



To preserve the public trust as guardians of the people's records and assets

**DATE** 

December 19, 2025

NO.

2025-006

**CHARLOTTE COUNTY FIRE/EMS** 

**CONTROLLED SUBSTANCES** 

INTERNAL AUDIT DIVISION

ROGER D. EATON

CLERK OF THE CIRCUIT COURT AND COUNTY COMPTROLLER

CHARLOTTE COUNTY FLORIDA

To: The Honorable Roger D. Eaton, Charlotte County Clerk of the Circuit Court and County

Comptroller

From: Dan Revallo, Internal Audit Director

Date: December 19, 2025

Subject: Charlotte County Fire EMS Controlled Substances

Honorable Clerk Eaton,

The Internal Audit Division has completed a review of the Charlotte County Fire and Emergency Medical Services procedures for dispensing of controlled substances. Misti Payette, Internal Auditor II conducted this review.

We would like to thank client management and staff for their cooperation and assistance in the completion of this audit.

The report will be posted to the Clerk of Courts website, charlotteclerk.com, under Internal Audit, Audit Reports. A link to this report has been sent to the appropriate parties.

Should you have any questions, please do not hesitate to contact me.

Sincerely,

Dan Revallo, CIA, CFE Internal Audit Director

Daniel ( bwells-

Charlotte County Clerk of the Circuit Court and County Comptroller

# TABLE OF CONTENTS

EXECUTIVE SUMMARY	1
BACKGROUND	2
AUDIT OBJECTIVES	
AUDIT SCOPE AND METHODOLOGY	
COMMENTS AND RECOMMENDATIONS	
CONCLUSION	
ACKNOWI FDGFMFNT	q

### **EXECUTIVE SUMMARY**

The Internal Audit Division completed an audit of Charlotte County Fire & Emergency Medical Services (EMS) Division's Controlled Substances Inventory Management.

The Fire & EMS Division implemented Operative IQ in December 2022, which replaces the manual accountability logs previously used to track the inventory, usage and responsibility of controlled substances. The Operative IQ, *Narcotics Tracking Module*, manages controlled substances usage from receipt to administration or waste in an electronic format.

A few specific control weaknesses were noted; generally however, controls evaluated are adequate, appropriate, and effective to provide reasonable assurance that risks are being managed and objectives should be met.

Based upon the results of our review, we offer a summary of recommendations. These recommendations are discussed in detail later in this report:

- We recommend management ensure par levels are maintained in compliance with the Charlotte County Fire & EMS Standard Operating Procedures, Controlled Substances Policy and update the policy to include more specific time parameters for replenishing controlled substances.
- We recommend management perform physical inventories at least every two (2) years in compliance with Federal Regulations and update the *Charlotte County Fire & EMS Standard Operating Procedures, Controlled Substances Policy* to include biennial inventory procedure requirements.
- 3. **We recommend** management update the *Charlotte County Fire & EMS Standard Operating Procedures, Controlled Substances Policy* to document the referenced reverse distribution procedure.
- 4. **We recommend** management update the *Charlotte County Fire & EMS Standard Operating Procedures, Controlled Substances Policy (Section 1.32 Rev. 06-2023)* to reflect verification of controlled substances at shift change when custody is transferred.
- 5. **We recommend** management implement controls to ensure dual-control procedures to access Central Storage are enforced and can't be circumvented.
- 6. **We recommend** management develop formalized procedures to ensure incident reports are i) completed by the responsible person, ii) include all relevant facts, and iii) are appropriately signed, witnessed and communicated to a battalion chief or deputy chief.
- 7. **We recommend** management increase controls over the procurement of controlled substances to ensure complete and accurate records, compliance with record keeping requirements, and update the *Charlotte County Fire & EMS Standard Operating Procedures, Controlled Substances Policy* procurement guidelines and time parameters for handling and receiving controlled substances into Operative IQ.

- 8. We recommend management implement controls to ensure the dosages administered are accurately recorded within Operative IQ and the ePCR (electronic prehospital care report) within ImageTrend. The amounts administered should agree between the two data sources, and any discrepancies should be well-documented and tracked for training and/or disciplinary purposes.
- 9. **We recommend** management ensure the drug screening process includes all of the controlled substances administered by Fire & EMS.

### **BACKGROUND**

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

Only Advanced Life Support vehicles are equipped with controlled substances. All 17 rescue units are designated as ALS and 12 engines and one (1) mini-pumper 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.

The Fire & EMS Division uses four (4) controlled substances, ranked per Florida Statute 893, *Drug Abuse Prevention and Control*. These are: 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 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 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 statutes, chapters and code sections give specific direction related to the required audit trail for controlled substance transactions.

Prior to the implementation of Operative IQ in December 2022, manual controlled substance accountability log books were used to track the inventory, usage and responsibility of controlled substances. Daily inventories were recorded in these manual log books along with usage, waste, and transfer of controlled substances.

Operative IQ is a web-based program used to manage controlled substances without the use of manual, log books. The program provides a complete view of a narcotic's journey from cradle-to-grave by tracking the movement from receipt to administration or waste.

### **AUDIT OBJECTIVES**

The objectives of this audit were:

- 1. To determine the adequacy and effectiveness of the system of internal controls over the procurement, storage, security, inventory and distribution of controlled substances.
- 2. To determine the degree of compliance of controlled substance activities as required by the Florida Administrative Code, Florida Statutes, Federal Regulations, the Medical Director's protocols, and the Department's policies and procedures.
- 3. To evaluate the effectiveness of management controls currently in effect over controlled substance activities.
- 4. To evaluate the drug testing policy and practice in effect for Fire & EMS Division employees.

### **AUDIT SCOPE AND METHODOLOGY**

The audit scope included an evaluation of the policies and procedures and the system of internal controls related to the administration of Fire & EMS controlled substances. Our scope included controlled substances only; other medications and supplies were not included. The audit period included Fire & EMS controlled substances activities during calendar year 2024 through March 2025.

Audit procedures included an evaluation of the Fire & EMS methods for the procurement, storage, security, inventory and distribution, and disposal activities, etc. It also considered compliance with the Fire & EMS Division's documented policies and procedures, as well as the applicable laws and regulations. Specific procedures performed included, but was not limited to, staff inquiries and observations, documentation reviews, field visits to the Fire & EMS Headquarters and Central Storage, and field visits to eight (8) of the 19 Charlotte County fire stations.

Internal Audit also requested and obtained independent, third-party confirmation from Bound Tree Medical, LLC to verify the controlled substances purchases made during the audit period. Total purchases confirmed totaled \$15,035 and consisted of 1,860 vials.

Total Purchased (in vials) by Calendar Year and Controlled Substance Type:

Controlled Substance	<u>2025</u> *	<u>2024</u>	Total by Type
Fentanyl	275	675	950
Ketamine	40	180	220
Midazolam (Versed)	120	170	290
Morphine	<u>225</u>	<u>175</u>	<u>400</u>
Total by Year	660	1,200	1,860

<sup>\*(</sup>Through March 18, 2025)

Number of Times Administered by Calendar Year and Controlled Substance Type:

Controlled Substance	<u>2025</u> *	<u>2024</u>	<u>2023</u>
Fentanyl	122	1,474	1,121
Ketamine	15	102	117
Midazolam (Versed)	52	277	237
Morphine	<u>115</u>	<u>377</u>	<u>367</u>
Total by Year	304	2,230	1,842

<sup>\*(</sup>Through March 18, 2025)

### **COMMENTS AND RECOMMENDATIONS**

### 1. Below minimum par levels of controlled substances identified.

Internal Audit performed unannounced, field storage and apparatus inspections at eight (8) of the 19 Charlotte County fire stations, a sample of approx. 42%. We observed blind counts performed on all three (3) battalion Medvaults, seven (7) of the 13 ALS Engines (a sample of approx. 54%) and eight (8) (including Medic 1) of the 17 ALS Rescues (a sample of approx. 47%).

During this audit procedure, Internal Audit identified two (2) instances where the field storage battalion level did not meet the minimum par level established by policy. Specifically, during the field inspections performed, Battalion No. 2 maintained only nine (9) vials of Versed (Midazolam) on hand, and Battalion No. 3 maintained only one (1) vial of Fentanyl on hand.

The minimum par levels established by the *Charlotte County Fire & EMS Standard Operating Procedures, Controlled Substances Policy (Section 1.32 Rev. 06-2023)* for the field storage battalion level are 10 vials for each controlled substance type maintained by Fire & EMS. The policy adds, "replacement ASAP" for directive.

Maintaining less than the minimum par levels could negatively impact the Advanced Life Support (ALS) measures that are readily available for an emergent event.

**We recommend** management ensure par levels are maintained in compliance with the *Charlotte County Fire & EMS Standard Operating Procedures, Controlled Substances Policy* and update the policy to include more specific time parameters for replenishing controlled substances.

### 2. Biennial inventories not performed.

Since implementation of the Operative IQ program in December 2022, no physical inventories of controlled substances stock have been performed by Fire & EMS. A biennial inventory is required per the Code of Federal Regulations; specifically, Title 21 CFR 1304.11(c) states, "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."

**We recommend** management perform physical inventories at least every two (2) years in compliance with Federal Regulations and update the *Charlotte County Fire & EMS Standard Operating Procedures, Controlled Substances Policy* to include biennial inventory procedure requirements.

# 3. Reverse Distribution Procedures are not formally documented.

The Charlotte County Fire & EMS Standard Operating Procedures, Controlled Substances Policy (Section 1.32 Rev. 06-2023) references a "reverse distribution section" on page 5 of the document; however, a reverse distribution section is not included in the document, and separate procedures could not be located by Fire & EMS personnel.

When an essential procedure, such as reverse distribution, is not formally documented, and personnel changes ensue, there can be significant challenges and risks involved (i.e. inconsistent practices, errors, and regulatory non-compliance, etc.).

**We recommend** management update the *Charlotte County Fire & EMS Standard Operating Procedures, Controlled Substances Policy* to document the referenced reverse distribution procedure.

### 4. Policy inconsistent with actual shift change verification procedures.

The Charlotte County Fire & EMS Standard Operating Procedures, Controlled Substances Policy (Section 1.32 Rev. 06-2023) defines "Audit" as a user-initiated action, that allows for verification and inspection of controlled substances/control numbers." The definition adds, "This process shall be performed as needed for an extended shift (double) or when considered appropriate by a supervisor." The current, approved practice requires verification at every shift change when controlled substances custody is transferred. The documented procedures do not appear to be consistent with the current, approved practices.

Verification of controlled substances stock at shift change is considered best practice to ensure a responsible party can be properly identified and held accountable should a variance occur.

**We recommend** management update the *Charlotte County Fire & EMS Standard Operating Procedures, Controlled Substances Policy (Section 1.32 Rev. 06-2023)* to reflect verification of controlled substances at shift change when custody is transferred.

### 5. Dual-control access to Central Storage can be circumvented.

Central Storage access is not properly restricted to enforce dual-control access procedures. Both Deputy Chiefs maintain a key and the required pin code to access the Central Storage safe, which means the dual-control access procedures can be circumvented.

Personnel authorized to access Central Storage should not maintain a key and the required pin code, simultaneously. This creates a control weakness in that dual-control access procedures can be circumvented, which increases the risks of drug diversion, as well as an inability to determine an accountable party should a stock variance occur.

**We recommend** management implement controls to ensure dual-control procedures to access Central Storage are enforced and can't be circumvented.

# 6. Some control deficiencies were identified with incident reports.

Internal Audit reviewed the incident reports prepared during calendar year 2024 through March 2025. For this time period, we identified six (6) incident reports prepared that impacted a total of 54 vials of controlled substances. Internal Audit identified some control deficiencies with the incident reports reviewed; specifically:

- a) Five (5) of the six (6) incident reports reviewed included the same primary verification name (pin/password verified) OR witness name (pin/password verified) as the battalion chief or deputy chief reported as notified of the incident after it occurred.
- b) Five (5) of the six (6) incident reports reviewed included summaries that were generally vague and lacked pertinent details (i.e. names of key personnel involved and the complete facts and circumstances of the incident that occurred, etc.).
- c) Two (2) of the six (6) incident reports reviewed included custody transfers to a battalion chief prior to the incident report being completed by the responsible party.

Improper or insufficient incident reporting could impede management from identifying improper actions performed by Fire & EMS and/or failed diversion attempts.

We recommend management develop formalized procedures to ensure incident reports are i) completed by the responsible person, ii) include all relevant facts, and iii) are appropriately signed, witnessed and communicated to a battalion chief or deputy chief.

# 7. Some control deficiencies were identified with procurement and receipt procedures.

Internal Audit evaluated the methods for ordering controlled substances (i.e. authority, required documents, vendor and procurement methods, etc.). Internal Audit also reviewed the controlled substances purchases that occurred during calendar year 2024 through March 2025, and received confirmation from the third-party vendor.

Internal Audit identified some control deficiencies with the procurement and receipt of controlled substances; specifically,

- a) Internal Audit identified six (6) instances of untimely input (receiving) into Operative IQ, approx. 26.1% of all procurements reviewed and including 410 vials. Five (5) of the six (6) instances identified were input (received) into Operative IQ six (6) or more days after the date the controlled substances were received from the carrier.
- b) Internal Audit identified a single lot of 25 vials of Fentanyl purchased and received into Operative IQ with the wrong expiration date. It was determined that a "narcotics edit" subsequently corrected 16 of the 25 vials. The remaining nine (9) vials did not get corrected. The expiration dates in Operative IQ reflected 11/1/2024 and should have reflected 3/1/2025.
- c) The DEA (Drug Enforcement Administration) Forms 222 completed for the purchase of Schedule 1 and Schedule 2 controlled substances are not maintained separately from all other records. These are maintained in binder, along with all other controlled substances purchased.
- d) Internal Audit identified one (1) purchase transaction that was paid for by check, not procurement card (deputy chief or his/her designee).
- e) Internal Audit identified a 38.5% void rate on the DEA Forms 222 completed over the scope period. These were largely due to address errors.

The Code of Federal Regulations (CFR); specifically, Title 21 CFR 1304.21(a) states, "Practitioners must maintain complete and accurate records on a current basis for each controlled substance purchased, received, sold, stored, distributed, dispensed, or otherwise disposed of."

In addition, 21 CFR 1304.04(h)(1) states, "Records and inventories of schedule II controlled substances must be maintained separately from all other records of the registrant." 21 CFR 1304.04(h)(3) adds that, "All records and inventories of schedules III, IV, and V controlled substances must be maintained either separately from all other records, or in such a form that the information required is readily retrievable from the ordinary business records."

Delays in receiving controlled substances into Operative IQ can lead to discrepancies between physical inventory and system records, and also provide an opportunity for theft and diversion. To

mitigate these risks, it is crucial to implement proper procedures and controls for handling and receiving controlled substances.

We recommend management increase controls over the procurement of controlled substances to ensure complete and accurate records, compliance with record keeping requirements, and update the *Charlotte County Fire & EMS Standard Operating Procedures, Controlled Substances Policy* procurement guidelines and time parameters for handling and receiving controlled substances into Operative IQ.

8. Dosage discrepancy between Operative IQ and ePCR (electronic prehospital care report). Internal Audit identified one (1) record of administration, out of a sample of 30, where the dosage recorded in Operative IQ did not agree with the dosage recorded in the ePCR in ImageTrend.

The Code of Federal Regulations; specifically, Title 21 CFR 1304.21(a) states, "Practitioners must maintain complete and accurate records on a current basis for each controlled substance purchased, received, sold, stored, distributed, dispensed, or otherwise disposed of."

When discrepancies exist between data sources, it can raise concerns about the overall reliability and accuracy of the data presented. In addition, inaccurate input of controlled substances administered to a patient on the ePCR could put the patient's overall well-being at risk.

We recommend management implement controls to ensure the dosages administered are accurately recorded within Operative IQ and the ePCR within ImageTrend. The amounts administered should agree between the two data sources, and any discrepancies should be well-documented and tracked for training and/or disciplinary purposes.

# 9. One (1) of four (4) controlled substances administered by Fire & EMS is not included in the routine, drug screenings performed.

Through inquiry procedures performed, Internal Audit determined that one (1) of the four (4) controlled substances administered by Fire & EMS is not included in the routine, drug screenings performed. The controlled substance in question is a Schedule III narcotic.

Testing for all controlled substances administered by Fire & EMS would help ensure complete confidence in the test results performed.

**We recommend** management ensure the drug screening process includes all of the controlled substances administered by Fire & EMS.

### CONCLUSION

A few specific control weaknesses were noted; generally however, controls evaluated are adequate, appropriate, and effective to provide reasonable assurance that risks are being managed and objectives should be met.

# **ACKNOWLEDGEMENT**

We would like to thank Charlotte County Public Safety Department; specifically, the Fire & EMS Division, as well as the Charlotte County Human Resources and Risk Management Divisions, for their assistance in the completion of this audit.

Audit completed by:
Misti Payette, CIA, CRMA, CGAP
Internal Auditor II
Charlotte County Clerk of Court and Comptroller



December 11, 2025

Clerk of the Circuit Court & County Comptroller Charlotte County 18500 Murdock Circle Port Charlotte, FL 33948 Attn: Daniel Revallo Internal Audit Director

Subject: Response to Internal Audit Findings – Controlled Substances

Dear Mr. Revallo,

Thank you for the opportunity to review and respond to the findings outlined in your July 31, 2025 report concerning Charlotte County Fire & EMS' controlled substances program. We appreciate the thorough work of the Clerk's Office and Internal Audit team and recognize the value of ongoing evaluation and oversight. Following a comprehensive internal review and the opportunity to discuss these items with your team, we would like to offer clarifications on several points.

# Finding No. 1 – Minimum Par Levels

We acknowledge that the inventories at Battalions 2 and 3 were below par at the time of inspection; however, this was a temporary and actively monitored condition, not indicative of systemic noncompliance. Medications were available for restocking, and no patient care or operational readiness was impacted. The SOP's "ASAP" replenishment guidance previously provided operational flexibility to accommodate real-world demands. However, recognizing the value of clearly defined expectations, we have revised the policy to include a reasonable and defined timeframe for replenishment once inventory reaches the minimum threshold. This update clarifies responsibilities while preserving field responsiveness and mission readiness.

# Finding No. 2 – Biennial Inventories

While a standalone biennial physical inventory per 21 CFR 1304.11(c) has not been conducted since the implementation of Operative IQ, our Central Safe controlled substances are continuously tracked through RFID technology. In addition to this technology, we will maintain appropriate documentation to ensure compliance with 21 CFR 1304.11(c). That said, in response to the audit and as part of our ongoing commitment to improvement, we have implemented a manual monthly inventory of the Central Storage safe as of June 2025. This manual count supplements the electronic system and ensures an additional layer of oversight.

We have updated our internal controls to require a documented monthly audit of all Central Safe medication inventory.

# Finding No. 3 – Reverse Distribution Procedures

Although a specifically labeled "Reverse Distribution" section is not present in the SOP, the process is conducted regularly and has been consistently documented. We believe this demonstrates that the practice is adequately operationalized. Nevertheless, we have updated our controlled substances policy to reflect and formalize the reverse distribution process.

# Finding No. 4 – Shift Change Verifications

Verification at every shift change has long been standard practice within our organization. While we agree the SOP language warranted improvement to clearly reflect this expectation, we maintain that the process itself has not been absent or inconsistently applied. In response to the audit, we have updated our controlled substances policy to explicitly incorporate this shift-change verification requirement.

# Finding No. 5 – Central Storage Access

With the June 2025 implementation of the Knox MedVault system, which utilizes individualized access codes and maintains detailed audit logs, the risk associated with central storage access has been substantially mitigated. The presence of a mechanical override key is strictly for use in the event of keypad failure and is securely stored in a separate location under restricted access. Due to this system upgrade and the availability of electronic access logs, we do not believe the issues identified in this finding remain applicable. Dual-control is functionally preserved through system design, and we are confident that the current safeguards exceed the intent of the controlled substances policy and federal requirements.

### Finding No. 6 – Incident Reporting

We acknowledge the observations related to incident reporting and remain confident in our current supervisory processes in this area. The level of detail in certain reports—particularly those involving personnel matters—often reflects a deliberate and appropriate use of supervisory discretion based on the nature of the incident.

# Finding No. 7 – Procurement Practices

We appreciate the audit's attention to procurement procedures and agree that consistent controls are essential. Several of the issues identified—such as delayed entry into Operative IQ or use of a check for payment—occurred during a transitional period and reflect isolated exceptions rather than ongoing deficiencies.

In recent months, leadership responsibilities for procurement oversight have been realigned, and we have taken steps to strengthen internal controls and procedural consistency. Most notably, Charlotte County Fire & EMS has implemented the DEA's electronic Form 222 (e222) system, which enhances accuracy and streamlines controlled substance ordering. An updated system for ordering and documenting Schedule II controlled substances has been implemented, providing centralized tracking, clearer documentation, and stronger internal

controls. This enhanced process improves traceability from order through receipt and stocking and better aligns our practices with applicable federal requirements.

# Finding No. 8 – Dosage Discrepancy

We acknowledge the concern raised in this finding and agree that clear, consistent documentation is essential to safe medication practice. In this case, however, the issue reflects a documentation discrepancy rather than the absence of a general policy. The dosage administered was consistent with established protocol, and the variance occurred only in how the dosage was recorded between systems. Importantly, there was no patient harm and no indication of diversion.

To address the root cause of the discrepancy between system entries, we have revised our documentation workflow so that providers are required to record both the total administered dosage and the corresponding mg/kg calculation when applicable. This change directly resolves the inconsistency between Operative IQ and the ePCR platform and ensures clearer, more reliable documentation going forward.

# Finding No. 9 – Drug Screening Scope

We concur with the recommendation and are coordinating with Risk Management and Human Resources to ensure that our drug screening panel include ketamine and any other controlled substances maintained and administered by personnel.

In closing, Charlotte County Fire & EMS remains firmly committed to compliance, transparency, and continuous improvement. We thank your team for its professionalism throughout this process and for the opportunity to meet and provide additional context, which we believe will support a well-informed final report that advances both regulatory alignment and operational effectiveness.

Respectfully,

Bryan Carr

**Deputy Chief** 

Charlotte County Public Safety

Cc: Hector Flores, County Administrator Emily Lewis, Deputy County Administrator Matthew McElroy, Public Safety Director



Serving with compassion, expertise and efficiency in support of our community