

INTRODUCTION

“The matrix of substance misuse knows no boundaries. We must provide the nurse an opportunity to seek treatment and continue in practice while protecting the public’s health, safety and welfare.” **Myra Broadway, Executive Director Maine Board of Nursing**

Maine healthcare leaders want all nurses and employers of nurses to know about chemical dependency and impaired practice. How do we best address the needs of the chemically dependent nurse while protecting the patient? To deal with this complex issue, our Steering Committee was established in 2008, led by the Nursing Leaders of Maine (OMNE) and Maine Society of Healthcare Human Resources Administration. We have worked to prepare resources that can be used to learn more about chemical abuse, addiction, and impaired practice. It is a goal that any Maine nurse who is willing to seek chemical dependency treatment and pursue recovery deserves to remain employable and supported in the process he/she will be involved in.

Included in this education and outreach is the Maine Impaired Nurse Toolkit.

Maine’s Impaired Nurse Toolkit does not provide addiction counseling, intervention, treatment, or monitoring during recovery services, but rather support for employers and employees who may find they are facing the challenge of working with, or knowing, an impaired nurse in Maine. This Toolkit is designed to provide education and awareness of the issue of impaired nursing staff, a guideline for employers and employees to follow to provide safety for patients, protection of an employer on the risks associated with this issue, and to encourage advocacy and support of the recovering impaired nurse in their process of recovery.

Although Maine’s Impaired Nurse Toolkit originated with registered nurses in mind, the advice and recommendations given may be appropriate for other employees in the healthcare setting. Each reader should consider making it available to those employees and agents who require such access for training needs or for immediate support in addressing the impaired employee. The focus of recovery from substance abuse can work in harmony with a no tolerance for injury policy, and those employees willing to learn from these profiles described are welcome to join in the growing number of organizations committed to the highest quality healthcare.

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THIS HAS BEEN A GREAT LEARNING EXPERIENCE FOR US!
...a word from the Employer Toolkit Task Force

As healthcare leaders, we've all had to deal with this at one point or another. You receive a report that an employee is suspected to be at work under the influence of alcohol or drugs. Perhaps drug diversion is even involved! In many cases, the reaction is...if we can prove it, they're gone! After all, we have a no tolerance policy and we are driven to protect our patients. But a closer look at the issue raises our awareness of other possibilities. Are we ignoring the true numbers of employees with alcohol/drug issues? Aren't many of these individuals the same people we've looked up to in the past as "stars"? Are our current policies driving the problem underground and delaying/preventing people from getting help with their issues? In a time of impending healthcare worker shortage, can we afford to discard even one nurse? Shouldn't other healthcare professionals be offered the opportunity for full recovery, like doctors?

"Please hurt my feelings before I die!"

Looking deeper into the issue also provides a more nuanced understanding of the problem. Recognizing alcohol and drug addiction as a disease does not excuse the non-acceptable behaviors. In fact, it empowers the employer to hold the employee accountable. We learned that from a treatment provider's perspective, you are doing the employee a favor by bringing light to the concerns. Denial is a key coping mechanism to those with an addiction. The sooner employees are forced to face their issues, the sooner they will either get the help they need and improve or be forced to deal with the consequences. In either case, the sooner you confront the employee, the sooner you will have an improved work environment and greater assurance of safeguarding your patients. The possibility DOES exist of achieving zero tolerance of drugs/alcohol in the workplace while also allowing a safe re-entry of the formerly impaired healthcare worker.

We have developed this toolkit to help you guide your organization through a more in-depth step-by-step approach to addressing this vexing issue. A lot of the information is not original. We hope you will benefit from our many hours of research by having what we felt were the most effective tools all available in one place.

Employer Toolkit Task Force

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THE IMPAIRED PROFESSIONAL

Impairment is defined as a situation in which an individual is rendered unable to perform their professional duties and responsibilities in a reasonable manner because of a variety of health problems, including physical disease, psychiatric problems, substance abuse, and chemical dependence. (Roche, Substance Abuse Policies for Anesthesia, p188.) We fully recognize that there can be an array of potential reasons why an employee might be impaired. This toolkit focuses primarily on individuals who are impaired due to some type of substance abuse.

SUBSTANCE ABUSE: UNDERSTANDING THE ISSUE

Why do we need to address the issue of impaired nurses/healthcare workers?

- Chemical dependency is a chronic brain disease, with fatal consequences, that CAN be treated.
- Research (ANA, Trinkoff) shows that 8 to 10 percent of nurses (conservative estimate) have impairment issues related to drug or alcohol abuse. In our organization of (insert number of nurses in your organization) nurses, that would mean (your number times 8 to 10 %). The number is higher for nursing sub-specialties such as the ER, ICU, and significantly higher for nurses in anesthesia practice.
- Nurses are at even higher risk, due to high stress jobs that also provide access to drugs.
- Alternative to Discipline programs for physicians have a proven approximately 75 percent track record of successful re-entry into practice when there is a well-defined contract.
- In many cases, these can be our “star” employees. Can we afford to discard nurses, especially if programs exist that can help with successful re-entry into the workplace?

Seeking a different approach:

2002 American Nurses Association Resolution -

- Promote awareness of impaired practice, its prevalence, management, and implications for patient safety if left unaddressed and untreated.
- Education promotes earlier identification, intervention, and treatment.
- Policies that promote alternative to discipline programs combine strict accountability provisions to protect patients while providing an avenue that allows employee retention based on improved performance.

DEVELOPING AN ORGANIZATION PHILOSOPHY

Before your organization can develop a comprehensive policy and procedure on how to handle the subject of substance abuse/chemical dependency of its nurses/healthcare workers, it is important to agree upon the overall philosophy that will serve as the foundation.

Refer to DEVELOPING AN ORGANIZATION POLICY section first before having your first stakeholders meeting. This will clarify in advance some of the issues you will want to address.

- **Involve stakeholders.** Consider representatives with subject matter expertise as well as authority to determine the organization's position. Examples include Nursing, EAP, Administration, Medical Staff, Human Resources. Depending on your organization, this group can either make the final determination or submit for approval to the CEO for final approval. Consider whether endorsement by your organization's Board of Directors is something that is required or will be of benefit.
- **Setting the stage.** Providing some or all of the information in the *Substance Abuse-Understanding the Issue* section of the toolkit. This information might prepare decision makers to understand why it is important to devote time to this topic.
- **How does the organization view the issue of chemical/substance abuse?**
 - Is the primary focus to communicate the importance of a "no tolerance" to impairment in the workplace approach?
 - Is there a willingness to acknowledge that chemical dependence is a chronic but treatable disease?
- **Position statement regarding the affected employee.**
 - What is the primary desired outcome?
 - What is the organization's position with respect to re-entry to practice?
 - If re-entry is an option, what are the primary elements required for re-entry?
- **Position statement regarding discipline vs. alternative to discipline approach.**
- **Position statement regarding consistency of approach for individuals at all levels of the organization.**
 - What happens when there are potential safeguards for a licensed person (i.e., can be on a regular external monitoring plan as part of a return-to-work contract vs. a non-licensed person who does not have a license/certification at stake)?
 - Is the organization willing to apply to have full drug-testing status?
- **Organization's position in regards to its role in supporting education, early identification, and encouragement of treatment.**
 - Should the organization policy be shared as part of orientation?
 - Should the organization have an education plan for all staff on this topic?

Sample Philosophy Statement: (Organization name) is committed to protecting the safety, health, and well-being of all employees, patients/residents, and other individuals in our workplace. We recognize that alcohol abuse and drug use pose a significant threat to our goals and that alcohol/drug abuse and addiction are treatable illnesses. We also realize that early identification, intervention, and support improve the success of rehabilitation. Because we greatly value our employees and believe in the potential for rehabilitation, we have established an approach that balances our respect for individuals with the need to maintain an alcohol and drug-free work environment.

DEVELOPING AN ORGANIZATION POLICY

Once you have developed your organization's philosophy, you have the foundation for building a policy. The U.S. Department of Labor has created a GREAT tool to help you! This automated tool will walk you through a series of questions that will result in a fully developed policy which you can then save for further customization/editing. Reviewing these questions prior to your philosophy development meeting is recommended. This tool is available at: <http://www.dol.gov/elaws/asp/drugfree/menu.htm>

DIVERSION

Source for much of the material below in the diversion related sections is from Resource Manual – The Impaired Nurse Colorado Board of Nursing, July 2003.

Nurses who administer controlled drugs to patients have ready access to the supply. There are systems level strategies that can be implemented to both prevent and detect the diversion of controlled drugs.

Definition of Diversion: “Diversion occurs when a controlled substance or a drug having a similar effect is not used as prescribed. Drug diversion includes obtaining a controlled substance or drug having similar effects from wastage.”

PREVENTION OF DIVERSION

Most health care facilities report drug diversion as a result of an incident (e.g., a patient reports that he did not receive his pain medication, a nurse is found in a bathroom unconscious from an overdose of narcotics). Regular monitoring of medication records can greatly reduce or prevent these incidents. The following are recommendations for preventing drug diversion in a health care facility:

Drug access/administration protocol:

- Use state and federal resources for ensuring the proper storage, surveillance, and administration of controlled substances.
- Regularly inspect controlled substance packaging and appearance for drug substitution.
- Establish and enforce procedures for the safe disposal of controlled substances, including disposal at the time of a patient's death.
- Establish and enforce procedures for accepting deliveries of controlled substances from pharmacies.
- Audit automated drug dispenser reports (e.g., Pyxis machines) on a routine basis.
- Regularly monitor how drugs are administered, wasted, and documented. Refer to “red flags” tool in appendix.
- Prohibit nurses from sharing or revealing their controlled substance access code to other nurses.
- Strictly limit and monitor access to codes by Information Services and other supporting departments.

Other prevention strategies:

- Conduct pre-employment screening (e.g., drug screening, criminal background checks, licensure verification)
- Education & training.
- Explore utilizing education/training materials from your drug dispensing vendor.
- Review information on cases brought before the Maine Board of Nursing to get insight into any recent developments/fact patterns/potential weaknesses in your processes.

A Special Note on Fentanyl

Fentanyl is one of the most frequently diverted drugs because 28% to 84% of the medication remains in a fentanyl patch after 72 hours (Wyoming Pharmacy Association NewsLetters-www.wpha.net/may2000.asp). Nurses divert patches by: removing the patch from the patient and keeping it; removing a new patch, keeping it and replacing the used patch on another part of the patient's body; removing the medication from the patch with a syringe; removing patches from sharps containers; and removing fentanyl from drug stock.

The following are recommendations for the prevention and detection of the diversion of fentanyl:

- During shift count of controlled substances, inspect the foil packets containing fentanyl patches for signs of tampering.
- Each time a fentanyl patch is newly applied to a patient's skin, use a pen or felt tip marker to write the date, time, and initials of the medication nurse on the patch. During the time the patient wears the patch, regularly check this documentation against medication administration records. Also, inspect the patch for cuts, needle holes or other evidence of tampering, such as a dried-out appearance.
- Return used fentanyl patches to the pharmacy for destruction. Have two nurses count used fentanyl patches on each shift as part of the narcotics count until they are returned to the pharmacy. Document and require a witness of the number of patches returned to the pharmacy.
- Never allow the injectable form of fentanyl to be left unsupervised (e.g., some nurses in surgery and emergency departments remove vials/ampules of fentanyl from the narcotic cabinet or draw up the fentanyl in a syringe in advance and leave it at the patient's bedside before medicating the patient).

A Special Note for Long-Term Care Facilities Using Emergency Drug Boxes

The following are recommendations for discouraging diversion of controlled substances from emergency drug boxes in long-term care facilities:

- When the box is delivered from the pharmacy, a contents list of the box is checked by two licensed nurses. If the drugs documented on the contents list are in the box, the two licensed nurses sign the list as received and lock the box. If there are medications missing, return the emergency box to the pharmacy staff member who delivered it.
- Keep the contents list for the emergency drug box in the controlled substance count book. Write the number of the lock on the contents list. Document that the lock number was checked and verified each shift by two nurses.
- If medication from the box is needed, the medication is signed out on the contents list by a licensed nurse. The medications in the box are counted by two licensed nurses each change of shift until the medication is replaced and the box is relocked.
- Record administration of the controlled substance on a separate control sheet.

A Special Note for Home Health

Unfortunately, home care and hospice situations provide an even greater diversionary challenge than hospitals or nursing homes. Staff work independently and are unsupervised in the home. Even the most closely controlled medications are often within reach of patients, family, friends, staff, and even medical delivery personnel. Additionally, family caregivers are often tired and grieving and not at their most astute. Special care needs to be taken in educating family and staff about the seriousness of diversion and the need to protect against it. General suggestions are set out below. (Please refer to your organization's policies and procedures as they may vary slightly from our recommendations).

- Educate client/family about safeguarding medication, including keeping medications out of reach and out of sight. Document patient teaching and response.
- Whenever possible, order and dispense a minimum amount of medication. Never allow staff to pick up medication from the pharmacy.
- Have family caregivers and staff write down what they give, when they give it, and who gave it.
- Have family or staff count pills at the beginning and end of shift (day, week, whatever is appropriate).

If drug diversion is suspected

- Inform the family of the medication discrepancy and suspicion of drug diversion.
- Re-educate the family about the importance of safeguarding medications.
- Encourage the family to utilize a “lock box” to safeguard oral, intravenous and/or subcutaneous infusion medication over which the client or their representative maintains the key or utilize another system for securing medications.
- Notify the physician.
- If nurse or other staff is suspected, perform an investigation.

If suspicion of drug diversion persists, consider additional steps.

- Notify the pharmacy of suspected drug diversion.
- Collaborate with the prescribing physician and the pharmacy to determine the minimal amount of drug availability in the home.
- Inform patient/ family of our intent to notify the police if appropriate.

When home care or hospice services have ended, make sure the family knows the proper way to dispose of medication. In the case of hospice, you might suggest that the hospice nurse and a family member dispose of medications together with both signing off. Information on the proper disposal of medications is available on the Internet.

WHAT TO DO WHEN YOU RECEIVE AN ALLEGATION OF SUSPECTED IMPAIRMENT/DRUG DIVERSION

IMPORTANT NOTE: Supervisors should work in collaboration with their HR professional and/or legal counsel in all of these steps.

...it's 3am "ON-THE-SPOT" TOOL

We know that critical situations don't always come up Monday through Friday between 8 am and 5 pm! Does your "off hours" person in charge have the knowledge to address an issue of potential employee substance abuse/diversion appropriately? We recommend that you customize this brochure to meet your organization's specific information and make it easily accessible to all your supervisors. See Appendix 7 of the toolkit for a sample brochure.

IMPORTANT NOTE: If you are in a leadership role, you should be familiar with your organization's philosophy and how to refer easily to your policy/protocol. This will facilitate a timely, complete, consistent response.

Preliminary fact finding

As with all other issues, there is a need to be careful and not to jump to conclusions. Drill down to determine the facts currently available to support the concern.

What to do with the employee pending investigation

Employee safety:

An assessment needs to be made regarding the employee's condition and safety. The response can be tailored to the specifics at hand and can range from taking steps to ensure that the employee can get home safely (i.e., if presents with alcohol on breath and slurred speech) to contacting law enforcement if the employee refuses to comply and poses a risk to self or others.

We have some tools to help you make an assessment:

- See Appendix 7 for a "...its 3am" or on the spot tool for the individual in charge who needs to act when administrative leaders are not immediately available.
- See Appendix 2 for a more detailed assessment tool that can help capture critical information to support reasonable suspicion.

Patient safety: This concern is paramount. Steps should be taken to assure that the employee is not in any position to potentially jeopardize patient safety. Depending on the circumstances, a determination is made to make either an alternate non-patient care assignment or keeping them out of the workplace.

Should you place the employee on leave pending investigation?

This decision is based on a review of the facts/circumstances in this specific case.

Points to consider:

- What is the employee's performance history?
- How strong is the evidence in the case? The greater the certainty that serious wrongdoing has occurred, the greater consideration should be given to keeping the

employee out of the workplace. If the case is very gray, you might want to make a greater effort to keep the employee at work.

- Access. Based on the allegations, how easy is it to keep the employee working while minimizing potential access to items/substances we don't want them to access.
- Patient care. Based on the allegations/staff person role, are patients being put at risk if the employee is allowed to be in the workplace? Is there an alternate, value added assignment that can be given?
- Are there reasonable grounds to believe that the organization is at risk by having the employee in the workplace?

Should a leave pending investigation be paid or unpaid?

An organization should determine in advance how it will handle an employee who is put out of work while it is conducting an investigation into whether or not the employee has committed a serious offense that could, if substantiated, result in suspension or discharge.

Options include:

- Unpaid
- Utilize Earned Time/vacation time, if available
- Paid administrative leave

You should consider including in your policy the following provisions:

- Management has the discretion to determine if such an investigatory suspension is warranted, based on the circumstances of the case.
- If it is determined that the employee has not committed the offense or that it does not warrant an unpaid suspension, then the employee will be paid retroactively (or have the vacation/earned time restored) for the period of the suspension.
- If an unpaid disciplinary suspension for a specific period of time is determined to be warranted, then the employee will have pay or vacation/earned time restored for the balance in excess of the disciplinary unpaid suspension.

Factors to consider:

According to the Department of Labor, you can suspend hourly non-exempt employees with or without pay in Maine (only NEED to pay for time actually worked). However, in most cases, you cannot suspend salaried, exempt employees without the proper alignment of events. To suspend an exempt employee without pay, the suspension must be for greater than one week, because an exempt employee must be paid their salary for the full period for work performed in that period. The allowable rationale is relatively broad for exempt employees: 1) disciplinary suspensions for workplace conduct for which there exists a policy prohibiting such conduct which applies to all employees; and 2) a major infraction of workplace safety rules.

From a legal perspective, a paid suspended employee is less likely to sue than a non-paid suspended employee. Whatever system chosen must be managed consistently. In other words, if you suspend a pharmacist without pay pending an investigation for drug diversion, you must also do the same for any other employee suspected of the same or similar conduct.

If the investigation yields innocence, it would be grossly unfair not to pay the employee retroactively. To do otherwise will likely push the employee right to the courthouse.

For additional information refer to:

http://www.dol.gov/dol/allcfr/ESA/Title_29/Part_541/29CFR541.602.htm

Conducting an investigation

The main goal of any investigation is to provide a sound, factual basis for decisions by management. The investigation should also produce reliable documentation that can be used to support management actions. Finally, an investigation of employees should reveal whether any misconduct has occurred, identify (or exonerate) specific employees who are suspected or guilty of misconduct, and put a stop to further wrongful actions.

- Who do you include in the investigation? Typical members include the employee's supervisor, a representative from Human Resources, and other individuals who have expertise regarding the specific allegations at hand. For example, if the allegation involves potential drug diversion, you should involve someone from the pharmacy.
- There are a number of resources available to help you plan an effective investigation. Examples include (these are really helpful!):
 - SHRM.org (investigations toolkit)
 - http://www.twc.state.tx.us/news/efte/workplace_investigations_basics.html
 - http://www.twc.state.tx.us/news/efte/cultural_differences.html
- Can you set up surveillance? Although it is not unlawful to set up electronic surveillance in certain areas, care needs to be taken not to be at risk of "invasion of privacy" complaints. Maine law prohibits hidden surveillance in areas where there are privacy expectations (ex. bathrooms, locker rooms, etc). You should provide notice that video monitoring exists in the organization. Consult with law enforcement and/or legal counsel before setting up any targeted monitoring.
- Conducting searches. As with surveillance, there are considerations with respect to expectations of privacy. It is likely to be okay to search an employee's desk or locker, but not a purse. It is advisable to have something in your policies or employee handbook covering expectations in your organization. Of course, there is also nothing to prevent you from asking the employee if you can search. Searches should always be conducted with at least one other witness for the employer.
 - Your organization policy should articulate the protocol for involving law enforcement. This will be helpful if you feel a strong case exists to search something where there IS an expectation of privacy (i.e., employee vehicle) and want to have law enforcement take over.
 - You may detain an employee for no longer than 30 minutes while waiting for the police without running afoul of the statutes pertaining to false imprisonment, which is an actionable tort in Maine.
- Can you submit the employee to drug or alcohol testing? Only if you have an approved policy with the Maine Department of Labor.

Drug testing policies may be approved for one or all of the following types of testing:

- job applicant testing
- employee testing
 - probable cause testing – where reasonable grounds exist to believe that an employee may be under the influence of a substance of abuse.

- random/arbitrary testing – a method of selecting people to be tested where all potential testees have an equal chance of selection by chance or where testing is based on criteria unrelated to substance abuse, such as date of hire anniversary.

Employers must meet certain requirements, which include having a policy with specific provisions (i.e., disclosure, specific procedures, approved labs, access to an approved EAP) as well as annual reporting.

What if the employee being investigated states “I’ll even submit to a drug test!” Can the employer accept that? No, unless the situation complies with an approved drug testing policy.

For guidance on drug testing statutes in states other than Maine, refer to:

<http://www.ncsl.org/programs/employ/drugtest.htm>

For additional information, refer to:

<http://janus.state.me.us/legis/statutes/26/title26sec683.html> (Maine Drug Testing Statutes)

http://www.maine.gov/labor/labor_stats/publications/substanceabuse/modelpolicy.htm (model drug testing policy)

<http://www.nationaldrugscreen.com/dfmanual-supervisors-checklist.html;jsessionid=513851457E245B98F1033DFB1DB9FB96>

(Supervisor checklist for making reasonable cause determination)

<http://www.dol.gov/elaws/drugfree.htm>

The Drug Free Workplace Law of 1988 has provisions regarding drug testing, which applies to those with federal contracts or grants.

- Risk Management considerations: Team approach is beneficial as all have different perspective. Patient safety is the key. If not sure, go slowly. It is very important to stick to objective vs. subjective documentation. Don’t use the term “abuse”. For example, if patient didn’t get prescribed medications, can document that fact and the effect that this had, but not the subjective assessment of abuse.
- Record-keeping: Remember that investigation related documents are all discoverable and may need to be turned over to authorities or any opposing parties. Be wary of comments that could be construed as discriminatory. Focus on facts, quotes, etc. Particular care should be taken with any email exchanges pertaining to a case, as these can all be discoverable, as well as the personnel file, supervisor file, and investigation notes.
- Concluding the investigation: Determine if allegations are founded, unfounded or inconclusive and document that conclusion.

Major point to recall if nothing else:

DO NOT DIAGNOSE!

Focus on what is OBJECTIVE, VERIFIABLE, and OBSERVABLE.

TELL FACTS, NOT INTERPRETATION OF FACTS.

Progressive Discipline

- **Consistency.** Organizations should have guidelines already in place to provide parameters as to levels of discipline imposed for categories of offenses. These serve as guidelines, not absolutes, so that circumstances of the specific situation can be fully weighed. Formulating these in an objective fashion as opposed to when you are dealing with a specific situation can be helpful so that your approach is based on the facts, not the person. These guidelines will also help so that employees across the organization are treated consistently, regardless of position.
- **Compassion vs. accountability.** It can often occur that these cases can be quite compelling. For example, a long-term valued nurse develops a problem after a significant life event. It is important that we keep patient safety in the forefront while providing needed support systems.
- **Referrals to EAP.** See Appendix 3

Exercise caution when initiating a referral to EAP to address a performance issue. Sending an employee to EAP in response to performance issue(s) but before discipline or documentation in a performance log, can create problems for a couple of reasons:

- Employees can think that sending them to EAP is the outcome of their incident. They then can feel like they have been treated unfairly should management send them to EAP and then take severe disciplinary action.
- Sending them to EAP before taking disciplinary action or documenting in a performance log can also muddy the waters with respect to whether this is a performance issue or a disability. Some individuals have come back and said that their problems are as a result of a disability and therefore need accommodation. This then calls into question our ability to hold them accountable for the incident. They can also say that management "regards them" as disabled, since we sent them to EAP. The law protects not only people with disabilities, but also anyone PERCEIVED as being disabled.

What should a supervisor do?

- Offer EAP as a potential tool the employee can use to help them come up with a plan of action when you address the incident/performance issue.
- DO NOT DIAGNOSE or mention any specific conditions! DO NOT use terms such as: "you seem to have a drinking problem", "you're all stressed out"; or "we want you to go for counseling or therapy". Instead, refer to the specific performance issue such as: "We received three complaints of smelling alcohol on your breath"; "We've observed you being rude to our customers and some co-workers. This is unacceptable"; "EAP is a tool we can offer to assist you with any issues that may be having an impact on your performance";
- Avoid the temptation to be a social worker (even if you ARE one!). EAP can actually make things easier for you as a supervisor. You can state that it is not your role (or don't have the proper training) to get involved in any personal matters that may be impacting their work, but that we can make such a service available to them through the EAP. Another danger to getting too involved in someone's personal problems is that the employee may later suspect that any adverse employment decisions are based on your knowledge of their personal circumstances.

- Of course, sometimes there are extenuating circumstances, such as if the person has some serious personal issues that need to be addressed immediately, that may warrant the necessity to make a referral even before you formally address the performance issue(s).

REPORTING REQUIREMENTS

There are a number of different reporting requirements, some more prescriptive than others with respect to the amount of discretion available to employers. One thing to consider is, particularly in a small state like Maine, these different agencies interact all the time. Therefore, your organization will want to consider the pros/cons of self-reporting.

- **Drug Enforcement Agency (DEA- federal).** Requirements are quite specific.

For cases of drug diversion, in accordance with [Title 21, Code of Federal Regulations, Sec. 1301.74\(c\)](#) & [Title 21, Code of Federal Regulations, Sec. 1301.76\(b\)](#), the registrant shall notify the Field Division Office of the Administration in his area of the theft or significant loss of any controlled substances immediately upon discovery of such loss or theft. The registrant shall also **complete DEA Form 106** regarding such loss or theft. When determining whether a loss is significant, a registrant should consider, among others, the following factors:

- (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 which may take place involving the controlled substances;
- (4) A pattern of such 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 material.

See Appendix 5 for further explanation and details

- **Attorney General's Office: Healthcare Crimes Unit 207-626-8870**
http://www.maine.gov/ag/crime/crimes_we_prosecute/healthcare_crimes.shtml
The Attorney General's Healthcare Crimes Unit (the State's designated Medicaid Fraud Control Unit) is a federally-funded unit charged with investigating and prosecuting
 - MaineCare fraud; and
 - Abuse, neglect or financial exploitation occurring in MaineCare facilities or committed by MaineCare providers or their employees.

They investigate MaineCare providers and their employees. Their scope includes doctors, nursing homes, hospitals, adult care homes, and home health agencies.

If you suspect that MaineCare fraud has occurred, or abuse, neglect or exploitation has occurred in a MaineCare facility or by someone working for a MaineCare provider, immediately report the incident to the HealthCare Crimes Unit by calling 207-626-8870, or by [filling out an on-line form](#).

- **Drug Enforcement Agency (DEA- Maine).**
<http://www.maine.gov/dps/Mdea/homepage.htm>
- For drug diversion cases, the Maine branch will likely get the information from the federal DEA as a result of filing the DEA Form 106, but you may want to contact them for more immediate assistance, if dealing with significant diversion or other emergent cases.
- **Licensing Boards.** In accordance with [Title 24, §2506: Provider, entity and carrier reports](#) you have the following obligation:

A health care provider or health care entity shall, within 60 days, report in writing to the disciplined practitioner's board or authority the name of any licensed, certified or registered employee or person privileged by the provider or entity whose employment or privileges have been revoked, suspended, limited or terminated or who resigned while under investigation or to avoid investigation for reasons related to clinical competence or unprofessional conduct, together with pertinent information relating to that action. Pertinent information includes: a description of the adverse action; the name of the practitioner involved; the date, the location and a description of the event or events giving rise to the adverse action; and identification of the complainant giving rise to the adverse action. Upon written request, the following information must be released to the board or authority within 20 days of receipt of the request: the names of the patients whose care by the disciplined practitioner gave rise to the adverse action; medical records relating to the event or events giving rise to the adverse action; written statements signed or prepared by any witness or complainant to the event; and related correspondence between the practitioner and the provider or entity. The report must include situations in which employment or privileges have been revoked, suspended, limited or otherwise adversely affected by action of the health care practitioner while the health care practitioner was the subject of disciplinary proceedings, and it also must include situations where employment or privileges have been revoked, suspended, limited or otherwise adversely affected by act of the health care practitioner in return for the health care provider's or health care entity's terminating such proceeding. Any reversal, modification or change of action reported pursuant to this section must be reported immediately to the practitioner's board or authority, together with a brief statement of the reasons for that reversal, modification or change. If the adverse action requiring a report as a result of a reversal, modification or change of action consists of the revocation, suspension or limitation of clinical privileges of a physician, physician assistant or advanced practice registered nurse by a health care provider or health care entity for reasons relating to clinical competence or unprofessional conduct and is taken pursuant to medical staff bylaws or other credentialing and privileging policies, whether or not the practitioner is employed by that health care provider or entity, then the provider or entity shall include in its initial report to the disciplined practitioner's licensing board or authority the names of all patients whose care by the disciplined practitioner gave rise to the adverse action. The failure of any health care provider or health care entity to report as required is a civil violation for which a fine of not more than \$5,000 may be adjudged. [2005, c. 397, Pt. C, §15 (AMD); 2005, c. 397, Pt. C, §16 (AFF).]

- **Department of Health and Human Services.** Division of Licensing and Regulatory Services, Medical Facilities Unit, is responsible for health care licensing activities and is the federally designated State Survey Agency for the Medicare certification process. They maintain oversight for compliance with the Medicare health and safety standards for
 - Laboratories
 - Acute and continuing care providers, including
 - Hospitals
 - Nursing facilities
 - Home health agencies (HHAs)
 - End-stage renal disease (ESRD) facilities
 - Hospices
 - Other facilities serving Medicare and Medicaid beneficiaries
http://www.maine.gov/dhhs/dlrs/medical_facilities/home.html

*** IMPORTANT NOTE: Investigate through your billing and compliance department whether there have been any improper costs that have been billed as these may need to be reversed based on the circumstances of the case. An example might be if a patient has been charged for drugs that were determined to have been diverted and never given to the patient.
- **Local Police Department.** You should consider developing a working relationship with your local police department in advance to gain an understanding of mutual expectations. Your organization should then develop a policy that articulates the protocol for involving law enforcement. In cases of drug diversion, activities are often coordinated with the Attorney General's Office or the Maine Drug Enforcement Agency.

SHARING INFORMATION

Sharing information with others in your organization

- As with all personnel matters, information should be provided only to those with a “need to know.”
- If the result is an offense that is reportable to outside parties (i.e. drug diversion to law enforcement) it is advisable to inform the individual in your organization responsible for public relations.

Sharing information with other employers

In these days of shortages in key healthcare professions, we are aware of how easy it is for experienced nurses to find other employment. We therefore are challenged by the valid concern we may have that an employee who may pose some risk might find employment in another healthcare setting. Current reference practices have evolved to providing titles and dates of employment only.

Can I provide information to another employer “off the record”? There is no such thing as “off the record.” Providing such information places not only the organization but also the one sharing the information at *personal risk* for defamation of character.

The State of Maine does have an Employment Reference Immunity statute.

Title 26: LABOR AND INDUSTRY

Chapter 7: EMPLOYMENT PRACTICES

Subchapter 1: CONDITIONS FOR EMPLOYMENT

§598. Employment reference immunity

An employer who discloses information about a former employee's job performance or work record to a prospective employer is presumed to be acting in good faith and, unless lack of good faith is shown by clear and convincing evidence, is immune from civil liability for such disclosure or its consequences. Clear and convincing evidence of lack of good faith means evidence that clearly shows the knowing disclosure, with malicious intent, of false or deliberately misleading information. This section is supplemental to and not in derogation of any claims available to the former employee that exist under state law and any protections that are already afforded employers under state law.

Source: <http://janus.state.me.us/legis/statutes/26/title26sec598.html>

Although Maine does have an Employment Reference Immunity statute, disclosure is not without risk. It is important that, if you do choose to disclose information you make sure that the only information shared is based on objective, concrete facts and not interpretation of facts.

EMPLOYEE PROTECTION CONSIDERATIONS

- **Alcoholism:** Under the ADA, someone with alcoholism is an individual with a disability if the alcoholism currently substantially limits a major life activity, was substantially limiting in the past, or is regarded as substantially limiting. An employer may not

discriminate against, and may need to accommodate, a qualified applicant or employee with past or present substantial limitations relating to alcoholism that can competently perform his job and can comply with uniformly-applied employer conduct rules prohibiting employees from drinking alcohol at work or being under the influence of alcohol at work. Employers may discipline, discharge, or deny employment to alcoholics whose use of alcohol impairs job performance or conduct to the same extent that such conduct would result in disciplinary action for other employees.

- **Illegal Use of Drugs:** The **ADA** and the **Rehabilitation Act of 1973** affect drug and alcohol policies. Individuals **currently** engaging in the illegal use of drugs are **not** "individuals with a disability" when the employer acts on the basis of such use. "Currently" means that the illegal use of drugs "occurred recently enough to justify the employer's reasonable belief that involvement with drugs is an ongoing problem."
 - Employers may discharge or deny employment to persons who currently engage in the illegal use of drugs.
 - Employers may not discriminate against drug addicts who are not currently using drugs and have been rehabilitated or have a history of drug addiction.
 - Employers may not discriminate against drug addicts who are currently in a rehabilitation program. (The EEOC has clarified that a rehabilitation program includes inpatient or outpatient programs, Employee Assistance Programs, or recognized self-help programs such as Narcotics Anonymous.)
 - Reasonable accommodation efforts, such as allowing time off for medical care, self-help programs, etc., must be extended to rehabilitated drug addicts or individuals undergoing rehabilitation.

(Source & for further details see:

<http://www.dol.gov/asp/programs/drugs/workingpartners/regs/ada.asp>)

- **Weingarten rights in union/non-union setting**

On June 15, 2004, The National Labor Relations Board ruled by a 3-2 vote that employees who work in a non-unionized workplace are not entitled under Section 7 of the National Labor Relations Act to have a co-worker accompany them to an interview with their employer, even if the affected employee reasonably believes that the interview might result in discipline. This decision effectively reversed the July 2000 decision of the Clinton Board that extended Weingarten Rights to nonunion employees.

PREPARING STAFF FOR THE RETURN OF THE RECOVERING EMPLOYEE

Of course, staff cannot be told the specifics of the illness of any employee. Information that is shared should be told by the employee him/herself. It is strongly recommended to share only minimal information. Review goals of the communication (the goal is to reduce the sense of judgment? Deal with staff anger? Focus on staff level of comfort with co-worker's ability)? Patrice to check with EAP to see how they coach a person returning to the workplace.

OR Its very helpful to get your peers they don't need to know specifics. A sample script might be..."Thank you for your support. (I know I could have done some things differently but I'm getting the help I need.) I am ready willing and able and look forward to working with you in the long haul. Stay out of the details.

However, it is imperative that staff be supportive of the recovering employee. They can be told that the employee is returning after successful treatment of a chronic condition and that while there may be certain limitations in practice or schedule, you expect her to do well in her position and to be fully reintegrated into the department. You should ask staff to be supportive and welcoming while at the same time be clear that standards of care will not be compromised and if they have any questions or concerns to please bring them forward right away. As always, as her manager or supervisor, it is your job to provide clear, consistent feedback on job performance.

TRAINING TOOLS

- **Supervisor Training.** The Department of Labor has great training tools already developed including power-point presentations that can be easily adapted to meet your needs.
- **<http://www.dol.gov/asp/programs/drugs/workingpartners/dfworkplace/st.asp>**
- **Employee Training:** The Department of Labor has great training tools already developed including power-point presentations that can be easily adapted to meet your needs.
- **<http://www.dol.gov/asp/programs/drugs/workingpartners/dfworkplace/ee.asp>**
- **Case studies for training sessions.**

OTHER ISSUES

What do you do with OUI arrests or other public disclosures of infractions?

Typically, we address only issues that occur at work. However, there are times when infractions occurring outside of work become part of the public domain and can have an impact at work. Any work related actions taken as a result of a public illegal activity must be measured against the employee's position and adverse impact on his/her ability to be effective in his/her role.

Employers should strongly recommend that an employee self-disclose if convicted of an OUI. Most professional licenses (including nursing) ask about any convictions at time of renewal, so it would be a good pro-active move to contact the licensing agency first. Employers should also strongly encourage the physician or nurse to contact the Medical Professionals Health Program, again as a pro-active move.

APPENDIX 1
Audit/Investigation “red flags” checklist

- Does one nurse document the administration of more PRN medications than other nurses?
- Was the patient on the unit at the time the dose was documented?
- Was the dose signed out from the narcotic supply but not documented in the medication administration record and/or nurse’s notes?
- Did the nurse medicate another nurse’s patient?
- Does the nurse say s/he was “too busy” or “forgot” to obtain a witness to waste the controlled substance?
- Does the nurse sign out a larger dose of controlled substance when the ordered dose is available, then sign that the remaining medication was wasted?
- Did the nurse say s/he gave her/his controlled substance access code to another nurse?
- Do controlled substance withdrawal times generally correspond to administration times?
- Are patients reporting that the pain medication ordered does not relieve their pain on the nurse’s shift?
- Is the controlled substance count inaccurate when a particular nurse works?
- Are controlled substances signed out for a patient who has no order for them?
- Are times and amounts of controlled substances signed out authorized by physicians’ orders?
- Do staff signatures/initials appear to be forged?
- Do liquid medications have normal color, odor, and consistency? If so, have a pharmacist inspect the medication. Determine if testing by a chemical or forensic lab is indicated. If testing is indicated, send a sample of the medication to a chemical or forensic laboratory. Have someone witness that the sample sent to the lab came from the bottle of medication in question. Save the bottle with the remaining medication for evidence. Please note that most toxicology laboratories do not test for the chemical composition of substances.
- Have a pharmacist inspect any medications that are returned to the facility by a nurse, (e.g., the nurse says she took the missing controlled substance(s) home in her pocket by mistake). Determine if testing by a chemical or forensic lab is indicated. Refractometers may be purchased for drug identification at a facility. See the Internet for purchasing options.

APPENDIX 2
REASONABLE SUSPICION INCIDENT CHECKLIST

Employee's name _____
Department _____
Date(s) _____

This checklist is to be completed when an incident has occurred that provides reasonable suspicion that an employee is under the influence of a prohibited drug substance or alcohol. You should note all pertinent behavior and physical signs or symptoms, that lead you to reasonably believe that the employee has recently used or is under the influence of a prohibited substance as well as any relevant patterns. Mark each applicable item on this form and add any additional facts or circumstances, which you have noted.

Nature of Incident/Cause for Suspicion

- Observed/reported possession or use of a prohibited substance (including patient complaint)
- Apparent drug or alcohol intoxication
- Observed abnormal or erratic behavior
- Arrest for drug-related offense
- Other (e.g., flagrant violation of safety or serious misconduct, accident or “near miss,” fighting or argumentative/abuse language, refusal of supervisor instruction, unauthorized absence on the job) please specify.

Behavioral Indicators Noted

- Verbal abusiveness
- Physical abusiveness
- Extreme aggressiveness or agitation
- Withdrawal, depression, tearfulness, or lack of responsiveness
- Inappropriate verbal responses to questioning or instructions
- Frequent breaks or unexplained absences at work
- Other erratic or inappropriate behavior (e.g. hallucinations, disoriented, excessive euphoria, talkativeness, confusion) Please explain, use quotes if possible.

Physical Signs

- Slurred or incoherent speech
- Possession, dispensing, or using prohibited substance
- Unsteady gait or other loss of physical control, poor coordination
- Dilated or constricted pupils or unusual eye movement
- Bloodshot or watery eyes
- Extreme aggression or agitation
- Excessive sweating or clamminess of skin
- Flushed or very pale face
- Highly excited or nervous
- Nausea or vomiting
- Odor of alcohol
- Odor of marijuana
- Disheveled appearance or out of uniform
- Dry mouth (frequent swallowing/lip wetting)
- Dizziness or fainting
- Shaking hands or body tremors/twitching
- Breathing irregularity or difficulty breathing
- Runny nose or sores around nostrils
- Inappropriate wearing of sunglasses
- Inappropriate clothing (i.e., long sleeves in warm conditions)
- Puncture marks or “tracks”
- Other/comments _____

Work Patterns

- Inconsistency in quality of work
- High and low periods of productivity
- Poor judgment/more mistakes than usual and general carelessness
- Lapses in concentration
- Difficulty in recalling instructions
- Difficulty in remembering own mistakes
- Using more time to complete work/missing deadlines
- Increased difficulty in handling complex situations
- Deteriorating relationships with co-workers and others
- Other/comments _____

Absenteeism

- Acceleration of absenteeism and tardiness, especially Mondays, Friday, before and after holidays
- Frequent unreported absences, later explained as "emergencies"
- Unusually high incidence of colds, flus, upset stomach, headaches
- Frequent use of unscheduled vacation time
- Leaving work area more than necessary (e.g., frequent trips to locker room/ bathroom)
- Unexplained disappearances from the job with difficulty in locating employee
- Requesting to leave work early for various reasons
- Comments _____

APPENDIX 3

EAP Referral Template

Human Resources Department

DATE:

TO:

FROM:

PH:

CC: Personnel file, until followed through on appointments, and then destroyed

RE: EAP Referral

You are being referred to XXXXXXXXXX Employee Assistance Program by your manager, _____ . As discussed, you have behaviors in the workplace which are inappropriate to the care of XXXXXXXXXX clients, and which are limiting your success in your employment.

You are required to follow through on _____ visits, and the EAP program director will notify us that you fulfilled this requirement, although NO other information will be shared with XXXXXX Hospital staff. You will be asked to sign a release for the EAP program granting them permission to tell us that yes; you did fulfill your obligation to talk with them.

EAP can be reached at (207) XXX-XXXX. The EAP office is located at _____. However, you may be assigned an outside contracted provider at another location.

EAP is an employee benefit offered to XXXXXX employees to help them garner the skills needed to succeed in the workplace. I hope you will take full advantage of the support the EAP provider can offer to you.

Thank you.

APPENDIX 4

Guidelines for an Employee to Report a Colleague Who May Have a Substance Abuse Problem

Be knowledgeable. Know the signs and symptoms of impairment, so you do not falsely accuse.

Document facts clearly, concisely, and with dates and times noted.

Do not assume that it will be possible to remain anonymous as the reporter.

Do not be surprised if some colleagues retaliate (ex. the cold shoulder, overt harassment, increased workload, denigration of personal competency or integrity).

Do not gossip--Malicious gossip can tarnish the nurse's reputation.

Focus on the disclosure, not on the personality of the person being reported, by providing objective data; personalizing disclosures could result in a lawsuit for libel or slander.

Have other professionals verify the information, if possible, to lend objectivity.

Maintain confidentiality.

Use institutional channels of communication before considering going public.

Write a clear, short summary of the information and provide the source of the information.

Sources:

"Blowing the whistle on incompetence: One nurse's story," *Nursing 19* (July 1989):47-50.

A Taylor, "Support for nurses with addictions often lacking among colleagues," *The American Nurse 35* (September/October 2003): 10-11.

APPENDIX 5

Visit the following website to view this online along with other links:
http://www.deadiversion.usdoj.gov/fed_regs/rules/2003/fr0708.htm

[Federal Register Notices](#) > [Rules - 2003](#) > **Reports by Registrants of Theft or Significant Loss of Controlled Substances**

Rules - 2003

FR Doc 03-17127 [Federal Register: July 8, 2003 (Volume 68, Number 130)] [Proposed Rules] [Page 40576-40579] From the Federal Register Online via GPO Access [wais.access.gpo.gov] [DOCID:fr08jy03-20]

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1301

[Docket No. DEA-196P] RIN 1117-AA73

Reports by Registrants of Theft or Significant Loss of Controlled Substances

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of proposed rulemaking; guidance.

SUMMARY: DEA is proposing the amendment of its regulations to clarify its policy regarding reports by registrants of theft or significant loss of controlled substances. There has been some confusion as to what constitutes a significant loss, and when and how initial notice of a theft or loss should be provided to DEA. This Notice of Proposed Rulemaking proposes the clarification of DEA regulations and provides guidance to registrants regarding the theft, significant loss and explained loss of controlled substances.

Background

DEA is publishing this Notice of Proposed Rulemaking (NPRM) to propose the clarification of its policies and procedures regarding the reporting by registrants of the theft or significant loss of controlled substances.

[Title 21, Code of Federal Regulations, Sec. 1301.74\(c\)](#) "Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs." requires that: "The registrant shall notify the Field Division Office of the Administration in his area of any theft or significant loss of any controlled substances upon discovery of such theft or loss. The supplier shall be responsible for reporting in-transit losses of controlled substances by the common or contract carrier selected pursuant to Sec. 1301.74(e), upon discovery of such theft or loss. The registrant shall also complete DEA Form 106 regarding such theft or loss. Thefts must be reported whether or not the controlled substances are subsequently recovered and/or the responsible parties are identified and action taken against them."

[Title 21, Code of Federal Regulations, Sec. 1301.76\(b\)](#) "Other security controls for practitioners." further requires that: "The registrant shall notify the Field Division Office of the Administration in his area of the theft or significant loss of any controlled substances upon discovery of such loss or theft. The registrant shall also complete DEA (or BND) Form 106 regarding such loss or theft."

A number of questions have arisen regarding the meaning of certain terms in these paragraphs. Specifically, there seems to be confusion within the regulated industry as to the exact meaning

of the phrase "upon discovery". Therefore, as further discussed below, DEA is proposing the amendment of the regulations to insert the word "immediately" before the phrase "upon discovery" to clarify this point. Further, DEA is proposing the amendment of its regulations to list certain factors which registrants should consider when determining whether a loss of controlled substances is significant. Finally, this document provides guidance to registrants on the reporting of breakage, spillage or other explained losses of controlled substances. No regulatory amendments are being proposed regarding this guidance.

Theft or Other Unexplained Significant Loss of Controlled Substances

What Is a DEA Registrant Required To Do When a Theft or Significant Loss Is Discovered?

Every DEA registrant is required to notify the DEA field office in their area of any theft or significant loss of controlled substances upon its discovery. DEA has always viewed "upon discovery" to mean that notification should occur immediately and without delay. Every DEA registrant (practitioner, pharmacy, hospital/clinic, manufacturer, distributor, etc.) must comply with this requirement, and such compliance cannot be overridden by an internal corporate policy that is contrary to the notification requirement. For example, a DEA-registered pharmacy must provide notice to the local DEA field office when a theft or significant loss is discovered. This requirement is not satisfied by the reporting of the theft or significant loss internally to individuals in corporate management. DEA must be notified directly and immediately of the theft or significant loss of the controlled substances. A corporation that owns/operates multiple registered sites and wishes to channel all notifications through a central point such as corporate loss prevention, corporate security, or other corporate entity may do so but must still fulfill the requirement to provide notice to DEA immediately upon discovery by the actual registrant. However, this immediate notification does not always occur. Therefore, DEA is proposing the amendment of its regulations to insert the word "immediately" before the phrase "upon discovery" to clarify this point.

The purpose of immediate notification is to provide an opportunity for DEA, state, or local participation in the investigative process when warranted, and to create a record that the theft or significant loss was properly reported. It also alerts law enforcement to more broadly based circumstances and patterns of which the individual registrant may be unaware. This notification is considered part of a good-faith effort on the part of the regulated industries to maintain effective controls against the diversion of controlled substances, as required by 21 CFR 1301.71(a). Lack of prompt notification could prevent effective investigation and prosecution of individuals involved in the diversion of controlled substances. Withholding or failing to provide information is a violation of the law and regulations ([21 U.S.C. 821](#), [21 U.S.C. 842\(a\)\(5\)](#), [21 CFR 1301.74\(c\)](#), [1301.76\(b\)](#)).

How Should Notice of a Theft or Significant Loss Be Provided?

The regulations require that notice of a theft or significant loss must be reported to DEA upon its discovery. As noted above, DEA has always viewed "upon discovery" to mean that notification should occur immediately and without delay. Where circumstances of the theft or significant loss are immediately known, a DEA Form 106, Report of Theft or Loss of Controlled Substances, should be used to detail the circumstances of that theft or significant loss. When details concerning the specific circumstances surrounding the theft or loss are unknown at the time of discovery, DEA recommends initial notice be provided by faxing a short statement to DEA advising of the theft or significant loss. While such initial notice may alternatively be mailed, delays occurring due to the mailing process may hinder investigative efforts by DEA. A DEA Form 106, Report of Theft or Loss of Controlled Substances, is not immediately necessary. The registrant may then make efforts to determine the facts involved by conducting inventories, internal audits, and/or investigations using internal or law enforcement resources, as appropriate. The DEA Form 106 should be submitted once the circumstances surrounding the theft or significant loss are clear. The DEA Form 106 must

document the circumstances of the theft or significant loss and the quantities of controlled substances involved. DEA recognizes that some time may elapse between the time initial notice of a theft or loss is provided and the conclusion of the investigation. DEA suggests that if an investigation takes more than two months to complete, registrants provide updates regarding the investigation to DEA. The conduct of an investigation does not obviate the need for immediate notification of the theft or significant loss by the registrant to the local DEA field office. If, after an investigation of the circumstances surrounding the disappearance of the material, it is determined that no theft or significant loss occurred, no DEA Form 106 need be filed. However, DEA recommends the registrant advise DEA that a DEA Form 106 is not needed or will not be filed regarding the incident.

What Other Actions Should a Registrant Take When a Theft or Significant Loss Occurs?

The theft of controlled substances from a registrant is a criminal act, and a source of controlled substances diversion requiring notification of DEA. Although not specifically required by DEA law or regulations, the registrant should also notify local law enforcement and state regulatory agencies. Prompt notification of law enforcement agencies will allow them to investigate the incident and prosecute those responsible for the diversion.

Complete accountability by a registrant for all controlled substances handled is a fundamental requirement of the closed distribution system mandated by the Controlled Substances Act (CSA). The CSA requires: "* * * every registrant under this title manufacturing, distributing, or dispensing a controlled substance or substances shall maintain, on a current basis, a complete and accurate record of each such substance manufactured, received, sold, delivered, or otherwise disposed of by him,* * *." ([21 U.S.C. 827\(a\)\(3\)](#)). No registrant should disregard any unexplained shortage of controlled substances. Registrants should treat an individual theft or significant loss seriously and should monitor occurrences so that patterns do not remain undetected. Record keeping must be accurate and complete so as to serve as a reliable reporting and recording device.

DEA has become aware of instances in which registrants have used a DEA Form 106 to document or explain minor inventory discrepancies, thereby "balancing the books." DEA wishes to stress that the DEA Form 106 should be used only to document thefts or significant losses of controlled substances. Minor inventory discrepancies, not attributable to theft, should not be reported to DEA or recorded on a DEA Form 106. Rather, registrants should make appropriate notations of minor inventory discrepancies in their records, indicating the amount of variance between the physical count and the amount accounted for through records. Such discrepancies need not be reported to DEA if they are not significant or actual losses. If a registrant is unsure of the significance of a loss after considering the factors described below, the registrant should file the report. Any continuing pattern of loss of seemingly insignificant quantities should always be considered significant.

What Specific Regulations Does This Rulemaking Propose To Amend?

Specifically, this rulemaking proposes the amendment of [21 CFR 1301.74\(c\)](#) and [1301.76\(b\)](#) to insert the word "immediately" before the phrase "upon discovery" to clarify the points raised in the previous discussion. Although not specifically mentioned in the previous discussion, such reports include the report by a supplier of in-transit thefts or losses of controlled substances by the common or contract carrier selected by the supplier pursuant to 21 CFR 1301.74(e). Further, this rulemaking proposes a minor technical correction to Sec. 1301.76(b) to remove the reference to BND Form 106, as this form is no longer used.

Significant Loss of Controlled Substances

What Constitutes a Significant Loss?

Questions have arisen as to exactly what constitutes a "significant loss." There is no single objective standard which can be established and applied to all registrants to determine whether a loss is significant. Any unexplained loss or discrepancy should be reviewed within the context of a registrant's business activity and environment. What constitutes a significant loss for one registrant may be construed as comparatively insignificant for another. For example, the loss by a pharmacy of a 100-count bottle of controlled substance tablets would be viewed as significant, whereas the same loss by a full line distributor may be viewed differently, particularly if the loss is an unexplained inventory discrepancy that may have resulted from a picking error. A manufacturer may experience continuous losses in the manufacturing process due to atmospheric changes, mixing procedures, etc. Such losses may not be deemed by the registrant to be significant, and may be recorded in batch records. Conversely, for registrants other than manufacturers, the repeated loss of small quantities of controlled substances over a period of time may indicate a significant aggregate problem which must be reported to DEA, even though the individual quantity of each occurrence is not significant.

When determining whether a loss is significant, a registrant should consider, among others, the following factors:

- (1) The actual quantity of controlled substances lost in relation to the type of business;
- (2) A pattern of such losses, and the results of efforts taken to resolve them; and, if known,
- (3) Local trends and other indicators of the diversion potential of the missing material.

Specific questions which a registrant should ask to identify whether a loss is significant include, but are not limited to:

- (1) Has a pattern of loss been identified? Would this pattern result in a substantial loss of controlled substances over that period of time?
- (2) Are specific controlled substances being lost, and do the losses appear to be random?
- (3) Are the specific controlled substances likely candidates for diversion?
- (4) Can losses of controlled substances be associated with access to those

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controlled substances by specific individuals? Can losses be attributed to unique activities which may take place involving the controlled substances?

Individual registrants should examine both their business activities and the external environment in which those business activities are conducted to determine whether unexplained losses of controlled substances are significant. When in doubt, registrants should err on the side of caution in alerting the appropriate law enforcement authorities, including DEA, of thefts and losses of controlled substances.

What Specific Regulations Does This Rulemaking Propose To Amend?

Specifically, this rulemaking proposes the amendment of [21 CFR 1301.74\(c\)](#) and [1301.76\(b\)](#) to include the factors listed above as factors which a registrant should consider when determining whether a loss is significant and, thus, must be reported to DEA. DEA encourages registrants to use other criteria, as well as those factors listed above, which they have found to be useful in the evaluation of losses of controlled substances when determining whether such losses are significant, but is proposing the provision of these factors as the minimum which registrants should consider.

Guidance Regarding Breakage, Spillage and Other Explained Loss of Controlled Substances

What Is Required of a DEA Registrant When Breakage or Spillage Occurs?

DEA has encountered instances in which registrants have attempted to report spillages or explained losses of controlled substances on a DEA Form 106. The breakage, spillage or other witnessed controlled substance losses do not require the immediate notification of DEA. If

controlled substance containers are broken or damaged, or controlled substances spilled, the substances are not considered "lost" because they can be accounted for. When breakage, spillage or damage of controlled substances occurs, the affected controlled substances must be disposed of according to DEA requirements.

If there is breakage, spillage or other damage to controlled substances, but the controlled substances are still recoverable, then the registrant has two options for disposing of the controlled substances. The registrant may dispose of the controlled substances by either (1) Contacting their local DEA field office and receiving permission from that office to dispose of the controlled substances pursuant to [21 CFR 1307.21](#), or (2) the registrant may send those controlled substances to a firm registered with DEA to handle returns/ disposals.

If the registrant receives permission from DEA to dispose of the controlled substances pursuant to 21 CFR 1307.21, then that registrant must complete a DEA Form 41, Registrants Inventory of Drugs Surrendered, explaining the circumstances of the breakage. Two individuals who witnessed the breakage, spillage or damage must sign the DEA Form 41, indicating what they witnessed. Registrants must submit three copies of the DEA Form 41 to their local DEA field office (21 CFR 1307.21(a)(1)). Registrants are also required to maintain a copy of the DEA Form 41 in their records.

If the registrant sends the controlled substances to a DEA registered disposer, then the registrant must complete the necessary paperwork showing the distribution of the damaged controlled substances to the registered disposer.

If the breakage or spillage is clearly observed but the controlled substances are not recoverable, then the registrant must document the circumstances of the breakage in their inventory records. Two individuals who witnessed the breakage must sign the inventory records, indicating what they witnessed. These records must be maintained in the registrant's files.

Regulatory Certifications

Regulatory Flexibility Act

The Deputy Assistant Administrator hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation, and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities. This regulation seeks to clarify existing DEA regulations regarding the reporting of thefts and losses of controlled substances. No new recordkeeping or reporting requirements are proposed in this rulemaking.

Executive Order 12866

The Deputy Assistant Administrator further certifies that this rulemaking has been drafted in accordance with the principles in Executive Order 12866 Section 1(b). DEA has determined that this is not a significant rulemaking action. Therefore, this action has not been reviewed by the Office of Management and Budget. This rulemaking merely seeks to clarify existing DEA regulations, policies and procedures.

Executive Order 12988

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

Executive Order 13132

This rulemaking does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more in any one year, and will not

significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

List of Subjects in 21 CFR Part 1301

Administrative practice and procedure, Drug traffic control, Security measures.

For the reasons set out above, 21 CFR part 1301 is proposed to be amended as follows:

PART 1301--REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

1. The authority citation for part 1301 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 871(b), 875, 877.

2. Section 1301.74 is amended by revising paragraph (c) to read as follows:

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Sec. 1301.74 Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs.

* * * * *

(c) The registrant shall notify the Field Division Office of the Administration in his area of any theft or significant loss of any controlled substances immediately upon discovery of such theft or loss. The supplier shall be responsible for reporting in-transit losses of controlled substances by the common or contract carrier selected pursuant to Sec. 1301.74(e), immediately upon discovery of such theft or loss. The registrant shall also complete DEA Form 106 regarding such theft or loss. Thefts must be reported whether or not the controlled substances are subsequently recovered and/or the responsible parties are identified and action taken against them. When determining whether a loss is significant, a registrant should consider, among others, the following factors:

- (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 which may take place involving the controlled substances;
- (4) A pattern of such 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 material.

* * * * *

3. Section 1301.76 is amended by revising paragraph (b) to read as follows:

Sec. 1301.76 Other security controls for practitioners.

(b) The registrant shall notify the Field Division Office of the Administration in his area of the theft or significant loss of any controlled substances immediately upon discovery of such loss or theft. The registrant shall also complete DEA Form 106 regarding such loss or theft. When determining whether a loss is significant, a registrant should consider, among others, the following factors:

- (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 which may take place involving the controlled substances;
- (4) A pattern of such 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 material.

Dated: June 25, 2003.

Laura M. Nagel,

Deputy Assistant Administrator, Office of Diversion Control.

APPENDIX 6
Alternative to Discipline Comparison Chart

ISSUE	TRADITIONAL APPROACH	REVISED APPROACH
Attendance issues i.e. tardy, unexcused absences	<p>Follow organizations progressive discipline approach (typically written warning-suspension- termination)</p> <p>Offer EAP should there be an issue outside of work affecting employment.</p> <p>If issue moves to suspension and/or termination, notify Board of Nursing as per regulation.</p>	<p>Follow organization’s progressive discipline approach. Offer EAP should there be an issue outside of work affecting employment. Educate EAP that if dealing with an RN who has substance abuse issue, refer to Nurse Health Program.</p> <p>If issue moves to suspension and/or termination, notify Board of Nursing as per regulation</p>
Reporting to work under the influence	<p>Follow organization’s progressive discipline approach (suspension-termination).</p> <p>Offer EAP should there be an issue outside of work effecting employment.</p> <p>If issue moves to suspension and/or termination, notify Board of Nursing as per regulation</p>	<p>Follow organization’s progressive discipline approach (suspension- termination).</p> <p>In lieu of suspension, offer reduced discipline if willing to comply with treatment/monitoring program.</p> <p>If non-compliant, issue moves to suspension and/or termination, and notify Board of Nursing as per regulation.</p>
Performance issue (i.e., attitude, substandard work: no adverse patient impact etc.)	<p>Follow organization’s progressive discipline approach (typically written warning-suspension-termination).</p> <p>Offer EAP should there be an issue outside of work effecting employment.</p> <p>If issue moves to suspension and/or termination, notify Board of Nursing as per regulation.</p>	<p>Follow organization’s progressive discipline approach. Offer EAP should there be an issue outside of work affecting employment. Educate EAP that if dealing with an RN who has substance abuse issue, refer to Nurse Health Program.</p> <p>In lieu of suspension, offer reduced discipline if willing to comply with treatment/monitoring program.</p> <p>If non-compliant and issue moves to suspension and/or termination, notify Board of Nursing as per regulation.</p>
Illegal drug violation outside of work	<p>If found guilty, follow organization’s progressive discipline approach (suspension/termination) based on relationship to their position.</p> <p>Notify Board of Nursing as per regulation.</p> <p>Notify DEA as per regulation.</p> <p>Notify AG’s office.</p>	<p>In lieu of suspension or termination, offer reduced discipline if willing to comply with treatment/monitoring program.</p> <p>Notify Board of Nursing as per regulation .</p> <p>Notify AG’s office?</p> <p>Notify DEA</p>

ISSUE	TRADITIONAL APPROACH	REVISED APPROACH
Drug diversion – for self; diverted from patient	Follow organization’s progressive discipline approach (termination). Notify DEA as per regulation. Notify Board of Nursing as per regulation. Notify AG’s office. Notify DHHS. Notify Law Enforcement.	In lieu of termination, offer reduced discipline (ex. suspension) if willing to comply with treatment/monitoring program. Notify DEA. Notify Board of Nursing as per regulation . Notify AG’s office? Notify DHHS. Notify law Enforcement.
Drug diversion – larger quantities and/or for sale	Follow organization’s progressive discipline approach (termination) Notify DEA as per regulation. Notify Board of Nursing as per regulation. Notify AG’s office. Notify DHHS. Notify law enforcement.	No change in approach.

If you suspect drug or alcohol theft or impairment

1. Protect Patients. Do not have possibly impaired nurse care for patients. Make sure both patients and employee are safe.
2. Call HR or your administrator. Express your concern, state your observations. Work with them to conduct an investigation as quickly as possible.
3. Speak to employee about your observations. If still uneasy, send home (pay for cab) with or without pay pending the investigation. If appropriate, offer EAP.
4. If you think the employee may have drugs or alcohol hidden, you may ask them if you can look through their property (with a witness) but do not search their property without their permission.
4. Document facts (only what you see or hear) and behavior, not suspicions, not possible diagnoses.

Dealing with Suspected Impaired Professionals

How to protect your patients, your organization, and the rights of your employees

Three Critical Steps

- Understand and clearly state your organizational Philosophy.
- Educate your staff re. prevention, symptoms, necessary actions, legal rights and responsibilities.
- Work together for the safety and well-being of both patients and staff.

Performing a Fact-finding Investigation

- As always, be fully respectful throughout the investigation.
- start the interviews soon after the situation arises – delay can cause witnesses and documents to disappear
- hold individual interviews to uphold confidentiality and minimize peer pressure
- maintain objectivity while being both empathetic and professional.
- take good notes.
- hold the interview in a private, quiet location. Consider including another witness during the interview.
- never promise absolute confidentiality (because the company may have to release documents and names of witnesses due to legal requirements), but go ahead and tell witnesses that the company will do its utmost to protect employees' privacy unless forced by a court or agency order to do otherwise
- keep the interview on track
- do not interrupt witnesses while they are coming out with relevant information
- start out with general questions, then graduate to more closely-focused questions to get better details
- repeat important questions, but with different wording, to see whether the witness sticks with the same answer
- avoid confrontational or accusatory questions
- pay attention to witnesses' body language
- use silence after a question as a technique to encourage reticent witnesses to start talking be ready with follow-up questions if needed
- Document your observations, what you hear, see, smell. Do not diagnose. Do not make assumptions.**

If concerned about a possibly impaired nurse:

First call _____

Review symptoms set out in _____

Review Policy _____

Document facts