Cheshire Medical Center

Report on Controlled Substances Assessment

Third Party Monitor Reporting Period 2

October 7, 2022, through October 20, 2022

Building a better working world

October 28, 2022

To: David T. Haig
Vice President, Compliance and Audit Services, Dartmouth Health

Re: Controlled Substances Assessment #2

Pursuant to our Statement of Work dated September 12, 2022 and as amended September 28, 2022, Cheshire Medical Center ("CMC") requested that we provide advisory services in connection with its Settlement Agreement with the New Hampshire Board of Pharmacy ("Board") effective July 28, 2022. Specifically, we were asked to perform certain controlled substances testing procedures pursuant to the role of Third-Party Monitor as described in the Settlement Agreement.

The attached report describes our procedures performed and the results of our testing for the period from October 7 through October 20, 2022. The appendix describes important limitations to our work and should be read in conjunction with the report.

This report is confidential, and distribution is limited as described in our Statement of Work. We appreciate the cooperation and assistance provided to us during our work. If you have any questions regarding this report, please contact Tom Gregory.

Very truly yours,

Ernst & Young LLP

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1. General Procedures and Scope

1.A Time frame covered

This assessment covered the second biweekly period covered by the Third-Party Monitor, which was the period from October 7, 2022, through October 20, 2022. This time period was determined based on the schedule described on Page 5 of the Settlement Agreement, moving forward in two week increments from the Effective Date of the Settlement Agreement. As further described below, certain of our procedures were performed as of a certain date falling within this biweekly period. For certain testing procedures involving a date range, we obtained data beginning October 3, 2022, to align with the date range covered by our assessment in the last testing period. In instances where the end date of our testing was before the last day of this biweekly period, we will include any gaps with the next cycle such that all days are ultimately assessed.

1.B Objective

The objective of the testing was to present findings to CMC related to the eight specific testing areas identified in the Settlement Agreement and further described below for the designated biweekly scope period.

1.C General procedures

In general, and as a basis for this engagement, we performed the following procedures:

- Met with representatives of CMC to discuss its operational processes and controls related to ordering, managing, and dispensing controlled substances.
- Prepared a work plan and discussed with CMC the specific procedures to be performed. The work plan reflects the eight testing areas identified in the Settlement Agreement. We understand that these testing areas also reflect the scope performed by auditors representing the Board in its prior audits performed pursuant to the Settlement Agreement.
- Prepared and submitted to CMC requests for data detailing the information necessary for us to conduct the Controlled Substances Audits.
- Worked with representatives of Dartmouth Health's Internal Audit and Compliance function to obtain source data.
- Performed testing procedures as described below for each of the eight focus areas: and
- Clarified information for each of the eight focus areas where needed and submitted this report to CMC.

2. Summary of Procedures and Findings

Pursuant to the Settlement Agreement, our testing procedures covered eight focus areas:

A. Permittee Invoice to Controlled Substance Manager reconciliation audit;
B. Controlled Substance Manager Exception Report audit;
C. Omnicell Override Report audit for controlled substances;
D. Omnicell Pick List Report audit;
E. Omnicell Dose Reconciliation Report audit;
F. Controlled Substance Infusion audit;
G. Diversion Training audit; and
H. Physical Inventory audit.

2.A Permittee Invoice to Controlled Substance Manager reconciliation audit

CMC pharmacy representatives provided EY with a list of 25 purchase orders for Controlled Substances representing the full population of such orders for the time period of October 4, 2022 through October 14, 2022. This list of orders is a report from the vendor's system which included the following detail to support the transaction: vendor name, invoice number, invoice date, and an itemized list of drugs from the vendor. CMC provided us with the corresponding itemized invoice of purchase, signed documentation acknowledging receipt, and Omnicell documentation for receipt and inventorying of the substances.

We utilized the documentation provided by CMC to reperform a reconciliation of inventory to identify any discrepancies between the type and quantity of controlled substance ordered, received, and stocked into the pharmacy. We compared the 25 invoices to the respective wholesaler summary and the Controlled Substances Manager (CSM) inventory log and observed no variances.

Permittee Invoice to Controlled Substance Manager reconciliation audit			
Testing sample elements	Variances	Variance (%)	Observation(s)
25	0	0.00%	N/A

2.B Controlled Substance Manager Exception Report audit

CMC utilizes the Omnicell system to manage and track the flow of controlled substances throughout the hospital. We obtained the full population of exception reports generated by Omnicell for the period September 29, 2022, through October 16, 2022, which lists any instances where a respective drug/order left the pharmacy but was not subsequently stocked into an Omnicell at its respective location (e.g., Automated Dispensing Cabinet (ADC), anesthesia carts).

For each item on the report, we assessed the documentation from the Omnicell reports provided by CMC pharmacy representatives to assess whether there was documentation evidencing that exceptions were investigated and whether any associated resolution is consistent with the supporting documentation provided. The supporting documentation obtained included, for example, independent Omnicell reconciliation counts or EMS receipt logs with witness signatures.

For each item on the exception reports, we noted the presence of evidence documenting its investigation and resolution.

Testing sample elements	Variances	Variance (%)	Observation(s)
49	0	0.00%	N/A

2.C Omnicell Override Report audit for controlled substances

An override report demonstrates that any tracked controlled substance removed from the respective cabinet(s) on an override has been reconciled through an order or an identified discrepancy has been investigated, documented with explanation, and closed out.

We obtained the Omnicell Override report representing the full population of overrides for the period from October 4, 2022, through October 17, 2022, discussed each item with CMC pharmacy representatives and observed that an explanation is provided for the override. We filtered out any "key retrieval" only overrides, bringing the total controlled substances overrides to 14 for the period. We compared the overrides to the Pharmacy Discrepancy report to confirm a corresponding order was placed for each override. No variances were noted.

Testing sample elements	Variances	Variance (%)	Observation(s)
14	0	0.00%	N/A

2.D Omnicell Pick List Report audit

Controlled substances picked from the CSM must be verified by a pharmacist. A Pick List Report generated by Omnicell identifies if a pick was verified or unverified.

We obtained a Pick List Report from Omnicell for the period October 4, 2022, through October 17, 2022, and assessed whether the unverified picks are supported by documentation. The report indicated that there was only one unverified pick for this testing period. We observed that documentation was provided by CMC pharmacy and the item was documented as resolved.

Omnicell Pick List Report audit			
Testing sample elements	Variances	Variance (%)	Observation(s)
1	0	0.00%	N/A

2.E Omnicell Dose Reconciliation Report audit

CMC runs on a closed loop for Omnicell. Omnicell describes this process as one that, "automatically identifies variances between medications dispensed from the Omnicell® Automated Dispensing Cabinet and Anesthesia Workstation™ versus medications documented as administered and/or wasted." The CMC team completes a daily dose reconciliation between the Omnicell report and CMC's Electronic Health Record (EHR) system (Epic) and/or wasted per Omnicell. As part of its reconciliation, the CMC pharmacy

team closes all doses that reconcile between the two systems and further investigates those that do not reconcile following a standardized escalation process. CMC also utilizes a contracted diversion control consultant who investigates and reconciles any variances as well following the same escalation process.

We obtained the dose reconciliation records for the period October 3, 2022, through October 18, 2022. We observed documentation evidencing that each variance was investigated (or being investigated) and resolved by CMC pharmacy. Variances were noted as resolved with the exception that there are four occurrence events still open as of October 20, 2022. We will follow up on these occurrence events during the next audit cycle.

2.F Controlled Substance Infusion audit

CMC utilizes an external drug diversion consultant who performs an analysis of all infusions of controlled substances. The information captured during the drug diversion specialist's infusion audits assesses whether that infusion volume is calculated based off the start time of infusion, end time of infusion, and the rate of infusion provided in the EHR. The drug diversion team uses this calculated rate to compare to Omnicell for potential loss considering any waste and that infusion bags have a volume variance at arrival. Any variances are investigated using a standardized escalation process following through to resolution.

We obtained documentation of the diversion specialist's testing and completed a walkthrough of the infusion audit with the diversion specialist. For any volumes with a variance, we assessed whether an explanation was provided for the respective variance and the potential variance was either being investigated or resolved.

We observed documentation noting that the diversion control specialist had performed the infusion audit described above including that any volume variances were investigated (or being investigated) and resolved. We observed that four calculated variances triggered an occurrence event. As of October 21, 2022, three remained open and the Diversion Team sequestered a pump for testing due to these occurrence events. We will follow up on the pump during the next audit cycle and any other associated investigations to understand if the pump testing provided a resolution for these three.

2.G Diversion Training audit

We requested and obtained a listing generated by CMC Human Resources (HR) of the Diversion Awareness training modules assigned to employees along with a status indicating whether the assigned training had been completed. For those incomplete, we identified how many days past the due date the training was as of October 20, 2022. We observed that, across all assigned training related to diversion, 92.43% of assigned trainings are marked as complete. This is an increase of 1.82% from the previous audit cycle. For those marked as incomplete and past due, the average number of days past due was 64.

CMC personnel indicated that Vice Presidents will be receiving a second request with the list of staff who still need to complete the training and they will be responsible for ensuring compliance within the week and ensuring ongoing compliance. During the audit cycle, HR updated the personnel list to remove terminated employees or other non-relevant personnel and is encouraging leaders to continue to update personnel listings to remove any inactive employees.

Diversion Training		
Training	Employees Assigned	Completed %
Diversion Awareness Education for all staff CMC	1,990	91.36%
Diversion Awareness for all staff (OFFSITE)	15	86.67%
Diversion Awareness for Clinical Staff	374	98.13%
Diversion Awareness Training	12	100.00%

2.H Physical Inventory audit

We performed physical inventory sample testing onsite at CMC on October 18, 2022. On that day, we obtained a current CMC CSM log, which is a count of all drugs inventoried in each Omnicell bin at the time the report was pulled, and judgmentally selected 35 items to perform a blind cycle count. We accompanied and observed two CMC pharmacy representatives who performed the cycle count of the selected items at seven different Omnicell cabinets. The six Omnicell cabinets where we performed cycle counts were CSM, ICU, ER, Thompson 1, Thompson 2, and Radiology. We documented the cycle count and compared the count to the CSM log.

During our inventory counts, we noted two variances between the Omnicell and the inventory listing pulled – one over and one under. However, the cycle count did not trigger a discrepancy in the Omnicell system. Given several hours passed between when the inventory report was pulled and when the cycle counts were performed, we requested the documentation to bridge the gap between the inventory report and the cycle count. The differences were resolved by pharmacy personnel, who provided documentation of a return from Radiology and a dispense in the ER. For reporting purposes, this is not a variance since we had documentation of the correct count.

Physical Inventory audit			
Testing sample elements	Variances	Variance (%)	Observation(s)
35	0	0.00%	N/A

3. Appendix

Limiting conditions

- Our procedures were limited to those described in this report.
- To perform this engagement, we relied upon certain information provided to us by CMC. Except where specifically indicated, we performed no procedures to evaluate the reliability or completeness of the information provided.
- Our services are advisory in nature and performed pursuant to the AICPA's Standards for Consulting Services. Our work does not represent a compliance attestation or other audit or assurance function as defined by the AICPA. Accordingly, we express no opinion or other form of assurance on CMC's compliance with the terms of the Settlement Agreement or any law or regulation. Our services do not constitute legal advice.
- We do not assume any management responsibilities in connection with this engagement. Our services represent an assessment and do not include any design, implementation, or operation of management controls. Management decisions rest solely with CMC.
- While we believe the procedures performed and findings provided are substantially responsive to your request, we are not in a position to assess their sufficiency for your purposes.
- This report is provided as of a point in time. We have no responsibility to update this report for events or circumstances occurring after the date of this report.
- As described in our Statement of Work, distribution of our report is limited to CMC except that CMC may share it with the New Hampshire Board of Pharmacy. Further distribution or reliance by any other party is strictly prohibited.
- Please refer to the Statement of Work and associated Agreement for additional information and important terms and conditions relative to our work.