# 21-118 Pharmacy Drug Diversion and Bluesight® Post Implementation Review

## EXECUTIVE SUMMARY

MD Anderson created a multidisciplinary Medication Diversion Prevention Program Committee (MDPP) in 2018 aimed at preventing, identifying, and addressing medication diversion. In September 2020, MD Anderson implemented Bluesight® for Controlled Substances, which is a controlled substance tracking and diversion detection software solution. Bluesight® analyses medication dispense, administration, waste, return, and other data from electronic health records to identify undocumented events or Pyxis users (i.e., Anesthesia, Pharmacy, and Nursing) that may be at higher risk for diversion. Internal Audit performed a drug diversion and post-implementation review over Bluesight® and other monitoring, investigation, and reporting processes and tools in place to ensure alignment with the American Society of Health System Pharmacists (ASHP) guidelines[1] and with the following objectives:

- Assess the Institution's controlled substance monitoring program, processes, and controls.
- Evaluate the implementation of Bluesight® and the use of data and analytics to mitigate risks related to drug diversion.

**Audit Results:**

Internal Audit observed the following notable successes of the Medication Diversion Prevention Program:

- Existence of a multidisciplinary Medication Diversion Prevention Program Committee (MDPP) and detailed charter.
- Automatic reconciliation of over 98% of controlled substance transactions (over 48k transactions monthly) and 100% reconciliation after review of unreconciled transactions. Average auto-reconciliation of controlled substance transactions for large hospitals using Bluesight is 93%.
- Continued partnership with Bluesight® to identify, develop, and implement enhancements. Refer to **Appendix B** for existing software enhancement and product development details.

Additionally, Internal Audit noted the following opportunities to enhance the Program:

- Drug Diversion Monitoring, Investigating, and Reporting – Monitoring is limited to review and investigation of unresolved controlled substance events, without incorporating reviews of clinicians whose behavior Bluesight® has identified as having a higher risk for diversion activity.
- Policy & MDPP Committee Charter Updates – Existing processes and their respective policies, including the MDPP Committee Charter, require updates to align with current practice.
- Camera Resolution & Placement – Pyxis and controlled substance waste areas are not effectively monitored via high-resolution cameras.

[1] Source: https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/preventing-diversion-of-controlled-substances.ashx

**Management Summary Response:**
Management agrees with the observations and recommendations and has developed action plans to be implemented on or before August 31, 2023.

**Appendix A** outlines the methodology for this project.

The courtesy and cooperation extended by the personnel in Pharmacy are sincerely appreciated.

Sherri Magnus

Sherri Magnus, CPA, CIA, CFE, CRMA, CHIAP
Vice President & Chief Audit Officer
June 29, 2021

Observation 1:
**Enhance Drug Diversion Monitoring, Investigation, and Reporting** ***RANKING: High***

Bluesight® contains functionality that is not being fully utilized for monitoring, investigation, and reporting to the Medication Diversion Prevention Program Committee (MDPP). The Individual Risk Identification Score (IRIS) Dashboard within Bluesight® uses machine learning to identify clinicians who may be at higher risk for diversion as compared to their peers. We currently have a process in place to monitor and investigate unresolved controlled substance events. However, no process is in place to consistently monitor, investigate, and report clinicians with a higher risk for diversion activity.

For the period of January through March 2021, the IRIS Dashboard identified an average of 16 high risk nurses and 2 anesthesia providers per month. Further investigation was not performed, beyond missing documentation, for these clinicians (e.g., interview, drug screen). As a result, we may be placing patients at risk by allowing these clinicians to remain in the workforce without additional investigation to ensure they are not impaired. Additionally, we may be delaying assistance to struggling team members by failing to identify them quickly and provide them with necessary resources. The American Society of Health System Pharmacists (ASHP) recommends that trends and variances indicating potential diversion be acted upon timely.

Recommendation:
Management should fully utilize the IRIS Dashboard within Bluesight® to monitor, investigate, and report any potential high-risk diversion activity. Specifically, management should develop and implement procedures to substantiate any potential drug diversion activity.

Management's Action Plan:
Executive Leadership Team Member: Rosanna Morris
Division/Department Executive: Ryan Roux
Owner: Brian Miller
Implementation Date: August 1, 2021

*Effective for the month of June 2021, we reviewed 10 users identified as high-risk according to their IRIS scores. Our plan going forward is to review from 5 to 10 new users per month. Findings will be reported to immediate supervisors and Medication Diversion Prevention Committee.*

Observation 2:
**Develop and/or Update Policies** ***RANKING: Medium***

Standard Operating Procedures (SOPs) do not exist to address investigation procedures for high risk clinicians identified by the IRIS Dashboard. Additionally, there are no documented requirements for retaining investigative support for suspected or confirmed diversions.

In addition, three policies related to controlled substance monitoring have not been reviewed since 2019 or earlier. Per discussion with Pharmacy leadership, policies should be reviewed at least every two years. The three policies requiring review are:

- Fitness for Duty Policy #ADM0274 (2017)
- Practitioner Health and Impairment Policy #CLN0619 (2016)
- Employee Assistance Program Policy #ADM0275 (2016)

Without policies and Standard Operating Procedures (SOPs), it is difficult to ensure consistency and hold individuals accountable.

Recommendation
All existing policies reviewed prior to 2019 should be reviewed and updated to align with current practice and comply with the requirement of reviewing every two years.

Policies and/or SOPs should be developed to clearly identify IRIS investigation steps, such as chain of custody, waste and cancel activity, and timing and amount of controlled substance administration compared to peers. Consideration should include, but not be limited to:

- A defined threshold for investigating users,
- Required review if high risk clinicians were investigated the previous month but continue to appear on the IRIS dashboard,
- Responsible parties for investigation and reporting,
- Documents to be retained,
- Interviewing protocols,
- Drug screening protocols, and
- External and internal reporting requirements (upon self-reporting, suspicion, resignation, and/or termination).

Management's Action Plan:
Executive Leadership Team Member: Rosanna Morris
Division/Department Executive: Ryan Roux
Owner: Brian Miller
Implementation Date: January 1, 2022

*We are working with committee members Dr. Georgia Thomas and Mark Berg to review and update the three policies overdue for review. All 3 policies are in the process of being reviewed and will be presented to appropriate approval committees over the next few months.*

*The Medication Diversion Prevention Team has developed a Standard Operating Procedure to outline the monthly review of top IRIS users. Total number of investigations will be reported routinely at Medication Diversion Prevention Committee meetings.*

*All recommendations will be incorporated into revised Policies and/or Standard Operating Procedures.*

Observation 3:
**Enhance Camera Resolution and Review Placement** ***RANKING: Medium***

Per conversations with process owners, although cameras are in place, the resolution does not always allow for proper investigation through review of activities, and some cameras do not have visibility over some Pyxis machines and controlled substance waste areas.

Recommendation
Pharmacy should review existing camera placement and resolution and determine the number of cameras that require upgrading and/or installation to ensure all Pyxis machines and controlled waste areas are visible and resolution is appropriate to review controlled substance medication management and investigate potential diversion.

Management's Action Plan:
Executive Leadership Team Member: Rosanna Morris
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Implementation Date: August 31, 2023

*Pharmacy is working with UTPD and Information Services to obtain Capital budget approval for the purchase and installation of approximately 300 High-Definition cameras for Medication dispensing (Pyxis) and preparation areas (Sterile Compounding). Successful completion of this recommendation will be dependent on budget approval and vendor timelines for installation.*

Observation 4:
**Update MDPP Committee Charter** ***RANKING: Medium***

The Medication Diversion Prevention Program Committee (MDPP) charter does not reflect current practice related to the following areas:

- Implementation and oversight of a Diversion Response Task Force (DRTF) to effectively respond to suspected diversions of medications. The DRTF, in turn, should be conducting diversion risk rounds.
- Meeting monthly (or as frequently as necessary, but not less than monthly) per the Charter.
- Update listing of required attendees within the charter and confirm within meeting minutes that all required attendees were invited and if they are present.

Recommendation
The MDPP charter should be reviewed and updated to align with current practice, or the existing practice should be modified to align with the charter where appropriate.

Management's Action Plan:
Executive Leadership Team Member: Rosanna Morris
Division/Department Executive: Ryan Roux
Owner: Brian Miller
Implementation Date: August 1, 2021

*The MDPP charter was reviewed at the June 17, 2021 meeting. All comments/edits will be incorporated and will be presented for final approval at July 15, 2021 meeting.*

*Diversion risk rounds have been removed from the charter, but all other recommendations will be incorporated into revised Policies and/or Standard Operating Procedures.*

**Appendix A**

**Objective, Scope, and Methodology:**
The objective of this engagement was to assess drug diversion monitoring, investigation, and reporting processes following the Bluesight implementation. The scope of this engagement focused on validating the effectiveness of drug diversion detection and reporting controls, and if practice aligns with the American Society of Health System Pharmacists (ASHP) guidance and leading industry practice. State and federal regulatory compliance were also considered.

Our procedures included the following:

- Review of relevant policies/standards, Medication Diversion Prevention Program Committee Charter, investigation, and reporting documentation
- Bluesight® planned enhancements and bi-weekly meeting to discuss issues and improvements
- Discussions with key personnel on drug diversion monitoring, investigation, and response procedures
- Walkthroughs of in-scope process areas and procedures, include Bluesight® capabilities and restrictions
- Evaluating design and effectiveness of controls to detect, investigate, and report diversion
- Analyzing Bluesight® reporting data and any additional drug diversion system control and alert functions

Our internal audit was conducted following the *International Standards for the Professional Practice of Internal Auditing*.

The internal audit function at MD Anderson Cancer Center is independent per the *Generally Accepted Government Auditing Standards* (GAGAS) requirements for internal auditors.

**Number of Priority Findings to be monitored by UT System:** *(None)*
A Priority Finding is defined as "*an issue identified by an internal audit that, if not addressed timely, could directly impact achievement of a strategic or important operational objective of a UT institution or the UT System as a whole.*"

**Appendix B**

Pharmacy has identified and is working towards the following planned Bluesight® controlled substance monitoring enhancements:

- Integrate Kronos data to normalize the data based on shifts worked and identify risky activity occurring at beginning/end of a shift or during off-shift times (will incorporate into IRIS score and better outline high priority users for investigation),
- Roll out Bluesight® tool access to nursing leaders to assist with investigation and documentation,
- Communication with C2 safe and wholesalers to have a better picture into anomalous Pharmacy activity and replace manual reconciliation of orders to receipts,
- Review and reconciliation of epidurals and IV infusions,
- Reconciliation of controlled substances ordering and receiving in Retail Pharmacies; transfer of inventory between pharmacies, and
- Additional reporting within Bluesight® that is currently being developed includes canceled orders, overrides, the ability to drill down reporting to a nurse, department, drug level, pain-related analysis, action sequences, and changes in behavior over time.

Pharmacy is also working with Bluesight® to develop monitoring around:

- Monitoring of variances and trends between drug administration and impact on pain scores,
- Monitoring of prescription trends at Retail Pharmacies,
- Monitoring of prescriptions prescribed and filled at external Retail Pharmacies,
- Monitoring of prescriptions prescribed by providers for their family members,
- Monitoring of opioid prescription volume, strength, and frequency above Federal and State guidelines,
- Monitoring of high-risk co-prescriptions, and
- Monitoring of patients receiving and/or filling prescriptions from multiple providers or pharmacists.