LEGAL CORNER

Evaluate and Structure Your Hospital-Physician Affiliations

by Susan W. Berson, JD

The passage of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) in 2003 has further complicated an already complex, somewhat outdated Medicare reimbursement system for physician services. Couple these changes with other regulatory restrictions, such as the self-referral laws, and some physician practices are finding it impossible to survive independently.

In the 1990s changes in the reimbursement system and the adoption of the federal self-referral law resulted in the growth of what became known as physician practice management companies or PPMs. While this allowed physicians to take advantage of economies of scale, increased purchasing power, and off-loading of administrative burdens, PPMs failed to a large degree due to complex state regulatory restrictions, such as restrictions on the corporate practice of medicine and fee-splitting prohibitions, and the resistance of physicians to give up autonomy, as was often required by PPMs.

So what does the future hold now that further reimbursement reductions seem imminent and some physician practices are once again finding it difficult to survive on their own? One alternative that some oncology practices are pursuing is to explore affiliation possibilities with hospitals or health systems. Whether these affiliations succeed remains to be seen, but in the meantime certain regulatory pitfalls to these hospital/practice affiliations exist.

Any practice/hospital affiliation will raise issues under the federal self-referral law (the so-called "Stark law"), as well as analogous state laws. Under the Stark law, unless an exception applies, a physician cannot refer a patient for designated health services to an entity in which he or she has a financial interest. Designated health services include inpatient and outpatient hospital services. Thus, the affiliation of the practice with the hospital may turn an otherwise "non-designated" service into a designated health service. Exceptions include leases for space or equipment (but not a lease of the practice itself), certain service agreements, and employment relationships. This means that a hospital could assume the real estate lease of the practice and enter into service agreements or employ the practice physicians. In fact, under Phase I of the Stark regulations, the hospital may even be able to compensate the physicians for chemotherapy or radiation therapy services on a "per click" or "per unit" basis. However, the hospital could not simply "lease" or even acquire (except for cash) the practice without creating issues under Stark.

While the recently issued Stark Phase II regulations are perceived as making certain financial arrangements more acceptable if structured appropriately, one area of continuing concern is physician recruitment or retention payments that, as of the end of July 2004, must meet specific requirements, which have created a stir. Bottom line: Any such payment by a hospital affiliating with a practice and its providers must be carefully evaluated.

Additional issues would also need to be evaluated for a hospital/physician affiliation proposal. These include review of state requirements such as fee-splitting and certificate-of-need requirements, the impact on certain types of reimbursement resulting from the hospital affiliation, and state kickback issues, to name a few.

In the case of kickback concerns, in April 2003, the Office of the Inspector General (OIG) in the Department of Health and Human Services issued a Special Advisory Bulletin on Contractual Joint Ventures (the "Bulletin"). The Bulletin discusses the concerns raised when a healthcare provider in one line of business (the "Provider") expands into a related healthcare business by contracting with an existing provider of a related item or service (the "Supplier") to provide this new item or service to the Provider's existing patient population, including federal healthcare program patients. According to the Bulletin, concerns arise when the Provider contracts out substantially the entire operation of the related line of business to the Supplier, receiving in return the profits of the business as remuneration for its federal program referrals. The Bulletin goes on to describe certain common elements that these arrangements exhibit. While the Bulletin may not be directly on point for many of the contemplated affiliations, it could raise issues under circumstances where an oncology practice "affiliates" with a hospital and all chemotherapy or radiation therapy services are then provided by the hospital.

My advice to physician practices exploring ways to joint venture with hospitals or even other practices is to first ensure that the affiliation is an appropriate solution for the practice and its providers and second, to carefully evaluate and structure the affiliation to comply with any applicable legal requirements.

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