Controlled Substances Considerations for Mobile Integrated Health

Presented By

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About Me

- I am not an attorney
- I am not a pharmacist
- I have 27+ years in healthcare,
  - 24 years as a Paramedic, 23 as a Registered Nurse
- I am a trained investigator
- I am a compliance professional
- I love our industry
- I want to help you protect our teams and your programs

Agenda

- History of Opium in the United States
- Opioid Use Disorder
- Healthcare Provider Statistics
- Healthcare Team Considerations
- DOJ Guidance
- Regulations
- Strategies
- Diversion
- System Design
- Vulnerabilities

The Storied History of Opium

3400 BC: Opium was first cultivated in Mesopotamia. *Hul Gil "joy plant"*

1200s AD: Opium is introduced to Far East and Europe.

1500s AD: Paracelsus introduces opium to Western medicine.

1700s AD: Thomas Sydenham introduces Laudanum, an opium, wine, and herb compound.

1806 AD: Morphine (named after Morpheus, the god of dreams) is isolated from opium.

1800s AD: Paracelsus introduces opium to Western medicine.

1900s AD: Harrison Narcotic Act of 1914 regulating medical opium.

(DEA Museum, 2017)
(PBS.org, n.d.)

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Opioid Use Disorder

In 2020, opioid deaths rose nearly 30% from 2019
(CDC.gov, 2021)

As with other addictions, both genetic factors and environmental factors, such as ease of access, contribute to the risk of opioid use disorder (American Psychiatric Association, 2021).

Predisposing factors:
1. Poor social support
2. Psychological stress
3. Psychological trauma
4. History of legal problems
5. Childhood adversity
6. Financial strain
(Webster, 2017)

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Healthcare Provider Statistics

- How many healthcare providers suffer from some form of mental health or substance use disorder?

- 10-15% of the US population suffers from some form of substance use disorder (U.S. HHS, 2015)

- 26% of the US populations suffers from a diagnosable mental health disorder (Johns Hopkins Medicine, 2021)

- Dual Diagnosis

Healthcare Team Considerations

Mental Heath Disorder

- Chronic and Acute Occupational Stress
- Unhealthy Coping Mechanisms
- Lack of Social Support
- Lack of Safety and Support (real or perceived)
- Demanding Schedules

(SAMHSA, 2018)

Substance Use Disorder

- 10-15% of the US healthcare population will misuse substances during their career (Baldisseri, 2007).

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Healthcare Team Considerations

Mental Health + Substance Use = Suicide

- People suffering from Mental Health Disorder are more susceptible to addiction (NIH, 2020)

- Dual diagnosis of a mental health disorder and addiction are at significantly higher risk (Lessier, 2021)

- EMS providers are 1.39 times more likely to die by suicide than the public and these deaths are likely underreported (Tiesman, et. al., 2021)

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DOJ Guidance

- 2020 DOJ Compliance Program Guidance

- This is not a compliance lecture, but DEA compliance is an important (and a high risk) aspect of your larger compliance program

- What is DOJ looking for?

"the adequacy and effectiveness of the corporation's compliance program at the time of the offense, as well as at the time of charging decision."

Three Questions:

"Is the corporation's compliance program well designed?"
"Is the program being applied earnestly and in good faith?"
"Does the corporation's compliance program work?"

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Regulations

- Federal 21 CFR 1300-end

- State regulations are very important considerations

- Registration, procurement, storage, transfer, inventory, use, destruction

- No EMS specific rules in the Federal Regs (yet) so be careful

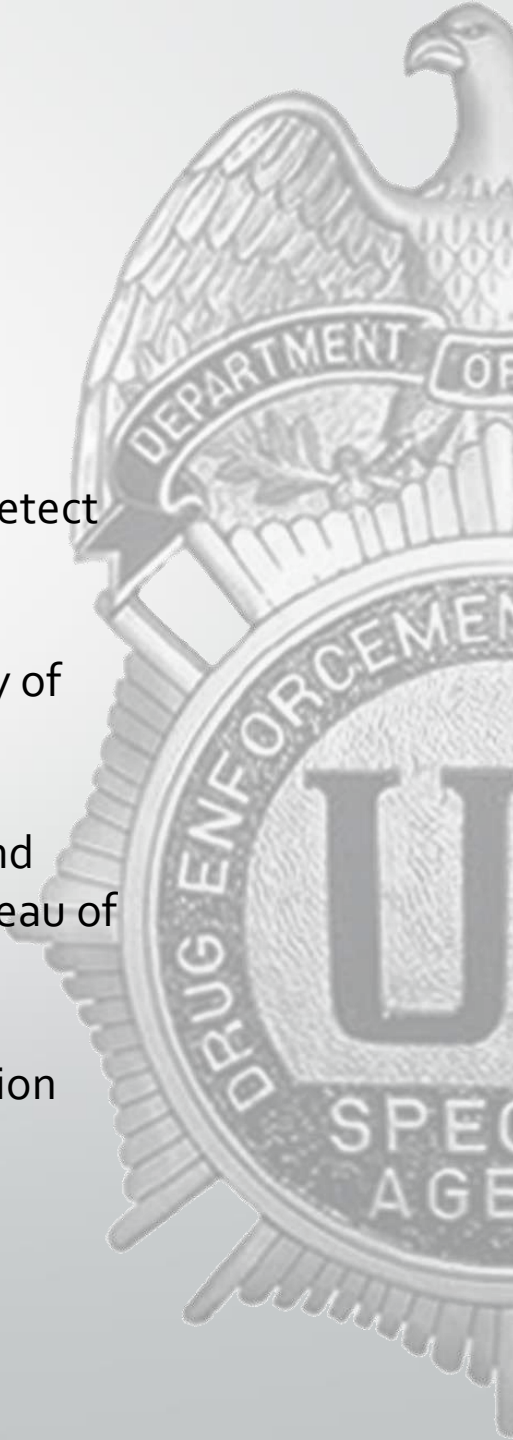- We have adapted healthcare regulations to meet EMS operations

Strategies

- **Monitoring** – How and where do you look to detect diversion? You can't find it if you're not looking

- **Indicators** – What are some common tells of diversion?

- **Opportunity** – How can we minimize opportunity to divert?

- **Risk** = Probability of a threat agent successfully exploiting a vulnerability

- **System Design** – Build a comprehensive system to minimize vulnerabilities
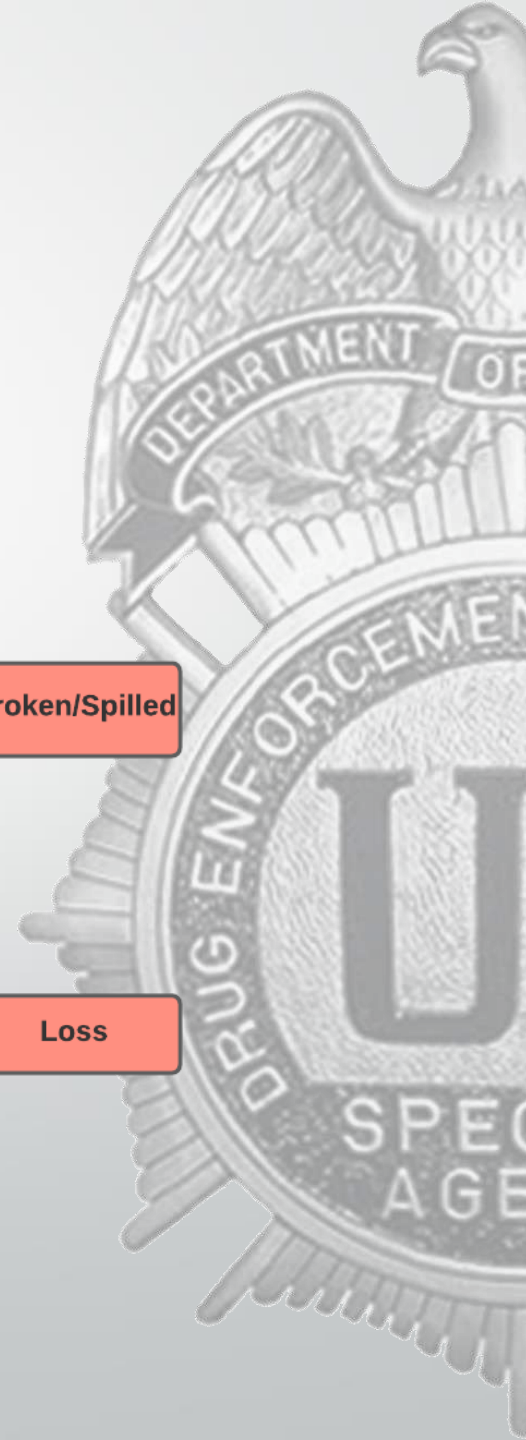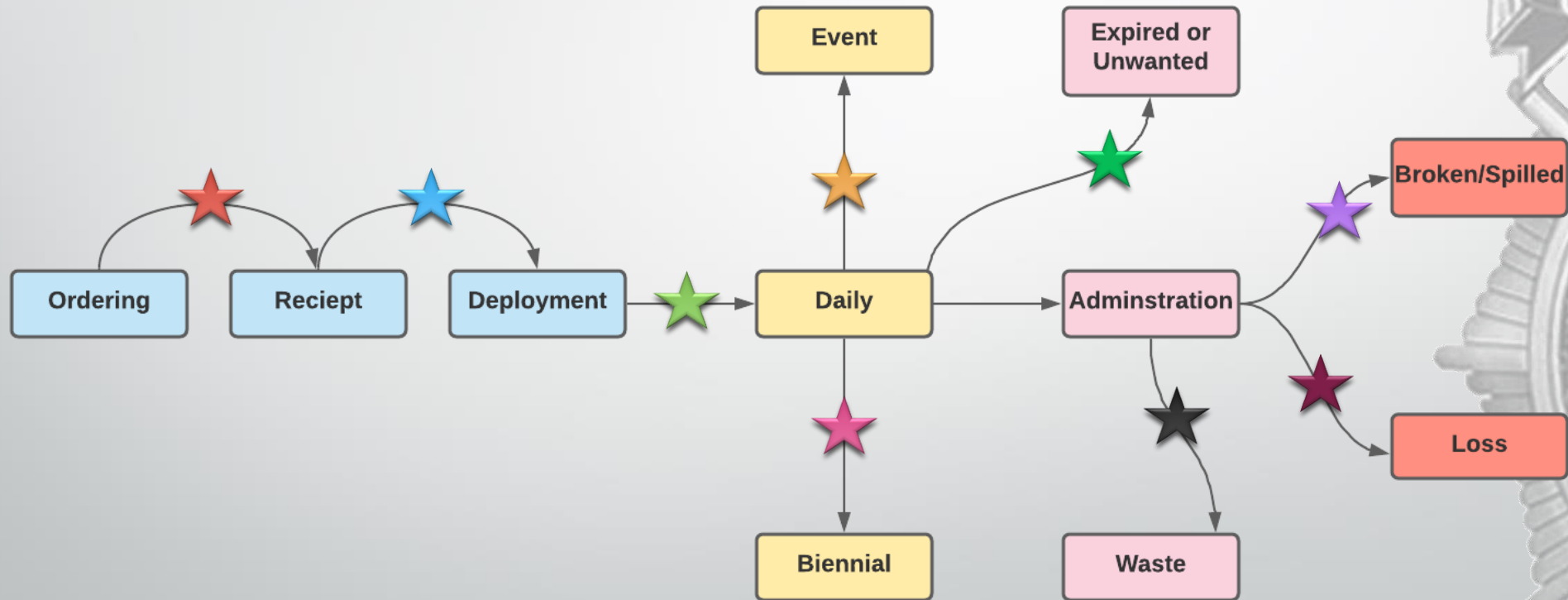
Diversion

- **Detection** – Programs should have strategies and procedures in place to detect diversion, but to do that, you need to know where to look.

- **Investigation** – The investigation of detected diversion is the responsibility of the program leadership, including compliance office

- **Reporting** – Diversion of controlled substances is reportable to the DEA and may also require notification to state regulators, boards of licensure, bureau of EMS, etc. Be sure to know your reporting requirements.

- **Mitigation-** Develop tactics, techniques, and procedures to prevent diversion before it occurs

System Design

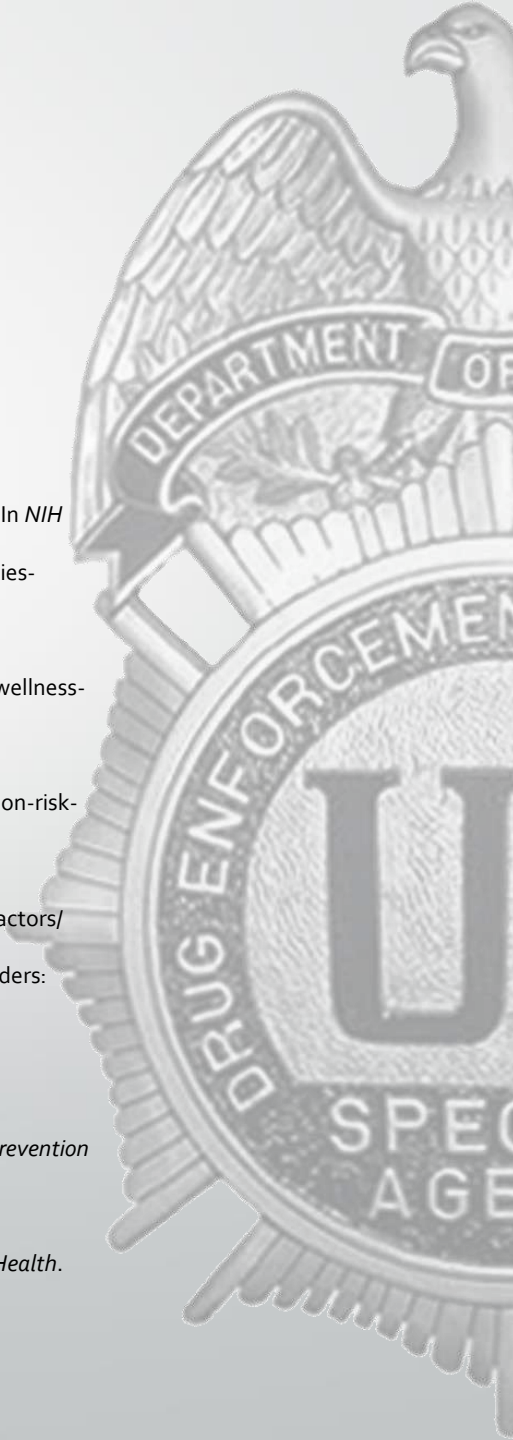Remember: **RISK = THREAT * VULNERABILITY**

Vulnerabilities

★ Is the same person who orders also the person who intakes?

★ Is the person stocking the safe doing so alone?

★ How are the operational kits restocked?

★ Are the vials handled during daily inventory? How are they stored?

★ Are you meeting your biennial inventory requirement?

★ How are you disposing of expired or unwanted?

★ What is your wasting procedure?

★ How do you manage a vial that breaks or a syringe that leaks?

★ How do you manage a vial that is lost (unaccounted for)?

References

American Psychiatric Association. (2021). Opioid Use Disorder. In *Addiction and Substance Use Disorder*. Retrieved from https://www.psychiatry.org/patients-

families/addiction/opioid-use-disorder

Baldisseri, M. R. (2007). Impaired Healthcare Professional. *Critical Care Medicine*, *35*(2), S106-S116. Retrieved from

http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.423.1845&rep=rep1&type=pdf

Cannabis, Coca, & Poppy: Nature‚Äôs Addictive Plants. (2017, November). In *DEAMuseum.org*. Retrieved from https://www.deamuseum.org/ccp/opium/history.html

Common Comorbidities with Substance Use Disorders Research Report Why is there comorbidity between substance use disorders and mental illnesses?. (2020, April). In *NIH*

National Institute on Drug Abuse; Advancing Addiction Science. Retrieved from https://www.drugabuse.gov/publications/research-reports/common-comorbidities-

substance-use-disorders/why-there-comorbidity-between-substance-use-disorders-mental-illnesses

Johns Hopkins Medicine. (2021). Mental Health Disorder Statistics. In *Johns Hopkins Wellness and Prevention*. Retrieved from https://www.hopkinsmedicine.org/health/wellness-

and-prevention/mental-health-disorder-statistics

Lessier, B. (2021, March 22). Suicide Risks Due to Suicidal Depression. In *Dualdiagnosis.org*. Retrieved from https://dualdiagnosis.org/depression-and-addiction/depression-risk-

suicide/

Risk and Protective Factors. (n.d.). In *American Mental Wellness Association*. Retrieved from https://www.americanmentalwellness.org/prevention/risk-and-protective-factors/

SAMHSA Substance Abuse and Mental Health Services Administration. (2018, May). Disaster Technical Assistance Center Supplemental Research Bulletin First Responders:

Behavioral Health Concerns, Emergency Response, and Trauma. In *SAMHSA.gov*. Retrieved from

https://www.samhsa.gov/sites/default/files/dtac/supplementalresearchbulletin-firstresponders-may2018.pdf

Tiesman, H. M., Elkins, K. I., Brown, M., Marsh, S., & Carson, L. M. (2021, April 6). Suicides Among First Responders: A Call to Action. In *Centers for Disease Control and Prevention*

NIOSH Science Blog. Retrieved from https://blogs.cdc.gov/niosh-science-blog/2021/04/06/suicides-first-responders/

U.S. Department of Health & Human Services. (2015, November 18). 10 percent of US adults have drug use disorder at some point in their lives. In *National Institutes of Health*.

Retrieved from https://www.nih.gov/news-events/news-releases/10-percent-us-adults-have-drug-use-disorder-some-point-their-lives

Webster, L. R. (2017, November). Risk Factors for Opioid-Use Disorder and Overdose. *Anesthesia & Analgesia*, *125*(5), 1741-1748. doi:10.1213/ANE.0000000000002496

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Handy Resources

U.S. Department of Justice, Criminal Division, Evaluation of Corporate Compliance Programs (Updated June 2020)
https://www.justice.gov/criminal-fraud/page/file/937501/download

DEA Diversion Control Division, Title 21 Code of Federal Regulations, Part 1300-End
https://www.deadiversion.usdoj.gov/21cfr/cfr/index.html

DEA EMS Regulations, Notice of Proposed Rulemaking
https://www.federalregister.gov/documents/2020/10/05/2020-21675/registering-emergency-medical-services-agencies-under-the-protecting-patient-access-to-emergency

HHS Practical Guidance for Healthcare Boards on Compliance Oversight
https://oig.hhs.gov/compliance/compliance-guidance/docs/Practical-Guidance-for-Health-Care-Boards-on-Compliance-Oversight.pdf

HCCA Measuring Compliance Program Effectiveness: A Resource Guide
https://assets.hcca-info.org/Portals/0/PDFs/Resources/ResourceOverview/oig-hcca-roundtable.pdf?ver=2017-03-28-062709-153

Air Medical Journal: Controlled Substances Compliance for Transport Programs
https://www.sciencedirect.com/science/article/abs/pii/S1067991X19300549