

Closed Claim Abstract

CASE #1

A certified medical assistant began taking samples of steroid ointment from her employer's internal medicine practice. She took the ointment to treat a family member's skin "rash." The "rash" worsened so she tried another type of ointment also taken from the sample closet. Finally, after several months the employee admitted what she had done and asked for assistance from her physician. The family member was subsequently diagnosed with basal cell carcinoma on her back. Because of the delay in diagnosis and treatment she required more aggressive excision and treatment.

CASE #2

Antibiotics were dispensed to a patient suffering from a UTI. He had severe adverse reactions to the antibiotic and subsequently developed renal failure. Because no documentation supported proper dispensing, dosing instructions or warnings there was insufficient documentation to show that the physician met appropriate standard of care for prescribing.



Sample Medications: Some Ideas to Promote Safety

By John S. Antalis, M.D.

Sample medications can benefit patients in financial savings and in providing a perception of greater value to their office visit. Physicians may enhance a culture of goodwill when they give samples of medications instead of simply writing prescriptions. This is especially true when assessing the efficacy of a new medication. Sampling of medications can also enhance the bond between physicians and patients by giving patients an opportunity to ask questions and interact with the physician. Also, feedback from patients is valuable when assessing the effectiveness of medications. Additionally, pharmaceutical representatives provide physicians information and education in regard to medications.

When the management of samples and other medications is too informal, patients, physicians and their staff may be at risk. Some office practices keep sample medications in unlocked cabinets, sometimes in patient examination rooms. An increasingly casual attitude toward sample medications has developed in some settings by patients, physicians and staff. Incidents have been reported

when staff dispensed inappropriate medications to patients or other staff members without physician awareness. In a recent report, one employee dispensed contraindicated sample medication to another employee. In another reported incident, a front-office employee took prescription medication samples to an acquaintance in her community. Such activities, although often unknown to the physician, can delay proper treatment while exposing the physician to potential liability.

Another liability exposure occurs when medication is dispensed according to physician orders but without documentation of the quantity, dose schedule or other instructions. When the patient observes his or her physicians treating medication casually, the serious nature of their instructions may be undermined. When instructions given to the patient are merely verbal, the risks may increase even more. Instructions such as "take as directed" or "as needed" aren't specific. We should document enough information to confirm that the patient received and understood adequate instructions.¹

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Sample Medications: Some Ideas to Promote Safety

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Georgia and other state statutes provide rules for dispensing medication. These laws apply to samples of prescription medications as well as prescription medications obtained from a pharmacy.² State laws dictate how prescriptions should be written and how medications may be dispensed. Your own medication policies and procedures should be in

compliance with the state laws where you practice.

Marketing and advertising by pharmaceutical companies may have further shifted the general public's attitudes. Patients are told in advertisements that they may benefit from a new drug for a variety of reasons. They are told in some advertisements to ask the physician for a sample to see if "this drug" is right for you. The advertisements may not effectively impress the listener with possible problems or potential drug interactions. Because some advertisements raise patient's expectations unrealistically, resentment toward the physician may occur if the patient is told the medication is not clinically indicated. However, experience has shown that a thorough explanation of why the medication is not needed can usually resolve a patient's concerns.

Problems may arise when no one is aware of which medications are on hand, and medical records fail to document the names of medication dispensed, the quantity or the dosing instructions. Notations such as "samples given" or "antibiotic samples given" are not specific and may lead to medication errors. Documentation should include what the patient was told concerning when, how, what duration, what dose, what frequency and if special instructions were needed.³ The physician's rationale for prescribing the medication should be apparent.

We suggest that you look at your method of securing, recording, dispensing and documenting all medications. Remember that instructions should be thorough. Vague instructions such as "as needed or directed" may be unclear even if verbal instructions were very thorough. If the dose is variable, it is helpful to provide written instructions to which the patient may refer if changes are made via telephone.⁴

Sample medications can benefit both the patient and the physician. Medication-related liability exposures can be decreased by actively assessing your weaknesses and improving your overall culture in regard to medication safety. Ultimately

CASE #3

A patient who did not speak English came to the physician's office with his son as an interpreter. The patient was given a prescription for medication and verbal instructions were given to the son. The patient was taking another medicine at the time that seriously contraindicated the new medication. The son was unaware that his father was taking other medications. Later, the patient was found at home hypotensive and unconscious. He was rushed to a hospital where he recovered to a degree but suffered sustained organ impairment due to the extended period of severe hypotension.

when you as a physician accept sample medications, you are responsible for proper storage, record keeping and dispensing. You may face liability exposures when you fail to adequately supervise and dispense sample medication.

In order to minimize risks related to sample medications, consider the following risk management suggestions:

1. Know what you have on hand
2. Reasonably secure all medications including samples
3. Inventory samples monthly and discard any about to expire
4. Dispense by physician order only and document name of medication, quantities given and a description of any instructions and warnings given to the patient
5. When appropriate, give the patient written instructions as you would for any prescription medication in accordance with your states laws

Footnotes

1. <http://www.ismp.org/Consumer/Samples.html>
2. Official Code of Georgia Annotated 26-4-1 et. seg. Georgia Pharmacy Practice Act
3. What Works: Effective Practices for Office-based Care/Medication Management/Sample Labeling/ Wisconsin Patient Safety Institute: Maximizing Patient Safety in the Medication Use Process
4. July 14, 1999 Institute for Safe Medication Practices, Medication Safety Alert. Sample medications: Safe management is a difficult but necessary process

Release of Medical Information

Checklist for Compliance

By David Tansill, JD

Under the HIPAA Privacy Rule, physicians and other healthcare providers generally 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, the physician must be provided with authorization signed by the patient or an appropriate personal representative. Under the HIPAA Privacy Rule, physicians must treat personal representatives as the patient for matters relating to medical records access and release. Examples of personal representatives include, but are not limited to, parents of minors, executors of deceased patients' estates, and persons holding Durable Powers of Attorney for Healthcare.

The HIPAA Privacy Rule requires certain elements to be present in a proper authorization for release of medical information. The authorization must be written in plain language. If it is the physician that seeks an authorization from a patient for a use or disclosure of protected health information, the physician must provide the patient with a copy of the signed authorization. 45 CFR § 164.508(c) (3) & (4)

When a copy of the patient's medical record is released to a third party, physicians should document the release by filing the "authorization" form in the medical record to show when and to whom records were released. Physicians should never release the original record without prior consultation with their professional liability insurance company.

The patient's medical record belongs to the physician. However, the information belongs to the patient and that information generally may not be released to third parties unless the patient "authorizes" the release in writing. By contrast, the patient is entitled to "access" his or her own records (in which case, the patient, rather than a third party may view the records or obtain copies). The HIPAA Privacy Rule provides that the physician may refuse to furnish the record to the patient if the disclosure is likely to endanger the "life or physical safety" of the patient or another person. State laws may have other restrictions. Physicians should use their best professional judgment in determining whether to refuse to release records on these grounds. When the physician refuses to furnish a copy of the record to the patient on this basis, he/she must document the reason for this decision in the medical record. The patient has a right to have the denial

reviewed by a licensed healthcare professional, selected by the physician, who will act as a reviewing official and the physician must provide or deny access in accordance with the reviewing official's determination. However, upon written request from the patient, the physician should furnish a copy of the medical record to another physician designated by the patient. 45 CFR § 164.524 (2).

The HIPAA Privacy Rule establishes several exceptions to the general rule that medical information may be released to third parties only upon the patient's written authorization. Three frequently applicable exceptions involve release of information for purposes of payment, treatment and healthcare operations.

Payment – A physician may release a patient's health information to third parties (e.g., to an insurance company) for purposes related to payment for medical services rendered, and patient authorization is not required for such disclosure.

Treatment – A physician may release 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.

Healthcare Operations – A physician may release patient information without authorization when the disclosure is made for the purpose of conducting some 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. For example, under the healthcare operations exception, a physician may disclose patient health information to a risk management consultant who is conducting a quality improvement study involving the physician's practice. Similarly, the healthcare operations exception would permit a physician to disclose a patient's health information to the physician's medical professional liability insurer for the purpose of defending a claim brought by the patient.

The confluence of longstanding state law on patient privacy and the relatively new HIPAA Privacy Rule have created a detailed body of law governing the release of medical information. With careful analysis and assistance from legal counsel when appropriate, physicians can establish sound policies and procedures that will ensure their ability to maintain patient privacy.

To download a sample Authorization Form, please go to www.magmutual.com/risk.



HIPAA FAQ's

The U.S. Department of Health and Human Services (DHHS) provides answers to many helpful frequently asked HIPAA questions. The following is a sample of questions and answers published by DHHS.

Q: Does the HIPAA Privacy Rule allow parents the right to see their children's medical records?

Yes, the Privacy Rule generally allows a parent to have access to the medical records about his or her child, as his or her minor child's personal representative when such access is not inconsistent with State or other law.

A: There are three situations when the parent would not be the minor's personal representative under the Privacy Rule. These exceptions are: (1) when the minor is the one who consents to care and the consent of the parent is not required under State or other applicable law; (2) when the minor obtains care at the direction of a court or a person appointed by the court; and (3) when, and to the extent that, the parent agrees that the minor and the healthcare provider may have a confidential relationship. However, even in these exceptional situations, the parent may have access to the medical records of the minor related to this treatment when State or other applicable law requires or permits such parental access. Parental access would be denied when State or other law prohibits such access. If State or other applicable law is silent on a parent's right of access in these cases, the licensed healthcare provider may exercise his or her professional judgment to the extent allowed by law to grant or deny parental access to the minor's medical information.

Finally, as is the case with respect to all personal representatives under the Privacy Rule, a provider may choose not to treat a parent as a personal representative when the provider reasonably believes, in his or her professional judgment, that the child has been or may be subjected to domestic violence, abuse or neglect, or that treating the parent as the child's personal representative could endanger the child.

Q: Can a physician's office FAX patient medical information to another physician's office?

A: The HIPAA Privacy Rule permits physicians to disclose protected health information to another healthcare provider for treatment purposes. This can be done by fax or by other means. Covered entities must have in place reasonable and appropriate administrative, technical and physical safeguards to protect the privacy of protected health information that is disclosed using a fax machine. Examples of measures that could be reasonable and appropriate in such a situation include the sender confirming that the fax number to be used is in fact the correct one for the other physician's office, and placing the fax machine in a secure location to prevent unauthorized access to the information.

For more HIPAA-related FAQs refer to
<http://www.cms.hhs.gov/hipaa/>,
www.practice-management.org or
<http://practice-management.org/hipaa.html>.
For HIPAA-related service, please contact
David Miller at **678-226-0035**.

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OMISSION

Due to an oversight, MAG Mutual would like to attribute the "Diagnosis and Management of Appendicitis" algorithm which was included with Volume 11/Number 26/2005 of the *Healthcare Risk Manager* to: Figure 6. Algorithm for suspected appendicitis. "Surgical referral is appropriate at any step." American Family Physician, January 1, 2005, Volume 71, Number 1 www.aafp.org/afp.



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