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Tuesday, July 27 | 10:30 – 11:15 AM

The Compliance Crosswalk

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Disclosures / Potential Conflicts of Interest

- AJ Rivosecchi has a vested interest in or an affiliation with Kit Check, Inc.; all relevant financial relationships have been mitigated

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| Learning Objectives

At the end of this session, participants should be able to:

1. Identify the current regulatory bodies and requirements related to controlled substances in the acute care setting
2. Recognize the role that a controlled substance diversion detection software platform can play in meeting current controlled substance regulatory requirements.
3. Identify best practices that can assist their own facility in fortifying its current controlled substances diversion prevention program

The background of the slide is a blurred photograph of a hospital hallway. In the foreground on the left, an IV drip chamber is visible, hanging from a stand. The hallway in the background shows a series of doors and a person walking in the distance, all out of focus. The overall color palette is a cool, muted blue.

The Landscape

Regulatory compliance in the diversion space is difficult to achieve due to the numerous medication access points embedded within most hospital distribution systems



| The Players

Regulatory Bodies

- Centers for Medicare & Medicaid Services (CMS)
- The Joint Commission (TJC)
- Department(s) of Health (DOH)

- Det Norske Veritas (better known as, DNV)

- “Deemed Status”

Accreditation

Accreditation

The Joint Commission

- TJC aims to inspire organizations to improve their care, treatment and services
- Seeks to help identify known or unknown risks to quality and patient safety
- Highly sought after by hospitals
- Symbol of excellence
- Difficult to fully comply with all regulations



| Accreditation

DNV

- NIAHO®
- Safeguarding life, property, and the environment
- Value quality and process
- Less fault focused
- Culture driven
- Annual



DNV

Key Differences with TJC

- Collaborative process which includes 3 annual surveys and ISO 9001 Quality Management System fostering continual improvement vs Triennial Survey
- NIAHO Standards directly aligned with CMS CoPs reducing clarification issues vs a more prescriptive standard in addition to the CMS CoPs
- DNV does not have a scoring system, tipping points or levels of accreditation.
- Accredited or not accredited vs categories such as Preliminary Denial or Conditional Accreditation
- Integrating the ISO 9001 Quality Management System vs. Quality chapter more aligned with measurement yet lacking some of the infrastructure



Assessment Question #1 of 4

Which regulatory body focuses most strongly on process and culture?

- a. DNV
- b. TJC
- c. CMS
- d. DOH

The Joint Commission

Failure to address diversion cited as a frequent cause of non-conformance to MM.03.01.01.

| The Joint Commission

Medication Management

- MM.01.01.01 – The hospital safely manages high-alert and hazardous medications
 - EP5 – reporting abuses and losses of controlled substances
- MM.03.01.01 – The hospital safely stores medications
 - EP4 – policy for medication control including administration, storage, handling, wasting security and disposition

| The Joint Commission

Medication Management

- MM.08.01.01 - The hospital evaluates the effectiveness of its medication management system
 - EP 1 – collection of data on performance of medication management system, compares data over time, identifies risk points, trends, etc.
 - EP 5 – based on data analysis and new technologies and best practice, hospital identifies opportunities for improvement in medication management system
 - EP 16 – ADC policy including override review

Medication Management Standard Risk Assessment

The Joint Commission

Failure to address diversion cited as a frequent cause of non-conformance to MM.03.01.01

Medication Management- Top Non-compliant Standards/NPSGs for Hospitals (Jan-June, 2017)	
Standard/NPSG	% Non-compliant
MM.04.01.01 Medication Orders	49.28%
MM.03.01.01 Storage and Security of Meds	47.84%
MM.05.01.01 Medication Order Review	14.94%

| The Joint Commission

Environment of Care

- EC.02.01.01 – The hospital manages safety and security risks
 - EP 1 – implements process to identify safety and security risks as identified by internal sources and high-risk processes
 - EP 10 – when incidents occur, the hospital follows its identified procedures

| The Joint Commission

Leadership

- LD.04.03.13 – Pain assessment and pain management, including safe opioid prescribing, are identified as an organizational priority for the hospital
 - EP 1 – leadership team responsible for pain management and opioid prescribing and well as developing and monitoring performance improvement activities
 - EP 3 – provides practitioners with education and programs to improve pain assessment, management and safe opioid use

| The Joint Commission

Performance Improvement

- PI.01.01.01 – The hospital collects data to monitor its performance
 - EP 40 – collects data on pain assessment and pain management including types of interventions and effectiveness
- PI.02.01.01 – The hospital compiles and analyzes data
 - EP 3 – statistical tools and techniques to analyze and display data



A recent advisory from
The Joint Commission,
Quick Safety, Issue 48:

*“Drug diversion and impaired
health care workers,” encourages
health care organizations to
establish a comprehensive
controlled substances diversion
prevention program to help detect
and prevent drug diversion.*

DNV - Healthcare

| DNV

Medication Management

- MM.1 – Management Practices
 - SR.5 – All drugs and biologicals must be controlled, secured and distributed in accordance with applicable standards of practice and consistent with Federal and State law at all times.
- MM.3 – Scheduled Drugs
 - SR.1 – Current and accurate records must be kept of the receipt and disposition of all scheduled drugs, and in compliance with all Federal and State documentation requirements.
 - SR.2 – Abuses and losses of controlled substances must be reported, in accordance with applicable Federal and State laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate.

DNV

Medication Management

- Accountability procedures to ensure control of the distribution, use, and disposal
- Ability to trace the process for moving scheduled drugs throughout the service from the point of entry into the hospital to the point of departure either through administration to the patient, destruction or return to the manufacture
- Identify the pharmacist responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and reconciled
- Accounting of all scheduled drugs and any discrepancies in count are reconciled promptly
- Capability to readily identify loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual loss or diversion to the time of detection and determination of the extent of loss or diversion

DNV

Physical Environment

- PE.4 – Security Management System
 - SR.1 The hospital shall develop a Security Management System that provides for a secure environment

DNV

Quality Management System

- QM.1 – Quality Management System
 - The governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring that the hospital implements and maintains an effective quality management system. This quality management system shall ensure that corrective and preventive actions taken by the hospital are implemented, measured and monitored
 - SR.1
 - The hospital shall implement hospital-wide quality assessment and performance improvement efforts to address priorities for improved quality of care and patient safety and that corrective and preventive actions are implemented and evaluated for effectiveness.

| DNV

Quality Management System

- QM. 7 – Measurement, Monitoring, Analysis
 - Measurement, monitoring and analysis of processes throughout the organization requires established measures that have the ability to detect variation, identify problem processes, identify both positive and negative outcomes, and effectiveness of actions taken to improve performance and/or reduce risks. The governing body of the organization must define the frequency and detail of the measurement.
 - SR.2 – Medication therapy/medication use; to include medication reconciliation, high risk drugs, look alike- sound alike medications, and the use of dangerous abbreviations;
 - SR.7 – Effectiveness of pain management system

Audience Poll Question #2 of 4

For which TJC standard is failure to address diversion often cited as a reason for non-compliance?

- a. EC.02.01.01
- b. MM.03.01.01
- c. MM.04.01.01
- d. PI.01.01.01

Why Do These Standards Matter?

CMS & Federal Regulations

Medicare/Medicaid Conditions of Participation

- §482.13(c) (2) – safe care setting
- §482.21 – quality improvement program
- §482.21(a) (2) – performance tracking / assessment of care and operations
- §482.21(b) (2)(ii) – data collection for PI
- §482.21(c) (2) – analyze cause and implement preventative measures of events and errors
- §482.21(e) (1) - ongoing program for quality improvement and patient safety
- §482.23(c) – preparation of drugs
- §482.24(c) – medical record
- §482.25(a) – pharmacy management and administration
- §482.25(a) (3) - Current and accurate records must be kept of the receipt and disposition of all scheduled drugs

- **Title 21 United States Code (USC) Controlled Substance Act (CSA)**

Common Risk Points



Procurement

**Preparation and
Dispensing**

Prescribing

Administration

**Waste and
Removal**



Georgia health system paying \$4.1M to settle opioid diversion claims

AUTHOR
[Meg Bryant](#)

PUBLISHED
May 18, 2018

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Dive Brief:

- In the largest settlement of its kind involving a hospital, Effingham Health System has agreed to pay the U.S. \$4.1 million for alleged large-scale diversion of opioids, according to the Drug Enforcement Administration.
- The DEA launched the investigation in 2017 after receiving reports of missing tablets and possible diversion at the Springfield, Georgia-based health system. The inquiry turned up tens of thousands of missing oxycodone 30 mg tablets spanning back more than four years.
- Effingham failed to notify authorities of the suspected diversion within the time proscribed by federal law, the DEA said.

Monday, September 28, 2015

Resolve Drug Diversion Allegations

and involving allegations of drug diversion at a hospital, agreed to pay the United States \$2.3 million to resolve employees to divert controlled substances for personal use. In settlement, MGH has agreed to implement a comprehensive plan to address future diversions.

special responsibility to ensure that controlled substances are not used for non-medical uses," said U.S. Attorney Carmen M. Ortiz. "This diversion contributes to potential illegal drug sales, and fuels the opioid epidemic in the Commonwealth. We commend MGH for disclosing and taking steps to ameliorate future diversion by hospital

prescription

patient
s found to have
done, on 85

The Cost of Non-Compliance

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Outbreak of hepatitis C virus infection associated with narcotics diversion by an hepatitis C virus–infected surgical technician

Amy E. Warner, MPH^{a,*}, Melissa K. Schaefer, MD^b, Priti R. Patel, MD, MPH^a, Jan Drobeniuc, MD, PhD^c, Guoliang Xia, MPH, MD^d, Yulin Lin, MD^d, Yury Khudyakov, PhD^d, Candace W. Vonderwahl, BA, BS^a, Lisa Miller, MD, MSPH^a, Nicola D. Thompson, MS, PhD^e

PlumX Metrics

DOI: <https://doi.org/10.1016/j.ajic.2014.09.012> | [Check for updates](#)

Article Info

Abstract Full Text Images References

Background

Drug diversion by health care personnel poses a risk for serious patient harm. Public health identified 2 patients diagnosed with acute hepatitis C virus (HCV) infection who shared a common link with a hospital. Further investigation implicated a drug-diverting, HCV-infected surgical technician who was subsequently employed at

PubMed [Advanced](#)

1;67(6):845-853. doi: 10.1093/cid/ciy193.

Outbreak of Hepatitis C Virus Associated With Drug Diversion by a Healthcare Technician.

Warner AE¹, Schaefer MK², Patel PR^{1,2}, Drobeniuc J³, Xia G⁴, Lin Y⁴, Khudyakov Y⁴, Vonderwahl CW¹, Miller L¹, Thompson ND⁵, Adamski C¹, Dionne-Odom J^{1,2}, Talbot EA^{1,2}, Gao F¹, Cavallo SJ¹, Hansen K¹, Mahoney JC¹, Metcalf E¹, Loring C¹, Bean C¹, Camili S³, Montero JT¹; New Hampshire and Centers for Disease Control and Prevention Investigation Teams.

On May 2012, the New Hampshire (NH) Division of Public Health Services (DPHS) was notified of 4 persons with newly diagnosed hepatitis C virus (HCV) infection at hospital X. Initial investigation suggested a common link to the hospital cardiac catheterization unit because the infected persons included 3 CCL patients and a CCL technician. NH DPHS initiated an investigation to identify the source and control the outbreak.

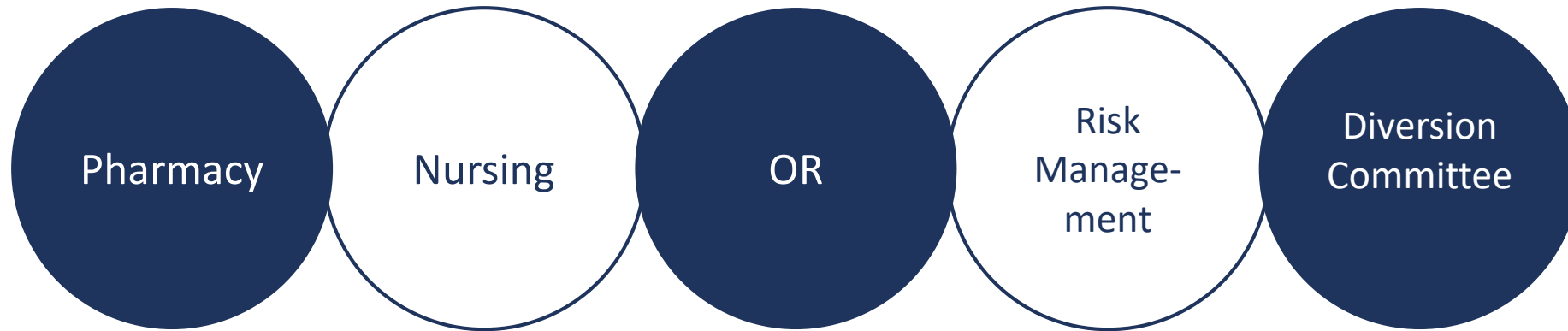
One patient was infected with the bacterium *Serratia marcescens*, the hospital

said in a Dec. 23 statement. "Further investigation showed that in five patients, the infectious agent was genetically identical. One of those patients died."



Compliance Stakeholders

Stakeholders



Controlled substance monitoring and surveillance rely on the availability and use of data and information, including timely access to actionable reports that support an effective surveillance and detection system.



| Goals

Shared Intent

The goals of all stakeholders ultimately are aligned

- Regulations
 - Patient safety
 - Organizational safety
 - Employee Safety
- Institution
 - *Comply with regulations*
 - Patient safety
 - Organizational safety
 - Employee safety

| From Regulations to Action – Keep Goals in Mind

Regulations

Institutional Policy
and Procedure

Accountability

| How?

Aligning Regulations with Action

- Efficient software solutions to meet regulatory stipulations to allow focus on the goals
 - Shared governance among all bodies guides a solution
- Automation and Trending
 - Accurate records
 - Retrievable
 - Ability to report loss
 - Robust data models
 - Actionable insights
 - Focus attention and reviews on process improvement
 - Patient safety
 - Employee safety
 - Organizational safety

Audience Poll Question #3 of 4

Which is the most important stakeholder group for addressing regulatory compliance around drug diversion?

- a. Pharmacy
- b. Executive Leadership
- c. Nursing
- d. All of the above

Audience Poll Question #4 of 4

Which strategy is not a preferred option for driving a substantive diversion detection and mitigation program?

- a. Data modeling and software platform(s)
- b. Organizational stakeholder alignment
- c. Pharmacy owns responsibility as the experts
- d. Using a shared goals framework for regulatory compliance pull through

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Thank you...

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