Internal Control and Organizational Performance

Controlled Medications Inventory Audit

Operating Unit:	Niagara Region
Date of Audit:	September 2018 – January 2019
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Distributed To:	Niagara Region Audit Committee Ron Tripp, (Acting) Chief Administrative Officer Dr. Mustafa Hirji, Commissioner, Public Health Adrienne Jugley, Commissioner, Community Services Henriette Koning, Director, Senior Services Kevin Smith, Chief, EMS Kim Eros, Associate Director, Clinical and Support Services Richard Ferron, Deputy Chief, EMS Roger Mayo, Deputy Chief, EMS Cindy Bourgault, Manager, Clinical Practice Michael Franklin, Commander, Quality Management and Professional Standards Randy McDougall, Manager, EMS Logistics *cc:* Maciej Jurczyk, Director, Internal Control and Organizational Performance
Date Issued:	January 22, 2019

EXECUTIVE SUMMARY

BACKGROUND

In accordance with the 2018 Audit Plan, Internal Control and Organizational Performance (ICOP) performed a comprehensive review of the internal controls surrounding controlled medications at the Niagara Region. The audit was conducted within professional standards published by the Institute of Internal Auditors.

The purpose of this audit was to ensure that controlled medications are appropriately managed. This included a review to ensure that adequate internal controls exist over the intake, storage, usage and disposal of controlled medications.

The audit reviewed the procedures in places for Niagara Emergency Medical Services (NEMS) and in Niagara Region's Long Term Care (LTC) Homes and reviewed controlled medications as defined in the *Controlled Drugs and Substances Act.*

SCOPE

A risk based auditing approach was used to determine the scope of the audit. The following processes, procedures and items were considered in scope:

- Ensure that medication inventory is appropriately tracked and reconciliations are completed on a regular basis
- Determine if there are adequate physical safeguards in place in order to mitigate the risk that controlled substances may be misappropriated
- Ensure compliance with internal policies and procedures as well as external regulations and legislations
- Determine if sufficient internal controls exist to ensure that controlled medications are properly managed and controlled in a manner that reduces and mitigates risk
- Determine if there are opportunities for process improvements

Due to the two distinct operating units reviewed during the audit, observations in the report have been directed toward either NEMS or the LTC Homes (Seniors Services division).

ICOP used the definition of controlled medications stated in the *Controlled Drugs and Substances Act* in order to determine which substances were deemed to be included or excluded from scope.

The scope of the audit did not include the following:

- Legacy pharmacy provider for the LTC Homes
- Procurement processes relating to the acquisition of the suppliers used by NEMS and the LTC Homes

INTERNAL AUDIT FINDINGS

Overall, the internal control environment for managing controlled medications within NEMS and the LTC Homes is effective. No significant issues were identified during the audit. The following areas were deemed to be operating effectively:

- Long Term Care (LTC) Homes
    - Physical security surrounding controlled medications within the Homes
    - Methods for tracking the administration and destruction of the controlled medications
    - High control frequency which ensures that any count variances would be discovered quickly
    - Inspection of the Resident's medication record which reviews the log for completeness
- Niagara Emergency Medical Services (NEMS)
    - Physical security surrounding controlled medications at main and restocking locations
    - Methods for tracking the administration, replenishment of controlled medications at the restocking locations
    - High control frequency which ensures that any count variances would be discovered quickly
    - Usage sheets are reconciled on a weekly basis to ensure that controlled medications taken out of the cabinets are accounted for

Staff from both NEMS and the Long Term Care Homes were open in discussing and sharing information with ICOP which demonstrated a willingness and openness to the process review. ICOP would also like to draw attention to the following positive attributes noted from discussion with Management:

- Staff from both operating units were familiar with the legislation and regulation that they are required to follow in relation to controlled medications.
- LTC Homes – Pharmacy provider selected through formal RFP process has extensive knowledge in working with long term care homes and as a result has developed a policy manual which is provided to the Homes. The policy manual covers areas such as:
    - Order and receiving medication through the pharmacy provider
    - Administration, documentation and storage of medications
    - Services to be provided by the pharmacy provider
    - Medication disposal
    - Medication risk management
- NEMS – There is an effective, continuous improvement methodology as demonstrated by Management proactively taking steps to update and improve current processes.

Please note that a limited portion of the report is being provided to Audit Committee on a confidential basis in closed session in reliance upon section 239(2)(a) of the Municipal Act by reason of the fact that those recommendations/observations provide detail regarding NEMS practices/procedures related to controlled medications that could represent a risk to the security of the property of the municipality and safety of staff if disclosed to the public.

ICOP appreciates the assistance and co-operation from the NEMS and LTC Home teams during the course of this audit.

OBSERVATIONS AND RECOMMENDATIONS

The following are all the observations from the audit along with recommendations and Management's Action Plans to address these issues. See Appendix I for the risk ranking justification.

Observation #1 – NEMS – Internal controlled medications policy needs to be updated	
Risk Ranking	**LOW**

The NEMS internal controlled medications policy needs to be updated to represent the current business practices.

NEMS' *Controlled Medication Process* was last updated January 2016. Since this time there have been changes to the business processes which need to be reflected in the policy.

The following chart shows examples of areas within the *Controlled Medication Process* which need updating:

Policy Reference	Policy States	Updates Required
22.2.1 *Access and Transport*	*"Niagara Health System pharmacy technicians have access to supply boxes …"*	As a result in the change in the process NEMS staff are the only individuals with access to the supply boxes
22.4 *EMS Base Controlled Medication Stock*	*"… station has a maximum of 15 ampoules of Morphine and 10 vials of Midazolam…"*	Policy does not meet current business practice
22.5 *NHS Sites with Controlled Medications*	*"The local hospital pharmacies are responsible for monitoring the levels and restocking of the ALS supplies and controlled medications contained within these cabinets."*	NEMS is solely responsible for the controlled medication monitoring and restocking of the ALS supplies and controlled medications
22.9 *Expired Controlled Medications*	*"…. controlled medications that have expired need to be returned to pharmacy for proper disposal."*	NEMS is now responsible for the destruction of expired controlled medications. The internal policy should be updated to document how NEMS handles expired controlled medications

In addition to the required changes listed above, the following areas are not discussed in the internal policy:

- Policy for destruction
- Policy for documenting wastage on call logs

Implication

Up-to-date internal policies and training ensure that all levels of staff have the necessary information to be able to perform their job duties.

Recommendation

1. NEMS Management should updated the internal policy to include all current business process.
2. Once the internal policies have been updated, all changes should be communicated to staff.

Management Action Plan

Person(s) Responsible	Michael Franklin, Commander, Quality Management and Professional Standards	**Completion Date**	June 1, 2019

1. The recommended updates will be made within the policy.
2. Training surrounding the updates will be delivered to affected staff.

Observation #2 – LTC Homes – Obtain family's confirmation of incoming and outgoing controlled medications during respite stays

Risk Ranking	**LOW**

Certain long term care home locations provide respite stay (short stay) programs. When a resident is admitted for a respite stay, the following is required:

- A list of the individual's medications is sent from their respective physician (stating type of medication, strength of medication and dosage frequency)
- Medication brought into the LTC Home for this program are provided by the Resident / Substitute Decision Maker (SDM) in blister packaged cards
- When the individual is admitted, there is a count of all incoming controlled medications by two registered staff members at the Home

As per review of documentation during fieldwork and discussion with Management, registered staff signatures were observed on the medication list from the respective physician. In addition, there was a medication record set up and signed off by the two registered staff. Although there was confirmation by the registered staff on the list of medications, it did not appear that the individual's respective family member was confirming the incoming and outgoing quantity of controlled medications.

Implication

When the individual's family signs off on the incoming and outgoing quantities of controlled medications, it provides an additional layer of security and confirmation for the Home.

If the incoming and outgoing count confirmation by the individual's family is not completed, this may open the Home up to questions about what the actual incoming and outgoing quantities were.

Recommendation

1. The incoming and outgoing quantity of controlled medications should be documented and signed off by the resident's family in addition to the two registered staff.
2. The *Narcotics and Controlled Substances* policy should be updated to include this requirement.

Management Action Plan

Person Responsible	Kim Eros, Associate Director Clinical and Support Services	**Completion Date**	n/a

1. The Action Plan is to not follow-through on the recommendation put forward given a number of considerations:
    - Seniors Services is required to follow a number of pieces of legislation in providing care and services for short-stay and long-stay residents including:

- Health Care Consent Act (to determine resident's capacity)
- Municipal Freedom of Information and Protection of Privacy Act (MFIPPA - right to access personal health information)
- Personal Health Information Protection Act (PHIPA - sets out rules for protecting the privacy of patients and the confidentiality of their personal health information)
- The recommendation suggests that the quantity of medication should be documented and signed off by the respite service client's family. This direction presumes that the client of the program is not competent (i.e. assumes a lack of capacity under the Health Care Consent Act (HCCA)) and it also presumes that the individual dropping off / picking up the client for the respite stay is the Substitute Decision Maker or Power of Attorney for Personal Care and Services. We are not able to make the blanket assumption recommended through this proposed policy change that all clients of the program lack capacity under the HCCA. We do not know if a family member has any status to speak for the resident either by POA or pursuant to applicable statute. All residents are deemed to be competent (a legal term) unless otherwise determined by a court or clinical process. A POA or SDM only goes into effect if a resident is incapable of making decisions. We are not able to ascertain that the SDM / POA is in effect without applicable documentation (Health Care Consent Act, Personal Health Information Protection Act).
- The recommendation assumes that all residents who use respite services lack capacity and that the individual dropping them off / picking them up for their respite stay is the Substitute Decision Maker. It is not unusual for clients of the program to be dropped off / picked up by a family member, a neighbour or a friend who is not their Substitute Decision Maker and as such should not have access to their medical information including their narcotics usage.
- This recommendation would introduce a considerable risk of disclosing personal health information in contravention of PHIPA. (Disclosing personal health information in contravention of PHIPA is considered a privacy breach and on conviction an individual may be liable to a fine of up to $100,000 and a corporation up to $500,000.)

Observation #3 – LTC Homes – Missing documentation	
Risk Ranking	**LOW**

A new pharmacy service provider was introduced into the Long Term Care (LTC) Homes in the fall of 2018. With the change in pharmacy service provides came a change in some of the policies and procedures within the Homes. There has been a learning curve for the staff in the Homes as they become accustomed to new paperwork and documentation requirements.

During fieldwork, ICOP noticed the following instances of missing documentation:

- A change in status form was not sent to the pharmacy provider and as a result an unneeded weekly supply of controlled medication was sent to the Home
- Administration of medication was documented on the electronic medical record (EMAR) but in four instances, the administration of the controlled medication was not recorded on the Narcotic and Controlled Drug sheet at the time of administration
- Eight instances (out of 123) where staff did not log medication on the Controlled Substance Destruction Log to indicate that the controlled medication had been placed in the secured destruction bin
- Several instances of missing second/witness signatures where required

Implication

Best practice would be ensure that documentation is recorded in a timely manner (i.e. at the time of dosage), if this is not done, it increases the possibility that it will be missed entirely or may cause an unnecessary error (for example the controlled medication counts showing off when they are in fact accurate).

Recommendation

1. Management, along with the pharmacy service provider if possible, should conduct follow up re-training of the new business processes implemented by the new pharmacy service provider.
2. When the Homes are conducting their own documentation inspections, if trends in missing documentation or errors are observed, they should be communicated and corrected with the Home staff. Follow up training should be completed with staff where Home Management deems necessary.

Management Action Plan			
Person Responsible	Kim Eros, Associate Director Clinical and Support Services	**Completion Date**	April 15, 2019

1. Finalize implementation of the final phase of the pharmacy transition plan including audit of new systems and processes to determine training needs. Will ensure through this process that all required documentation as per the new pharmacy provider is captured in a timely manner.
2. Ensure that all audits are consistently completed and that training needs identified through audits are addressed.

BEST PRACTICES/ADDITIONAL OBSERVATIONS

Observation #1 – NEMS – Opportunity to create process efficiencies as NEMS looks to future-state model

The control environment surrounding controlled medications at NEMS is a manual system.

While manual systems can be extremely effective, there is a risk in the degree of human error. The more times you require human intervention for a system to operate effectively, the higher the risk of error.

Some of the limits of the manual system include:

- The usage sheet is updated by the paramedic(s) each time a controlled medication is added or removed from the medication storage (due to administration during a call, wastage, breakage and/or expiration). Data from the usage sheet is then manually updated to spreadsheets in order to generate trend data for NEMS Management.
- At a given point in time, NEMS Management is unable to determine the total controlled medication inventory levels as the manual system does not allow them to monitor the inventory levels at the restocking locations.
- Inventory levels at restocking locations are only known on delivery days when NEMS staff replenish stock levels.
- Paramedics have to complete the usage sheets after the completion of the call when they are restocking their controlled medication pouches, as a result, the data on the usage sheets may not always be accurate (For example, during fieldwork, ICOP noted instances where a call log number or date was written incorrectly on the MAR sheet).
- The manual process may allow another individual to fill out the usage sheet on behalf of someone else

NEMS is currently undergoing strategic end state and inventory management reviews which will allow them to be able to monitor inventory levels at all of the locations in real-time. These reviews did not include the review of controlled medications. NEMS Management may see the benefits of applying some of the findings in the future-state reviews to the controlled medications process.

Recommendation

1. NEMS Management should determine the cost-benefit of having the ability to monitor controlled medication inventory levels on a real-time basis.
2. Depending on the outcome of the future-state model, NEMS Management should determine if there is a potential to apply some of the lessons from the inventory management to the management of their controlled medications.

Management Action Plan (Optional)	
Person Responsible	Randy McDougall, Manager EMS Logistics

1. The same solution mentioned in confidential observation #1 that will allow for the roll out of Ketamine would also provide enhanced reporting on usage, wastage and inventory levels in real time.
2. The solution selected would be transferable to a future state delivery model for NEMS. Although narcotics where out of scope during the inventory management project any lessons learned have been easily applied to the two narcotics.

APPENDIX I - RATING SCALE

Rating	Definition
CRITICAL	Requires immediate action by Senior Management to avert a severe/disastrous risk event in the near-term. Internal controls are deemed to be ineffective, absent or poorly designed. Management Actions Plans (MAP's) are to be implemented immediately to mitigate risk of substantial financial losses, business interruption, loss of reputation and/or environmental, public health & safety risk.
HIGH	Requires prompt action by Management to avert, reduce or transfer a major risk event. Internal controls are deemed to be ineffective, absent or poorly designed. MAP's should be implemented to mitigate the risk of financial losses, loss of reputation, address fraud issues or legal/regulatory non-compliance.
MEDIUM	Requires timely actions by Management to reduce risks to a low level. Internal controls are deemed to be ineffective or poorly designed. Management action is required, but is not immediate. Moderate financial losses, temporary/minor reputational impairment, lesser potential for fraud or regulatory non-compliance may occur without timely MAP's.
LOW	Management actions are recommended to address the weaknesses identified. Internal controls are operating effectively or partially address the control objective; however they may be poorly designed and/or operational inefficiencies exist which may result in an opportunity for improvement. Low risk events may cause operational inconvenience or minor financial losses.