


Did someone say
DIVERSION? What to
do when controlled
substances go missing.

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1



Disclosure

*I do not have any relevant personal,
professional or financial relationships
with respect to this educational activity.*

2

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Objectives

- Don't panic! What to do first—let's discuss how to review the situation and determining next steps.
- After the first 24 hours...regulator reports are filed, what are next steps? Interviews, investigations, audits, and immediate actions.
- The aftermath, what happens with the dust settles? Implementing corrective actions, working with regulators, and finding ways to proactively detect diversion.

3

3



Take a deep breath

- Don't panic

4

4

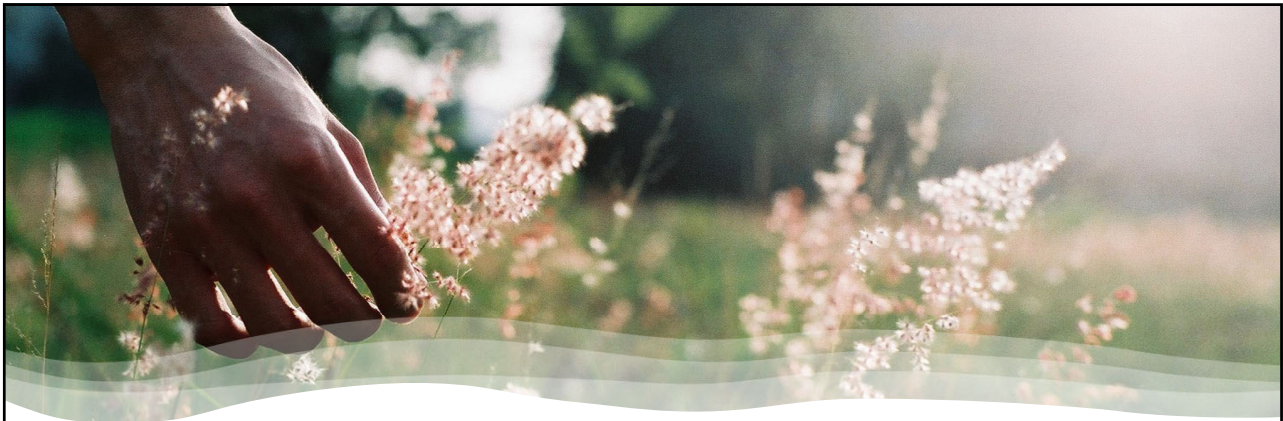
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Initial thoughts...

- What's thought to be missing?
- Are their remaining drugs in the cabinet?
- Are they secured?
- How was it discovered?
- Who discovered it?
- Do you know who took them?
- Is this a diversion?
- Are there safety concerns?

5

5



Take a deep breath

- Don't panic

6

6

What security measures need to be taken?



TAKE PICTURES



SECURE CONTROLLED
SUBSTANCES



SECURE THE CONTROLLED
SUBSTANCES CABINET

7

7

Initial Steps

1

Initial audit/review of
substances/documentation

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Determine
reporting/preliminary
reporting obligations

- DEA: 1 business day
- State: MA=24 hours

3

Internal reporting

- Senior leadership
- Departmental leadership
- PI
- Human Resources
- Police & Security
- Diversion task force

8

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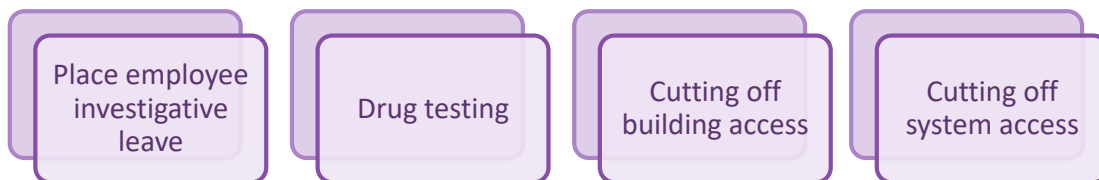
Contacting Police & Security



9

9

Get Human Resources Involved



10

10

Drug Diversion Task Force

...or something like this

- Usually, a multidisciplinary group that evaluates diversions (see mostly on clinical side)
 - Physician
 - Nurse
 - Risk Management
 - Police & Security
 - Pharmacy
 - Compliance
 - HR



11

What about the employee?

Resources

- Employee Assistance Programs
- Employee Health
- Mental Health Referrals
- Other Community Resources

12

12



Take a deep breath

Prepare for Round 2

13

Taking a Deeper Dive

- **Make a Plan**
 - What is the time sensitivity
 - Who needs to be involved
 - Who needs to be interviewed
 - Collection of evidence
 - Review of documentation
 - Presenting the findings
 - Maintaining confidentiality

14

Time Sensitivity



INTERVIEWS WITH
REGULATORS



FOLLOW-UP REPORTING



SELF-IMPOSED VS. REGULATOR
DRIVEN TIMELINES

15

15

Who needs to be involved?

Expertise	Do you need a specific expertise (OGC, IT, etc.)
Access	Do you need access to data, reports, documentation, etc.
Holds	Do you need legal holds (email, share drives)
External Services	Do you need external services (outside counsel, forensic work)
Help!	Do you just need more hands

16

16

Who needs to be interviewed?



Do you need to consider the order of the interviews



Location of interviews



Who will do the interview(s)



Documentation of interviews



What questions need to be asked



17

17

What evidence needs to be collected?

- Camera footage
- Badge access reports
- Logbooks
- Inventories
- Other documentation (DEA 41 Forms, DEA 106 Forms, DEA 222 Forms, Power of Attorney, State Forms, etc.)
- Items/tools used for “break-in”

18

18

What to review for the audit?

Full audit of documentation

- Authorized User Log
- Disposition log
- Biennial inventory
- Disposal slips (DEA 41)
- Packing slips
- Loss/Stolen (DEA 106)
- DEA 222 forms/Power of Attorney
- Any other helpful documentation
 - IACUC Reports
 - Previous audits



19

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19



What to give to regulators?

- Know the whole story
- Provide same information to both the state and DEA
- 3-Ring binder
 1. DEA registration
 2. State registration
 3. List of Authorized Users
 4. Lab floorplan with safe location indicated
 5. Diversion calculations
 6. Logbook copies
 7. DEA 106 Loss or Stolen Report
 8. State loss/stolen reporting form
 9. Any follow-up reports
 10. DEA 41 forms
 11. Internal purchasing records
 12. Police report (if required)
 13. Photographs
 14. Org Chart

20

20

Onsite Inspections

Prep for the visit

- Consult with your Office for General Counsel
- Provide talking points
- Corrective actions that have already taken place

DEA

- Many times will take lead
- Will come onsite for inspection
- Provide 3-ring binder
- Have appropriate stakeholders/institutional officials at meeting

State

- Provide same documentation as DEA
- May do onsite investigation/inspection
- Provide 3-ring binder
- Have appropriate stakeholders/institutional officials at meeting

21

21

Institutional Corrective Actions



TRAINING



BETTER
SECURITY



FREQUENT
MONITORING



CHANGE IN
PRACTICE

22

22

Regulator Corrective Actions

Potential Regulator Actions

- Loss/suspension of registration
- Restrictions on registration
- Reporting obligations
- Additional audits

Responding to Regulators

- Be consistent between State and Federal
- Help with response

23

23

Preventing Future Diversions



Institutional Training



Resources



Key Lock Boxes



Proactive Audits

24

24



Who do you train?

- Everyone!
- Departments
- Standard research meetings
- Newsletters
- Quarterly discussion groups
- Mandatory training
- One-on-one training
- Webpages

25

25

Questions?

Thank you for attending HCCA!

26

26

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