EXAMINER'S PERSPECTIVE:
USE OF MEDICATION INFORMATION SHEETS

Q. To enhance my informed consent process when prescribing medications, I am considering developing patient information sheets for the medications I prescribe. I don't want to "re-invent the wheel" if such patient information sheets already exist and are available. Do you know of any?

A. Patient information sheets for medications can be extremely valuable in managing some of the risks associated with prescribing. These patient handouts, however, must be utilized as *part of* the informed consent process, rather than *instead of* the informed consent / communication process. No handout, no matter how explicit, will ever replace the communication required between patient and physician to discuss the risks and benefits of the medication, alternatives to the medication (including no medication), and the risks and benefits of the alternatives. Some of the resources for existing patient medication information sheets are listed below.

Resources:

- The FDA has issued many medication information sheets for patients:
  - Patient Information Sheets for more than 200 medications can currently be accessed online at www.fda.gov/Drugs/DrugSafety/ucm085729.htm

- There are additional resources for children and adolescent patients:
  - The APA and AACAP have jointly prepared guides for patients and families about mediations for depression and ADHD which can be accessed online at www.parentsmedguide.org

Reminders for physicians choosing to use medication information sheets:

- ***Physicians utilizing these models will be responsible for tailoring them to meet their patients' needs and will be required to ensure the information is up-to-date.*** A valuable resource available to keep up to date on the latest developments with medications is the FDA's MedWatch program. Physicians can view the safety information online at www.fda.gov/medwatch/index.html and sign-up to receive e-mail alerts of FDA announcements, such as product safety alerts, withdrawals, and important labeling changes.

- ***Be sure to document in the patient record that the medication information sheet was reviewed with the patient and the patient was provided a copy.*** It may be advisable to place a copy of the medication information sheet that was given to the patient in the patient record.

- ***Physicians may want to consider incorporating the medication information for the patient into an informed consent form, which is signed by the patient.*** Having a patient sign an informed consent form may not be required – if a form is not used, the physician should make an entry about what the patient was told, the patient's understanding of the disclosure, and the patient's consent. However, incorporating a form signed by the patient into the overall informed consent process is valuable for at least risk management reasons. First, the formality of the process may force a patient to focus on what he or she is consenting to and, thus, make it less likely that he or she will later believe that the informed consent was not adequate. And second, the signed form supports the assertion that the consent process took place and establishes at least some of what was disclosed. If a consent form is used, a copy of what the patient signed and received should be retained in the chart.

For additional information on documentation of informed consent, see *Documentation of Informed Consent: When to Use a Form.*

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