

RISK MANAGEMENT NEWS

A RISK MANAGEMENT NEWSLETTER FOR MILLENNIUM INSURANCE CO. INSURED

Monitoring Samples Reduces Medication Errors

Aside from writing prescriptions, offering patients sample medications can enhance a culture of goodwill and can strengthen physician-patient interaction by allowing patients the opportunity to discuss the prescribed medications as it relates to their medical diagnosis. However, when the management of samples is unrestricted and informal, patients, physicians and their staff may be at risk. Storing medications in unlocked cabinets, especially in patient examination rooms, is a primary example of impending risk. Other casual actions include unauthorized staff dispensing medications to patients or other staff members, and employees taking samples from the office for personal use or for family members. These activities usually occur without physician knowledge or consent and can delay proper treatment to a patient while exposing the physician to potential liability.

When patients observe their physicians treating medications casually, the serious nature of their instructions may become undermined. Providing patients with only verbal instructions may also increase liability risks. Issuing instructions as “take as directed” or “as needed” are incomplete

and nonspecific. Patients should receive written as well as verbal instructions so that patients may refer to them if they fail to remember the verbal instructions or if other changes become necessary. Dispensed medications should be clearly documented in the medical record confirming that the patient in fact received and understood the instructions given.



Problems in medical practices commonly arise when tracking of stored medications is not performed and medical records fail to document the names of medication(s) dispensed, the quantity, or the

dosing instructions. Notations such as “sample given” or “antibiotic samples given” are nondescript and may lead to medication errors. Documentation should clearly reflect what the patient was told concerning when, how, what durations, what dose, what frequency and if special instructions were needed. Most importantly, the physician’s rationale for prescribing the medication should be apparent.

In order for sample medications to remain a benefit for both the patient and the physician, medication-related liability exposures should be assessed. What are your present methods for securing, recording, dispensing and documenting all medications stored within your office? Invariably, liability becomes a factor when medications are inadequately supervised and dispensed.

INSIDE THIS ISSUE:

Monitoring Samples Reduces Medication ErrorsPage 1

Proper Disposal of Prescription DrugsPage 3

The Only Lawyer You Should Speak to... Is Your OwnPage 3

Responding to Subpoenas: Knowing Your Obligations.....Page 4

Certificate of MeritPage 4

HIPAA Compliance: Checking Your List TwicePage 5

Are Your OSHA Protocols Current?....Page 6

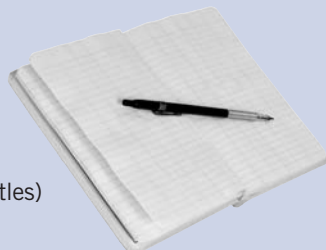
To improve your overall medication safety protocols your office should accept responsibility for proper medication dispensing. The first step is to commit to following established policies and procedures. Consider these risk management recommendations when developing protocols for your practice:

1. Limit access of sample medications to clinical personnel. Do not allow employees to access or request free samples. Self-medication can lead to adverse events of which the practice could be held liable. Dispensing should only be done by a physician or mid-level provider with prescribing authority.
2. Secure all sample medications by storing them in a locked room or in locked cabinets. Medications should not be stored in examination rooms where patients are left unattended.
3. Organize samples by drug or drug group. Medications with similar names should be located in separate areas.
4. Inventory samples monthly and discard those that are about to expire.
 - a. Assign responsibility to a specific person for monthly inspection and document that medications have been inspected. See Fig. 1 – *Developing an Inventory Inspection Log*.

Figure 1. Developing an Inventory Inspection Log

Develop your own log using the following fields. You may also download a prepared log from our website www.millenniumins.com.

- Date of Receipt
- Drug
- Lot #
- Quantity (#Boxes/Bottles)
- Dose/Concentration
- Expiration Date
- Initials of Reviewer
- Date of Review



(continued from page 1)

- b. Discard samples according to federal, state and local laws – See page 3 for *Proper Disposal of Prescription Drugs*.
 - c. Track each patient that receives medications, including lot number. See Fig. 2 – *Developing a Patient Distribution Log*.
5. Ensure that lighting in the storage area allows for easy reading of medication names and dosages. Prior to dispensing medications, the authorized medical professional should:
- a. Review the patient's name and second identifier, i.e., date of birth
 - b. Double check the name of the medication on the package
 - c. Confirm the expiration date of the medication
 - d. Verify the patient's allergies to medications
6. Label all medications as follows:
- a. Patient's name
 - b. Medication name
 - c. Dosage frequency and time
 - d. Route of administration
 - e. Form, i.e., liquid, tablet, drops, etc.
 - f. Date dispensed
 - g. Lot number
7. Document all discussions with the patient regarding allergies, side effects, dosage, special instructions for taking medications and any other related issues in the patient's medical record.
8. Provide written information about the medication and written instructions on how to take the medication and place a copy of the written instructions in the patient's medical record. See Fig. 3 *Patient Instructions for Sample Drugs*. Written instructions should include the name of the physician, the name of the patient, the date the sample was dispensed, the name and strength of the drug, the address and telephone number of the practice. The instruction sheet should provide a place for the patient or their guardian to sign acknowledging receipt of the medication information. Retain a copy of the instructions in the patient's medical record.

Summary

Medical practices that distribute sample medications should ensure that mechanisms are in place for securing, storing, and monitoring sample medications. Developing detailed policies and procedures is the first step to identifying the processes to be followed in your practice and minimizing liability.

Enhance patient education by providing written and verbal instructions and documenting the medications dispensed and counseling conducted. Requiring patients or their guardian to sign an acknowledgement of receipt of the medication information and retaining a copy for the patient's medical record further reduces liability risk.

Figure 2. Developing a Patient Distribution Log

Develop your own log using the following fields. You may also download a prepared log from our website www.millenniumins.com.

- Date Dispensed
- Patient/DOB
- Drug
- Lot #
- # Boxes/Bottles & Doses
- Expiration Date
- Initials of Dispenser
- Prescriber



Figure 3. Patient Instructions for Sample Drugs

Patient Instructions for Sample Drugs	
Patient Name: _____	Date: _____
Dispensing Provider: _____	
Medication: _____	Dose/Strength: _____
Quantity Given: _____	Lot #: _____
Patient Allergies: _____	
Patient Instructions: (Dose, Route, Frequency, Special Instructions, i.e., Time of Day, With or Without Food, etc.)	
Possible Side Effects or Adverse Reactions:	
Other Written Information Provided: _____	
Please call the office should you have any questions or concerns while taking this medication.	
Name of Practice	
Address	
Telephone Number	
The above information has been reviewed with me and I have been given a copy of these instructions.	
Patient/Guardian Signature _____	Staff _____
____ Copy to patient	
____ Copy to patient medical record	

Proper Disposal of Prescription Drugs

- Take unused, unneeded, or expired prescription drugs out of their original containers and throw containers in the trash.
- Mixing prescription drugs with an undesirable substance, such as used coffee grounds or kitty litter, and putting them in impermeable, non-descript containers, such as empty cans or sealable bags, will further ensure the drugs are not diverted.
- Flush prescription drugs down the toilet only if the label or accompanying patient information specifically instructs doing so.
- Take advantage of community pharmaceutical take-back programs that allow the public to bring unused drugs to a central location for proper disposal. Some communities have pharmaceutical take-back programs or community solid-waste programs that allow the public to bring unused drugs to a central location for proper disposal. Where these exist, they are a good way to dispose of unused pharmaceuticals.

Office of National Drug Control Policy

The Only Lawyer You Should Speak to... Is Your Own

If you should get a call from an attorney who would like to discuss the care of a patient, risk management specialists agree that physicians should refrain from calling the lawyer back. Rather than speaking to attorneys, physicians should:

1. Review the patient's medical record to determine if possible malpractice occurred;
2. Notify Millennium Insurance Company, if you think there may be a potential lawsuit; and
3. Appoint a staff member to return the lawyer's call and advise that such requests must be received in writing.

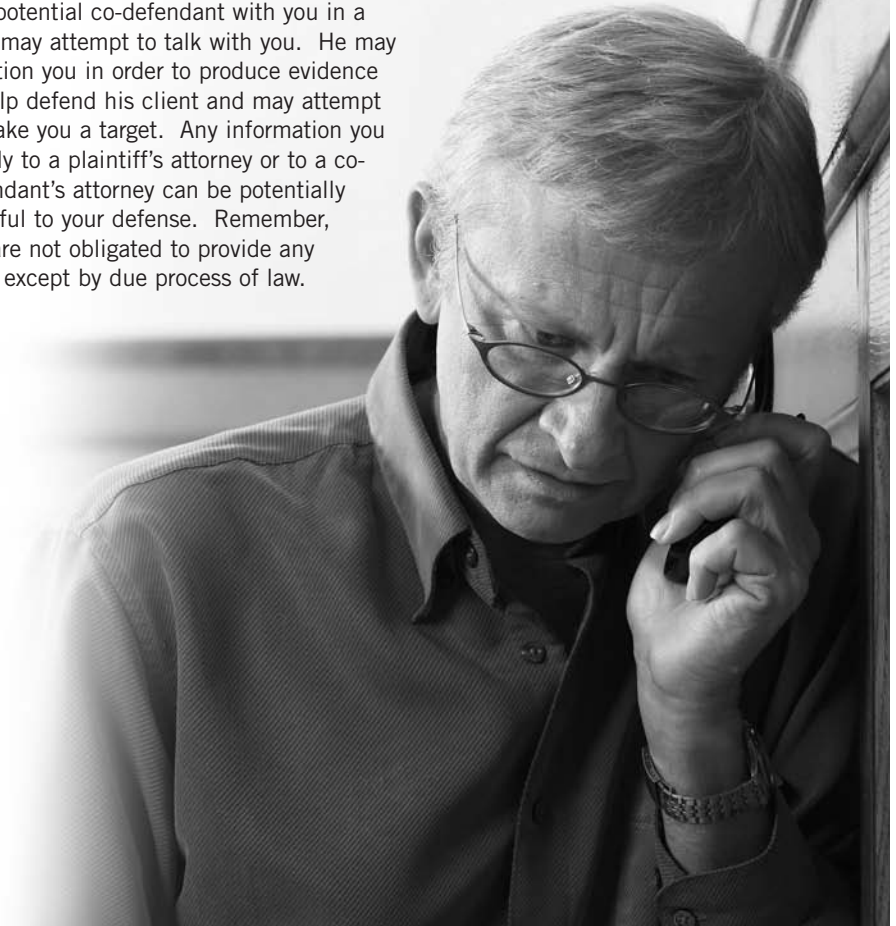
If an attorney thinks you may have some malpractice culpability, he may question you hoping that you'll say something that will make a case for him. Or the attorney may be searching for a free assessment of the patient and/or free expert testimony to assess and document the damages.

In another case scenario, a defense attorney for another physician who is a co-defendant or a potential co-defendant with you in a case may attempt to talk with you. He may question you in order to produce evidence to help defend his client and may attempt to make you a target. Any information you supply to a plaintiff's attorney or to a co-defendant's attorney can be potentially harmful to your defense. Remember, you are not obligated to provide any facts except by due process of law.

The law defines specific procedures by which parties can learn facts about a case. A plaintiff's attorney should begin by requesting a copy of your records, accompanied by a HIPAA-compliant authorization signed by the patient. After such a request is received, review the record, but do not change it in any way because such alterations may be viewed as self-serving. In the event you have concerns about the treatment of a patient for which records are requested, contact Millennium's Claim Department to discuss the possible need for legal representation.

After the attorney receives copies of your records, he should not seek further information from you via telephone or email. Rather, a deposition can be requested. At the deposition, defense counsel will be present to protect your interests and prevent you from answering inappropriate questions. You will likely be instructed not to speculate about your treatment or any departures from the standard of care on your or another physician's behalf.

*The bottom line...
the only lawyer you
should communicate
with is your own.*



Responding to Subpoenas: Knowing Your Obligations

You receive a letter from an attorney requesting that you “produce all medical records relating to your treatment of...” Sudden feelings of alarm and anxiety may strike as to the purpose of the subpoena, but do you know what your obligations are to your patients as well as the law in response to such requests?

If you receive a subpoena for medical records and you suspect it could be related to malpractice, call the Millennium Claim Department for guidance. With respect to other medical record requests, ensure that a policy has been established and personnel identified to appropriately respond to such requests. In the event you are unsure as to the purpose of the request, contact your own attorney to ensure you do not release unauthorized or inappropriate information.

A subpoena duces tecum is simply a document signed by an attorney as “an officer of the court.” Although official in appearance, it has not been issued, reviewed, or approved by a judge and therefore it does not have the authority of a court order unless otherwise indicated. If you refuse to release the records, the attorney must then petition a judge to issue such an order for you to produce them. Even then, a signed release from the patient is advised. The type of case it seeks information about – civil or criminal, personal injury or medical malpractice – makes a big difference in the power of the subpoena and your obligation to respond to it.

“Some attorneys may demand that you produce records immediately and threaten to call you for a deposition if you don’t. That is still no reason to comply before you have the proper authorization.”

The type of subpoena you are most likely to receive is a request for the medical records of a patient you have treated. Although the request may seem routine, don’t react hastily as you are obligated to protect the confidentiality of the physician-patient relationship.

Remember, the unauthorized release of a patient’s records can result in a civil suit against you by the patient, or a disciplinary action – including possible loss of license – by the State Board of Medicine.

Once you have a release signed by the patient authorizing you to provide records, you are obligated to do so. Make sure you send copies, not originals. Some attorneys may demand that you produce records immediately and threaten to call you for a deposition if you don’t. That is still no reason to comply before you have the proper authorization.

However, if you are requested to produce the records under a court order, you are legally obligated to do so, even without a patient’s release.



Sometimes an authorized subpoena demands your testimony, not just your records. If that’s the case, contact the attorney who issued the subpoena and attempt to negotiate a mutually convenient time for your appearance. Most attorneys will try to accommodate your schedule and travel to a location of your choice.

How much should you charge for medical record copying?

Regardless of who subpoenas your medical records, you have a right to be paid for retrieval of the record and making the requested copies. Effective January 1, 2007 the maximum charges for medical record reproduction is as follows:

\$1.25	for 1 – 20 pages
\$0.93	for 21 – 60 pages
\$0.31	for 61 or more pages

A retrieval fee of \$18.24 may also be assessed to attorneys and insurance companies, however not to patients. In addition to the above amounts, charges may also be assessed for postage, shipping and delivery of the requested records.

CERTIFICATE OF MERIT: Does it really prevent frivolous lawsuits?

Physicians claim that there is nothing more disheartening than being named in a frivolous lawsuit. Fortunately, Pennsylvania is one of 12 states that addresses this issue by requiring a Certificate of Merit in order for a patient to bring legal action against a physician.

The General Rule

Pennsylvania Rule of Civil Procedure 1042.3 requires that a certificate be filed with the complaint or within 60 days after filing of the complaint indicating that “either an appropriate licensed professional has supplied a written statement that there exists a reasonable probability that the care, skill, or knowledge exercised or exhibited in the treatment, practice, or work that is subject of the complaint, fell outside acceptable professional standards and that such conduct was the cause in bringing about the harm; or the defendant deviated from an acceptable professional standard is based solely on allegations that other licensed professionals for whom this defendant is responsible deviated from an acceptable professional standard.”

What does this mean?

The plaintiff needs a medical expert to attest to the validity of a claim before proceeding with their lawsuit.

Does the expert have to be in the same specialty as the defendant?

The MCARE Act - Section 512 Expert Qualifications, states:

“Part (b), an expert testifying as to a physician’s standard of care must also meet the following qualifications:

- (2) Practice in the same subspecialty as the defendant physician or in a subspecialty which has a substantially similar standard of care for the specific care at issue, except as provided in subsection (d) or (e).
- (d) Care outside specialty. – A court may waive the same subspecialty requirement for an expert testifying on the standard of care for the diagnosis or treatment of a condition if the court determines that:
 - (1) the expert is trained in the diagnosis or treatment of the condition, as applicable; and

- (2) the defendant physician provided care for that condition and such care was not within the physician's specialty or competence.
- (e) Otherwise adequate training, experience and knowledge. – A court may waive the same specialty and board certification requirements for an expert testifying as to a standard of care if the court determines that the expert possesses sufficient training, experience and knowledge to provide the testimony as a result of active involvement in or full-time teaching of medicine in the applicable subspecialty or a related field of medicine within the previous five-year time period.”

What can you expect as a Millennium insured?

Millennium currently requires that experts be of the same specialty. Our defense counsel have been instructed to file “Motions to Strike” when a Certificate of Merit is received from an expert of a different specialty.

Under the rule, plaintiffs typically contend that their experts are merely required to review the file and assure the Court that the case is not frivolous and that there exists a reasonable probability that the care, skill or knowledge exercised or exhibited in the treatment, practice or work that is the subject of the complaint fell outside acceptable professional standards and that such conduct was a cause in bringing about harm to the patient.

A Case Study:

In a recent general surgery claim, the plaintiff's attorney used an internal medicine expert to sign the Certificate of Merit. He claimed that the patient's infection should have been diagnosed and treated in a timely fashion. The attorney advised the Court that his expert was qualified to determine if the general surgeon deviated because he was familiar with the diagnosis and treatment of infection, as demonstrated by his education, training and experience. The Judge reviewed the defendant's motion to strike and the plaintiff's opposition and ruled that the expert had to be of the same specialty to sign the Certificate of Merit. The plaintiff had 30 days to appeal the judge's decision.

HIPAA Compliance: Checking Your List Twice

Since the inception of the Health Insurance Portability and Accountability Act in 1996 medical practices were required to develop and implement a privacy policy and security standards regarding those who can access Personal Health Information (PHI). If yours is like most medical offices, your practice likely started out diligently but has become more relaxed with its HIPAA provisions. Now is good time to revisit and review your policies and privacy safeguards to avoid any impending violations.

Many obvious actions can compromise patient privacy such as counseling patients on medical issues, medications, etc. in audible range of others. A good way to begin your evaluation of your practice's privacy protocols is by sitting in your reception area - as your patients would - to identify gaps in compliance.

The law says health care providers may share information with others unless the patient objects, but does not require you to do so. Thus, disclosures are voluntary leaving you to use your best discretion. Consistently remind staff that only the *minimally necessary* information should be disclosed to third parties. Conduct periodic staff meetings to review office policies as to what should and should not be disclosed.

Under the HIPAA Privacy Rule, physicians and other healthcare providers must furnish a complete and current copy of the patient's medical record to third parties upon written request by the patient. The patient must identify the records to be released and the person or class of persons that may receive copies of them. To release copies, your office must receive an authorization signed by the patient or an appropriate personal representative such as parents of minors, executors of deceased patients' estates and persons holding Durable Powers of Attorney for Healthcare.

When a copy of the patient's medical record is released to a third party, the release should be documented by filing the original authorization form in the medical record to show when and to whom records were released. Patients are also entitled to access his or her own record. Either a physician or clinically qualified representative from your practice should

offer to review the record with the patient to explain clinical terms and most importantly to avoid potential misconceptions regarding their PHI. If deemed appropriate, physicians may refuse to furnish the record to a patient if the disclosure is likely to endanger the *life* or *physical safety* of the patient or another person. Physicians must use their best professional judgment in determining whether to refuse release of records and must document the reason for their decision in the medical record. The patient has the right to have the denial reviewed by a licensed healthcare professional.

Although medical information should only be released to third parties upon receiving a patient's written authorization, the HIPAA Privacy Rule acknowledges several exceptions including *payment*, *treatment* and *healthcare operations*.

Payment – A physician may release a patient's health information to third parties (e.g., an insurance company) for purposes related to payment for medical services rendered.

Treatment – A physician may release a patient's health information without patient authorization when the disclosure is made for the purpose of providing treatment to the patient. For example, a specialist treating the patient may disclose the diagnosis and treatment plan to the patient's primary care physician without specific patient authorization. When using a fax machine to share patient information, implement reasonable and appropriate administrative and technical safeguards to prevent unauthorized access to PHI.

Healthcare Operations – Healthcare operations are certain administrative, financial, legal and quality improvement activities of a covered entity that are necessary to run its business and to support the core functions of treatment and payment. In the event you are contacted by your broker or self-request a risk management assessment of your practice (a service provided by Millenium Insurance Company), you may disclose patient health information to the consultant who is conducting the quality improvement study. Similarly, the healthcare operation exception would permit a physician to disclose a patient's health information to Millennium for the purpose of defending a claim brought by a patient.



Disclosure Statement

The information in this publication is provided for educational purposes only and is not intended to set or reflect the standard of care within medical practice. Millennium Insurance Company is not engaged in rendering legal or other professional service and the information provided does not constitute legal advice. If legal or other expert assistance is desired or needed, the services of a competent professional should be sought.

Are Your OSHA Protocols Current?

OSHA provides guidelines to ensure that your practice is a safe environment for your employees. In addition to conducting regular safety meetings and training staff to maintain a safe workplace, OSHA requires that you maintain certain records to foster compliance.

First, if your practice has more than 10 employees, there are three types of logs that OSHA inspectors request during an inspection. These forms assist the employer and OSHA review the extent and severity of work related injuries.

OSHA **Form 300** – Log of Work-Related Injuries and Illnesses;
Form 300A – Summary of Work-Related Injuries and Illnesses and
Form 301 – Injury and Illness Incident Report may be accessed from the OSHA website at www.osha.gov/recordkeeping/OSHArecordkeepingforms.pdf.



Next, OSHA requires that your practice implement numerous written programs and procedures in dealing with hazard communication along with workplace hazard assessments. Failure to train, keep adequate records and certification may result in citations and penalties.

Finally, when reviewing your OSHA compliance strategies, ensure your staff has had their hepatitis vaccines. Your records should reflect whether they were provided by your office or if they were received elsewhere. Employees refusing vaccination should be required to sign a declination waiver and offered future opportunities for vaccination.

Visit Our Website

Visit the Millennium website at www.millenniumins.com for the latest information on claims made coverage, application procedures, risk management and claim reporting.

We welcome your feedback!

