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Audit Report for

**Emergency Medical Services (EMS) Drug Management**

*Fire and Emergency Services*  
Audit Plan Year 2021

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## **Background and Scope**

Gwinnett County's Department of Fire and Emergency Services (the Department) provides fire protection and emergency medical services (EMS) for the County. The Department typically responds to over 84,000 emergency calls each year. The Operations Division (the Division) within the Department is primarily responsible for managing EMS responses. The Division operates 33 ambulances from fire stations strategically located throughout the County. The ambulances are staffed by Emergency Medical Technicians (EMTs) and paramedics who provide care to patients while enroute to local hospitals. Patients may receive various controlled substances<sup>1</sup> and pharmaceuticals (drugs) from EMTs and/or paramedics to treat injuries, medical conditions, and relieve pain depending on drug administration protocols established by the Department's Medical Director. To fulfill this service, Resource Management (RM) must purchase and safely store drugs at several locations to handle emergency call volume while minimizing spoilage associated with manufacturer expiration dates. At the same time, RM must minimize the impact of potential wholesale drug shortages. To fulfill these requirements, the Department maintains a contract with Northside Hospital Gwinnett (the Hospital) to supply drugs for all EMS operations. RM manages drug purchases and fire station replenishments through a central warehouse (the Warehouse) located in Lawrenceville which contains a pharmacy room (the Pharmacy) where controlled substances and emergency pharmaceutical inventory is stored. Pharmacy personnel use highly standardized processes for managing fire station replenishments. This includes inventory management procedures for tracking and safely storing federally regulated controlled substances on emergency vehicles. The Department's key inventory management objectives are as follows:

- Maintain optimal drug quantities to meet EMS volume requirements and reduce spoilage.
- Safely store and dispose of drugs to minimize harm to the public and the environment.
- Mitigate the potential for drug diversions.

The purpose of this audit was to evaluate the adequacy and effectiveness of management's control activities that are designed to provide reasonable assurance of achieving these objectives. Management asked Internal Audit (IA) to specifically review procedures that are designed to prevent or detect any diversions of controlled substances for illicit use. IA interviewed employees, reviewed documentation, and reperformed certain control activities on a sample basis for the audit period January 1, 2020, through April 30, 2021. We believe the evidence provided a reasonable basis for our assessment. See **Exhibit A** for a summary of our review procedures. We excluded the Continuity of Operations Plan from the scope because it will be covered in a separate audit.

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<sup>1</sup> Controlled substances, as defined by the Drug Enforcement Administration (DEA), are drugs and other substances that are divided into five schedules based on whether they have a currently accepted medical use in treatment in the United States, their relative abuse potential, and likelihood of causing dependence when abused.

## **Assessment**

Management's control activities were generally adequate and effective in providing reasonable assurance of achieving their control objectives. We found no evidence of abuse or drug diversions. We made four recommendations to improve control activities. The recommendations are considered improvement opportunities rather than significant weaknesses that could prevent management from achieving one or more objectives.

## **Recommendations**

### **1. Receiving steps may allow for drug diversions without timely detection.**

The Pharmacy purchases controlled substances and emergency pharmaceuticals from the Hospital for patient care. The process is governed by a pharmacy agreement and certain federal DEA guidelines applicable to the distribution and use of controlled substances. To initiate the procurement process, the Pharmacy Officer enters the desired controlled substance descriptions and quantities into a Microsoft Excel spreadsheet and emails it to the Hospital, usually each week. Hospital personnel fill the order through their pharmaceutical distribution company, McKesson Corporation. At pick up, the Pharmacy Officer and a Hospital clerk match information contained on vials to the McKesson invoice to verify controlled substance types, quantities, and vial sizes. They both sign and date the invoice as evidence of completing these control activities. The Pharmacy Officer transports the controlled substances to the Pharmacy and stocks them in inventory. Other RM personnel use the invoices to enter the controlled substances into SAP which routes invoices to a business associate or section manager for verification. The Department's Medical Director must also complete and sign DEA Form 222, U.S. Official Order Form, for any Schedule I or II controlled substance purchases. Copies are sent to the Hospital and the DEA.

We selected a judgmental sample of 25 purchases that were completed during the audit period and sought evidence they were verified by the Pharmacy Officer and Hospital clerk, accurately entered in SAP, and, when applicable, reported on DEA Form 222. There were no exceptions pertaining to DEA reporting. However, three of the 25 orders did not contain signatures to evidence verification of orders at the Hospital. We believe that, although unlikely, the Pharmacy Officer could potentially short orders in transit without detection if there is not anyone else verifying the physical quantities placed in stock against the McKesson invoice. Two people should check controlled substances into the Pharmacy against the McKesson invoice used to update SAP.

#### Recommendations:

The Pharmacy Officer and Hospital clerk should sign all McKesson invoices as evidence they verified order quantities at the Hospital. The Pharmacy Officer and another employee with authority should check controlled substances into the Pharmacy and sign/date the applicable McKesson invoices.

They should also confirm the Pharmacy Officer and Hospital clerk signed the invoice before completing stocking procedures. Any signature discrepancies should be resolved with Hospital personnel that day.

**Management Response:**

*RM has approved policies for the purchase, delivery, and verification of the controlled substances and pharmaceuticals that are ordered from Northside Gwinnett Hospital Pharmacy. During the audit, the policies at the Hospital changed to include a dual signature process within the Northside Gwinnett Pharmacy prior to the purchase leaving the Hospital. RM includes verifying hospital and Department pharmacy signatures during the SAP check in process at the Department pharmacy to include the receipt of a copy of the signature page from the Northside Gwinnett Pharmacy at the point of acceptance. This will create a chain of custody that is easily verifiable based on signatures. In addition, the delivery of the controlled substances and pharmaceuticals at RM will be confirmed through a randomized selection of authorized personnel to aid in the check in process at RM. This will eliminate any potential for collusion in this process.*

*The Department includes the verification of the signatures during the check in process, and a second person assists in checking the controlled substances into SAP. This process will be improved upon by the randomization of the personnel involved in the check in process described above.*

**2. Some differences exist between CSAR and ESO records.**

EMTs and paramedics assigned to ambulances are required to record each controlled substance vial received from the Pharmacy on a manual form called a Controlled Substance Administration Record (CSAR). They also use these forms to record all patient dosages and waste amounts from each vial as usage occurs. CSARs serve as the primary tool for replenishing the Warehouse Pharmacy, tracking controlled substances distributed from the Warehouse Pharmacy to ambulances, and tracking usage in the field. Paramedics must account for every milliliter (ml) and milligram (mg) of controlled substances issued to them on these forms. In addition to CSARs, EMTs and paramedics enter patient dosages into the Department's electronic health record system, referred to as ESO, via onboard computer terminals in ambulances. These entries are made for billing and protocol compliance purposes. The Pharmacy Officer will obtain CSARs from each ambulance when fulfilling controlled substance drug replenishments for the field. Pharmacy personnel will then review CSAR activity for mathematical accuracy and consistency with ESO usage for oversight purposes. They will initial each line after completing their checks. Any discrepancies between the medication records must be resolved by paramedics. To evaluate the effectiveness of these control activities, IA selected a judgmental sample of 25 CSAR transactions and reperformed reconciliations. The following is a summary of our observations:

- The amounts dispensed to patients and the residual amount wasted in the field exceeded vial volume capacity on a CSAR.

- CSARs contained four patient dosage amounts that did not agree with ESO.
- Pharmacy personnel failed to initial two CSARs after completing their oversight reviews. The volume differences are most likely due to transcription errors, but they should be investigated and accounted for to eliminate the possibility of controlled substance diversions. Steps should also be taken to improve detection of record discrepancies.

Recommendation:

The Pharmacy Officer performs reconciliations once ambulance replenishments occur and they receive CSARs from paramedics or EMTs. Ambulances may keep controlled substances without replenishments for long periods due to low consumption and lengthy expiration dates. This means anomalies could occur and go undetected for an extended period. To enhance timely detection of anomalies, fire station officers with sufficient authority or the newly created Quality Assurance (QA)/Quality Inspection (QI) team should also complete CSAR-ESO reconciliations within prescribed timeframes prior to Pharmacy replenishments. This step will provide an additional layer of oversight which may improve reconciliation outcomes.

Paramedics and EMTs administer drugs to patients based on written protocols that are approved by the Department's Medical Director. Some Medical Supervisors (MS Officers) review ESO patient activity to confirm dosages complied with protocols. This is a good practice for ensuring the quality of patient care. The procedure could also be used to detect possible controlled substance diversions. We suggest this procedure be incorporated into the Division's standard operating procedures.

**Management Response:**

*Fire Operational Operating Guidelines and General Operating Guidelines for the Department have been revised to incorporate these recommendations. These revisions have been approved by the Fire Chief and have been distributed and implemented.*

*A new CSAR form has been developed to incorporate company officer level audit after the controlled substance has been dispensed to a patient. This provides timelier oversight of both administration and documentation of the waste and usage of the controlled substance in ESO. This will aid in reducing the timeframe between reconciliations and potentially eliminating the potential for an anomaly to go undetected for extended periods. The reconciliations will still occur at the Pharmacy level to maintain a system of checks and balances.*

*Continuous Improvement and the MS Officers complete a review of ESO documentation as a part of their daily duties to confirm proper compliance with Standing Medical Orders and ensuring the correct Standing Medical Orders were followed or a physician signature from online medical control is obtained to support deviations from Standing Medical Orders as approved by the receiving physician. Part of this process is the evaluation of controlled substance usage on incident reports and determining if usage was appropriate.*

### **3. Shift change reconciliations of controlled substances may be incomplete.**

At the beginning of each daily shift change, incoming paramedics perform physical counts of all controlled substances contained within their assigned response vehicle which could be an ambulance or a medical first response unit. Paramedics record the results on Form FD-14 and verify expiration dates. Paramedics then compare count results to the CSAR perpetual records and identify any discrepancies which must be fully accounted for. They are required to check a box on Form FD-14 signifying these procedures were successfully completed before work starts.

IA counted controlled substances contained in a judgmental sample of 11 vehicles at five stations and compared our results to FD-14 forms without exception. However, we understand two consecutive counts failed to detect a discrepancy for Versed in November 2020, which suggests paramedics may be checking the box without effectively counting and comparing results to CSAR records. Also, paramedics occasionally transfer controlled substances from their ambulances to other station vehicles to manage the possibility of simultaneous emergencies with injuries. Paramedics may not always count all controlled substances at the beginning of a shift change if vehicles are somewhere other than the station, or they may rely on others. This may warrant additional oversight to ensure the counts are done.

#### Recommendation:

Shift change counts are an important control activity to detect potential controlled substance diversions, particularly when controlled substances are kept in multiple station vehicles. The following recommendations are designed to improve compliance and completeness:

- a. Form FD-14 should identify vehicles with controlled substances to ensure completeness of counts. A station officer should periodically review counts to ensure they include all vehicles.
- b. The outgoing paramedic, driver, or a fire station officer should verify shift change reconciliations for accuracy and completeness. Both individuals should sign, date, and check the appropriate box on FD-14 as evidence of completion. This will ensure more timely oversight.
- c. Pharmacy or QA/QI personnel should re-perform FD-14 counts on a sample basis at least twice a year. This will help ensure counts are performed at all locations (vehicles).
- d. Pharmacy personnel should include Form FD-14 in the CSAR-ESO reconciliation process. All discrepancies should be fully investigated by the appropriate level of management.

#### **Management Response:**

*The FD-14 check is performed on a daily basis for each vehicle that is issued controlled substances. Oncoming crews typically check the counts prior to the end of shift in order to address any discrepancies in the controlled substance counts.*

*A paramedic is expected to sign, date, and check the CSAR and confirm through daily counts the contents of the controlled substance box which houses all the controlled substances.*

*Personnel assigned to each apparatus are responsible to count and document on the FD-14 the supply of controlled substances on their unit. Counts are regularly verified by the company officer's verification of reconciliation after a controlled substance is used.*

**IA Comments:** We believe the recommendations would increase the likelihood of detecting discrepancies. We encourage management to implement them but defer to their cost-benefit analysis.

**4. Controlled substance disposals may not comply with best practices.**  
(Previously Identified by Management)

Pharmacy and EMS personnel routinely dispose of controlled substances in the field or at the Pharmacy due to patient safety concerns. Paramedics cannot use a single vial to medicate more than one patient. They also cannot administer controlled substances or drugs that exceed manufacturer safety expiration dates unless authorized by the State of Georgia Office of EMS. These drugs must be destroyed to prevent legitimate or illicit use. The DEA's Diversion Control Division recommends two people participate in all aspects of destruction, including transport to destruction sites. Their guidelines also state destruction methods must make controlled substances non-retrievable to prevent illicit diversions and protect public health and safety. IA walked through Pharmacy and field disposal procedures on a sample basis to understand their respective control activities that are designed to accomplish these objectives. IA also reviewed documentation on a sample basis to confirm the effectiveness of the procedures.

Two Pharmacy personnel dispose of controlled substances in front of a video recording system located in the Warehouse. They place the controlled substances, including needles, in garbage cans for pickup by the local commercial waste service provider. One of them enters the activity in SAP and both witnesses sign and date a scrap report printed from SAP. Pharmacy personnel disposed of 609 controlled substance vials on 16 separate days during the audit period. To evaluate the effectiveness of control activities, IA selected a judgmental sample of 392 vials disposed of on five separate days and traced the activity to signed SAP scrap reports. We also verified the transactions in SAP. There were a few instances of noncompliance or opportunities to improve control activities. We obtained signed scrap reports for four of the five days. The missing report was for 75 (19%) vials disposed of on June 15, 2020. This exception may have gone undetected because Pharmacy personnel enter destruction activity in SAP without management confirmation. We also noticed Pharmacy personnel did not render controlled substances unusable or place them, including needles, in hazardous waste containers for garbage pickup.

Paramedics are required to destroy controlled substances in the field with a witness and record the disposals including witness signatures on CSAR forms. The Pharmacy Officer obtains CSAR forms from fire stations during replenishment runs and records disposals in SAP after returning to the Pharmacy.

To evaluate the effectiveness of these control activities, IA selected a judgmental sample of CSAR forms and verified dual signatures for 19 vials destroyed in the field during the audit period. We also verified SAP was updated in a timely manner. The disposal transactions had appropriate signatures. Although the transactions were entered in SAP, they were classified as standard operational refills rather than disposals and we could not distinguish field usage from disposal using SAP. Witnesses were sometimes Hospital personnel which was acceptable per policy, but we could not verify that these individuals worked for the Hospital or were qualified to witness disposal. We understand paramedics dispose of controlled substances in garbage cans too which may not be best practice.

Recommendation:

Although Pharmacy personnel and EMS paramedics rely on two people to dispose of controlled substances, there are opportunities to further improve detection and prevention of diversions. Also, the methods used to destroy controlled substances may not render them sufficiently non-retrievable. We recommend the following additional steps to enhance the effectiveness of diversion control activities:

- a. Someone other than Pharmacy personnel should record controlled substance disposals in SAP. At a minimum, a business associate and/or section manager should authorize Pharmacy write-offs of controlled substances in SAP based on signed disposal statements.
- b. CSAR disposal should be recorded in SAP as disposals or write-offs rather than replenishments. Management should use the data to try to reduce the risks of higher spoilage costs and to assess the effectiveness of par values.
- c. Paramedics should rely on County EMS personnel to witness controlled substance disposals instead of Hospital personnel.
- d. The Division should rely on a DEA registered reverse distributor to dispose of controlled substances. At a minimum, Pharmacy and field personnel should use items such as carbon chemicals, cat litter, or coffee grinds to render controlled substances unusable.
- e. Controlled substances and needles should be placed in biohazard storage containers for all storage and transport activities, including waste pick-up by third parties.

**Management Response:**

*Management agrees that there are some changes needed in the disposal process to remedy the observations of IA. Since the audit process, controlled substances that have received mechanical damage to the vial, expired, or other reason to dispose outside of normal waste procedures shall be placed into an evidence bag that is tamper evident and serialized. These bags are delivered to the Pharmacy at RM where the process of disposal is completed in front of a video monitoring system along with two personnel. In addition, the use of a substrate material will be used to bind to the controlled substance to render it unretrievable.*

*The needles used in the process are disposed of in tamper proof sharps containers to prevent inadvertent needle sticks from a cap or safety device being dislodged during the transport process.*

*Documentation procedures in SAP will be modified to differentiate between replenishment and disposal. This will enable RM to better understand the cost of spoilage compared to usage or damage. In the SAP process, the section manager of RM will complete the authorization of signed disposal statements.*

### **Other Considerations**

IA observed opportunities to improve certain business activities based on best practices and included advisory comments for management consideration only. Management is not required to provide written responses or corrective action plans. The advisory comments are as follows:

- The Division relies on manual procedures with many forms to manage drugs in the field. The records rely on par values and manual entries. They do not provide a perpetual record of actual drugs on-hand by location or vehicle to better manage drug life cycles, risk of diversions, or waste. The Division should use a barcode-based system to manage drug inventory. Automation may be initially costly and disruptive, but we believe the potential long-term benefits from reduced paperwork and spoilage could offset the initial costs.

**Management Response:**

*RM and Operations are working together to identify a potential electronic checkoff for the daily check off procedures which would not allow the oncoming shift to see the counts from the previous shift. This would also allow the ability to run reports on certain items or any deficiencies in the daily reconciliation process would be immediately sent to appropriate contacts to remedy the deficiency.*

- Safes used to secure controlled substances in EMS vehicles rely on key access. Employees may lose or copy keys. The Division should upgrade to safes with user-specific Personal Identification Numbers (PINs) and smart cards if cost effective. PIN code or card access capabilities have several security advantages among others including multi-factor authentication, activity reporting, and user deactivations.

**Management Response:**

*RM and Operations are working together to identify electronic access options to controlled substances and other medications. Current procedures do have controls in place, but there is opportunity for improvement by creating an electronic chain of custody in the future.*

- The Warehouse contains over 20 security cameras, including one in the Pharmacy. Management has direct access to all cameras, which serves as an effective monitoring control. However, while back-up footage must be maintained for 30 days, IA was unable to verify footage was maintained for this timeframe or that back-ups are tested for viability.

Management should periodically view historical footage to verify that cameras are working, and archived footage is available.

**Management Response:**

*Monthly verification of camera operation is done by the Battalion Chief of Logistics. This verification will include verifying the availability of historical, archived footage. Consistent, reliable access for the Battalion Chief is an ongoing process. The Fire Chief, the Deputy Director, all Assistant Chiefs, the Battalion Chief of Logistics, and the section manager over Fire Investigations have access to the Avigilon software to pull footage when requested. We did identify an issue with providing this information to parties that are not accessing the information via Gwinnett County devices. Even with the viewer enabled data, the security features do not allow easy viewing of this data. We are going to contact the vendor to determine how to package data so it can be viewed by third parties. This will be particularly important in the event of open records requests for video surveillance in the future.*

## Exhibit A Summary of Audit Procedures

IA performed the following procedures to evaluate the adequacy and effectiveness of control activities:

- Interviewed management to identify key control activities. Performed walkthroughs at Fire Warehouse and multiple fire stations to confirm understanding of the procedures.
- Reviewed Pharmacy policies and the Northside Hospital Gwinnett Pharmacy Agreement for key terms.
- Selected a random sample of 25 controlled substance purchase orders and confirmed proper approvals, support, and separation of duties (**Recommendation 1**).
- Reviewed Fire procurement card transactions for any purchases of controlled substances made outside approved processes.
- Confirmed Department Medical Director had DEA certification.
- Observed daily controlled substance cycle counts at the Pharmacy and shift change counts at various fire stations.
- Reviewed 25 CSARs and reperformed two weeks of CSAR to ESO reconciliations (**Recommendation 2**).
- Inquired about known instances of drug diversion. Obtained police report and DEA Form 106 filed in December 2020 for missing vial of Versed detected in November 2020.
- Inspected 11 vehicles located at five stations for physical security and shift change procedures (**Recommendation 3**).
- Reviewed operability of Pharmacy cameras and attempted to validate backup retrievals.
- Inspected documentation to support dual destruction of controlled substances in the Pharmacy and field (**Recommendation 4**).
- Verified drug tests were completed for EMS personnel for two quarters.
- Observed disposal methods for needles to ensure they promote health and safety.