The topic of physician dispensing comes with polarizing views on both sides. Proponents of physician dispensing cite improved patient access to medications, patient convenience, greater use of lower-cost generic medications and therapeutic substitutions due to the physician’s enhanced awareness of medication costs, and improved patient adherence with medication regimens. Opponents of physician dispensing cite serious medication safety concerns, particularly the loss of a crucial second check by a pharmacist and use of software to detect prescribing errors, and lack of regulatory oversight, which may lead to lax procedures for medication labeling, record-keeping, storage, and supervision of the dispenser.

There’s also a sense of unease regarding a potential conflict of interest when the physician prescribing the medication is also the person dispensing the medication and, perhaps, making a profit from the sale.

The Institute for Safe Medication Practices (ISMP) fully supports the removal of any barriers to patients’ access to medications, cost containment that can be achieved by use of lower-price but effective medications, and steps that improve patient adherence to prescribed medication therapy. However, we cannot support unbridled physician dispensing due to the increased risk of medication errors, particularly with high-alert medications such as chemotherapy. While physician dispensing is permitted in most states, it is often carefully regulated and restricted to samples or conditions of immediate need. Some states require dispensing physicians to be licensed by or registered with the Board of Pharmacy, or they must obtain a special permit. The American Medical Association Code of Ethics notes, “Physicians may dispense drugs within their office practices provided such dispensing primarily benefits the patients.” However, we worry about the unintended consequences of physician dispensing, as described in more detail below.

Pharmacy Checks and Balances

Physician dispensing bypasses a crucial second independent check of the prescribed drug therapy by a pharmacist. Preventable adverse drug events that harm patients originate most often when prescribing the medication. At least half of these prescribing errors are detected and corrected when pharmacists review the safety and appropriateness of the medication. A pharmacist’s review of prescribed medications is especially important with chemotherapy given the difficulty in achieving adequate therapeutic effect without causing undue toxic side effects.

Pharmacists possess expertise in a drug’s “therapeutic index,” which is the ratio between the dosage of a drug that causes a lethal effect and the dosage that causes a therapeutic effect. Physicians may not have access to software that pharmacists can use to screen prescribed drug therapy for overdoses, subtherapeutic doses, drug–drug interactions among all medications the patient takes (not just the chemotherapy regimen), contraindications due to allergies or disease state, and duplicate therapy. If they do have access to screening software, physicians may not enter all of the medications the patient takes besides the prescribed chemotherapy and adjunct medications.

During the past few years, oral chemotherapy has become increasingly available, heralding a new era of cancer care. An estimated one-quarter of the 400 antineoplastic agents now in the pipeline are planned as oral medications. Important safety concerns exist with oral chemotherapy, and these concerns are only magnified as the use of oral chemotherapy increases. One survey found that few of the safeguards in routine use for infusion chemotherapy at major U.S. cancer centers have been adopted for oral chemotherapy. These cancer centers are now working to make sure safety checks for oral chemotherapy match the safety checks for infusion chemotherapy. Knowing this, it is difficult to see how physicians and their assistants can safely prescribe and dispense this therapy without a system of checks and balances provided by pharmacists. Further, having the same physician prescribe and dispense a medication introduces a potential single-pathway failure, meaning there is no safety net to catch the error before it reaches the patient. Single-pathway failures suggest low reliability when it comes to safety.

Labeling and Education

As with sample medications, physician dispensing also raises concerns regarding proper labeling of dispensed products using the same standards that pharmacies must follow. Regardless of where the prescription medication is dispensed, each product should include a label with the patient’s name, medication name, strength, dose that should be taken, route of administration, frequency of taking the medication, reason for taking the medication, special precautions (e.g., may cause drowsiness; take with food; or, as with a number of oral targeted therapies, take after fasting for a specified period of time), an expiration date (if not on the package), the prescribing physician’s name, and a telephone number in case the patient has questions.

Patient counseling, including review of any serious side effects, is also a necessity, particularly given that insufficient knowledge about health and medication therapy is a key contributor to patients’ nonadherence to their prescribed drug therapy. Much of the patients’ education (as well as dispensing tasks) may be delegated to office or clinic staff who may not have sufficient knowledge of the drug. As with sample medications, drug storage conditions, checking for expired drugs, safe handling of toxic medications (e.g., chemotherapy), and the security of drug continued on page 695
storage may also be compromised more easily in a physician’s office or clinic than in a pharmacy.

Third-Party Reimbursement

Another issue with physician dispensing relates to the drug reimbursement system and the willingness and proficiency of office staff to conduct online adjudication of medications with third-party payers, including challenges to denials when appropriate to facilitate coverage. This function comprises a substantial part of the dispensing process and is not without its unique set of challenges and frustrations that pharmacists typically tackle every day. Physicians and office staff may have limited or no experience with this grueling facet of the dispensing process, and they may not be prepared to invest in the expensive and user-intensive software that is required for online adjudication. Out-of-pocket expenses may skyrocket for angry patients who are taking costly medications that are not reimbursed by Medicare Part D or another prescription benefit program largely because the physician did not have the software for adjudication.

In addition, physicians’ office staff may not be adept regarding the nuances of signing up for and accepting Part D insurance plans, particularly when dispensing drugs such as oral chemotherapy that are not covered under physician-administered intravenous medications. Patients will be rightfully upset if a physician dispenses a medication during an office visit without ensuring coverage, after which they receive a bill for the full amount of the medication with an explanation that the patient should have known what his or her insurance would cover (a situation sometimes encountered with immunizations). Furthermore, pharmacies often negotiate with drug manufacturers and wholesalers to obtain medications at the lowest possible costs; physicians and their staff may not be in a position or have the time to negotiate for lower prices, thus increasing the overall costs associated with drug therapy.

Conflict of Interest

It is hard to overlook the potential conflict of interest that may exist when a physician could profit from medications he or she prescribes. Yet, despite this risk, we believe the vast majority of physicians put the health and safety of their patients well above profit margins.

In the end, physician dispensing without regulatory oversight that upholds the same standards required of dispensing pharmacists could be quite costly to patients in terms of their health, safety, and wallet. Both the Office of the Inspector General of the U.S. Department of Health and Human Services and the National Association of Boards of Pharmacy emphasize the necessity of regulatory oversight and accountability in the drug distribution and dispensing process in order to protect patient safety. Any state legislation that grants dispensing privileges to physicians should ensure that the requirements mimic existing language in the state’s pharmacy practice act. Borrowing from the Joint Commission’s stance, physician dispensing and pharmacy dispensing should be held to equivalent standards of care. The potential safety issues with physician dispensing cannot be dismissed easily, and the proper regulatory oversight of this practice needs to be well thought out and funded if physician dispensing trends continue. Otherwise, the potential harm from physician dispensing is too great, and the medication dispensing process should continue to be managed by a licensed pharmacist and state regulatory agencies that aggressively enforce standards of care in dispensing pharmacies.

REFERENCES