Outpatient care, including outpatient parenteral antimicrobial therapy (OPAT), is increasingly seen by both clinicians and insurers as a safe, effective, and economical adjunct or alternative to hospitalization. Despite this, perhaps the least understood reimbursement and regulatory policies for health care services are those that apply to OPAT. We present a brief review and update of current rules and regulations relating to OPAT, with emphasis on areas of special interest to physicians serving as medical directors of home or ambulatory infusion programs or providing OPAT as an extension of their office practices.

Over the past 20 years, both patients and providers have developed an appreciation of the benefits of outpatient care, and payers have now come to expect their beneficiaries to be treated as outpatients. The majority of outpatient parenteral antimicrobial therapy (OPAT) in the United States is provided by home infusion pharmacies, which often coordinate care with home health agencies. In addition, a significant percentage of OPAT is provided in ambulatory settings, most of which are either hospital-based or extensions of office practices. Regardless of setting, up-to-date knowledge of state and federal policies and requirements is necessary before an OPAT program is initiated, and after it is established, close attention to periodic policy modifications is critical. Regulatory and reimbursement policies will vary according to where OPAT is provided (in the home or an ambulatory clinic), the type of provider (hospital, retail pharmacy, or physician), and the third party payer (Medicare, Medicaid, or commercial insurance).

MEDICARE

The Medicare program has 3 mechanisms for reimbursement: Parts A, B, and D [1–3]. None will guarantee or give pre-authorization for payment, although coverage is outlined by the Centers for Medicare and Medicaid Services (CMS) and by local fiscal intermediaries and carriers, and CMS policies may be interpreted differently in different locations.

Medicare Part A. In addition to hospitals and skilled nursing facilities, Part A covers some home care services. To meet home care requirements, patients must be confined at home and require intermittent care (at least once every 60 days but not daily except for short periods) and skilled care as determined by a physician. Skilled service is that provided by a licensed nurse, physical therapist, or speech therapist. After a patient is eligible for these services, he or she may also take advantage of occupational therapy, medical social services, and a home health aide, also provided on an intermittent basis only.

Also included when skilled services are provided under Part A are some designated medical equipment and supplies. With some specific exceptions, drugs are not included, nor are home infusion services. Skilled nursing visits to support such services can be reimbursed, but only when other skilled care is part of the treatment plan.

Medicare Part B. Part B expands Part A to include physician services, ambulance transportation, prosthetic devices, independent laboratory tests, durable medical equipment, and medically necessary drugs and biological agents administered in outpatient physician
clinics as part of the physician’s care of their patient. The durable medical equipment benefit covers a limited number of intravenous drug therapies administered in the patient’s home, including only 4 antimicrobials (acyclovir, ganciclovir, amphotericin, and foscarnet), based on the need for an infusion pump (if durable and reusable). Payment for provision of these specific drugs requires a durable medical equipment provider number, which physicians may obtain. The program also pays for telephone or administrative time of physicians overseeing home care plans, if claims are supported by sufficient documentation of these services.

The Medicare Home Infusion Therapy Coverage Act of 2007 (HR 2567) proposed an amendment to Part B coverage to include items and services furnished by a qualified home infusion therapy provider to an individual, “which are provided in an integrated manner to an individual’s home under a plan established and periodically reviewed by a physician” [4]. In this proposal, a “qualified home infusion therapy provider” is defined as “any pharmacy, physician or other provider licensed by a State and which has expertise in preparation of parenteral medications, provides infusion therapy to patients in their homes, and meets other requirements established by the Secretary [of Health and Human Services]” [4]. To date, the amendment has not been passed.

Currently, Medicare will pay for the infusion of drugs when the drug is administered by a physician directly or by employees of a physician under his or her direct supervision. Thus, the physician must be present or immediately available when the patient is receiving care, whether in the office, clinic, or home. Some carriers allow nurse practitioners or physician assistants to replace physicians in this supervisory role. This remains a requirement when billing for physician office infusion procedures and drugs, and providers should be aware of the implications of noncompliance. Of note, although most commercial insurance carriers have never enforced this requirement, during audits, Medicare carriers use the Current Procedural Terminology definition for the drug infusion code(s), which clearly reflect the requirement that the infusion be directly supervised by a physician.

**Medicare part B reimbursement.** Coverage for OPAT services and supplies in any setting is determined by medical necessity. In some cases, this has been specifically outlined by advisory committees of local carriers. In the physician’s office, drugs, supplies, and services are reimbursed at 80% of the published Medicare allowable fee. Patients are then responsible for a 20% copayment. For those who have it, supplemental (Medi-Gap) insurers will pay the 20% copayment of anything covered by Medicare. Fee schedules for reimbursement for drugs administered in a physician’s office are currently published quarterly and are based on the Average Sales Price (ASP) plus 6%, as established in 2005 under direction from Congress.

The ASP is updated quarterly on the basis of submission of actual sales prices from pharmaceutical manufacturers. Drugs administered in the hospital outpatient setting are reimbursed using a different method, often including the drug in the payment for the procedure [5]. Providers were warned to expect further reductions starting on 1 January 2009, when payment rates could decrease as low as ASP plus 3%. However, the Medicare, Medicaid, and State Children’s Health Insurance Program Extension Act of 2007, S 2499, signed into law on 29 December 2007, blocked these reductions [6].

**Medicare pay for performance.** More than half of commercial health maintenance organizations in the United States currently use pay-for-performance incentives in their provider contracts [7]. In 2003, the CMS launched the Hospital Quality Improvement Demonstration Project, the largest pay-for-performance pilot project to date in the United States [8]. Building on the project’s conceptual framework, CMS is currently developing a strategy for value-based purchasing, to begin in fiscal year 2009 [9]. As part of this effort, the Physician Quality Reporting Initiative [10], a voluntary pilot pay-for-performance project, was initiated on 1 July 2007 to track 74 clinical measures across multiple conditions [11]. Under this program, individual providers and physicians have the opportunity to earn up to a 1.5% bonus payment for these services. Although OPAT was one of the procedures included in initial analyses, it has yet to be officially included in the pay-for-performance project.

**The Medicare Competitive Acquisition Program.** Section 303(d) of the Medicare Modernization Act required the implementation of a competitive acquisition program (CAP) for Medicare Part B drugs and biologicals not paid on the basis of a cost or prospective payment system. An alternative to the ASP methodology, the CAP is a voluntary program that offers physicians the option to acquire many injectable and infused agents from an approved CAP vendor [12]. Reimbursed costs of injectables given in a physician’s office have 2 components: cost of the medication and cost to administer it [13]. Before the Medicare Modernization Act, physicians had to purchase these drugs from wholesale providers or the drug manufacturer and bill Medicare directly for their cost. CAP fundamentally changes the options available. Participating physicians can continue to bill for administering the medication but may order the drug from an approved CAP vendor, who provides the drug to the physician and bills Medicare directly [13]. To date, antimicrobials have not been included in the CAP program.

**Medicare part D.** On 1 January 2006, the CMS began offering prescription drug coverage to >42 million Medicare beneficiaries [3]. A Part D, a covered drug is available only by prescription, is approved by the Food and Drug Administration, is used and sold in the United States, and is used for medically accepted indications. These include prescription drugs, biological products, insulin, and licensed vaccines. The
definition also includes medical supplies associated with the injection of insulin, defined to include syringes, needles, alcohol swabs, and gauze. Only the cost of the drug is included. As a result, most home and ambulatory infusion providers have not participated in this plan, because of the other less tangible costs involved when providing home infusion services.

**US PHARMACOPOEIA 2, CHAPTER 797**

The 2004 issue of the United States Pharmacopeia—National Formulary contained the first enforceable US Pharmacopoeia chapter on compounded sterile preparations, entitled “USP Tests and Assays Chapter 797, Pharmaceutical Compounding—Sterile Preparations” [14]. The intent of this new federal regulation is to prevent harm to patients from microbial contamination, excessive bacterial endotoxins, and large content errors in the preparation of parenteral medications that will not be administered to a patient. The chapter applied to pharmacies, health care institutions, physician practices, and any other site or type of health care facility that prepares or compounds sterile preparations.

This federal regulation has significant implications for any provider who prepares a parenteral drug for infusion, especially if the drug is dispensed to a patient to be administered at home. The standards are clear, addressing both primary and secondary engineering controls, and are enforceable by the Food and Drug Administration, The Joint Commission (formerly, the Joint Commission on Accreditation of Healthcare Organizations), and State Boards of Pharmacy. Alternatives include the immediate use exemption (eg, in an ambulatory infusion clinic where the drug can be mixed just before infusion), use of frozen or prepared drug, or use of closed transfer systems in which patients can be taught to mix the drug at home just before infusing it. As another alternative, providers may decide to contract with vendor pharmacies that already have the required engineering controls in place.

**STARK PHASE III REGULATIONS**

The Stark Phase III regulations were published in the Federal Register on 5 September 2007, to be effective on 4 December 2007. The original Stark prohibition on self-referrals covers 12 health care services, known as designated health services, including home health services and prescription drugs [15]. Stark I and II have been in effect for many years. The regulations addressed in Stark III are likely to be of interest only to physicians involved with OPAT as a medical director for a home infusion company or a hospital outpatient program, because it further defines acceptable indirect compensation arrangements.

The Stark regulations make a distinction between direct and indirect compensation arrangements, with different exceptions available for each type [15]. In accordance with Phase III, a direct compensation arrangement will exist if anything of value passes directly between a designated health services provider and a physician or his or her immediate family member who refers patients to that entity without going through an intervening person or entity or if the only intervening entity between the physician and the designated health services entity is a physician organization. A physician organization is defined as a physician, a professional corporation with a single physician as the sole owner, a physician practice, or a group practice [15, 16]. In accordance with the revised Phase III regulations, in which a physician organization provides services to a designated health services entity, each physician of the physician organization stands in the shoes of the physician organization; thus, the payments made by the designated health services entity are deemed to be direct compensation to each physician member, employee, and independent contractor of the physician organization and must satisfy the general exception according to the code of federal regulations.

For example, in accordance with the new regulations, a compensation arrangement between a hospital and a group practice that previously created an indirect compensation arrangement between the hospital and the individual physicians in the group practice now has a direct compensation arrangement between each hospital and physician in the practice [15, 16]. In addition, the ponderous Stark “safe harbor” survey regulation was deleted from the definition of fair market value in determining compensation for a physician’s personal services [15, 16].

The most straightforward way for physicians to avoid violation of any of these regulations remains a policy of not accepting direct or indirect compensation from a provider to which the physician also refers patients using Medicare or Medicaid, unless that compensation is clearly tied to independent services provided to the entity by the physician, unrelated to his or her referrals. As always, any contracts or other arrangements should be reviewed by a health care attorney before implementation.

**MANAGED CARE**

Most private insurance policies have some provision for outpatient benefits. Insurance companies may dictate the providers who will be reimbursed for OPAT and/or require prior authorization for treatment. Home infusion therapy providers continue to consolidate, making it more difficult for smaller providers to compete. Only rarely is OPAT included in a capitated contract of any kind; more often, it is either a fee-for-service procedure or reimbursed as a capitated payment, either for the entire procedure or by diagnosis. There are a few exceptions, and providers should verify the existence of any preferred or sole provider requirements before providing services. The majority of OPAT services continue to be reimbursed at a contracted fee-for-service rate, with the drug paid for separately.
Providers will find pre-authorization for treatment to be critical and, if possible, should include the identified process in general contracts or as separate addenda to facilitate the submission of claims and collection of payment. The alternative is to negotiate each patient’s care case by case, a prohibitive burden for some providers. Reimbursement continues to be a regional phenomenon; generalizations do not serve to inform providers.

CONCLUSION

This brief summary and update of regulations and reimbursement relative to OPAT contains 4 critical points. First, Medicare (and Medicaid) reimbursement policies continue to discourage physician profit and self-referral in the care of beneficiaries, specifically in regard to drug therapy. Second, the provision of OPAT in the physician’s office still requires direct supervision by a physician or mid-level practitioner—a rule that is unlikely to change in the near future. Third, the physician’s office or hospital-based ambulatory care clinic remain the only settings in which administration of an intravenous antimicrobial is clearly covered by Medicare reimbursement guidelines. Proposed legislation for Medicare coverage of self infusion at home has not been passed into law. Fourth, the current US Pharmacopoeia Chapter 797 presents a burden on all settings in meeting requirements for sterile preparation of parenteral drugs, especially those to be dispensed for administration at home, although alternatives are available.

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