



Use of Sample Medications in Physician Practices – A Risk Modification Approach

By: Ellen Flynn and Jessica Riley

Healthcare providers need to manage the economy's effects on their practices, the population they serve, their employees and themselves by staying focused on risk management, quality, and safety.

The current economy is claiming many victims: physicians, their patients, healthcare administrators and staff. Job loss with its resulting loss of health insurance, home foreclosures, tightening of the credit markets, and the devaluation of assets is creating an inordinate amount of stress amongst healthcare providers and their patients in almost every community in the United States. Healthcare providers need to manage the economy's effects on their practices, the population they serve, their employees and themselves by staying focused on risk management, quality, and safety.

During this recession, healthcare providers may experience a decrease in both patient volume and patient compliance. At the same time providers are seeing an increase in patient acuity, the number of patients seen without health insurance, the number of patients who may not be able to pay for services provided, non-compliant patients, the risk of malpractice claims and stress related disorders. One in three Americans said they have had problems paying their medical bills in the past year. Physician practices that focus on helping their patients and staff cope during these very hard times will be most successful in providing necessary care, growing their practices and reducing their malpractice risk.

One of the key risk areas for the patient and potentially for the physician is patient compliance with taking prescribed medications. It is especially important that providers conduct comprehensive medication reconciliation at each patient visit. Patients may be embarrassed to tell their physician that they cannot afford to purchase medications prescribed, but obtaining that information is essential for good patient care.

Providing Sample Medications

In these very challenging economic times, physician practices may choose to help their patients obtain sample medication so the patients can get the medication that they need and cannot afford. The best practice would be for the physician to work with pharmaceutical companies to see if the pharmaceutical companies would provide medication coupons and vouchers for patients. When physician practices are unable to obtain drug coupons and vouchers, they may choose to store and dispense sample medications as a way to help their patients get the medication they need. Issuing sample medications is a high risk activity for physician offices; if the decision is made to dispense sample medications, it is prudent to create and consistently use a medication management system that includes adequate preparation and education of physician office staff in order to mitigate potential risk exposure.

Risk Modification Process: Sample Medications

1. *Develop a Protocol for Determining the Appropriate Indications for Use.* Sample medication is intended to be provided to a patient when the patient is being asked to start a new medication. It is a cost effective way to evaluate if the patient can tolerate a new medication and/or whether the new medication will be effective for the patient. Therefore, it might be appropriate to consider providing a sample medication to begin the therapeutic regimen. If the issue is that the patient cannot afford to pay for maintenance drug therapy that has been effective and tolerated by the patient, it might be more prudent to work with the pharmaceutical company to see if vouchers or coupons are available for the patient.
2. *Develop Appropriate Office Policies to Monitor Sample Medications.* Establish policies with your office staff to ensure that proper storage, inventory management, tracking/logging, labeling and disposing of sample medications are all in place. Pay special attention to any state laws regarding disposal of medications to ensure your practice is in compliance. In addition, pre-determine how a drug recall will be handled and how patients who might have received that medication as a sample from your office will be contacted.

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3. *Storage of Sample Medications.* All medications need to be in locked and secured areas and manufacturer recommendations for storage need to be known and followed. This includes refrigeration and monitoring of appropriate refrigeration temperatures if you are housing medications that require certain temperature levels to maintain potency and effectiveness. If a physician practice is storing medications that require refrigeration, processes need to be in place to notify the practice if there has been a refrigerator (electricity) malfunction when your office is closed. There are some inexpensive devices available to help physician offices carry out this critical function during the times when it is closed.
4. *Inventory of Sample Medications.* An inventory process serves multiple purposes such as preventing unauthorized medication removal, removal of outdated and recalled medications and providing a way to trace back what medication had been given...this is critical if the wrong medication was given to the patient accidentally.
5. *Labeling of Medications for Patient Use.* It is important that all medications provided to patients are clearly labeled with medication name, strength and dosage unit, lot number and expiration date, instructions for use, information required by the FDA and cautionary statements (e.g. "May cause drowsiness"). In addition, there should be an open space to affix a label for the specific patient that includes at a minimum:
 - Patient name
 - Date Dispensed
 - Reason for medication
 - Clear directions for use
 - Amount that should be taken
 - Frequency of taking the medication
 - Special instructions/precautions for use
 - Any significant side effects

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6. *Issuing of Medications.* Ensure that only those with prescribing authority actually dispense the medication. Pay close attention to the scope of practice defined for physician extenders in your State. The physician is responsible to review the patient's medical record to make sure that there are no drug allergies, sensitivities, interactions, contraindications or duplicate therapy to sample medication being provided. When dispensing medications, the physician is also taking on the responsibility for patient education; it is critical to ensure that this is done properly and documented.
7. *Documentation.* It is essential to document in the patient's record what medication has been dispensed, the lot number and expiration date and the fact that the patient has received appropriate education regarding the medication dose, use, side effects and contraindications.
8. *Monitoring.* The physician office is responsible for contacting the patient if there is a drug recall on a medication dispensed from your office and is also responsible for tracking any adverse drug reaction related to the medication dispensed and reporting this reaction to FDA MedWatch.
(<http://www.fda.gov/Safety/MedWatch/HowToReport/ucm085692.htm>.) Document that the patient has been notified in the case of a recall and that the adverse drug report has been filed in the case of any adverse drug reaction.

Each healthcare professional in the medication management process fulfills a valuable role. To assist your patients with medication acquisition, consider working with your Pharmaceutical Representatives to obtain drug coupons and vouchers for your patients. If a physician decides to provide sample medications, the physician needs to understand that he is not only taking on the role of the pharmacist, but he is also taking on additional liability when storing and dispensing sample medications. In order to mitigate this risk exposure, it is important to develop a process for the proper storage and dispensing of sample medications. The process outlined above is a good way to get your staff started on developing the necessary processes to modify this risk exposure for your practice.

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Ellen Flynn, RN, MBA, JD
Vice President, RQS Consulting Services
Clarity Group, Inc.

Jessica Riley
Risk/Claims Management Associate
Clarity Group, Inc.

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