



Controlled Substance Diversion Auditing

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Learning Objectives

1. Gain an understanding of key regulations and enforcement trends related to controlled substances (CS).
2. Identify key areas and activities particularly at risk for diversion along with associated controls.
3. Share approaches, tools and methodologies to effectively audit an organization's CS management program.

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Key Regulations

The Controlled Substances Act (21 USC Section 801 et seq)

- Security, record keeping and valid prescription requirements

Regulation and enforcement

- Department of Justice, Drug Enforcement Agency, Office of Inspector General, Centers for Medicare and Medicaid Services

State Regulations and Agencies

- Boards of Pharmacy, Attorneys General

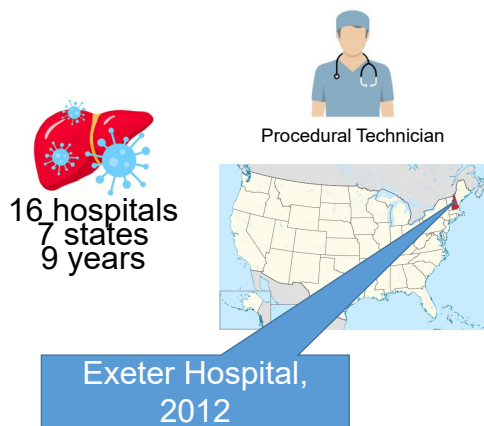
[U.S.C. Title 21 - FOOD AND DRUGS \(govinfo.gov\)](https://www.govinfo.gov)

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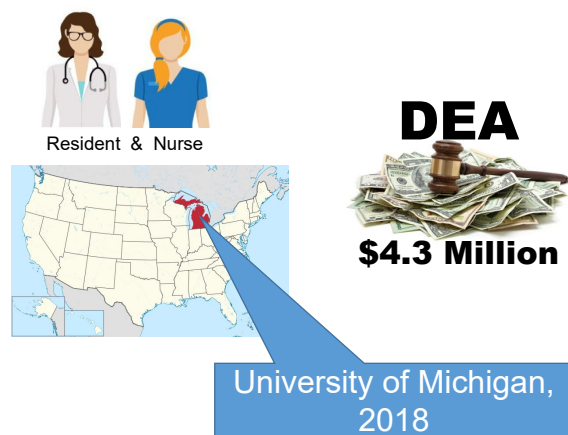
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The Stories

Multistate Hepatitis C
Outbreak



Tragic Overdoses

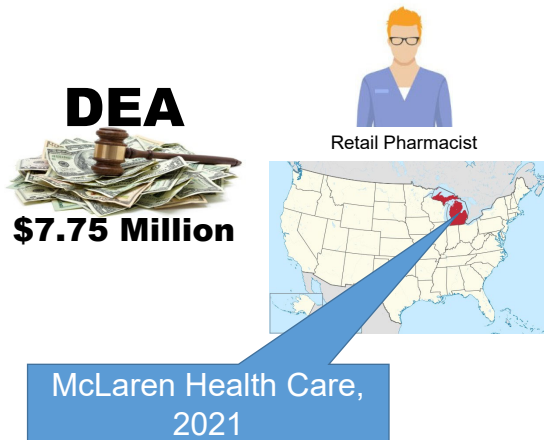


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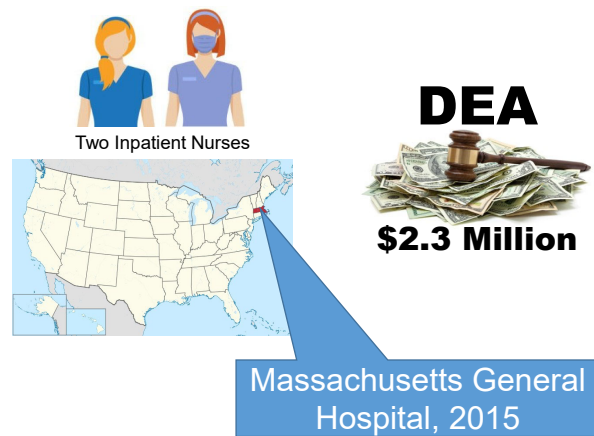
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The Stories

CS Distributed to
Unregistered Locations



>16,000 Missing CS



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Key Takeaways: Diversion

- Impacts patients, employees, and organizations
- Occurs across healthcare disciplines/roles, service location, and points along the medication use process
- Events often uncover opportunities for improvement in organizational regulatory compliance
- May result in large fines, and costly, multi-year corrective action plans

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Risk Lens

- Products – Schedule II's, opioids, fast movers
- Job functions – nursing, pharmacy, receiving, facilities
- Be alert to guests, visitors and onsite vendors
- Consider mitigating controls:
 - Segregation of duties
 - Background checks and drug screening
 - Physical security (e.g., secure areas, cameras, badges, biometrics, locks)
- Be alert to behavioral cues

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Controlled Substance Use Process

Process Stage	Diversion Method Examples	Control Examples
Procurement	Excessive, unauthorized ordering Purchase orders & packing slip records destroyed	Separate purchase & receiving roles Audit & reconcile inventory against records

References: Fan et al, 2019; Clark et al, 2022

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Approaches to Auditing Procurement

- Trace and Reconcile
 - Purchase Order / Invoice
 - Receipt at Dock
 - Loaded to Controlled Substances Manager (CSM)
- Reconcile DEA Forms
 - Form 222 (transfer of controlled substances)
 - Form 106 (theft or loss)
 - Form 41 (breakage, damage, spillage)

Considerations:

- Purchase volumes and product mix

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Controlled Substance Use Process

Process Stage	Diversion Method Examples	Control Examples
Storage	Product container compromised/tampering	Limit access Utilize tamper-evident packaging Establish clear audit trails

References: Fan et al, 2019; Clark et al, 2022

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Approaches to Auditing Storage

- Inventory Counts – compare reported to actual (spot checks or full counts)
- CSM Exception Report - Left central vault but not logged into an automated dispensing machine (ADM), anesthesia cart, etc.
- Pick List Verification – Items removed from CSM verified by a pharmacist
- Mandated DEA Inventories – Documentation they're performed

Consider:

- Perform inventory checks with an observer
- Unannounced and/or blind counts (counter doesn't know expected quantity)
- Random or rotational versus risk based

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Controlled Substance Use Process

Process Stage	Diversion Method Examples	Control Examples
Prescribing	Unverified verbal orders Forgery & self-prescribing	Monitor & trend prescribing practices Security of paper & electronic ordering system

References: Fan et al, 2019; Clark et al, 2022

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Approaches to Auditing Prescribing

- Data analysis of prescribing patterns
 - Volume and mix of products
 - Longitudinal (spikes)
 - Versus peer group (specialty, patient volume, acuity, department)

Consider:

- Security and management of system access and prescription pads

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Controlled Substance Use Process

Process Stage	Diversion Method Examples	Control Examples
Preparation & Dispensing	Tampering & substitution of compounded/re-packaged products	Targeted assay testing of prepared products
	Removing overfill from vials/premixed solutions	Purchase unit-dose packages when possible

References: Fan et al, 2019; Clark et al, 2022

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Approaches to Auditing Preparation & Dispensing

- **Overrides** - inventory leaves cabinet without a corresponding order
 - Causes can be verbal orders or emergencies
 - Ensure orders otherwise documented
 - Compare to patient medication administration record

Considerations:

- Be alert to frequency of overrides and common denominators
- Risks around transfers, ambulance stocking, reverse distribution

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Controlled Substance Use Process

Process Stage	Diversion Method Examples	Control Examples
Administration	Tampering/theft of prepared drugs left unsecured	Maintain security, including infusions
	Falsification of patient documentation	Routine compliance rounds, include patients Monitor & trend utilization

References: Fan et al, 2019; Clark et al, 2022

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Approaches to Auditing Administration

- Dose Reconciliation – are withdrawals from inventory reconciled to patient medical records
 - Many systems interface allowing automated reconciliations

Considerations:

- Be alert to patient reported pain inconsistent with administered medications

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Controlled Substance Use Process

Process Stage	Diversion Method Examples	Control Examples
Waste/ Disposal	Expired CS diverted from holding area	Secure waste and expired drugs
	CS waste removed from unsecured receptacle	Waste prior to admin. whenever possible
	CS waste replaced with saline	Targeted assay testing of waste

References: Fan et al, 2019; Clark et al, 2022

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Approaches to Auditing Waste/Disposal

- Infusions – may require special analysis due to potential for volume variances. Compare Electronic Health Record (start time, end time, rate) to amount withdrawn from CSM.
 - Account for waste and natural volume variances in bags, pump rates, etc.

Considerations:

- Presence and physical security of waste receptacles

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CS Management Program Oversight

Conduct routine surveillance auditing, trend findings at defined intervals.

Overarching Surveillance Goals:

1. Identify employees with outlier behavior compared to peers, or a pattern of concerning performance.
2. Identify gaps in regulatory compliance

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Elements of an Effective Compliance Program Include

- Training and education
- Policies and procedures
- Auditing and monitoring
- Management oversight (e.g., compliance officer and committee)
- Effective lines of communication (e.g., hotline)
- Disciplinary guidelines
- Prompt investigation, remediation and corrective action

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Monitoring & Surveillance Cycle



ASHP Guidelines on Preventing Diversion of Controlled Substances, American Journal of Health-System Pharmacy, Volume 74, Issue 5, 1
March 2017, Pages 325-348, <https://doi.org/10.2146/ajhp160919>

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Approaches to Program Oversight

- Engage leaders across disciplines and at every level in chain of command
- Leverage automation & technology
 - Third-party analytics programs offer efficiencies in longitudinal tracking of large data sets across multiple performance indicators
- Conduct on-site regulatory tracers at routine intervals to assess practices and documentation in person

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References

1. Fan et al, 2019, Diversion of Controlled Drugs in Hospitals: A Scoping Review of Contributors and Safeguards, Vol. 14, No. 7, p. 419 – 428
2. Clark et al, 2022, ASHP Guidelines on Preventing Diversion of Controlled Substances, <https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/preventing-diversion-of-controlled-substances.ashx>
3. ASHP Guidelines on Preventing Diversion of Controlled Substances, American Journal of Health-System Pharmacy, Volume 74, Issue 5, 1 March 2017, Pages 325–348, <https://doi.org/10.2146/ajhp160919>

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