



COUNCIL OF STATE AND TERRITORIAL EPIDEMIOLOGISTS

Healthcare-Associated Infections (HAI) Drug Diversion Planning and Response Toolkit for State and Local Health Departments



Council of State and Territorial Epidemiologists
HAI Subcommittee, Drug Diversion Workgroup

June 2019

Table of Contents



Contributors and Acknowledgments	5
Abbreviations	7
Toolkit Introduction	9
Partners to Engage	11
Methods to Identify and Respond to Drug Diversion Events	15
Patient Notification Following Drug Diversion and Tampering Events ..	21
Guidance for patient notification	
Example templates from state and local health departments	
Legal Considerations	23
Federal requirements for healthcare facilities	
Legal consideration	
Preventing Drug Diversion	25
Conclusion	27
References	29
Appendix 1: Additional Technical Resources	31
Appendix 2: Drug Diversion and Tampering Interview (Sample)	33
Appendix 3: Sample Script for Phone Call to Pursue HCP	
Blood-borne Pathogen Testing in Connection with Drug	
Diversion	41



Table of Contents

Appendix 4: Sample Patient Notification Letters43
Appendix 5: Sample State Laws Pertaining to Drug Diversion51
Appendix 6: Healthcare Facility Measures to Address Patient Safety Following Healthcare Personnel (HCP) Drug Diversion53
Appendix 7: Drug Diversion and Tampering Frequently Asked Questions (Sample)55
Appendix 8: Drug Diversion Surveillance and Reporting for Healthcare Facilities57

Contributors and Acknowledgements



The Council of State and Territorial Epidemiologists (CSTE) thanks the following individuals for their Contributions to this toolkit:

April Burdorf, RN, BSN, MPH, CIC, Colorado Department of Public Health and Environment

Nicole Spencer Bryan, MPH, CPH, CIC, (Former) CSTE

Jeffrey Eason, MPH, Utah Department of Health

Alana Cilwick, MPH, Colorado Department of Public Health and Environment

Katrina Hansen, MPH, New Hampshire Department of Health and Human Services,
Division of Public Health Services

Jessica Helms, (Former) CSTE

Jason Mehr, MPH, CIC, New Jersey Department of Health

Lynne Mercedes, BA, Georgia Department of Public Health

Kim New, JD, BSN, RN, Diversion Specialists, LLC

Michael Anderson, MPH, (Former) CSTE

Michelle Brown, BA, CSTE

Julie Reagan, Ph.D., JD, MPH, Jiann-Ping Hsu College of Public Health,
Georgia Southern University

Puja Shah, MPH, CLSSGB, CSTE

Pamela Talley, MD, MPH, Tennessee Department of Health

Roza Tammer, MPH, CIC, Oregon Health Authority, Public Health Division

Katie A. Thure, MPH, Tennessee Department of Health

Mary Beth Wenger, New York State Department of Health

Acknowledgements:

Joseph F. Perz, DrPH MA, CDC, Division of Healthcare Quality Promotion

Matthew B Crist, MD, MPH, CDC, Division of Healthcare Quality Promotion

We also thank the following groups for sharing their materials and expertise: state and local health departments, the Centers for Disease Control and Prevention, the CSTE Healthcare-Associated Infections Subcommittee, HONORreform, National Association of Drug Diversion Investigators, and International Health Facility Diversion Association.

For questions about these guidelines, please contact:
Council of State and Territorial Epidemiologists
2635 Century Pkwy NE, Suite 700 Atlanta, GA 30345
Tel: 770.458.3811 | Fax: 770.458.8516

Abbreviations



APIC: Association for Professionals in Infection Control and Epidemiology
ASTHO: Association of State and Territorial Health Officers
BBP: Blood-borne pathogen
CDC: U.S. Centers for Disease Control and Prevention
CMS: Centers for Medicare and Medicaid Services
CORHA: Council for Outbreak Response: Healthcare-Associated Infections and Antimicrobial-Resistant Pathogens
CSTE: Council of State and Territorial Epidemiologists
DEA: U.S. Drug Enforcement Administration
EMT: Emergency Medical Technician
EOC: Emergency Operations Center
FDA: U.S. Food and Drug Administration
HAI: Healthcare-associated infection
HBV: Hepatitis B virus
HCP: Healthcare personnel
HCV: Hepatitis C virus
HIV: Human immunodeficiency virus
NACCHO: National Association of City and County Health Officers
OCI: FDA Office of Criminal Investigations
PCA: Patient-controlled analgesia

Toolkit Introduction



Drug diversion is defined as “any criminal act or deviation that removes a prescription drug from its intended path from the manufacturer to the patient,” including everything from outright theft of the drug to doctor shopping, prescription forging, manufacture or sales of counterfeit drugs and international smuggling.¹

While any medication may be involved in a diversion event, some drugs are more commonly targeted than others:²

- Anti-anxiety medications and sedatives, including benzodiazepines
- Prescription pain medications, including opioids
- Stimulants, including those used to treat attention deficit disorder and narcolepsy
- Sleep aids
- Anesthetics, such as Propofol

These high-value medications are often sought for their particular psychoactive effects, and many are habit-forming. Although some of these drugs are controlled substances—and thus subject to greater federal regulation—some are not.

The current widespread use of prescription opioids, and many users’ addiction to these drugs, is a major driver of drug diversion.² According to the Office of National Drug Control Policy, prescription medication abuse is the fastest growing drug problem in the United States. Substance use is an occupational, mental, and behavioral health issue, and, as such, affects healthcare personnel (HCP) as well as the general public.³ However, unlike the general public, HCP have relatively easy access to certain medications that are preferentially diverted, making it possible for them to divert prescription drugs intended for patient care.

Alarming, in 2007, the U.S. Substance Abuse and Mental Health Services

Administration estimated that an average of 103,000 doctors, nurses, medical technicians, and healthcare aides a year were abusing or dependent on illicit drugs.

HCP may divert drugs via several mechanisms:²

- False documentation (e.g., the medication is not administered to the patient, as indicated, or it is falsely listed as “wasted”)
- Scavenging wasted medication (e.g., removal of residual medication from used syringes or the trash) one could argue this does not fall under the definition of drug diversion since it is not in the pathway to the patient but is in the trash
- Theft by tampering (e.g., substituting medication in a container or syringe with a similar-looking substance, which may then be administered to patients in place of the intended drug)

And this diversion can harm patients in at least four ways:²

- Reduced quality of care given by impaired HCP
- Failure to receive essential medications, possibly resulting in pain and suffering
- Exposure to infectious agents
- Falsification of patient records which could lead to additional medication administered to the patient to make up for medication unknowingly not received

The last of these—exposure to infectious agents—is where public health agencies have the greatest opportunity to intervene. From 2004 to 2014, drug diversion by HCP resulted in over 100 documented patient infections with blood-borne pathogens (BBPs) or bacteremia. And nearly 30,000 U.S. patients were notified about possible infectious exposures or given recommendations for precautionary, follow-up testing.¹

Because safe injection practices may not be followed during diversion events, the greatest risk of patient exposure to infectious pathogens comes from *injectable* medications (including those administered intravenously), rather than oral or topical drugs. For example, a patient may be exposed to a used syringe. Thus, drug diversion can directly expose patients to human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV) or other BBPs.

Development and Use of This Toolkit

In 2014, the CSTE Healthcare-Associated Infections (HAI) Subcommittee convened the Drug Diversion Workgroup (Workgroup) to define the role of state, local, and territorial public health agencies in (1) investigating and responding to drug diversion events involving injectable medications and (2) determining risk for BBP transmission to patients. In October 2015, the Workgroup surveyed state and territorial health department HAI coordinators as part of a larger infection prevention and control assessment. The goal was to estimate the frequency of drug diversion events and to assess health agencies' response options and relevant regulatory authorities, reporting requirements and partner engagement.

The assessment was completed by 49 states and two territorial public health agencies. Between 2010 and 2014, 29 survey respondents (57%) had investigated drug diversion as part of an outbreak, an event with unknown disease transmission, or both. At least one event was investigated in 2010, eight in 2011, nine in 2012, 23 in 2013, and 24 in 2014, for a total of at least 65 known drug diversion investigations during that 5-year period. Sixteen responding agencies (31%) reported that state laws and regulations mandated the reporting of drug diversion events involving injectable drugs within their jurisdictions. Where reportable, most jurisdictions require the report be sent to healthcare facility licensing or inspection programs. Conversely, drug diversion was not reportable in 22 jurisdictions (43%).

Twenty-seven (53%) agencies indicated some level of preparedness to respond to a drug diversion event, although additional technical assistance, legal assistance and

staff were identified as needed resources. Nineteen agencies indicated they were not prepared to respond to a drug diversion event and would require additional staff training (18%) or budgeted resources (20%) to do so. Five agencies (10%) did not view drug diversion investigations as falling within their purview. Overall, respondents reported that effective prevention and control of drug diversion within healthcare facilities would require a broad range of additional resources, including investigation tools, model protocols, model laws and regulations, a policy toolkit, increased multidisciplinary outreach and collaboration, and recovery resources for HCP suffering from addiction. Collectively, these findings point to large gaps in public health capability and capacity for drug diversion prevention, detection, and response.

This toolkit is intended to help fill that gap by defining best practices, providing customizable resources informed by past drug diversion investigations and offering recommendations to enhance collaboration among public health agencies and partners representing regulatory affairs; law enforcement; healthcare facility licensing, certification and accreditation; HCP licensing, certification and credentialing; organizations addressing infection prevention and substance use; and both HCP and patients.

Due to the Workgroup's limited scope, this document does not address prevention, policy recommendations, addiction or recovery resources, working conditions, or healthcare monitoring and pharmacy surveillance systems—although the Workgroup recognizes that they are crucial elements of a multidisciplinary approach to HCP drug diversion. Instead, the toolkit is designed to be a living document that will be revised and supplemented over time. Similarly, while the toolkit focuses on injectable medications and BBPs—associated with the greatest risk from HCP drug diversion—the Workgroup recognizes that all forms of drug diversion carry risks, potentially involving other types of pathogens.

It is the Workgroup's hope that public health agencies will use this toolkit to develop drug diversion prevention and response strategies that are content-appropriate, adaptable and scalable, to meet their needs.

Partners to Engage



It is important for each public health agency to establish a list of partners and stakeholders who may be contacted as part of a drug diversion investigation, as well as a protocol for doing so. Table 1 lists examples of entities that may be engaged by public health when formulating prevention/response plans or responding to a drug diversion event. Each public health agency should determine appropriate partners based on its jurisdictional level, resources and legal environment, and develop contacts—ideally, specific individuals or departments—in advance of an event. The process of developing these contacts is a valuable activity itself, as it builds inter-agency connections, rapport, and a shared understanding of roles, enabling more effective and timely collaboration when action is needed. When a drug diversion event is detected, the scope of the investigation will influence which partners to involve. For example, if a state public health agency determines that HCP may have diverted medications while working in other states, it is important to contact the public health department in each potentially impacted state as soon as possible, so concurrent investigations may be launched.

Table 1 List of partners and stakeholders to engage in HCP drug diversion planning and response efforts.

Partners and Stakeholders	Planning	Response
Internal Stakeholders: Contact internal stakeholders within your agency or at other agencies within your jurisdiction prior to an event to determine their role in HCP drug diversion and to develop internal notification protocols. Contact internal stakeholders during an event as appropriate.		
Agency leadership (e.g., State Epidemiologist, infectious disease leads): <ul style="list-style-type: none"> Find state epidemiologists at: http://www.cste.org/default.asp?page=StateEpi. 		
Legal representation: <ul style="list-style-type: none"> Involve health department legal representation early in the investigation, particularly when parallel investigations are being conducted by law enforcement and other investigative agencies (e.g., information-sharing protocol). 		
Press/public information office (PIO): <ul style="list-style-type: none"> Involve the PIO early in an investigation because of possible media attention. 		
Viral hepatitis, HIV/AIDS, or STD epidemiology and prevention programs: <ul style="list-style-type: none"> Work with epidemiologists to develop protocols for assessing BBP infections through existing surveillance systems. Consider working with prevention programs, particularly disease intervention specialists, to conduct interviews with HCP suspected of drug diversion. 		
Healthcare-associated infections and antibiotic resistance (HAI/AR) prevention programs: <ul style="list-style-type: none"> HAI/AR programs may have resources, expertise, and partnerships that can be tapped during a drug diversion investigation. 		
<ul style="list-style-type: none"> Other local, city, or state health departments: Coordinate plans and response efforts with other health departments in the impacted jurisdiction(s). 		

Table 1 List of partners and stakeholders to engage in HCP drug diversion planning and response efforts.












Partners and Stakeholders	Planning	Response
External Public Health Partners: Contact state, local and city public health departments to determine their role in HCP drug diversion as part of the planning process.		
State public health departments:: <ul style="list-style-type: none"> Find state HAI contacts at: https://www.cdc.gov/hai/state-based/index.html Find state and territorial health officers at: http://www.astho.org/Directory/ 		
Local public health departments: <ul style="list-style-type: none"> Find local health departments at: https://www.naccho.org/membership/lhd-directory 		
Centers for Disease Control and Prevention (CDC): <ul style="list-style-type: none"> Division of Healthcare Quality Promotion: https://www.cdc.gov/nceizid/dhqp/index.html HAI webpage: https://www.cdc.gov/hai/ Drug Diversion webpage: https://www.cdc.gov/injectionsafety/drugdiversion/index.html Contact your CDC public health advisor at HAIR@cdc.gov Report HAI outbreaks at haioutbreak@cdc.gov 		
Council for Outbreak Response: Healthcare-Associated Infections and Antimicrobial-Resistant Pathogens (CORHA): <ul style="list-style-type: none"> Find resources to facilitate HAI/AR outbreak detection and investigation at: https://corha.org/resources-and-products/ 		
Law Enforcement and Other Agencies With Investigative Powers: Building relationships with law enforcement prior to an event is crucial for timely outbreak response and to elucidate roles and missions across disciplines. Prompt response to law enforcement agencies may prevent reoccurring drug diversion by the same HCP in other healthcare settings.		
State and local law enforcement agencies: <ul style="list-style-type: none"> State and local law enforcement agencies have the authority to investigate all crimes related to drug diversion. 		
U.S. Department of Justice, Drug Enforcement Administration (DEA): <ul style="list-style-type: none"> Find a list of DEA offices at: https://www.dea.gov/domestic-divisions Diversion Control Division: https://www.deadiversion.usdoj.gov/index.html Note that all manufacturers, distributors and dispensers of controlled substances in the U.S. are required to register with DEA and to notify DEA in writing (DEA Form 106) of the theft or significant loss of any controlled substances within one business day of discovery. Federal regulations (Title 21) also require employers and employees to report drug diversion. 		
U.S. Food and Drug Administration (FDA): <ul style="list-style-type: none"> Office of Criminal Investigations: https://www.fda.gov/iceci/criminalinvestigations/default.htm Emergency Operations Center (EOC): 866-300-4374 Note that drug diversion with tampering must be reported to the FDA EOC for referral to the agency's Office of Criminal Investigations (OCI) in accordance with the Federal Anti-Tampering Act. OCI's areas of enforcement include, but are not limited to, product tampering, product substitution crimes, illegal diversion of pharmaceuticals, adulteration and misbranding of medications, and Prescription Drug Marketing Act violations. If you suspect or have evidence that any of the above crimes have been committed or are currently occurring, contact OCI as soon as possible; it is not necessary for an investigation to be complete. 		

Table 1 List of partners and stakeholders to engage in HCP drug diversion planning and response efforts.












Partners and Stakeholders	Planning	Response
Professional Licensing Boards for HCP: Contact the relevant boards at your jurisdictional level prior to an event to determine their role in HCP drug diversion and ensure prompt reporting if a drug diversion event is identified. Note that the professions licensed by such boards vary by jurisdiction.		
Licensing boards for pharmacists, physicians, dentists, nurses, and medical technicians: <ul style="list-style-type: none"> Healthcare facility administrators and licensed HCP may be obligated to report alleged drug diversion violations to the appropriate board(s), depending on state laws and rules. Develop and share a contact list of agencies regulating healthcare facilities before an event occurs. 		
Licensing boards for first responders [including paramedics and emergency medical technicians (EMTs)]: <ul style="list-style-type: none"> National Association of Emergency Medical Technicians: http://www.naemt.org/. Contact the local or state paramedic and EMT licensing agencies to understand their role in drug diversion investigations. Note: EMT/paramedic medication handling and security differs from that in inpatient settings due to emergency needs. 		
Healthcare Facility Licensing, Certification, and Accreditation Agencies: Contact relevant agencies at your jurisdictional level prior to an event to determine their role in HCP drug diversion.		
Centers for Medicare and Medicaid Services (CMS) certifying organization: <ul style="list-style-type: none"> CMS certification: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/index.html. The CMS certifying organization in your jurisdiction may be involved with oversight and reporting of drug diversion events. 		
Healthcare facility licensing and survey agencies: <ul style="list-style-type: none"> State HAI/AR programs can serve as a point of contact for your state survey agency. Depending on state or local laws and regulations, the agency(ies) licensing healthcare facilities in your jurisdiction may be required to report drug diversion to the public health department or may do so voluntarily. 		
Accrediting organizations: <ul style="list-style-type: none"> There are many different accrediting agencies. Your facility licensing agency or HAI program may be able to identify which organization, if any, accredits a specific healthcare facility. A listing of CMS-approved accrediting organizations can be accessed from: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Accreditation.html. 		

Table 1 List of partners and stakeholders to engage in HCP drug diversion planning and response efforts.

Partners and Stakeholders	Planning	Response
Infection Prevention and Professional Organizations: These organizations are crucial partners to engage in HAI efforts, including HCP drug diversion events. They can inform development of response protocols and help assess patient risks associated with specific drug diversion events.		
Association for Professionals in Infection Control and Epidemiology, Inc. (APIC): A leader in infection prevention. <ul style="list-style-type: none"> APIC website: http://www.apic.org/ Safe injection practices position paper: https://www.apic.org/Resource_/TinyMceFileManager/Position_Statements/2016APICSIPPPositionPaper.pdf 		
The Society for Healthcare Epidemiology of America (SHEA): <ul style="list-style-type: none"> SHEA's mission, in part, is "to promote the prevention of HAIs and antibiotic resistance." SHEA website: http://www.shea-online.org/ 		
Regional infection prevention organizations or local APIC chapter: <ul style="list-style-type: none"> Infection prevention staff are often excluded during a facility response to drug diversion events. However, their participation in assessment of potential BBP risks during an event can be quite valuable. 		
Regional or state occupational health organizations: <ul style="list-style-type: none"> If such organizations exist, they will be helpful during planning for BBP testing and prevention efforts to reduce HCP injury. 		
Substance Use and Prevention Organizations: Contact relevant organizations in your jurisdiction to understand the burden of substance use disorders in the region, as well as these groups' roles, resources and infrastructure.		
State or local bureau of drug, alcohol, or mental health services: <ul style="list-style-type: none"> These programs may be part of the health department or may be housed in another agency. 		
Organizations providing substance use recovery services to HCP (e.g., peer assistance programs): <ul style="list-style-type: none"> Many such programs are available. Do an internet search to identify those in your locale. 		
National organizations: Below are the two most prominent. <ul style="list-style-type: none"> Substance Abuse and Mental Health Services Administration (SAMHSA): https://www.samhsa.gov/ National Institute of Drug Abuse (NIDA): https://www.drugabuse.gov/about-nida/organization 		

Methods to Identify and Respond to Drug Diversion Events



As mentioned earlier, drug diversion by HCP can result in poor quality of care, ranging from failure to administer prescribed medications (which have been diverted) to reuse of contaminated injection equipment, placing patients at risk of infection with BBPs (see Figure 1).

When drug diversion is suspected by a healthcare facility, it is important for facility staff to promptly report their concerns, assess potential harm to patients, and collaborate with relevant internal and external stakeholders (see Table 1). In fact, healthcare employees have an obligation to report drug diversion under federal law (Title 21 Code of Federal Regulations §1301.91): “It is . . . the position of DEA that an employee who has knowledge of drug diversion from his employer by a fellow employee has an obligation to report such information to a responsible security official of the employer. The employer shall treat such information as confidential and shall take all reasonable steps to protect the confidentiality of the information and the identity of the employee furnishing information. A failure to report information of drug diversion will be considered

Figure 1

CDC One and Only Campaign graphic depicting how drug diversion can spread infection from HCP to patients⁴.



in determining the feasibility of continuing to allow an employee to work in a drug security area. The employer shall inform all employees concerning this policy.”

HCP drug diversion events are typically reportable to law enforcement agencies and licensing organizations for healthcare professionals. Depending on jurisdictional requirements, they may also be reportable to public health authorities and healthcare facility licensing agencies.

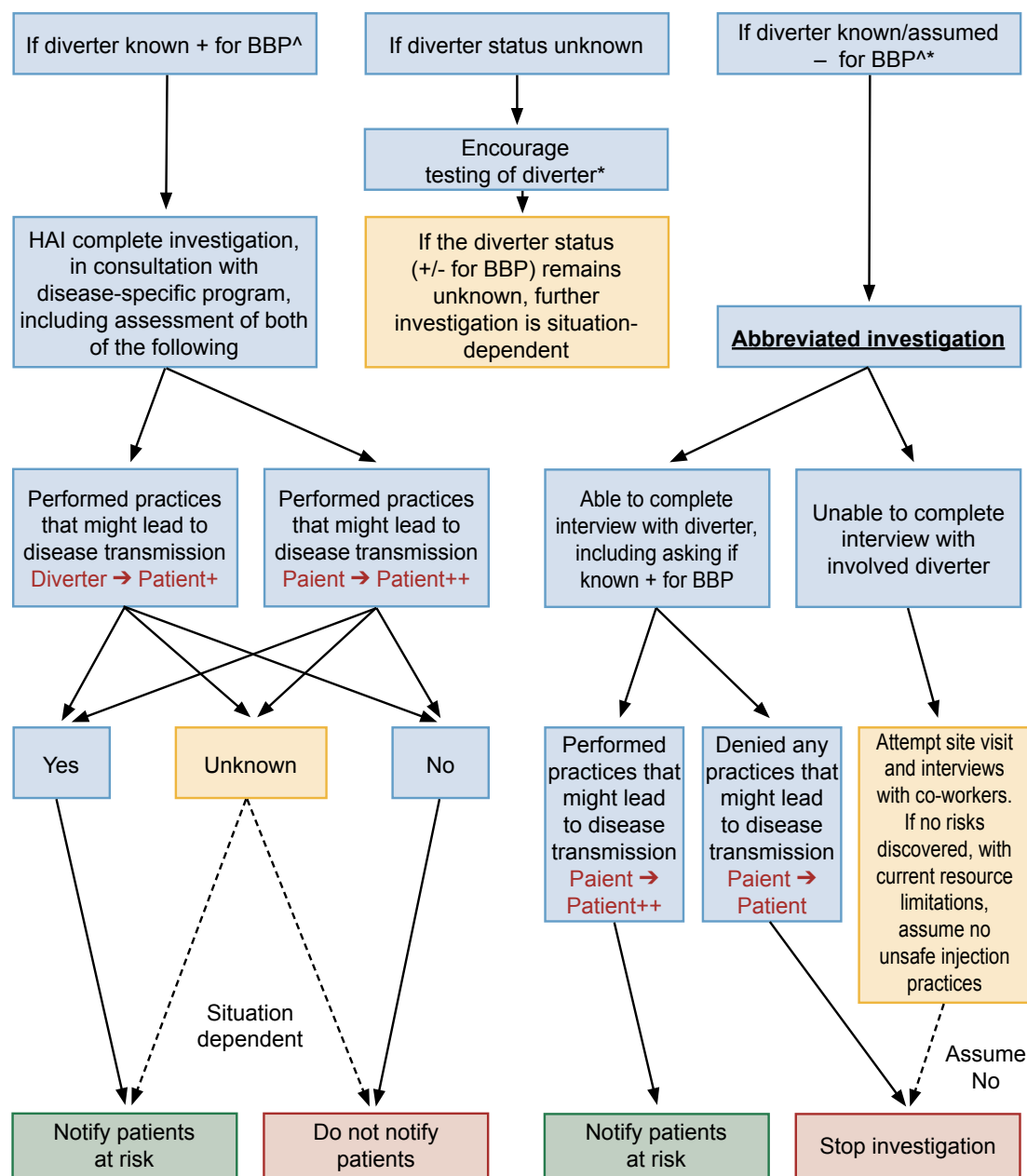
Unfortunately, public health agencies typically learn of HCP drug diversion from the news media or after a cluster of infections is identified, rather than via direct reports to them from the affected healthcare facility or system.

This delayed reporting results in a delayed public health response. Ideally, HCP drug diversion is promptly reported by the impacted healthcare facility to all agencies that will be involved in response efforts—categorized by public health, licensing, and law enforcement—so steps may quickly be taken to prevent further patient harm.

Several states have specific laws and rules that regulate reporting of drug diversion. Some have even developed algorithms detailing response activities when outbreaks are linked to drug diversion or when there are specific reports of drug diversion in a healthcare setting (see Figures 2 and 3).

Figure 2

Sample decision tree for public health response to HCP drug diversion events (courtesy of Colorado Department of Health and Environment).



^BBP = blood borne pathogen

* In general, if diverter is tested and negative, assume that there is no possible risk of undetected disease. If the diverter is interviewed and risk of transmission from diverter to patient exists, the window period will be considered and repeat testing might be necessary. Consult with appropriate program or advisory team.

+ Risk for known BBP

++ Risk for all 3 BBPs

All reports of HCP drug diversion involving injectable medication—whether or not disease transmission has been detected—should be investigated to assess patient risk. The four detailed investigative steps listed below align with the decision tree on Page 16 (Figure 2) and may serve as a helpful guide. However, because every investigation is unique, it is likely that some steps may need to be modified, repeated, eliminated, taken out of order, or supplemented with additional activities.

1. Hold a call or in-person meeting with the affected healthcare facility.
 - a. Educate the facility regarding the investigative process
 - b. Why a communicable disease investigation is taking place
 - c. Public health legal or regulatory authority to conduct the investigation
 - d. Goals of the investigation
 - e. What steps may be taken as part of the investigation
 - f. Which public health agency(ies) and agency staff will be involved in the investigation
2. Gather additional information from the facility.
 - a. Details of the event, including medication(s), diversion methods, and timeframe
 - b. Details related to the HCP suspected of diverting medications, including a description of diversion methods, unusual behavior, and associations with patients and other HCP
 - c. Results of any drug testing done as part of the investigation
 - d. Details of any unusual bloodstream infection clusters or newly diagnosed hepatitis infections among the patient population
 - e. Results of any BBP testing of the HCP, or related testing of other HCP or patients after the drug diversion event
 - f. If the HCP was facility employee or contractor
 - i. Dates of employment or contract at the facility
 - ii. Results of any pre-employment testing for BBPs that may help to identify the exposure time period and narrow the patient notification window

- iii. HBV vaccination status
- iv. Names of other relevant HCP to be contacted or interviewed, such as coworkers or others who are aware of the drug diversion event and the context in which it occurred

3. Make attempts to interview the HCP if there might be a risk of BBP transmission. This should be done in close communication and collaboration with law enforcement, but the interview may be best conducted privately without law enforcement present. The number of times to attempt contact and methods (e.g., phone or in-person) may vary based on jurisdiction resources, authority, or internal protocols. Consider coordinating with sexually transmitted disease investigation services (DIS) staff who are skilled at gathering sensitive information. Ask open-ended questions to collect relevant information, specifically:
 - a. Results and dates of any BBP testing (including HIV, HBV, and HCV)
 - b. Possible risk of BBP transmission from HCP to patients; detailed information on how diversion occurred including specific techniques and activities
 - c. Possible risk of BBP transmission between patients as a result of poor injection practices. Ask open-ended questions that may help determine if there were tampering, substitution of medication product, or inappropriate syringe usage
4. Interview others at the healthcare facility where the event occurred, such as risk management staff, colleagues of the HCP, and others who might have relevant information
5. Check communicable disease surveillance systems (HIV, viral hepatitis B and C) to obtain results of any BBP testing for the HCP

Activities related to the investigation will be influenced by two important pieces of information:

- BBP infection status of the HCP, determined by testing performed as part of the investigation or prior to the investigation

- Risk of disease transmission to patients due to the diversion method (e.g., refilling and reusing syringes after self-injection by the HCP; refilling and reusing syringes after use with one patient and then used again on other patient[s])

Regardless of known methods and potential risk, if the HCP has tested positive for a BBP, public health authorities may consider completing a full investigation. If the BBP status of the HCP is unknown:

- The facility should be encouraged to test the HCP for BBPs, particularly if high-risk behavior has been identified. Testing protocols for the HCP (and for exposed patients) should be determined prior to an investigation. If the HCP is no longer employed at the facility, public health investigators should consider contacting the HCP to encourage BBP testing, and arrange for test results to be sent to the public health agency. Under certain circumstances, law enforcement may be able to compel testing, though typically the HCP will agree to testing if asked.
- If the risk of disease transmission is unknown and the HCP has unknown BBP status, public health agencies should consider next steps and discuss the ethics of patient notification without known BBP transmission risk.

If the BBP status of the HCP is negative:

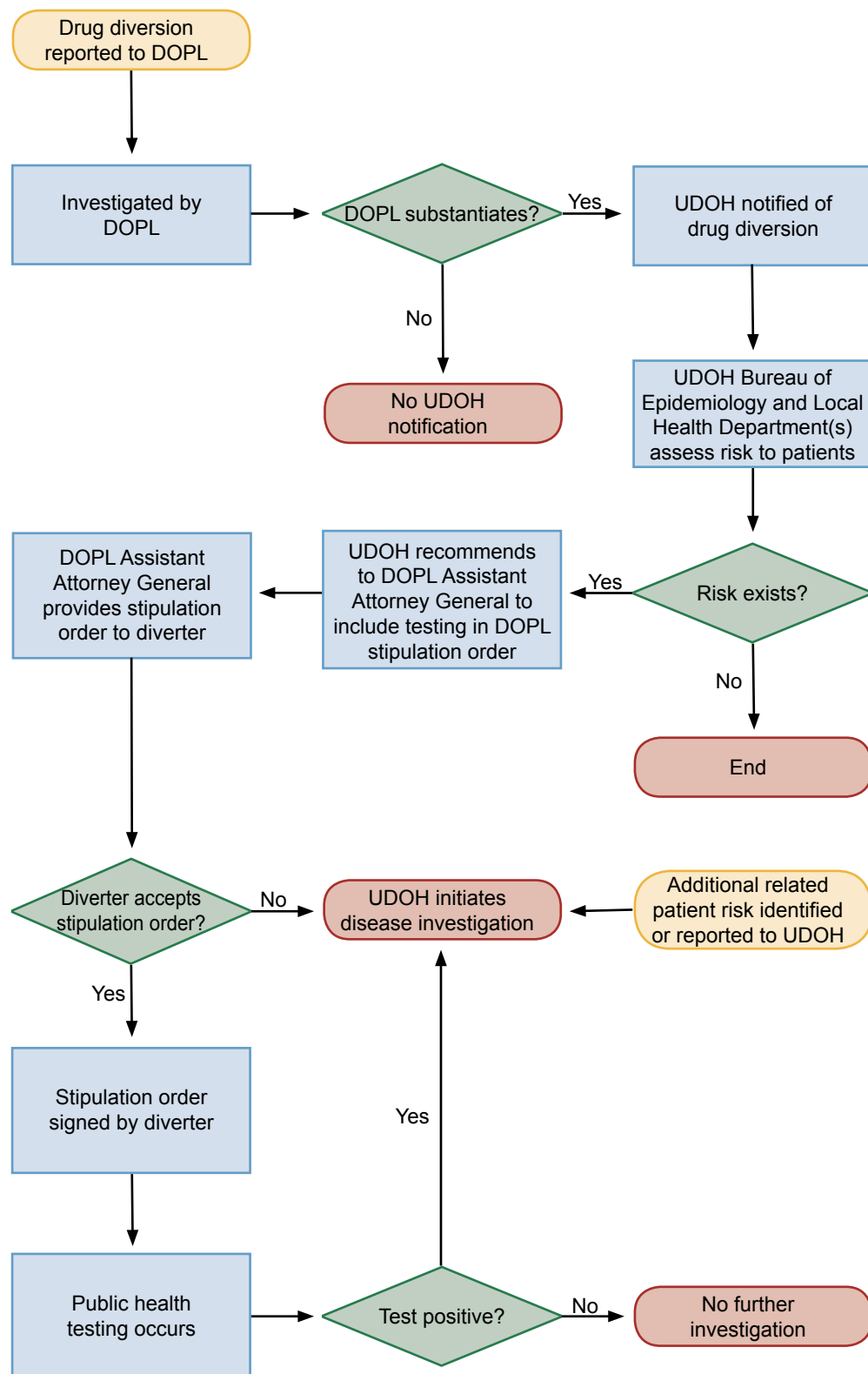
- If it is determined that the drug diversion method poses a risk of disease transmission from the HCP to patient, repeat testing of the HCP may be indicated based on the window of possible disease transmission prior to a positive test result. For example, individuals with early-stage HIV infection may be able to transmit the virus even though they will likely test negative on a standard HIV test. A determination should be made regarding the timing of follow-up testing to arrive at a definitive BBP status.

- If no risk of disease transmission is identified, or risk of disease transmission remains unknown after reasonable attempts to interview the HCP have failed (e.g., the HCP refuses to be interviewed or cannot be reached), the investigation will cease.

While BBPs are of primary concern in drug diversion cases, investigators should also consider the potential for transmission of bacterial infections.⁵ For example, bloodstream infections—including polymicrobial infections and atypical HAIs—have been reported as a result of tampering with patient-controlled analgesia (PCA) pumps and syringes. For diversion events involving tampering with PCAs or substitution of prescribed medication with non-sterile fluids, it may be reasonable to recommend a review of microbiology records (e.g., from the hospital's microbiology laboratory) to rule out an increase or unusual occurrence of bloodstream infections in the unit or area where drug diversion occurred.

Figure 3

Sample workflow for an HCV drug diversion investigation involving the Utah Division of Professional Licensing and Utah Department of Health (courtesy of Utah Department of Health)



Patient Notification Following Drug Diversion Events



Patient notification is recommended when the following three conditions are met:

1. There is evidence of drug diversion in a healthcare facility.
2. Diversion methods may have placed patients at risk for BBP infection (e.g., injectable medications were diverted or diversion methods are unknown).
3. Test results suggest the HCP was infected with a BBP while working at the facility.

When initial testing of the HCP is negative, but follow-up testing based on the window of infection is positive, additional discussion regarding patient notification should occur.

A CDC toolkit—posted at <https://www.cdc.gov/injectionsafety/pntoolkit/index.html>—contains information for public health agencies and healthcare facilities regarding patient notification after any infection control breach, including drug diversion. The toolkit addresses when to notify patients (early in the week is best), what to include in a notification letter (how/where the event occurred, possible symptoms, corrective actions taken, etc.), risk communication principles to consider when drafting a notification letter (e.g., acknowledge uncertainty and diffuse anger), media communication strategies and more.

Public health authorities can also contact the CDC Division of Healthcare Quality Promotion directly for one-on-one assistance.

See Appendices 4-6 for additional sample materials, including patient letters, talking points for call centers, and frequently asked questions specific to HCP drug diversion.

Legal Considerations



Laws addressing drug diversion in healthcare settings, whether in the form of statutes or administrative regulations, are highly variable and complex. Many target specific practice settings, specialties or other aspects of drug diversion including:

- Reporting drug diversion events to state public health officials.
- Professional licensure disciplinary measures for misappropriation or diversion of medications from the workplace.
- Facility CMS certification or licensure requirements aimed at preventing unlawful diversion of controlled substances.
- Board of medical examiner/practice guidelines, standards, and policies.
- Inventory maintenance record requirements.
- Reimbursement of payors for medications charged for but not actually received by patients.
- Random drug testing of HCP.
- Pharmacy controls against theft or diversion of medications or devices.

Public health authorities should familiarize themselves with the applicable federal, state and local legal requirements when responding to a drug diversion event. A sampling of relevant state laws comprises Appendix 5.

Federal Requirements for Healthcare Facilities

Healthcare facilities must comply with several federal laws and regulations pertaining to drug diversion. Some of the most notable requirements are listed below.

- In some cases, drug diversion falls under “misappropriation of patient property” (42 U.S. Code §484.50), which leaves room for interpretation regarding prosecuted/known drug diversion versus suspected diversion and can lead to under-reporting. To remedy this possible federal loophole, some states have made suspected diversion explicitly reportable to facility licensing or public health agencies.
- Federal regulations (Title 21 §1301.92) state that “employees who possess, sell, use or divert controlled substances will subject themselves not only to state or federal prosecution for any illicit activity, but shall also immediately become the subject of independent action regarding their continued employment. The employer will assess the seriousness of the employee's violation, the position of responsibility held by the employee, past record of employment, etc., in determining whether to suspend, transfer, terminate or take other action against the employee.”
- The 1983 Federal Anti-Tampering Act requires facilities to notify the FDA EOC (at 866-300-4374) if tampering is suspected.
- CMS Conditions of Participation—with which facilities must comply to meet Medicare and Medicaid hospital regulations—require that controlled substances abuses and losses be reported to the responsible party in the pharmacy and to the chief executive officer of the facility.

Legal Considerations for Public Health Agencies

Public health agencies may investigate and respond to HCP drug diversion at various stages during an event, and may receive anonymous tips. As part of the response, public health agencies may access protected health information maintained within surveillance databases or immunization registries, and actively lead a large patient notification and testing effort. Understanding the relevant legal considerations is essential to enable robust public health investigations and to inform advocacy for legal changes to enhance patient safety and facilitate a

thorough and timely response to safety breaches.

- If HCP testing is facilitated by public health authorities, the individual(s) tested should be informed in advance how this information will be used and shared, in accord with relevant laws and regulations.
- Public health agencies should have the authority to access relevant communicable disease surveillance databases to ensure a healthcare worker suspected of drug diversion is not already known to be infected with a BBP. Authorities should be aware of relevant laws governing the sharing of this information.

Preventing Drug Diversion



Public health agencies can play an important role in the prevention of drug diversion by HCP.

First, they can advise healthcare facilities to conduct pre-employment screening of HCP, non-licensed providers (e.g., environmental or technical staff), and licensed providers (e.g., physicians, pharmacists, advanced practice nurses, physician assistants, technicians) working in high-risk areas such as operating room floats, radiology units, and pharmacies. The DEA considers such screening essential to controlled substance security. It should be performed by the hiring facility or contracted staffing company at a contractually agreed upon frequency, and proof should be provided to the facility before employment commences. Screening should include:

- Criminal background checks
- Primary source verification of licenses
- Drug screening
- Written, signed response to the question: "Have you ever been disciplined, terminated, allowed to resign or denied employment because of mishandling a controlled substance or a drug diversion issue?"

Second, they can advise healthcare facilities to investigate and adopt enhanced security measures and engineering controls to make drug diversion more difficult and more readily detected.

Third, they can advocate for state laws or regulations providing immunity to employers of HCP (including staffing companies) when they share potentially negative information about HCP as part of the employment vetting process. For example, Maryland enacted such a statute in the aftermath of a large HCV outbreak caused by a radiology technician who diverted injectable medications; he had worked in and been terminated by multiple facilities in several states before his license was rescinded and legal prosecution occurred. If state statutes are inadequate or unknown, the minimum expectation should be for former employers to indicate whether a healthcare worker is eligible for re-hire or not.

Fourth, public health agencies can develop relationships with relevant internal and external partners and stakeholders (e.g., HCP licensing and investigatory boards, facility licensing agencies, and law enforcement) to ensure mutual understanding of roles and responsibilities and thereby facilitate a prompt, coordinated response to limit the adverse effects caused by drug diversion. See Table 1.

And fifth, public health agencies can take advantage of the opportunity afforded by after-action reports to identify regulatory and process changes that will help prevent HCP drug diversion and enhance the response to such events.

Conclusion



Prescription drug abuse is America's fastest-growing drug problem, fueled in part by an ongoing opioid epidemic. This problem is especially consequential for HCP, who may have relatively easy access to controlled substances and other drugs intended for patient use. Drug diversion from patients to HCP can place patients at risk for serious adverse consequences, including failure to take prescribed medications and infection with BBPs, when syringes are contaminated during drug diversion and subsequently reused.

While drug diversion by HCP is not a new problem, public health is just beginning to develop the capability and capacity to identify, investigate, and respond to these events. This toolkit is an aid to that end. The information and materials presented here are informed by public health agency experiences investigating and responding to HCP drug diversion. Among the many

topics addressed are methods for identifying drug diversion events, appropriate patient notification in the aftermath of an event, legal considerations, public health partners, and recovery resources for HCP.

Public health is committed to assuring patient safety and supporting HCP suffering from drug addiction. Ultimately, public health and healthcare leaders must work together—and with law enforcement and other partners—to document the burden of substance use among HCP, implement preventive measures, refine reporting and response protocols, and, ultimately, eliminate patient harms.

Because this toolkit is intended to be a living document, we encourage all readers to share their own materials and ideas to make it ever more useful. Please send these to hai@cste.org

References



- ¹Schaefer MK, Perz JF. Outbreaks of Infections Associated with Drug Diversion by US Health Care Personnel. *Mayo Clinic Proceedings*. 2014;89(7):878-887. doi:10.1016/j.mayocp.2014.04.007.
- ²Berge KH, Dillon KR, Sikkink KM, Taylor TK, Lanier WL. Diversion of Drugs Within Health Care Facilities, a Multiple-Victim Crime: Patterns of Diversion, Scope, Consequences, Detection, and Prevention. *Mayo Clinic Proceedings*. 2012;87(7):674-682. doi:10.1016/j.mayocp.2012.03.013.
- ³ONDCP. *Prescription Opioid Misuse, Heroin, and Fentanyl*. Accessed May 30, 2017, from <https://www.whitehouse.gov/ondcp/key-issues/prescription-opioid-misuse>
- ⁴Centers for Disease Control and Prevention (CDC). *Risks of Healthcare-associated Infections from Drug Diversion*. Accessed August 9, 2018, from <https://www.cdc.gov/injectionsafety/drugdiversion/>.
- ⁵Schuppener LM, Pop-Vicas AE, Brooks EG, et al. *Serratia marcescens* Bacteremia: Nosocomial Cluster Following Narcotic Diversion. *Infection Control & Hospital Epidemiology*. 2017;38(09):1027-1031. doi:10.1017/ice.2017.137.

Appendix 1

Additional Resources



1. *Minnesota Hospital Association, Drug Diversion Prevention Toolkit*. This resource is intended for healthcare facilities and includes sample policies and procedures, educational materials and more.
 - a. www.mnhospitals.org/quality-patient-safety/collaboratives/drug-diversion
2. *The Minnesota Controlled Substance Diversion Prevention Coalition, Final Report (March 2012)*. This 11-page report describes the objectives and outcomes of a broad coalition of stakeholders convened by the Minnesota Department of Health and Minnesota Hospital Association to address controlled substance diversion by healthcare professionals.
 - a. www.mnhospitals.org/Portals/0/Documents/ptsafety/diversion/drug-diversion-final-report-March2012.pdf
3. *New Hampshire Department of Health and Human Services, Hepatitis C Outbreak Investigation Report*. This detailed report describes NH's public health response to a 2012 multi-state hepatitis C outbreak, ultimately traced to drug diversion. It includes investigative methods, findings, recommendations to healthcare facilities, and questionnaires and other materials developed for the investigation.
 - a. www.dhhs.nh.gov/dphs/cdcs/hepatitisc/documents/hepc-outbreak-rpt.pdf
4. *Maryland Department of Health and Mental Hygiene, Public Health Vulnerability Review: Drug Diversion, Infection Risk, and David Kwiatkowski's Employment as a Healthcare Worker in Maryland*. This 54-page report details MD's official review of a 2012 multi-state hepatitis C outbreak, traced to drug diversion by healthcare personnel. It highlights system gaps and provides recommendations to prevent future drug diversion.
 - a. <https://health.maryland.gov/pdf/Public%20Health%20Vulnerability%20Review.pdf>
5. *CDC, Risks of Healthcare-Associated Infections from Drug Diversion, webpages*. These include links to videos, peer-reviewed publications, prevention resources and other materials assembled through CDC's One and Only Campaign.
 - a. www.cdc.gov/injectionsafety/drugdiversion/
 - b. www.oneandonlycampaign.org/content/risks-healthcare-associated-infections-drug-diversion
6. *Missouri Bureau of Narcotics & Dangerous Drugs, Drug Diversion in Hospitals: A Guide to Preventing and Investigating Diversion Issues*. This downloadable guide is intended for controlled substance registrants, such as hospitals, and includes reporting templates that may be adapted for use in other states.
 - a. <http://health.mo.gov/safety/bnodd/doc/drugdiversion.doc>
7. *Colorado Department of Health and Environment, Drug Diversion and Disease Transmission video*. This video describes the impact of drug diversion on one family.
 - a. www.youtube.com/watch?v=IT03XIJnB0Q
8. *New Jersey Department of Health, Drug Diversion Table Top Exercises*. This slide deck walks users through three drug diversion scenarios, with accompanying discussion questions.
 - a. http://www.oneandonlycampaign.org/sites/default/files/upload/image/Drug%20Diversion%20Exercise%20Slides_FINAL.pdf
9. *CDC, Patient Notification Toolkit*. This web-based toolkit includes sample templates and letters, communication strategies and best practices for notifying patients of an infection control breach, such as a drug diversion event.
 - a. www.cdc.gov/injectionsafety/pntoolkit/

10. *American Association of Nurse Anesthetists, Resources*. Find helplines and other addiction recovery resources tailored for nurse anesthetists. (Some may materials may be adapted for use with other healthcare professionals.)
 - a. www.aana.com/practice/health-and-wellness-peer-assistance
 - b. www.aana.com/practice/health-and-wellness-peer-assistance/About-AANA-Peer-Assistance/getting-peer-assistance-help-for-yourself-and-others
11. *Utah Department of Health, Health Status Update: Hepatitis C and Drug Diversion*. An April 2017 update on public health findings related to drug diversion in Utah.
 - a. https://ibis.health.utah.gov/pdf/opha/publication/hsu/2017/1704_HepCDrugDiv.pdf

Appendix 2

Sample Drug Diversion Interview Script



Guidance for interviewer: This form provides a script for interviewing healthcare personnel who may have diverted drugs, and thereby determining risk of patient exposure to blood-borne pathogens. This may be a cold call or scheduled interview, depending on the situation. The person conducting the interview may vary, potentially being a healthcare-associated infections program staff member, viral hepatitis or HIV program staff member or a disease intervention specialist. In all cases, adequate training and practice are crucial. Please note that this is a compilation of possible questions you may choose to ask during a drug diversion interview. Depending on the situation, questions may be added, modified, or omitted. Read this document carefully before conducting the interview to assure familiarity with the questions and appropriate modifications.

Hi, my name is **<interviewer name>**. How are you today? I work for **<your agency name>** and part of my job is to help control the spread of diseases and protect patient safety. I am not part of law enforcement.

<We're meeting today/I'm calling you today> because a report was received about unsafe injection practices at **<facility/healthcare organization name>**. I'd like to ask you some questions so that we can find out if people may be at risk of contracting a blood-borne disease like HIV, hepatitis B, or hepatitis C. It may take approximately 30 to 45 minutes to go through all the questions. I need your help to make sure people are safe, so thank you for taking time to talk with me.

Thank you. The next few questions will help me understand your role and work at <facility/healthcare organization name>.

Guidance for interviewer: We would like to know information about where and when this person worked at the facility where drug diversion is suspected to have occurred, including types of jobs, time period, locations of work within the facility, etc. We would also like to know about work at previous facilities, and if the person is currently working at another facility.

1. I'm going to start with some basic questions about your job at <facility/healthcare organization name>.
 - a. What date did you start working at <facility/healthcare organization name>?
 - i. Were you hired as full-time employee, contract employee, or traveling provider?
 - b. Are you currently working at <facility/healthcare organization name>?
 - i. (If no): When was your last day?
 - ii (If yes or no): Did you have any breaks in employment at the organization (for example, leave or long vacation)?
 - c. What is/was your job title?
 - d. Where did you do most of your work? For example, which unit, floor or office did you work in?
 - e. What were your duties?
 - f. Did your job duties ever require you to be outside of your regular work area?
2. Have you worked at any other healthcare facilities in the past?
 - a. (If yes): Where did you work and when?
3. Are you currently working at any other healthcare facility? Or planning to in near future? (If yes):
 - a. Where else do you work?
 - b. What are your duties?
4. Tell me about your work schedule.
 - a. What shift do/did you work? What are/were your typical hours?
 - b. Do/did you ever help out on your days off, or go to work when you aren't/weren't scheduled?
 - c. Do/did you ever help out with patients who you are not/were not assigned to?

Next, I have a few questions about your medical history.

- 5.** Have you ever been vaccinated for hepatitis B virus? Or tested for immunity to hepatitis B virus?
 - a. (If yes): When and where were you vaccinated or tested for immunity to hepatitis B virus?
 - b. (If yes): Did you receive the full series of vaccinations? This means you would have gotten three shots in total for hepatitis B.
- 6.** Have you ever been tested for hepatitis B virus, hepatitis C virus, or HIV?
(If yes):
 - a. When and where were you tested for hepatitis B virus? For hepatitis C virus? For HIV?
 - b. What were the results?

	Hepatitis B Virus	Hepatitis C Virus	HIV
Type of test (if known)			
When tested			
Where tested			
Results			

Thank you. The next few questions will help us to understand practices regarding giving injections at <organization>.

Guidance for interviewer: The following questions are used to assess risk of transmission of blood-borne pathogens from patient to patient.

- 7.** Please describe how and where injectable medications are prepared?
- 8.** Do you ever use a needle for more than one patient? Or have you ever seen someone use a needle for more than one patient?
 - a. (If yes): Describe an instance when a needle would be used more than once.
- 9.** Do you ever use a syringe (even if you put a new needle on the same syringe) for more than one patient? Or have you ever seen someone do this?
 - b. (If yes): Describe an instance when a syringe would be used more than once.

10. Have you ever accessed a vial of medication for one patient and then later accessed the same vial of medication for a different patient?
 - c. (If yes): Describe an instance when a vial of medication would be used for more than one patient? Was it single-use or multi-dose?
11. Have you ever used a needle that had been previously used on any patient (including a needle used on an IV line) to draw medication from a vial?
 - d. (If yes): Describe an instance when a previously used needle would be re-used to draw medication from a vial.
12. Have you ever used a syringe that had been previously used on any patient (including a syringe used on an IV line) to draw medication from a vial?
 - e. (If yes): Describe an instance when a previously used needle would be re-used to draw medication from a vial.
13. Did you ever need to dilute a medication?
 - f. (If yes): What did you use to dilute it (e.g., bag or bottle of IV solution)?
 - g. (If yes): Did you ever use a dilution solution for more than one patient? If so, please explain?

Thank you. The next few questions will help us to understand procedures for storing and handling medications at <organization>.

Guidance for interviewer: These questions are to determine how the facility stored, managed, secured, and wasted medications that the interviewee might have had access to. Some questions may need to be repeated if you are interested in more than one medication type (e.g., controlled substances vs. narcotics vs. other diverted substances). It may also be useful to find out how the facility or organization obtained these medications.

14. Please describe the policies <facility> has in place for storing and handling <controlled substances, narcotic medications, or other diverted substances>.
15. Describe the training you received at <facility/healthcare organization> for handling <controlled substances, narcotic medications, or other diverted substances>.
16. How do <controlled substances, narcotic medications, or other diverted substances> arrive and who receives them?

- 17.** How are <controlled substances, narcotic medications, or other diverted substances> packaged, including single-use, multi-dose, carpject, ampoules and pre-filled syringes. (Record all.)

Single-use	
Multi-dose	
Carpject	
Ampoules	
Pre-filled Syringes	

- 18.** Where are <controlled substances, narcotic medications, or other diverted substances> stored? Please include all locations, for example, carts, locked drawers in patient rooms, Pyxis, etc.
- 19.** How are <controlled substances, narcotic medications, or other diverted substances> secured in each location where they are stored?
- 20.** How are <controlled substances, narcotic medications, or other diverted substances> accessed, for example, with a key, biometric identifier or something else?
- h. (If keys): Where are the keys stored?
 - i. (If keys): Who has access to the keys?
- 21.** Who has access to <controlled substances, narcotic medications, or other diverted substances> and what kind of access do they have?
- 22.** Please describe how <controlled substances, narcotic medications, or other diverted substances> are wasted at <facility/healthcare organization>?
- j. Where are they wasted?
 - k. Who wastes them?
 - l. How are wasted medications tracked or logged?
 - m. Who tracks wasted medications? Is the person who receives them also the person who tracks them?
- 23.** Are there procedures for disposal of trash in areas where controlled substances or narcotics are stored?
- n. (If yes): What are they?

Unfortunately, it is common for people who work in healthcare to find themselves experiencing pain or overwhelming stress from their work or personal lives. This may lead them to seek relief through medication found at work. The next few questions are about ways someone might be able to get access to those medications at <organization>.

Your responses will be helpful for us as we learn more about how to better support healthcare providers. Are you ready to move on to the next section?

Guidance for interviewer: The following questions are used to assess risk of transmission of blood-borne pathogens from HCP to patients.

Guidance for interviewer: These next questions ask about how healthcare personnel might divert drugs and can be framed to the interviewee as though they are being asked in order for the interviewer to gain an understanding about how such an event might occur. Asking general questions before, or instead of, direct questions about the interviewee's own behaviors may make the interviewee feel more comfortable and responsive.

- 24.** If someone wanted to take medication intended for their patients, what are the possible ways they might do that?
- 25.** Have you ever heard of or seen anyone taking medication intended for patients?
- o. (If yes): Describe how they got access to that medicine and how they took it?
 - p. (If yes): How do you think <organization> could help keep this from happening?
 - q. (If no): Have you ever had a reason to think someone might be doing this?
 - i. (If yes): What makes you think that?

Guidance for interviewer: These questions ask what types of medications the interviewee had access to at work and directly asks how the interviewee diverted drugs. If the interviewee will not answer questions about themselves directly, the questions can be modified by asking them in a hypothetical fashion. As above, some questions may need to be repeated if you are interested in more than one medication type (e.g., controlled substances vs. narcotics vs. other diverted substances).

Thank you. At this point, our main goal is to find out about possible ways patients may have been put at risk. This information will help us to follow up with those people so they can be tested for diseases and we can prevent further spread of infection. Your openness and honesty are very much appreciated to help protect lives. I'm now going to ask about your personal access to <controlled substances, narcotic medications, or other diverted substances>.

- 26.** Did you ever have access to <controlled substances, narcotic medications, or other diverted substances>?
- r. (If yes): On which units or floors did you have access to controlled substances?
 - s. (If yes): Please describe type of access (e.g., prescribing authority, dispensing to patients, or working in an area with unsecured medications)?
- 27.** Have you ever used, injected, taken, or replaced injectable medications that were wasted at <facility/healthcare organization>?
- t. (If yes): Which of these have you done?
- 28.** Have you ever used, injected, taken, or replaced injectable medications that were intended for a patient while working at <facility/healthcare organization>?
- u. (If yes): Which of these have you done?

If no to both Question 27 and Question 28, skip to Question 38.

If yes to either Question 27 or Question 28:

- 29.** What medications did you do this with while working at <facility/healthcare organization>?
- 30.** Where did you get the medications (e.g., taking medicine from waste, PYXIS, operating rooms, patient homes, med cart, etc.)?
- 31.** Did you take the medicine to use yourself or for someone else?

If “someone else,” skip to Question 34.

- 32.** How did you take the medication?
- v. What items did you use while taking the medication? For example, you may have used syringes, needles, single or multi-dose vials or bagged solutions.
- 33.** Do you feel that you may have put yourself at risk of contracting a blood-borne pathogen—like hepatitis B, hepatitis C or HIV—while doing this?
- w. (If yes): Would you like to be tested? (Interviewer may want to mention testing assistance available through the health department, if any.)
- 34.** Did you ever replace a medication or liquid with another solution? For example, using saline or tap water to replace medicine intended for patient use?
- 35.** Did anyone help you to access, use, inject, take, or replace the medications?
- x. (If yes): Who?
- 36.** When was the first time you ever took medications from **<facility/healthcare organization>?**
- y. During what period of time in your shift did you take these medications?
- 37.** Do you think you may have put a patient at risk of contracting a blood-borne pathogen, like hepatitis B, hepatitis C or HIV?
- 38.** Did you ever use, inject, take, or replace injectable medications that were intended for a patient while working at any other healthcare facility?
- z. (If yes): Where?

If yes to Question 38, repeat Questions 29 to 37 (skipping Question 33) for each additional healthcare facility.

Thank you for your time, your cooperation and your honesty. That was the final question of the interview. This information will help prevent the spread of infection and help us learn how to prevent these things from happening to others. Do you have any questions for me?

Appendix 3

Sample Script for Phone Call to Pursue HCP Blood-borne Pathogens Testing in Connection with Drug Diversion



This script is intended for use when calling individuals suspected of drug diversion to secure their cooperation with blood-borne pathogen (BBP) testing. This will likely be a follow-up call after an investigation has begun. Although the caller may vary, adequate training and practice are crucial. Jurisdictions may opt to work with trained staff who are comfortable conducting outreach for BBP testing, such as healthcare-associated infection staff, viral hepatitis staff, HIV program staff or disease intervention specialists. Please note that this is a sample script that may need to be modified, depending on the specific situation.

1. We are contacting you based on recent news reports or communications with **<Healthcare Facility Name>**.

OR

We are contacting you because we were informed about an incident where medication intended for patients was possibly taken. We want to ensure that no patients are at risk.

2. We are contacting you because we have some concerns about an incident involving public safety, and we want to ensure that patients in healthcare settings are not at risk.
3. We are calling today to ask if you are willing to be tested for hepatitis C virus, hepatitis B virus, and HIV. We may also need to reach out and test again in six months.

4. If they answer yes:

a. Thank you for your cooperation. We have two options for testing:

i. Limited/free of cost to individual

1. You can have your blood drawn at **<pre-determined location>**, and we can have your blood tested here in our lab.

OR

ii. Costs not covered by state unless specimen tested at the state public health laboratory

1. You can get testing done at your primary care provider's office.
 2. You can get your blood drawn by your primary care provider and then our lab can do the testing at no cost.
 3. You can coordinate a blood draw with local free options (e.g. health departments, low cost clinics) and coordinate with the public health laboratory.
- b. Thank you so much for your willingness to be tested. We will be back in touch. Is this the best number to reach you? If you have any questions or concerns, I can be reached at **<phone number>**.

5. If they answer no:

- a. We understand your concern, but it may be for your benefit to know your status. This will help us ensure no patients were put at risk.

Appendix 4

Sample Patient Notification Letters



States may opt to adapt these letters according to each particular scenario, review CDC's patient notification best practices, and should consider working with an expert versed in writing using plain language as well as other relevant public health agency staff.

1. Patient Notification as part of Outbreak Investigation

The purpose of this letter is to conduct patient notification as part of an outbreak investigation.

2. Repeat Testing as part of Outbreak Investigation

The purpose of this letter is to conduct patient notification of repeat testing as part of an outbreak investigation.

3. Patient Notification with Known Blood-borne Pathogen Risk

The purpose of this letter is to conduct patient notification with known BBP risk but no known disease transmission.

4. Patient Notification with Unknown Blood-borne Pathogen Risk

The purpose of these two letters are to conduct patient notification with unknown BBP risk.

Patient Notification Letter: Outbreak Investigation

*Requires Immediate Attention
This is a health warning*

Date
Patient Name
Address

Dear <Name of Patient or Sir/Madam>,

<Healthcare Facility Name> recently identified <X> people who were patients over a several months period and who were recently diagnosed with <HCV, HIV, HBV> due to a healthcare provider diverting patient medications. <Healthcare Facility Name> reported the cases to the <State Public Health Agency> to seek its assistance. Testing by the <State Public Health Agency> has confirmed that the cases share an identical strain, which means they were infected by the same source.

As part of the investigation, together with the <State Public Health Agency>, we are reaching out to all patients who received care in the <Unit> since <Date> to recommend that you return for blood-borne pathogen testing. It is very important for you to be tested because people with these illnesses do not always have symptoms.

<Healthcare Facility Name> is providing confidential testing at no charge. In an effort to make the screening as convenient as possible, we have arranged for multiple dates and times. Test results could take 7-10 days and results will be sent directly to your primary care physician.

Please call <Healthcare Facility Name> Information and Referral Center at <(XXX)-XXX-XXXX> to schedule a time to have blood taken for this test. We have staff available to assist you at the Referral Center between the hours of 7:00am and 7:00pm Monday through Friday.

If you prefer to have your own healthcare provider do the testing, that is fine. Please ask them to send the samples to the <State Public Health Laboratories> for testing and indicate it is related to <Healthcare Facility Name>. The public health laboratories will process any appropriate labeled sample of a patient whose testing is indicated as part of this investigation.

We are working closely with the <State Public Health Agency>. If you have questions, please feel free to call them directly at (XXX)-XXX-XXXX.

Sincerely, <Name of Organization / Investigation Lead>

Patient Notification Letter: Outbreak Investigation

*Requires Immediate Attention
This is a health warning*

Date
Patient Name
Address

Dear <Name of Patient or Sir/Madam>,

You are receiving this letter to provide you the recommendation from the <State Public Health> for repeat testing following your potential exposure to <HCV, HIV, or HBV> at <Name of Healthcare Facility>.

Based on our experience with patient testing in this investigation of <HCV, HIV, or HBV> at <Name of Healthcare Facility>, and out of an abundance of caution, we recommend repeat blood work for all patients whose initial test was done less than six months from the time of most recent exposure. Your tests thus far were negative but given that you were tested less than six months from your potential exposure date it is recommended to repeat <HCV, HIV, or HBV> serology (testing for the presence of antibodies) for added assurance.

Please contact your healthcare provider to arrange <HCV, HIV, or HBV> testing. If you have a healthcare provider listed in our files, we have also reached out to him/her. If you do not have a healthcare provider, please see the attached list for providers who may be able to assist you and arrange for testing.

Please have your test results reported to <Name of Healthcare Facility>. Bureau of Infectious Disease Control, <Address>, <Town / City>, <State>, <Zip Code>, Secure Fax: <(XXX)-XXX-XXXX>

If you have any questions, please do not hesitate to contact us at <(XXX)-XXX-XXXX>

Sincerely, <Name of Organization / Investigation Lead>

Patient Notification Letter: Known Blood-borne Pathogen Exposure

*Requires Immediate Attention
This is a health warning*

Date
Patient Name
Address

Dear <Name of Patient or Sir/Madam>,

<Xxx> is sending you this letter because a terminated employee <describe healthcare worker position e.g. surgical tech, nurse etc.> may have put patients at risk for exposure to hepatitis C. We are working closely with the Department of Public Health in its investigation of this situation. Hepatitis C is a virus that can potentially cause serious damage to the liver.

Our records indicate that you had surgery at <Xxx> between <Date> and <Date>, either in the hospital or the outpatient surgery department. If this is correct, we believe, as does the state health department, that you **should take a free, confidential blood test**. This test may help determine if you were exposed to hepatitis C as a result of your surgery.

We first learned of this when the state health department contacted us about a cluster of cases with hepatitis C who had surgery at <Xxx> between the dates listed above. We do not know at this point if those patients were exposed to the virus at our hospital, but we are cooperating with the state health department to try to get the facts.

We have consulted with the state health department and the Centers for Disease Control and Prevention. While it is likely that most patients tested will not have been exposed to hepatitis C while at our facility, we believe the best precaution for patients is for *everyone* to be tested who had surgery in the main hospital or the <Xxx> Building between <Date> and <Date>. Based on the state's investigation, testing is not necessary for HIV or hepatitis B.

A person infected with hepatitis C often has no symptoms. For this reason, even if you feel perfectly healthy, it is important for you to be properly tested. This is the only way you will know if you've been infected with the virus – and if so, if you might benefit from additional medical therapy and guidance.

In an effort to make this as convenient as possible, we have made arrangements to provide free, confidential testing for hepatitis C at any <Xxx> location. You should call the <Xxx> location of your choice directly to make an appointment. Please bring this letter and enclosed form with you to the lab. To find a <Xxx> location, go to *website* or call <(XXX)-XXX-XXXX>.

For more information about hepatitis C, we recommend reviewing the CDC website: <https://www.cdc.gov/hepatitis/hcv/index.htm>

To keep you fully informed, we also have set up a **Patient Care Line** you can call with questions or to speak with a licensed healthcare professional. The number for the **Patient Care Line** is <(XXX)-XXX-XXXX>; someone will be available to speak with you Monday through Friday between 7 a.m. and 7 p.m. MT.

Continued on page 45

Continued from page 44

We recommend you discuss this letter with your personal physician. Also, be aware that the state health department may contact patients who test positive for the virus as part of its investigation.

At <Xxx>, we take to heart every day our mission, <"Xxx">. <Xxx> employees, nurses and physicians work very hard to ensure the safest, highest quality patient experience. While we deeply regret that a terminated employee may have put patients at risk while they were under our care, we believe that xxxxx has been, and continues to be, one of the finest hospitals in the country.

We greatly appreciate your support as we try to help all our patients, medical staff, and employees through this difficult time.

Sincerely, <Name of Organization / Investigation Lead>

Patient Notification Letter: Unknown Blood-borne Pathogen Risk

*Requires Immediate Attention
This is a health warning*

Date
Patient Name
Address

Dear <Name of Patient or Sir/Madam>,

<Xxx> regrets to inform you that we recently identified possible drug diversion (the stealing of narcotic pain medication intended for patients) by a former employee, <describe healthcare worker position e.g. surgical tech, nurse etc.>, which may have put some patients at risk for exposure to HIV, hepatitis B, or hepatitis C.

We are working closely with the Department of Public Health in its investigation of this situation.

We have no evidence of any patient infections. However, out of an abundance of caution, we are recommending confidential blood testing for patients who might have been affected. Our records indicate that you had surgery at <Xxx> between date and date, in a location where this employee worked. Therefore, you might have been exposed to these viruses. It is important that you be tested for all three viruses. Because a person who contracts HIV, hepatitis B, or hepatitis C may not have any symptoms, even if you feel perfectly healthy, it is important to be tested to know for certain if you have been infected with these viruses.

This testing is confidential and offered at no cost to you. To make this as convenient as possible for you, we have made arrangements to provide free, confidential blood testing at any <Xxx> location. You should call the <Xxx> location of your choice directly to make an appointment as soon as possible. Please bring this letter and a government issued photo I.D. with you to the lab. To find a <Xxx> location, refer to the enclosed maps or call <(XXX)-XXX-XXXX>.

If you have questions, you may call our Patient Care Line at <(XXX)-XXX-XXXX>. A nurse will be available to speak to you at any time. For more information about these viruses you may also call the information line through the state health department <(XXX)-XXX-XXXX>.

We recommend you discuss this letter with your personal physician. Also, be aware that the state health department may contact patients who test positive for the virus as part of its investigation.

At <Xxx>, we take to heart every day our mission, <Xxx> <Xxx> employees, nurses and physicians work very hard to ensure the safest, highest quality patient experience. While we deeply regret that a terminated employee may have put patients at risk while they were under our care, we believe that <Xxx> has been, and continues to be, one of the finest hospitals in the country.

We greatly appreciate your support as we try to help all our patients, medical staff, and employees through this difficult time.

Sincerely, <Name of Organization / Investigation Lead>

Patient Notification Letter: Known Blood-borne Pathogen Exposure

*Requires Immediate Attention
This is a health warning*

Date
Patient Name
Address

Dear **<Name of Patient or Sir/Madam>**,

We have a difficult but important message for you. We recently learned that an employee of our facility had been taking pain medicine that was meant for patients. This employee no longer works here. The way that the medicine was taken may have exposed people to HIV, hepatitis B, or hepatitis C.

We see that you had surgery at **<Xxx>** between *date* and *date*, where this employee was working. So, you might have been exposed to these viruses. It is important that you are tested for all three viruses. A person who gets HIV, hepatitis B, or hepatitis C may not have any signs and feel healthy. Testing is the only way to know if you have been infected.

We are providing free and confidential testing at any **<Xxx> location.**

Please make an appointment as soon as possible. To find a location, look at the map included with this letter or call **<(XXX)-XXX-XXXX>**.

Please bring these items to your appointment:

- This letter
- A government issued photo I.D.

Here are a few places you may call with questions:

- Our Patient Care Line at **<(XXX)-XXX-XXXX>** to speak with a nurse at any time.
- The state health department at **<(XXX)-XXX-XXXX>** for more information about these viruses.
- You may also talk with your healthcare provider.

We are working with the state health department to investigate and control this situation. If people test positive for these viruses, they will be contacted.

At **<Xxx>**, we take to heart our mission, **<Xxx>**. Safe, high quality care is our top priority. Although a former employee made a terrible mistake, we believe that ours has been, and continues to be, one of the finest hospitals in the country.

We deeply regret that you may have been put at risk while under our care. Thank you for your support as we work through this difficult time together.

Sincerely, **<Name of Organization / Investigation Lead>**

Appendix 5

Sample State Laws Pertaining to Drug Diversion



Drug Diversion Applicability	State	Requirement	Legal Citation
Healthcare Facility Report of Drug Diversion Event	Colorado	Requires licensed or certified healthcare facilities to report “[a]ny occurrence in which drugs intended for use by patients or residents are diverted to use by other persons. If the diverted drugs are injectable, the health care facility shall also report the full name and date of birth of any individual who diverted the injectable drugs, if known.”	Colo. Rev Stat. Ann. § 25-1-124(2)(g) (West 2017).
Licensing Board Reporting Requirements	Minnesota	Under certain defined circumstances, “[a]n employer of a person regulated by a health-related licensing board, and a health care institution or other organization where the regulated person is engaged in providing services, must report to the appropriate licensing board that a regulated person has diverted narcotics or other controlled substances in violation of state or federal narcotics or controlled substance law[.]”	Minn. Stat. Ann. § 214.33(Subd. 5).
Policies Required for Controlled Substance Abuse, Misuse, and Diversion Prevention / Drug Testing	New Hampshire	Licensed facilities and providers are required to “adopt a policy establishing procedures for prevention, detection, and resolution of controlled substance abuse, misuse, and diversion. The facility or provider shall establish written procedures to implement its policy that shall apply to employees, contractors, and agents of the facility who provide direct or hands on care to clients when acting within the scope of their employment or representation ...” Among other requirements, the policy must include: “[a] process for the investigation, reporting and resolution of drug misuse or diversion.” The policy must also include procedures for drug testing “where reasonable suspicion exists.” AND Licensed facilities and providers are required to report “any investigation of suspected or actual incident of diversion of injectable medication in a healthcare setting within 72 hours of initiation of such investigation”	N.H. Rev. Stat. Ann. § 151:41 (West 2017). And N.H. REV. STAT. ANN. § 141 C Administrative Rules He-P 301

Drug Diversion Applicability	State	Requirement	Legal Citation
Reporting of Controlled Substance Losses by Pharmacies	Minnesota	"Any pharmacy, drug wholesaler, drug manufacturer, or controlled substance researcher detecting the theft or significant loss of any controlled substance drug, where the loss is attributable to other than inadvertent error, must report the loss, in writing, to the board and to the Drug Enforcement Administration immediately. The report must include a description of how the loss occurred, if known, the date the loss occurred, if known, the steps being taken to prevent future losses, and an inventory of the missing drugs."	Minn. R. 6800.4800 (2017).
Drug Diversion Grounds for Professional Licensure Disciplinary Action	Alabama	Board of Nursing may "reprimand, fine, probate, suspend, revoke and/or otherwise discipline any registered nurse or licensed practical nurse upon proof that the person:" is unsafe or unreliable as demonstrated by "[m]isappropriation or diversion of drugs from the workplace for self-use."	Ala. Admin. Code r. 610-X-8.03(4) (2017).
Maintenance of Records by Practitioners Certified to Dispense Controlled Substances	Alabama	"Every dentist certified to dispense controlled substances by the Board of Dental Examiners of Alabama shall be required to maintain an accurate inventory and separate dispensing record of all controlled substances in Schedules II through V dispensed in his/her offices." "Failure to maintain and make available the inventory and separate dispensing record required by this rule shall be considered a failure to maintain effective controls against diversion of controlled substances into other than legitimate dental channels."	Ala. Admin. Code r. 270-X-2.12 (2017).
Facility Pharmacy Requirements	South Carolina	Facility pharmacies must "have a pharmacist who, while on duty, is responsible for the security of the pharmacy department including provision of effective control against theft or diversion of drugs or devices, or both ..."	S.C. Code Ann. § 40-43-86 (2017).
Licensed health care facilities must do when reporting thefts or losses of controlled substances	Massachusetts	Every licensed health care facility must report the theft or loss of controlled substances immediately to the Drug Control Program by telephone. This initial notification must be followed up in writing within 7 days of the incident.	105 CMR 700.00: Implementation of MGL c.94C

Appendix 6

Healthcare Facility Measures to Address Patient Safety Following Healthcare Personnel (HCP) Drug Diversion



This resource is intended to educate healthcare facilities about patient safety measures that should be implemented when HCP drug diversion is detected¹. It may be adapted for your jurisdiction and shared before or during a response.

1. Prevent further risk to patients at the facility	<ul style="list-style-type: none"> A. Remove the HCP from the clinical environment and revoke any previously authorized access to controlled substances pending further investigation (e.g., suspend computerized access to automated medication dispensing machines). B. Evaluate security of controlled substances and other high-value medications (i.e., those likely to be diverted) to assure adherence to required and recommended best practices. C. Identify any previous or current discrepancies in oversight of controlled substances and other high-value medications.
2. Prevent risk to patients at other healthcare facilities	<ul style="list-style-type: none"> A. Contact law enforcement agencies <ul style="list-style-type: none"> 1. State and/or local law enforcement 2. Drug Enforcement Administration (DEA) Controlled substances registrants are required to notify the DEA of the theft or significant loss of any controlled substance within one business day of discovery. 3. Food and Drug Administration Emergency Operations Center (EOC) Required if product tampering, including alteration or substitution, is suspected. Contact FDA EOC at: 866-300-4374. B. File report with applicable healthcare professional licensure agencies (e.g., boards of medicine, nursing, and pharmacy). C. File report with the state and/or local health department.
3. Assess retrospective risk to patients	<ul style="list-style-type: none"> A. Assess mechanism(s) of diversion by the HCP <ul style="list-style-type: none"> 1. Were injectable medications diverted? Or did the HCP have access to injectable medications? 2. Was there any tampering with injectable medication? If yes, assess potential for patient exposure to the HCP blood (e.g., via reuse of syringes). Consider risk of bacterial infection transmission (e.g., via substitution of non-sterile fluids in patient-controlled analgesia pumps/syringes). 3. Convene a response team that includes infection prevention and occupational health employee(s). B. If tampering with injectable medication is suspected, pursue blood-borne pathogen testing of the HCP. <ul style="list-style-type: none"> 1. If the HCP tests negative, retest six months past the last date of employment to account for any window of infection (when pathogens are transmissible, but disease is undetectable on laboratory tests). 2. If the HCP tests positive, save specimen for typing and comparison with any prospective cases of infection. C. Perform surveillance to detect acute cases of illness with no risk factors present or an increased number of hepatitis B, hepatitis C, or HIV cases. D. Consider performing a review of microbiology laboratory records to detect any clustering or unusual occurrence of bloodstream infections in the affected patient population. E. In consultation with the state or local health department, determine the need for patient notification and testing.

¹Schaefer MK, Perz JF. Outbreaks of Infections Associated With Drug Diversion by US Health Care Personnel. Mayo Clinic Proceedings. 2014;89(7):878-887. doi:10.1016/j.mayocp.2014.04.007.

Appendix 7

Sample Drug Diversion Frequently Asked Questions



This factsheet is intended to educate healthcare facilities about healthcare personnel drug diversion. It may be shared before or during a response.

Drug Diversion in Healthcare Settings: Frequently Asked Questions

What is drug diversion?

Drug diversion is the theft or deviation that removes a prescription drug from its intended path from manufacturer to patients or healthcare facilities for personal use.

How serious is drug diversion in healthcare?

Diversion by healthcare personnel is a serious issue that can lead to potential patient harm and has been the cause of blood-borne pathogen outbreaks.

How can drug diversion harm patients?

Drug diversion can:

- Lead to substandard care from impaired healthcare personnel.
- Deny patients needed medications.
- Expose patients to infectious diseases.
- Be accompanied by the falsification of patient records.

How can healthcare personnel prevent drug diversion?

- Protect medication during preparation, dispensing and wastage.
- Follow all controlled substances policies.
- Understand the signs of drug diversion, including the physical and behavioral symptoms of substance use.

How can healthcare facilities prevent drug diversion?

- Screen new healthcare personnel and consider drug testing.
- Review medication handling processes.
- Consider surveillance technology.

- Develop internal and external reporting processes.
- Audit controlled substance use in the facility frequently.
- Develop and/or maintain a drug diversion task force.
- Educate healthcare personnel and patients.

What are the signs of drug diversion in healthcare personnel?

- Has many unscheduled absences, sick days and tardy arrivals.
- Disappears frequently from the worksite, such as frequent long trips to the bathroom or medication storeroom.
- Volunteers for overtime and is at work when not scheduled to be there.
- Arrives at work early and stays late.
- Has a pattern of removal of controlled substances near or at the end of a shift.
- Alternates between periods of high and low productivity.
- Has poor interpersonal relations with colleagues.
- Insists on personal administration of injected medications to patients.
- Has heavy or no “wastage” of medications.
- Exhibits a pattern of holding waste until oncoming shift.
- Offers to help in non-assigned areas.
- Prefers to work with new healthcare personnel or orientees.

What are the symptoms of opioid abuse?

Physical: Constricted pupils, itching or scratching, sweating, chills, runny nose, vomiting, diarrhea, anorexia, needle track marks.

Behavioral: Malaise, fatigue, anxiety, insomnia, depression, apathy, paranoia.

What should healthcare personnel do if they suspect drug diversion?

Report any medication loss or suspicious behavior to the appropriate individuals in your institution.

What should healthcare facilities and systems do if they suspect drug diversion?

Investigate and report drug diversion to appropriate authorities and follow "Healthcare Facility Measures to Address Patient Safety When Drug Diversion Is Identified" (a separate health department information sheet, based on: Schaefer MK, Perz JF. Outbreaks of Infections Associated With Drug Diversion by US Health Care Personnel. *Mayo Clinic Proceedings*. 2014;89(7):878-887.)

Who are the appropriate enforcement authorities?

- Local/town police department:
<(XXX)-XXX-XXXX>
- State Police Narcotics Investigation:
<(XXX)-XXX-XXXX>
- U.S. Drug Enforcement Administration:
<(XXX)-XXX-XXXX>
Note: Title 21 Code of Federal Regulations requires employees and employers to report drug diversion.
- Food and Drug Administration (FDA):
www.fda.gov/ICECI/CriminalInvestigations/default.htm
Note: Suspected tampering or substitution must be reported to the FDA Emergency Operations Center at 866-300-4374.
- <State> Professional Licensing Agencies:
 - Board of Medicine:
<(XXX)-XXX-XXXX>
 - Board of Nursing:
<(XXX)-XXX-XXXX>
 - Board of Pharmacy:
<(XXX)-XXX-XXXX>
 - Board of Medical Technicians
<(XXX)-XXX-XXXX>
- Public Health Departments:
 - <State> Public Health Department:
<(XXX)-XXX-XXXX>
 - <City / County> Public Health Department:
<(XXX)-XXX-XXXX>

For more information

- <State / Local> Health Department: <Add Program / Organization. Phone, Email>
- CDC, Risks of Healthcare-Associated Infections from Drug Diversion: www.cdc.gov/injectionsafety/drugdiversion/
- Drug Enforcement Agency: www.deadiversion.usdoj.gov/
- National Association of Drug Diversion Investigators: www.naddi.org/aws/NADDI/pt/sp/home_page
- International Health Facility Diversion Association: <https://ihfda.org/>

Appendix 8

Drug Diversion Surveillance and Reporting for Healthcare Facilities



This handout is intended for distribution to healthcare facilities and may be modified as necessary.

Background

The National Association of Drug Diversion Investigators defines drug diversion as “any criminal act or deviation that removes a prescription drug from its intended path from the manufacturer to the patient.”

Drug diversion by healthcare personnel (HCP) is more likely to occur in settings with controlled substances onsite. HCP drug diversion includes stealing controlled substances (e.g., opioids) or other medications for personal use. This can result in patient harms, including:

- Substandard care delivered by an impaired HCP.
- Denial of essential pain medication or therapy.
- Transmission of infectious pathogens (e.g., hepatitis C virus, hepatitis B virus, HIV or pathogenic bacteria) if a provider tampers with injectable drugs.
- Falsification of patient records.

This document is intended to aid efforts to detect, report, and investigate drug diversion in healthcare facilities, and can be used in conjunction with the Drug Diversion and Disease Transmission video produced by the Colorado Department of Public Health and Environment and posted at: youtu.be/IT03XIjB0Q.

Potential Methods of Diversion

- Removal of controlled substances or other medications from automated dispensing cabinets too frequently.
- Giving less medication than ordered too frequently.
- Medication use from an inconspicuous vessel or equipment.
- Removal of controlled substances or other medications when not needed (this may include patches or other forms of medication)
- Withdrawal of medication for discharged or deceased patient.
- Removal of duplicate dose of medication.
- Removal of medication without an order.
- False verbal order for medication.
- Substitution in administration and wasting of medication.
- Frequent null transactions and discrepancies.
- Removal of larger doses than necessary or than ordered.
- Failure to waste medication.
- Frequent wasting of entire dose of medication.
- Swapping syringes filled with medication for syringes filled with saline solution.
- Removing medication from a pump cartridge and replacing with saline/water.
- High amounts of removals and cancellations from automated dispensing cabinet.
- Removal under sign-on of colleague.
- Removal of unspent syringes from sharps containers.
- Pilfering patient medications brought from home.

Signs of Potentially Impaired HCP

While surveillance of automated medication cabinets captures many controlled substance transactions, not all drug diversion events are detected this way; personal observation is crucial to recognize diversion.

Training to recognize and report drug diversion is essential for all HCP. Healthcare facilities should aim to develop a culture in which HCP recognize diversion behavior and feel a personal responsibility to report that behavior. HCP who ignore signs of diversion are enabling diversion to continue.

Behavioral Signs

Below are typical behavioral patterns of HCP who divert drugs. However, these behaviors, in and of themselves, do not automatically mean HCP drug diversion is taking place.

- Asks colleagues to write prescriptions for self.
- Volunteers to give medications for others.
- Has an unusual interest in pain medications or other drugs.
- Requests to work evening, nights, or weekends.
- Offers to work more shifts.
- Comes in early and stays late.
- Shows up on days off.
- Makes frequent bathroom trips or has other unusual absences at work.
- Does not follow proper medication disposal procedures.
- Wastes medications with the same coworker each time.
- Has a casual attitude about medication errors or poor documentation.
- Exhibits poor memory or concentration.
- Exhibits a change in attitude.
- Has suffered a recent tragic life event.
- Enters rooms of patients not under their care who are on a PCA pump or drip.
- Regularly asks for supplemental orders for controlled substances.
- Is linked to patient complaints about not receiving medications documented as administered.

Physical Signs

- Change in appearance.
- Slurred speech.
- Hand tremors.
- Constricted pupils.
- Unsteady gait.
- Runny nose.
- Disheveled.
- Change in weight.
- Shakiness.
- Smells of alcohol.
- Blood on scrubs, especially around arms or legs.

Healthcare Facility Prevention and Response Measures

Confidential Reporting System and HCP Training

Many HCP do not report drug diversion because they are uncertain or in disbelief of what they have witnessed. HCP also commonly hope the problem will go away on its own, and they will not have to get involved. To ensure that HCP suspicions are reported and heard, it is important to have a confidential reporting system in place. HCP should know that their concerns will be taken seriously and will be kept confidential. Certainty should not be required when reporting suspected diversion, just a good faith concern.

In addition, to encourage prompt reporting of suspected diversion, a diversion training program is necessary. HCP should receive comprehensive education on drug diversion at time of hire and at least annually thereafter.

Diversion Response Program

The diversion response program should include a:

- Diversion specialist, who collects data and actively surveils automated dispensing cabinet records on an ongoing basis.
- Diversion response team, comprising the diversion specialist, pharmacy staff and the supervisor of the HCP suspected of diverting drugs. Team members may be required to request a drug screen of the HCP and suspension from work, if necessary.
- Diversion committee, which should be multi-disciplinary and can consist of representatives from nursing, administration, pharmacy, risk management, security, quality improvement, patient safety, human resources and infection control, identifies and implements improvement measures.
- Diversion risk rounds should involve observing unit's medication handling practices such as dispensing, administration, and wasting. Rounds may need to be done in various units and times of the day. Risk rounds should involve be conducted at least quarterly.

Response Measures

The diversion response team should be alerted to any suspected diversion event so it may take the following actions:

1. Verify and assess the situation, including a review of medical records and medication cabinet records.
2. Remove the suspected HCP from patient contact.
3. Discontinue the suspected HCP's cabinet access.
4. Discontinue the suspected HCP's badge access.
5. Interview the suspected HCP,
6. Conduct a urine drug screen of the suspected HCP.
7. Conduct blood-borne pathogen testing of the suspected HCP.

8. Suspend the suspected HCP, pending conclusion of investigation.
9. Notify patients (if applicable); the team should work with local and state health departments to determine if patient notification is necessary.

Reporting

If diversion is suspected, facility leaders should report it immediately to the appropriate authorities.

State Health Department

Depending on the state where your facility is located, reporting drug diversion to the state health department may or may not be mandatory. However, if there are concerns regarding patient safety, a report should always be made to the state health department, whether mandatory or not.

Drug Enforcement Agency (DEA)

Federal regulations require that controlled substances registrants notify their local DEA field division office, in writing, of the theft or significant loss of any controlled substance within one business day of discovery. The registrant must also submit a completed DEA Form 106, "Report of Theft or Loss of Controlled Substances." This may be accessed and completed online at <https://apps.dea diversion.usdoj.gov/webforms/dtlLogin.do>.

If a registrant does not have internet access, a paper copy of Form 106 can be requested by writing to:

Drug Enforcement Administration
Attn: Regulatory Section/ODG
8701 Morrisette Drive
Springfield, VA 22152

To better track controlled substances reported as lost or stolen, DEA has incorporated use of the National Drug Code (NDC) number in its Form 106. The NDC number identifies the manufacturer, product, dosage form, and package size. Entry of the NDC number will prompt the system to auto-populate additional fields, such as the name of the product, dosage form, dosage strength, and quantity per container.

State Regulatory Agency

If the HCP is professionally licensed, a complaint must be made to the responsible licensing agency, whether located in-state or out-of-state.

State and/or Local Police Department

If a controlled substance is determined to have been diverted by any individual, the facility should report the diversion to the state and/or local police department.

Food and Drug Administration (FDA)

If tampering is suspected—including damaging or otherwise altering the drug, its label or its container—the event must also be reported to the FDA Office of Criminal Investigations. Staff should understand and learn the various methods of tampering. This may be done online at: <https://www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm>

Resources

- CDC Drug Diversion Website: <https://www.cdc.gov/injectionsafety/drugdiversion/index.html>
- ASHP Guidelines on Preventing Diversion of Controlled Substances, January 2017: <http://www.ajhp.org/content/early/2016/12/22/ajhp160919>