



## SUMMARY OF DIVERSION REPORTING REQUIREMENTS FOR NORTH CAROLINA HEALTH SYSTEMS

*Part of the Coalition for Model Opioid Practices  
in Health Systems*

*Published July 2018.*

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**You suspect that an employee in your health system has diverted a controlled substance on the job. What reporting is required in NC?**

**In all cases, the US Drug Enforcement Administration, the NC Board of Pharmacy, and the NC Drug Control Unit must be notified of health system diversion.**

### **US DRUG ENFORCEMENT ADMINISTRATION (DEA)**

Under DEA [21 CFR 1301.76](#), the DEA field division office must be notified, in writing, of the theft or significant loss of any controlled substance within ONE BUSINESS DAY of discovery of the loss or theft. In NC, health systems should send this notification to the DEA Diversion Unit to the attention of DEA Registration Program Specialist Betty Goodman at [Betty.L.Goodman@usdoj.gov](mailto:Betty.L.Goodman@usdoj.gov). Alternatively, initial notification may also be accomplished by filing a [DEA Form 106](#) via [www.deadiversion.usdoj.gov](http://www.deadiversion.usdoj.gov)

As long as the health system has given the DEA the required initial notification with one business day, it may take more time to investigate the circumstances of the theft or significant loss and submit the DEA Form 106. Updates should be provided to the DEA if the investigation takes more than two months. Online submission of DEA Form 106 is encouraged.



Thefts and significant losses must be reported whether or not the controlled substances are subsequently recovered and whether or not the responsible parties are identified and action taken against them.

In the case of a theft, there is no need to determine whether it is “significant;” all thefts of controlled substances must be reported to the DEA.

By contrast, losses must be reported only when they are “significant.” To determine whether a loss is significant, here are some factors the DEA has provided (found in [21 CFR 1301.76](#)).

- (1) The actual quantity of controlled substances lost in relation to the type of business;
- (2) The specific controlled substances lost;
- (3) Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;
- (4) A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known,
- (5) Whether the specific controlled substances are likely candidates for diversion;
- (6) Local trends and other indicators of the diversion potential of the missing controlled substance.

## NC BOARD OF PHARMACY

Under [NCGS 90-85.25](#), the pharmacist in charge of the health system pharmacy must report any drug theft or loss from the health system within 10 DAYS to the Board of Pharmacy. To fulfill this requirement, the pharmacist should file a NC Board of Pharmacy Drug Disaster & Loss Report, which is an online form only and is submitted through the pharmacy's portal log-in at <https://portal.ncbop.org/>.

Once in the online portal, select the "Facility Management" tab, choose "Pharmacy" under the dropdown menu for "Permit Type," and enter your pharmacy permit number and password. Once logged in, scroll down to see "Reports" and find the online Drug Disaster & Loss Report form. Because the Board of Pharmacy has converted to online-only reporting, the Board is no longer able to accept a copy of a DEA Form 106 to satisfy this reporting requirement.



## NC DRUG CONTROL UNIT

Hospitals that dispense controlled substances must [register with the Drug Control Unit](#) of the NC Division of Mental Health, Developmental Disabilities, and Substance Abuse Services and must renew this registration annually by submitting a Form 226-A, along with a fee. In addition to the Form 226-A, the hospital must annually submit a [Registrant Disclosure of Loss, Diversion, or Destruction of Controlled Substances form](#). This form requests information regarding employee convictions of drug-related crimes, loss or diversion of drugs in the previous year, and drug destruction/wasting procedures. It also asks for copies of all DEA Form 106s (reports of controlled substance loss or theft), DEA Form 41s (records of destroyed controlled substances), police reports of loss or theft, and documentation of controlled substances waste destroyed with the last month.

## ADDITIONAL REPORTING OBLIGATIONS

Depending on the licensure or job function of the employee who has diverted a controlled substance, additional reporting obligations may exist:

### Physicians, Physician Assistants, Anesthesiology Assistants, and Perfusionists

Under [NCGS 90-14.13](#), the chief administrative officer of a hospital or "other health care institution" must report actions involving a physician's privileges to the NC Medical Board within 30 days of the action taking effect (e.g., a summary or a final revocation, suspension or limitation of privileges, a resignation from practice or voluntary reduction of privileges).

In addition, the NC Medical Board requests that health systems report cases where there is substantial evidence of diversion by physicians, physician assistants, anesthesiology assistants, or perfusionists, even if the hospital does not take an action reportable under NCGS 90-14.13. Those reports can be made at [www.ncmedboard.org/complaints](http://www.ncmedboard.org/complaints).

The NC Medical Board has issued a position statement indicating that licensees of the NC Medical Board have a professional obligation to act when confronted with an impaired colleague ([Professional obligations pertaining to incompetence, impairment or unethical conduct of licensees](#)).

## Advanced Practice Registered Nurses, Registered Nurses, and Licensed Practical Nurses

Under [NCGS 90-171.47](#), any person who has reasonable cause to suspect misconduct or incapacity of a nurse shall report the relevant facts to the Board of Nursing. Examples of conduct the Board of Nursing considers “definitely reportable” are: drug abuse, impairment on duty, drug diversion, and positive drug screen. The Board of Nursing has an [online complaint form](#) specifically for employers.



## Pharmacists and Pharmacy Technicians

The NC Board of Pharmacy requests to be notified of instances of pharmacist or pharmacy technician diversion. Health systems may file a report on the [Public Complaint page](#) of the Board of Pharmacy’s website. Health systems may also notify the Board of suspected diversion when the pharmacist-manager submits the required [NC Board of Pharmacy Drug Disaster & Loss Report](#).

## Emergency Medical Services (EMS) Personnel

There are no statutory requirements for reporting Emergency Medical Services personnel who are found to be diverting controlled substances. Health systems are requested to report such cases to the [NC Office of Emergency Medical Services](#) at (919) 855-3935.

## Unlicensed Staff Who Have Direct Access to Patients or Their Property (Nurse Aides, Maintenance, Security, Transport, Nutrition, etc.)

Under [NCGS 131E-256\(g\)](#) and [10A NCAC 130 .0102](#), health care facilities must report to the NC Division of Health Service Regulation (DHSR)--[Health Care Personnel Investigations](#), in cases where unlicensed staff who have direct access to residents, clients, or their property divert drugs belonging to a patient or to the health care facility.

Health care facilities must report allegations against unlicensed personnel within 24 HOURS of becoming aware of the allegation, and this report must be in writing. Reports may be faxed to 919-733-3207, or mailed to Health Care Personnel Investigations, Division of Health Service Regulation, 2719 Mail Service Center, Raleigh, N.C. 27699-2719 (postmarked within 24 hours).

The results of all investigations are required to be submitted within 5-working days of the initial 24-hour report, whether the allegation was substantiated or not. The report should include the documentation and results of a thorough investigation.

DHSR has created report templates for both the Initial Investigation (due within 24 hours) and the Investigation Report (due within 5 working days of initial report). These may be found in the Forms section of the DHSR-Health Care Personnel Investigations website. The report templates exist in Excel spreadsheets with pre-populating features, along with detailed instructions. The use of these report templates to meet legal reporting requirements is not required but may be helpful.

## Students

If students who are working or volunteering in a health system are found to be diverting controlled substances, the occurrence should be reported to their educational institution.

## LAW ENFORCEMENT NOTIFICATION

No state statute requires health systems to notify law enforcement when employee diversion is suspected or confirmed. However, the NC State Bureau of Investigation-[Diversion and Environmental Crimes Unit](#) (DECU) requests to be notified of such cases. Health systems can report suspected employee diversion to the NCSBI DECU at 984-204-2722 or [online](#).

DECU agents have received specialized training in conducting facility diversion investigations. DECU can coordinate with facilities to help determine whether diversion has taken place or if there's an ongoing diversion issue. DECU can assist with conducting preliminary interviews, gathering potential evidence, and by providing general guidance, even if it is later determined that no crime was committed.

Health systems may also choose to notify their health system police force or local law enforcement entities of incidents of diversion by employees.

## ADDITIONAL CIRCUMSTANCES

### Drug tampering

**US Food and Drug Administration-Office of Criminal Investigations** - Drug diversion that involves tampering is reportable to the US Food and Drug Administration's Office of Criminal Investigations (OCI). Reports may be made to the OIC online at <https://www.fda.gov/ICECI/CriminalInvestigations/default.htm>.

### Errors in billing of US DHHS programs

**US Health and Human Services-Office of the Inspector General** - The US Health and Human Services--Office of the Inspector General (HHS-OIG) runs a hotline to accept tips and complaints from all sources about potential fraud, waste, abuse, and mismanagement in Department of Health and Human Services' programs, including Medicare and Medicaid.

Contact the HHS-OIG National Hotline, 1-800-HHS-TIPS (1-800-447-8477) or TTY 1-800-377-4950 or by visiting <https://oig.hhs.gov/fraud/report-fraud/index.asp>.

### Diversion involving injectable medications or injection supplies

**NC Division of Public Health-Communicable Disease Branch** - There are no statutory requirements to report diversion that places patients at risk for communicable disease to the state health department. However, the NC Division of Public Health's Surveillance for Healthcare-Associated Infections and Resistant Pathogens Patient Safety (SHARPPS) Program, operated by the Communicable Disease Branch, requests to be notified of incidents in which diversion occurs involving injectable medications or injection supplies. The SHARPPS Program provides the following resources and expertise to healthcare partners:

- ☐ Assists with assessing risk for bloodborne pathogen or bacterial exposure
- ☐ Determines whether the provider had been reported as positive for HIV, HBV, or HCV
- ☐ Facilitates laboratory support, including consultation and testing
- ☐ Provides consultation and materials for communication of risk to patients

The [NC SHARPPS Program](#) can be reached at 919-733-3419 or [nchai@dhhs.nc.gov](mailto:nchai@dhhs.nc.gov).

As a reminder, physicians are required under [NCGS 130A-135](#) to report cases of certain communicable diseases (listed in [10 NCAC 41A .0101](#)) to their local health department, which in turn is required to report these cases to the state health department. Under [NCGS 103A-137](#), health facilities may also make such communicable disease reports.



## FREQUENTLY ASKED QUESTIONS

[This information is provided for general reference only and is not intended to serve as legal advice about what a health system should do in any particular circumstance it may face. Please consult legal counsel for such advice.]

### Employee References

**Q:** Another hospital has contacted our hospital for a reference regarding our former employee who is applying to work at that hospital. The employee was terminated from his position at our hospital after he was discovered to have been diverting controlled substances on the job. Is our hospital allowed by law to share information about the reason for the former employee's termination with the inquiring hospital?

**A:** Yes--NC law explicitly protects the sharing of such information. Under [NCGS 1-539.12](#), an employer that discloses information about a current or former employee's job history or job performance (including the reason for the employee's separation) to a prospective employer upon request of the prospective employer is immune from civil liability and is not liable in civil damages for the disclosure or any consequences of the disclosure. This immunity does not apply if the information disclosed by the employer is false and the employer knew or reasonably should have known it was false.

### Timing of DEA Reporting

**Q:** We are hesitant to report a suspected diversion incident to the DEA before we have investigated it and have an idea about what happened. How can we file a report within one business day of the discovery of a significant loss or theft when we know so little about the circumstances?

**A:** It is understandable that you may be lacking significant pieces of information so soon after the discovery of a significant loss or theft of controlled substances. However, the law is clear that a report must be filed within one business day of the discovery. Simply report the information you have at the time. As you discover more information, you may file an additional report to give a more complete picture of what has taken place. If you have filed a Form 106, you can file an amended form to give more information.

The same principle applies to the Drug Disaster & Loss Report that must be filed with the NC Board of Pharmacy within 10 days of the discovery. Provide the information you know at the time of the required filing, and file updated reports as you gain more understanding about what has occurred.

**Q:** We are unsure whether a controlled lost we experienced would be considered "significant" under the law. Should we report the loss if we are unsure?

**A:** Yes, you should err on the side of reporting the incident if you are unsure whether a loss is "significant."

### DEA Form 106

**Q:** My health system filed an initial report of suspected diversion within 24 hours of its discovery. Does it need to submit a DEA Form 106 too?

**A:** Yes, the DEA Form 106 must be submitted at some point. It can be the initial report submitted within 24 hours, but a health system may also choose to file a brief initial report and then wait to submit the Form 106 until after

it has had the chance to learn more details about what happened. If the Form 106 is not submitted within two months of the initial report, the health system should contact the DEA to give an update on the investigation.

**Q:** Is there a cost associated with filing a DEA Form 106?

**A:** No, there is no cost to file a DEA Form 106.

**Q:** Is the DEA Form 106 a public record?

**A:** When a Form 106 is filed with the DEA, it is not available online to the public or by simple public request. Form 106s may be obtained by formal Freedom of Information Act requests.

### When to report if reporting time not stated by law

**Q:** In reporting to agencies where there isn't a specific requirement on the timing of reporting, what is a good rule of thumb of when to report?

**A:** In cases where there is not a legal requirement of when to report, it is reasonable to wait to report after you have conducted a preliminary investigation into the incident and have at least some idea what has happened. However, it is important to report as soon as practically possible, because evidence and witnesses disappear and memories fade over time; law enforcement and regulatory agencies need timely notice to be able to conduct their investigations and obtain accurate information. Furthermore, law enforcement and regulatory agencies can provide valuable assistance to health systems in conducting their own investigations, so it is never too early to involve them in a case of suspected diversion.



### Diversion investigations by law enforcement and regulatory boards and HIPAA concerns

**Q:** I am worried that disclosing information to law enforcement agencies about a diversion incident may violate our obligations regarding patient privacy under the Health Insurance Portability and Accountability Act (HIPAA). Does HIPAA prevent my hospital from sharing information with law enforcement?

**A:** Often, law enforcement agencies will not need access to HIPAA-protected health information (PHI) to conduct their investigations of diversion. However, if PHI is requested by law enforcement, HIPAA contains certain exceptions that allow HIPAA-covered entities to disclose PHI to law enforcement. For example, a hospital can report PHI that it in good faith believes to be evidence of a crime that occurred on hospital premises. The US Department of Health and Human Services has produced a guide on this topic: [https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/special/emergency/final\\_hipaa\\_guide\\_law\\_enforcement.pdf](https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/special/emergency/final_hipaa_guide_law_enforcement.pdf).

**Q:** Does HIPAA prevent my hospital from sharing patient information with the NC Medical Board or other professional regulatory board when it is investigating a diversion incident?

**A:** Hospitals are permitted to share HIPAA-protected health information with the NC Medical Board and other regulatory boards pursuant to 45 C.F.R. 164.512(d), because they are “health oversight agenc[ies]” authorized by state law to use that information in licensure and disciplinary activities.

### Provider recovery organizations

**Q:** I am worried about reporting an employee for diversion and subjecting her to possible criminal sanctions when I believe she suffers from the disease of addiction and needs medical care. What should I do?



**A:** There are certain reporting requirements that exist by law and must be followed, regardless of the sympathetic case an employee may present. However, many agencies, including law enforcement agencies and regulatory boards, share your view that in some cases medical treatment is the preferred path over criminal conviction or loss of professional license. In multiple cases every year, employees are allowed to seek treatment and show over time that they are in recovery and safely able to work around controlled substances and thus retain their licenses. Deferred prosecution may also be available to employees who are prosecuted criminally for their diversion and choose to seek substance use treatment.



North Carolina has strong provider recovery organizations available to help certain categories of providers with substance use disorders or other behavioral or mental health challenges. The [NC Physicians Health Program](#) serves physicians, physician assistants, pharmacists, pharmacy technicians, and veterinarians. The Board of Nursing offers programs for nurses—including nurse practitioners, certified registered nurse anesthetists, and certified nurse midwives—with substance use disorders, including its [Alternative Program](#).

## SUMMARY OF DIVERSION REPORTING REQUIREMENTS FOR NC HEALTH SYSTEMS

	Agency	Reporting mandated by law?	Time specified?
In all cases	DEA	✓	Within one business day
	Board of Pharmacy	✓	Within ten days
	DHHS Drug Control Unit	✓	Annually
Differing by employee licensure	Board of Medicine	✓	Within 30 days of action involving privileges being in effect
	Board of Nursing	✓	
	Board of Pharmacy		
	Office of Emergency Medical Services		
	Division of Health Service Regulation	✓	Within 24 hours
Other	Law enforcement - state and local		
	FDA		
	OIG		
	NC Division of Public Health - Communicable Disease Branch		



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