

# Medication Management for Medical Practices and Physicians

Compliance Officers Must Recognize the Need for Improved Quality and the Associated Risks to Both Patients and Organizations

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**M**edication management by physicians and medical practices is an area of increasing quality and regulatory compliance risk. With the passage of Medicare Part D regulations, doctors are under increased scrutiny in the area of prescribing practices and utilization. In addition, a variety of quality risks may exist in the area of medication management at the medical practice.



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## **THE PREVALENCE OF MEDICATION ERRORS**

According to the National Institutes of Medicine (IOM), medication errors are pervasive in all health care settings. In 2007, IOM issued reports estimating that errors in prescription, preparation, dosage, and administration occur with alarming frequency — at the rate of one medication error per hospital patient per day.<sup>1</sup> The IOM reached this conclusion after assessing data from 36 independent clinical studies conducted in a number of health care settings. Studies included direct observation of medication administration and excluded “wrong time” errors — when doses are given outside prescribed times.<sup>2</sup>

An adverse drug event (ADE) is the most serious type of medication mismanagement. This is an error that causes injury to the patient and is considered preventable. The cost of ADEs is extensive. According to the IOM:

In hospital acute care, a conservative estimate of 400,000 ADEs a year equates to extra hospital-based costs of \$3.5 billion in 2006 dollars.

In long term care, an estimated 800,000 ADEs a year occur. The costs associated with this quantity of errors have not been calculated.

In ambulatory care, the estimated ADEs involving Medicare beneficiaries only (age 65 and older) costs an additional \$887 million.<sup>3</sup>

According to IOM estimates, the total volume of these errors is at least 1.5 million errors per year in U.S. health care settings — each representing a preventable patient injury.<sup>4</sup> Obviously, medication management is an area of great need for quality improvement. In the physician and medical practice setting, medication management poses a variety of quality risks and regulatory compliance risks.

### **MEDICARE PART D ENSURES NEW SCRUTINY OF PHYSICIAN PRESCRIBING PRACTICES**

With the passage of the Medicare Part D prescription benefit, physicians may expect review of prescribing practices and volumes through a variety of auditing reports developed by Part D plan sponsors and payors. Sponsors are expected to develop and implement a plan to identify, correct, and prevent fraud and abuse under the requirements of 42 C.F.R. §423.504(b)(4)(vi)(H).

The Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) issued a Prescription Drug Benefit Manual to guide program sponsors and “downstream entities” (including prescribing physicians). Chapter 9 of the manual addresses programs to control fraud, waste, and abuse and can be found at [www.cms.gov/PrescriptionDrugCovContra/Downloads/PDBManual\\_Chapter9\\_FWA.pdf](http://www.cms.gov/PrescriptionDrugCovContra/Downloads/PDBManual_Chapter9_FWA.pdf).

Paragraph 50.2 of the manual addresses specific types of auditing and monitoring reports that program sponsors are expected to implement. These focus on the prescribing practices of physicians. The OIG, of course, does not limit sponsors to only these monitoring processes but encourages other monitoring and auditing techniques as well. Phy-

sicians should be aware that sponsors will develop data on their prescribing patterns.

Recommended report types include the following:

- **Prescribing Patterns by Physician Reports**, which identify the number of prescriptions written by a particular provider and typically focus on a class or particular type of drug such as narcotics. These reports should be generated to identify possible prescriber/provider or pharmacy fraud.
- **Geographic Zip Reports**, which identify possible doctor shopping schemes or script mills by comparing the geographic location (zip code) of the patient to the location of the provider that wrote the prescription and should include the location of the dispensing pharmacy. These reports should generate information on those enrollees who obtain multiple prescriptions from providers located more than the normal distance traveled for care (*e.g.*, 30 miles). “Normal distance” should take into account where the beneficiary resides (*i.e.*, beneficiaries in rural areas typically would have longer trips to a doctor or pharmacy than beneficiaries living in urban areas).<sup>5</sup>

### **ADDITIONAL REGULATORY SCRUTINY**

In addition to complying with Medicare Part D regulations, physicians are obliged to comply with a variety of additional regulations that relate to medication management. These include compliance with vaccine management guidelines promulgated by the Centers for Disease Control and Prevention (CDC);<sup>6</sup> the Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens Standard (29 C.F.R. §§1030-1910); the U.S. Drug Enforcement Agency (DEA); and the U.S. Food and Drug Administration and medication labeling requirements of Code of Federal Regulations Title 21 (21 C.F.R. §610.60 ).<sup>7</sup>

### **WHO MANAGES MEDICATIONS?**

Of course, all physicians and nonphysician providers with prescriptive privileges may prescribe medications in the medical

practice setting. Family practice, general practice, and internal medicine physicians commonly see and prescribe medications to most patients. According to the American Academy of Family Practice (AAFP), approximately 12 percent of physicians are family practice providers; 2 percent are general practice providers; 16 percent are internal medicine providers; 5 percent are OB-GYN providers; and 8 percent are pediatrics providers. All other medical specialties make up an additional 57 percent of the physicians in the United States.<sup>8</sup>

While the number of primary care providers is limited, the number of office visits to these physicians has increased over the past decade. Tracking data from 1996-2006, AAFP projects that every 100 Americans seek out 179.2 office visits to primary care physicians every year.<sup>9</sup>

### **MANAGING MEDICATIONS: AN IOM DIAGRAM**

The process of managing prescriptions is increasingly complex. A diagram of a closed loop process appears in Figure 1, with various stages clearly identified: the prescription, transmission of data to pharmacy, dispensing, administration, and monitoring of medical efficacy, including assessment of needs to change prescriptions.

### **DEA REQUIREMENTS FOR MEDICATIONS**

#### **Narcotic Storage and Management**

DEA enforces the Controlled Substances Act of 1970 (21 C.F.R. §1300), which outlines measures to be taken by health care practitioners with regard to narcotics management and security. DEA provides the *Controlled Substances Security Manual - An Informational Outline of the Controlled Substances Act of 1970*, at [www.deadiversion.usdoj.gov/pubs/manuals/sec/security.pdf](http://www.deadiversion.usdoj.gov/pubs/manuals/sec/security.pdf) (Accessed April 5, 2010).

*For absolute clarity, the following text is taken directly from the DEA Manual.* (This material is published in the public domain by a U.S. government agency. It is designed

to be used and distributed by the affected public and is not restricted or protected by the U.S. Copyright Law).

**Security Requirements for Practitioners.** Practitioners include physicians, dentists, veterinarians, researchers, hospitals, pharmacies, or other persons registered to do research, to dispense, or to use in teaching or chemical analysis a controlled substance in the course of professional practice.

Minimum security standards for practitioners are set forth in the regulations (Title 21 C.F.R. 1300-end) and are to be used in evaluating security. They may not necessarily be acceptable for providing effective controls and operating procedures to prevent diversion or theft of controlled substances. For example, a hospital that keeps large quantities of controlled substances on hand may need a safe or vault similar to the requirements for a distributor. The same reasoning also applies to other practitioners.

A practitioner's overall security controls will be evaluated to determine if they meet the intent of the law and regulations to prevent theft or diversion.

**Minimum Standards for Practitioners' Handling of Controlled Substances.** Controlled substances must be stored in a securely locked cabinet of substantial construction.

Pharmacies have the option of storing controlled substances as set forth above, or concealing them by dispersal throughout their stock of non-controlled substances.

Even though the Federal regulations do not specifically define locked cabinet construction, the

intent of the law is that controlled substances must be adequately safeguarded. Therefore, depending on other security measures, a wooden cabinet may or may not be considered adequate.

In an area with a high crime rate, a strong metal cabinet or safe may be required.

Some of the factors considered when evaluating a practitioner's controlled substances security include:

1. The number of employees, customers and/or patients who have access to the controlled substances.
2. The location of the registrant (high or low crime area).
3. Use of an effective alarm system.
4. Quantity of controlled substances to be kept on hand.
5. Prior history of theft or diversion.

Again, an overall evaluation of the practitioner's security will be made by DEA using the general and minimum security requirements as outlined in this manual to assure that the controlled substances are stored securely.

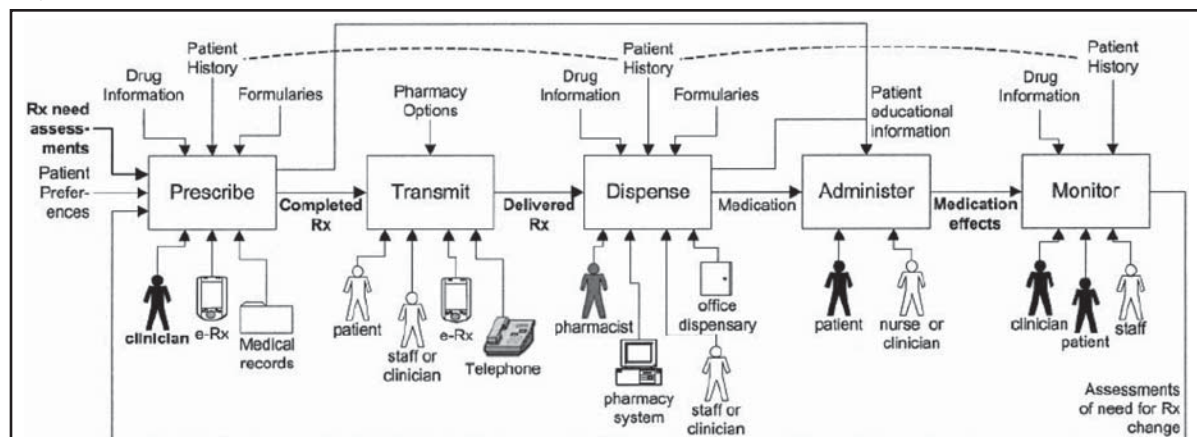
**Other Security Controls for Practitioners.** In order to minimize the opportunities for theft or diversion of controlled substances, practitioners have an obligation not only to provide effective physical security, but also to initiate additional procedures to reduce access by unauthorized persons as well as to provide alarm system where necessary.

**Employee or Agent.** A practitioner must not employ an agent or individual who has had his application for registration with DEA denied or revoked at any time, and who, as a result of his employment, will have access to controlled substances.

**Loss or Theft.** A practitioner shall notify the nearest DEA Field Office of the theft or significant loss of any controlled substance upon discovery of such loss or theft. The practitioner shall promptly complete and submit DEA Form 106 regarding the theft or loss.

**Blank prescriptions and DEA Order Forms.** A practitioner should develop the practice of keeping

Figure 1:



Source: National Institutes of Medicine (IOM), *Preventing Medication Errors: Quality Chasm Series, 2007*, published by the National Academies Press. [www.nap.edu/openbook.php?record\\_id=11623](http://www.nap.edu/openbook.php?record_id=11623)

blank prescription forms in locations which would preclude patients or casual visitors from stealing the forms for the purpose of falsification. Unused DEA Order Forms should also be kept in a secure location for the same reason.

## **CDC REQUIREMENTS FOR VACCINE MANAGEMENT**

Vaccines must be carefully managed in strict accordance with guidelines issued by the CDC and the National Center for Immunization and Respiratory Diseases. The guidance “toolkit” is available at [www2a.cdc.gov/vaccines/ed/shtoolkit/pages/storage\\_practices.htm](http://www2a.cdc.gov/vaccines/ed/shtoolkit/pages/storage_practices.htm) (Accessed 7/20/2009).

Practices that provide vaccines should copy and circulate to staff and physicians instructions on proper management. The excellent CDC vaccine guide is a U.S. government document published in the public domain. As such, it may be copied and distributed and is exempt from U.S. copyright law restrictions under USC 17, the U.S. Copyright Law.

Some important requirements for vaccine storage include:

1. Store vaccines at proper temperatures.
2. Avoid exposure to light.
3. Place vaccines properly inside the refrigerator/freezer.
4. Avoid similar packing and similar name confusion.
5. Use labels for shelves of specific vaccines.
6. Storage with non-vaccine products.

## **Food Storage in Medication/Vaccine Refrigerators or Freezers**

Food items provide a breeding ground for bacteria that can cross-contaminate medications or vaccines. Spills inside a medication storage refrigerator are also sources of bacteria and must be cleaned completely and immediately.

Guidance for medication and vaccine storage is provided by the CDC. The complete guidance is included in the CDC Vaccine Storage and Handling Toolkit, which

can be found in its entirety at [www2a.cdc.gov/vaccines/ed/shtoolkit/pages/storage\\_practices.htm](http://www2a.cdc.gov/vaccines/ed/shtoolkit/pages/storage_practices.htm) (Accessed 7/20/09).

In Storage of Non-Vaccine Products, the guidance states:

Never store food or beverages inside the vaccine refrigerator or freezer. This practice results in frequent opening of the storage unit door and greater chance for temperature instability and excessive exposure to light. It may also result in spills and contamination inside the compartment.

Although the CDC guidance specifically discusses vaccine management, the same principles of cross-contamination and temperature stability apply to other types of medications.

The OSHA Bloodborne Pathogen Standard (29 C.F.R. §§1030-1910) prohibits food items in areas where contamination may occur. Standards of the national accrediting body, the Joint Commission ([www.jointcommission.org](http://www.jointcommission.org)), also address these concerns and prohibit food and drink in patient care areas where cross-contamination may occur.

In Infection Prevention and Control FAQs, The Joint Commission notes:

- Standard LD.04.01.01 requires compliance with applicable law and regulation. The OSHA Bloodborne Pathogen Standard prohibits food and drink in areas where contamination is likely. For example, if lab specimens are handled in a work area, the OSHA standard would prohibit food and drinks if contamination might occur.
- Under the same LD.04.01.01 standard, many states prohibit food and drink in clinical areas, requiring that they be consumed in break areas.
- Many organizations have policies that prohibit this for infection control, risk management, or even public appearance purposes. These are often established after conducting a risk assessment, as required in Standard IC.01.03.01. Organizations must be in compliance with their own policies.

- An Environment of Care risk assessment should be performed to address potential patient safety issues, per EC.02.01.01.

For more information, visit the Joint Commission 2009 Standards FAQs at [www.joint-commission.org/AccreditationPrograms/CriticalAccessHospitals/Standards/09\\_FAQs/IC/Food\\_And\\_Drinks.htm](http://www.joint-commission.org/AccreditationPrograms/CriticalAccessHospitals/Standards/09_FAQs/IC/Food_And_Drinks.htm) (Accessed 7/20/09).

### **U.S. FOOD AND DRUG ADMINISTRATION (FDA) REQUIREMENTS**

Some medical practices mix special solutions or transfer solutions from one large container to several smaller dropper bottles or other containers. These solutions are governed by labeling requirements of the U.S. Food and Drug Administration (FDA) and Code of Federal Regulations Title 21 (21 C.F.R. §610.60 ).<sup>10</sup> The FDA requires the following information on drug labels:

1. the proper name of the product;
2. the name, address, and license number of manufacturer;
3. the lot number or other lot identification;
4. the expiration date;
5. the recommended individual dose, for multiple dose containers; and
6. the statement: "Rx only" for prescription biologicals.

C.F.R. Title 21 also provides for labeling of items in containers too small for a full label and for other packaging requirements.

Alternately, for container labels too small to contain all data, the expiration date, dose, statement "Rx only," and the date placed in the secondary container could be recorded. The original label with manufacturer's information could be maintained in a master file.

We recommend that solutions mixed or transferred in the practice should adhere to the following standards:

- placed in a sealed container with lid;
- dated with the date the solution was mixed or transferred;
- disposed of within 30 days of mixing or transfer; and
- new containers should be used for new solutions; do not re-use solutions containers.

For full text of 21 CFR, visit [www.access-data.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=610&showFR=1&subpartNode=21:7.0.1.1.5.7](http://www.access-data.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=610&showFR=1&subpartNode=21:7.0.1.1.5.7) (Accessed 2/10/2009).

### **COMMON MEDICAL PRACTICE MEDICATION MANAGEMENT ERRORS**

Outside of fraudulent prescription practices, a variety of errors in medication management are common, and some are unique, to medical practice settings. This article attempts to identify prevalent error situations and suggest ways to reduce risk to patients, physicians, and medical practices. With permission, it draws from information developed by the Healthcare Providers Insurance Exchange (HPIX), a professional medical liability insurance organization insuring physicians in the Atlantic Northeast United States.

**Obtain a list of medications at each practice visit.** At each office visit, patients should be asked to provide a list of all medication items they take, including medication names and doses. A current medication list is then prepared at each visit and assessed by the treating physician. Many practices also ask patients to provide information on over-the-counter (OTC) drugs they may be using. Patients also should be asked to identify any allergies of which they are aware.

**Use medication reconciliation processes or software.** The process of reconciling medications is best managed through an automated search system. A combination of factors makes it practically impossible for physicians or nonphysician prescribers to maintain current knowledge of every aspect of each medication they prescribe. Increasing numbers of medications are available for clinician prescription; many patients, especially the elderly, are using a large number of medications, and advanced clinical studies provide more information on possible drug-drug interactions and long-term effects of current medications. The IOM notes:

The underlying knowledge base is constantly changing, creating a sit-

uation in which it is almost impossible for health care providers to have current knowledge of every medication they prescribe. Clinicians therefore need access to critical syntheses of the evidence base.<sup>11</sup>

The IOM goes on to state, "All providers should use point of care reference information."<sup>12</sup>

A wide variety of software programs provide reconciliation of medications. Reconciliation may include identification of drug contraindications and drug-drug interactions, identification of overly high doses, allergy information, appropriate dosing based on age and projected renal function, and provision of prescription alternatives. Many programs feature open information technology architecture that allows them to interface with hospital and medical practice electronic medical record (EMR) systems. Some services offer an Internet-based application that can be accessed at any time, using computers or handheld devices.

**Adopt e-prescribing systems.** Physicians who follow patients in hospitals and/or long-term care facilities are likely already aware of and using e-prescribing systems (in some cases referred to as e-PS or e-Rx). Use of these systems follows publication of a variety of clinical studies that identify decreased error rates when e-PS or e-Rx is used compared to written or oral systems. In addition, significant cost savings are anticipated when e-Rx is combined with formulary use.

In January 2009, the Agency for Healthcare Research and Quality (AHRQ) released a landmark study, based on e-prescribing in over 200,000 filled prescriptions supported by clinical decision support systems over an 18-month period. The study indicates that cost savings of \$3.9 million per 100,000 patients could be accomplished if physicians would adopt e-Rx coupled with clinical decision support systems and use of an established formulary.<sup>13</sup>

Computerized order entry coupled with clinical decision support, as is discussed in

the earlier paragraphs on medication reconciliation, demonstrate the greatest clinical quality improvement.

While e-Rx is primarily used in the hospital setting at present, many medical practices are beginning to use these systems to transmit prescription orders to hospitals and pharmacies. In a number of pilot programs, AHRQ is sponsoring and monitoring development of industry standards for e-prescribing and medication management.<sup>14</sup>

**Communicate with patients.** Nationally, an increased number of professional medical liability (PML) claims are being made that allege a failure to communicate information, provide patient education, or obtain informed consent.

Situations in which one provider completes a "hand off" of a patient to another continue to be a nexus of opportunity for medication-related errors. Patients being transferred from long-term care to acute care, or from a medical practice to acute care, may arrive with incomplete medication information. In the medical practice to hospital transfer, or long-term care to hospital transfer, providers should take special care to ensure that a complete, accurate list of current medications is sent with the patient. The list should include, at a minimum, information such as:

- medication name;
- dose;
- route of administration;
- frequency of administration;
- duration; and
- date medication was started.

**Eliminate outdated medications.** Field studies completed by HPIX in four states during risk assessments of medical practices show many medical practices continue to stock and use outdated medication and supply items after the expiration date noted on the medication or supply item.<sup>15</sup> This typically indicates a failure of systems designed to identify and remove outdated medication items on a regular basis. It is a violation of the accepted standard of care to use outdated medications or supplies in the United States. This basic appli-

cation of an accepted standard of care obviates any argument that even recently outdated items may still be effective.

Common problems can be found with items that are seldom used. For instance, many practices with procedure rooms will stock a supply of Lidocaine or other injected anesthetics. These are commonly used when cleaning or suturing wounds. Since these multi-use vials are seldom used, they remain in use long periods and are frequently found to be outdated.

Items stored in medication refrigerators are also common culprits. Again, these items may be accessed very infrequently and, without a strong system of date checks, may expire before being completely used.

Medical practices should establish monthly checks of medications for expiration dates and dates vials are opened for use. Simple systems such as keeping a log of all medications used in a particular exam or procedure room, with expiration month, and discarding and replacing old medication items should be established and monitored regularly.

**Maintain proper documentation of prescription orders.** In many medical practices, nursing or medical assistant staff assists doctors in notifying pharmacies of new prescriptions. Practices should monitor documentation that records medication issuance. A lack of physician countersignature or initials on a nurse entry recording a medication refill allows interpretation as to whether the physician was actually involved in the refill.

Only licensed physicians registered with the DEA are allowed to prescribe medications. State Nurse Practice Acts restrict nurses from prescribing (with the exception of registered nurse practitioners who have prescriptive training and authority). Medical assistant staff has no prescriptive privileges. The lack of a physician countersignature can allow interpretation that the nurse is actually approving the prescription refill rather than simply carrying out orders of the prescribing physician.

**Medication refrigerator — temperature monitoring.** Medication refrigerator

temperatures should be monitored daily. Practices should place an easily observed thermometer inside the unit or a remote alarming sensor on the outside of the unit. A log of temperatures by date should be posted on the refrigerator. Temperature should be checked and logged daily.

A provision should be made for alerting staff if power to the building is lost for a period of more than one hour. Sustained power loss can raise temperatures in medication refrigerators and may cause damage to stored medications. If this occurs, refrigerated items must be destroyed, the refrigerator cleaned, and new medication items ordered and stored. Refrigerators should not be allowed to develop extensive icing in the freezer area; this may affect temperature readings and unit efficiency. Refrigerator units should be cleaned and defrosted, if needed, monthly or as often as necessary.

Maintenance of proper storage temperatures is typically noted as part of drug manufacturer storage recommendations. Monitoring is not typically required by standards organizations such as the Joint Commission; however, adherence to manufacturer's recommendations, and processes to ensure equipment such as refrigerators are properly functioning, is required. This functionally equates to providing refrigeration for appropriate medications, and monitoring performance of refrigeration equipment through logs and manual checks, or through electronic systems. Refer to [www.jointcommission.org/AccreditationPrograms/CriticalAccessHospitals/Standards/09\\_FAQs/MM/Medication\\_Refrigeration\\_Temperature.htm](http://www.jointcommission.org/AccreditationPrograms/CriticalAccessHospitals/Standards/09_FAQs/MM/Medication_Refrigeration_Temperature.htm) (Accessed 1/23/09).

Professional organizations such as the American Society of Health-System Pharmacists ([www.ASHP.org](http://www.ASHP.org)) provide guidelines for the management of medications and pharmacy services. Page 349 of the Best Practices Guidelines generally addresses refrigerated medication storage.

Refer to [www.ashp.org/DocLibrary/Best-Practices/ASHPGuidelinesMinimumStandardforPharmaciesinHospitals.aspx](http://www.ashp.org/DocLibrary/Best-Practices/ASHPGuidelinesMinimumStandardforPharmaciesinHospitals.aspx) (Accessed 1/23/09).

**Follow CDC guidelines for multi-use vials.** When multi-use injection vials are used, practice staff should follow three steps:

- Check expiration date; validate that medication and dose are correct as ordered.
- Write date opened on the vial label with a permanent marker.
- A common practice is to discard the vial after 30 days, regardless of how much of the medication has been used. Preservatives in many multi-use vials are judged effective only for a limited period after the vial has been accessed.
- Discard a multi-use vial anytime there is a concern about the safety of the vial (cloudy contents, visible contaminants, concerns regarding aseptic technique).

This is a commonly accepted and CDC recommended infection, medication verification, and quality control procedure for multi-use vials.

**Use proper aseptic technique for injections.** Staff members and physicians giving injections in the medical practice setting also should observe proper aseptic technique. The process of drawing a medication involves steps designed to prevent unintended transmission of pathogens and bacterial infection. The CDC provides an excellent reference guide for practice use, and it should be provided to all staff members who handle injection medications or provide injections.<sup>16</sup> The reference can be accessed at [www.cdc.gov/ncidod/dhqp/injectionSafetyFAQs.html#Q14](http://www.cdc.gov/ncidod/dhqp/injectionSafetyFAQs.html#Q14) (Accessed 2/10/2009).

## MANAGE SAMPLE MEDICATIONS

According to the IOM, sample medication prescription and distribution in the medical practice creates potential for medication error.<sup>17</sup> Physicians have a variety of valid reasons for distributing free medication samples. Giving samples allows patients to begin using prescriptions quickly. In some cases, samples are used to test tol-

erance and to allow for adjustment of prescribed doses. In the vast majority of cases, physicians issue sample medications to indigent patients or those with limited ability to pay for expensive prescriptions. Recognizing this need, many drug manufacturers have established free distribution programs to certain patients.

A primary concern with sample medication management relates to a frequent lack of documentation that sample medications have been given to patients. In many practices, there is no consistent method of documenting the name of the patient, the sample given, dosage or strength, and lot number of the medication. In the event of a product recall, the identity of many patients who received samples may not be recorded properly — which means those patients could not be readily reached or alerted.

Sample medication issuance also bypasses the standard prescription and dispensing process, which should involve drug interaction review and pharmacy consultation for patients. Several recommendations related to sample medication management follow.

**Restrict quantities.** Quantity restriction is one means of promoting sample medication safety. Many physicians limit the sample medications given to a three-day supply and instruct patients to contact them for a full prescription after the sample is depleted. This serves to ensure the patient will contact the physician or return to the practice for a prescription. It provides an opportunity for the physician to evaluate the patient's tolerance. In the event of a sample recall, it also limits the patient's exposure to the medication. While this is not an optimum process, it at least restricts sample size and provides some means of follow up.

**Outdated medication checks.** As with all other medications in the medical practice, sample medications should be regularly checked to ensure outdated drugs are not dispensed to patients. In most practices, the sample medications on hand rotate quickly, ensuring fresh stock is always given to patients.

**Manage drug manufacturer representatives.** Most practices have established systems requiring drug manufacturer representatives to identify and remove outdated samples when new samples are placed in storage closets. Practice administration should ensure that representatives are given monitored and limited access related directly to their duties in stocking and rotating sample medications. Interaction with physicians should be scheduled to avoid impeding practice workflow. Visits by representatives that involve interaction with staff and physicians should be centered on legitimate educational programs designed to address drug efficacy studies and interaction risks.

In 2003, the OIG issued compliance program guidance (CPG) for drug manufacturers. The CPG addresses then-common practices of providing gifts or incentives to physicians, which could have been construed as remuneration for use or prescription of certain medications.<sup>18</sup> The guidance is intended to restrict these practices by drug manufacturers.

**Document for the event of medication recall.** As noted earlier, many medical practices have not taken fundamental steps to ensure patients given samples can be quickly contacted in the event of a drug recall. In many practices, there is no consistent method of documenting the name of the patient, the sample given, dosage or strength, and lot number of the medication. In the event of a product recall, the identity of many patients who received samples may not be recorded properly – which means those patients could not be readily reached or alerted. Without a centralized method of tracking patients given samples, the practice would have to review a wide range of medical records to identify which patients should be notified of the recall.

The FDA issues alerts on mandatory or voluntary medication or supply item recalls. Some of these involve widely distributed medication items that are shown to injure patients only after significant dis-

tribution. The FDA issues email drug recall updates that are available to all registered users. To register, go to [www.fda.gov/opacom/7alerts.html](http://www.fda.gov/opacom/7alerts.html) and click on the “Sign Up for Recall E-Mail Updates” button in the top middle of the Web page (accessed 2/5/2009). You also may conduct a search of Class I Recalls by brand name, product, or company. The separate FDA Enforcement Index allows review of all Class I, II, and III recalls at [www.fda.gov/opacom/Enforce.html](http://www.fda.gov/opacom/Enforce.html) (accessed 2/5/2009). For a description of Class I, II, and III recalls, visit [www.fda.gov/oc/po/firmrecalls/recall\\_defin.html](http://www.fda.gov/oc/po/firmrecalls/recall_defin.html) (accessed 2/5/2009).

Ideally, sample medications issued patients should be added to the patient medication list maintained in the medical record. Staff should weekly (or more frequently, if needed) review sample medications issued and log them as samples in the patient medication list, with date of issue and sample size. This notation should be changed to reflect a regular prescription if use of the medication is regularly adopted by the patient and physician.

**Track sample medications with EMR systems.** Practices that have established EMR systems may have processes in place to quickly print a list of patients given a sample medication. Relational databases and search engines may allow quick sorting of patients by sample medication, for easy tracking. Such a process will be dependent on the physician entering or recording a sample medication issue to each patient.

Practices using or contemplating EMR systems should instruct programmers to establish simple processes for sorting patient data by medication name. Likewise, staff using the EMR system must accurately record the samples given each patient to ensure an electronic sorting process will work properly.

**Document telephone prescription refills.** Frequently, patients will call medical practices and request a refill of prescription medications on expiration. Physicians must evaluate the need to refill without a follow

up visit on a case-by-case basis. Most practices have established requirements that patients visit their physician annually to obtain a proper evaluation before continuing to refill prescriptions. In special circumstances a medication may be refilled for a limited time, until the patient can return to the practice for a regular appointment.

**Identify drug-seeking behavior.** In cases of obvious or suspected drug-seeking behavior, physicians must balance caution and sound medical judgment. Circumstances in which narcotics recipients repeatedly lose medications or require additional prescriptions are red flags that could alert a physician to drug seekers. These situations should be carefully documented and managed.

With the advent of pain management clinics and specialty practices that address chronic pain, many physicians have begun recommending these specialty practices to patients who repeatedly seek pain medication for chronic painful conditions. State-by-state data on substance abuse disorders is available from the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA), [www.samhsa.gov/statesinbrief](http://www.samhsa.gov/statesinbrief) (Accessed 4/5/2010).

**Documenting medication abuse by patients.** In situations where obvious or suspected medication abuse by patients has occurred, physicians should carefully document the facts related to the suspected abuse without making judgmental statements or interpretations. Physicians also should take suspected abuse into account when evaluating patients and consider the wisdom of referring suspected substance abusers to a different level of care that may better address their needs.

Many pain management clinics and other providers will enter into agreements with patients as part of their management regimen. The agreement stipulates terms under which medications will be provided and notes that any deviation from prescribed use will result in termination of the physician-patient relationship.

**Medication abuse among older Americans.** Another concern physicians must face involves the increasing use and potential abuse of medications by older Americans. The NIH notes the following information in program announcements for drug abuse research studies:

In general, prescription drug abuse in older adults begins with misuse due to inappropriate prescribing or lack of patient compliance with medication regimens. Continued misuse may progress to abuse and dependence. Older adults may be more vulnerable to prescription drug abuse because of age-related physiological changes that may influence the metabolism and response to prescription drugs, greater likelihood of having undiagnosed psychiatric and medical comorbidities, and difficulties in compliance with complex multiple drug regimens that may increase the likelihood of drug interactions. For example, benzodiazepines are frequently prescribed to older adults, but age-related changes in drug metabolism, interactions with other prescription and over-the-counter medications, and use of alcohol may lead to increased use/misuse/abuse and adverse consequences such as impaired functional capacity and cognition.

Yet, older Americans, their families, and their health care and service providers are frequently uninformed about the potential problems with psychoactive prescription drugs and, therefore, do not recognize these problems when they occur. The aging of the baby boom cohort may enhance the occurrence of substance abuse, including prescription drug abuse among older Americans because of this cohort's prior

use and abuse of psychoactive compounds. There is a need for research to develop screening, assessment, and diagnostic instruments (especially for use by health professionals in primary care settings) and prevention and treatment approaches targeted to prescription drug misuse and abuse in older adults.

Source: National Institute for Drug Abuse (NIDA), National Institutes for Health (NIH), Program Announcement PA 04-110, [grants.nih.gov/grants/guide/pa-files/PA-04-110.html](http://grants.nih.gov/grants/guide/pa-files/PA-04-110.html) (Accessed April 5, 2010).

Obviously, physicians must be especially cautious when prescribing medications to older Americans. This rapidly growing segment of the U.S. population is estimated to use one-third of all prescription medications issued.

## CONCLUSION

Medication management is an area of concern to all health care providers and regulatory compliance officers. The risks to patient safety are obvious when examining the high rate of medication error prescription and administration in all care settings. In addition, the complexity of the various regulations addressing medication management allow many opportunities for error. Health care organizations, physicians, and compliance officers must recognize the extensive need for improved quality in the area of medication management and the associated risks to both patients and organizations.

## Endnotes:

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15. Healthcare Providers Insurance Exchange (HPIX) is a medical professional liability insurer providing

- innovative risk management and regulatory compliance services to members in Pennsylvania, New Jersey, Maryland, and Delaware. HPIX provides onsite risk assessment services and continuing medical education services to member physicians and medical practices ([www.hpix-ins.com](http://www.hpix-ins.com)).
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