a stock increase or decrease.

We recommended Management ensure that Battalion Chiefs consistently initial stock transactions involving Central Storage inventories.

We additionally recommend that Fire EMS management enforce consistent and proper use of all CSA log columns.

As of the follow-up audit a portion of occurrences were by employees that are no longer employed. We are attempting to strengthen this by transitioning to an electronic process for controlled substances. These inconsistencies would immediately flag upper management. In the meantime, we will be pushing out another clarification email to all Fire-EMS to reinforce the correct procedures for this column.

3. Rescue vehicle-controlled substance inventories were not replenished prior to starting a new control substance accountability log book.

We additionally recommend that parameters be established and policy be updated to include approved controlled substance storage levels (maximum and minimum) for Central Storage.

Additional recommendations were made for Central supply to have set maximums and minimums. This will be set in the near future. The numbers will be 200 Morphine, 200 Fentanyl, 120 Midazolam, and 120 Ketamine.

4. Central storage of controlled substances is not maintained in accordance with internal controls.

We recommend Management ensure proper security over central storage of controlled substances.

We additionally recommend that management implement dual-control procedures over all Central Storage activities, including receipt, storage access, transfers out, etc.

It was recommended that a dual control procedure be established for receiving and transferring out controlled substances. This will be best accomplished by requiring dual signatures within the electronic tracking program. We will be instituting this procedure with all new orders. This will require the signature of the Deputy Chief and a member of administrative staff.



5. **Two of the controlled substances administered by Fire EMS are tested for in the drug testing process.**

We recommend Management ensure the drug testing process includes all of the controlled substances administered by Fire EMS.

We additionally recommend that management continue to assess applicable risks and evaluate the appropriateness of acceptance, at least annually.

We will continue to assess applicable risks and evaluate the appropriateness of acceptance annually.

6. **Transaction Receipts are not consistent to account for what controlled substances are received.**

We recommend Management ensure cardholder activity agrees with the itemized procurement card receipt and itemized vendor sales receipt.

We additionally recommend that the Medical Director's Policies and Procedures be followed and procurements for controlled substances be made only by the Deputy Chief of Training or his designee only.

We additionally recommend that best practices be followed and DEA Forms 222 be used in sequential order.

All transactions moving forward will be purchased on the Deputy Chief of EMS's procurement card and 222's be used in sequential order. We are also moving forward with electronically using a system to capture electronic 222's.



7. Fire/EMS does not follow *Audit Procedures* outlined in Medical Director Policies and Procedures.

We recommended management adhere to these audit procedures and use them to help avoid and correct the situations that gave origin to the first three findings.

We additionally recommend that management adhere to defined audit procedures and document completion accordingly.

The log books have set columns and parameters, it did not have a field to perform an audit and sign. This left the only area to the left of the column for an initial of the individual. This leads to confusion and we agree. The movement to the electronic tracking system will remove this confusion and fix this issue. Furthermore, the electronic system will audit each transaction live against expected levels and asset numbers. Audits will be done in the notes section by way of initials of BC performing the audit, in the format of "audit-date-initials".

Sincerely,

A handwritten signature in black ink, appearing to read "Michael Davis", with a large, stylized flourish at the end.

Michael Davis

Deputy Chief

