Legal Corner

Enhancing Oncology's Business Case: How the Hospital Can Help

By Alice G. Gosfield, JD

Oncologists are facing unprecedented business challenges. Perhaps even more dramatically than other specialties, oncology is struggling to meet the burgeoning mandates for demonstrated quality and performance, fraud and abuse avoidance, risk management, and efficiency as their fundamental business model predicated on revenues from pharmaceuticals reaches a crossroads. Whereas there are many things that oncologists could do to enhance their practice efficiencies, and thereby improve their financial margins,[1] the hospitals to which oncologists primarily relate can also be a source of help.

There is considerable mythology, which has impeded the development of creative techniques by which hospitals and their medical staff members can collaborate, not only in the furtherance of quality, but also to enhance the physicians' business case as well (see "Five Principles to Enhance the Physicians' Business Case for Quality"). Many hospitals, and even their legal advisors, are so fearful of potential liability under the Stark statute and the anti-kickback statute (AKS) that they thwart creative thinking in these arenas. This article elaborates on three areas of the law that have impeded more effective hospital-oncology relationships, and sets forth four practical strategies by which hospitals can help oncologists without running afoul of the law.

Legal Issues

Perhaps the most confounding legal pressure on these initiatives is the Stark statute, which limits opportunities for physicians to refer Medicare patients to entities with which they have financial relationships. Because the statute focuses exclusively on physicians,[2] exclusively on Medicare services, and only for a "hit list" of designated services, it is sometimes seen as limited in its impact. However, because it states a flat prohibition—a physician may not refer a Medicare patient for a designated health service to an entity with which he has a financial relationship, unless the relationships meets a statutory exception—its impact is very broad. Still further, because all inpatient and outpatient hospital services are designated health services, all financial relationships between physicians who refer to the hospital and the hospital itself are drawn into the ambit of Stark. The penalties of Stark are not criminal. Rather they involve one civil monetary penalty of $15,000 for an improper referral and an additional civil money penalty, also $15,000, for each claim submitted pursuant to an improper referral. However, Stark does not require proof of bad intent. Liability attaches simply for an improper transaction. There is, however, a specific regulation under Stark that permits the hospital to help physicians with their own business case.

A different set of problems is created by the AKS, which is far broader in its reach and located in an entirely different section of the Social Security Act. The AKS is relevant to all federal health care programs, not just Medicare. In addition, it affects anyone, regardless of status, who solicits, pays, offers, or receives any remuneration, cash or in kind, covertly or overtly, directly or indirectly, including kickback, bribe, or rebate, for the referral of a federal patient, to induce the referral, or for ordering, providing, leasing, furnishing, recommending, or arranging for the provision of any service, item, or good payable by a federal program. Violation of this statute does raise criminal liability and is punishable by a $25,000 fine, up to 5 years in jail, or both. However, because a violation requires knowing and willful behavior, the government finds it very difficult to mount a criminal prosecution under this law. However, Congress rectified this problem by providing for civil monetary penalties of $50,000 for each violative payment. Such a penalty does not require the criminal burden of proof. Still further, most cases under this statute are now concluding by settlements.

The third area of the law that has confounded hospital-physician relationships is the antitrust laws that impede otherwise competing entities from coming together collusively with regard to financial arrangements that hamper competition, such as setting fees or engaging in boycotts. The antitrust laws protect competition, above all. Although financial integration and financial risk are well understood as safety zones for joint activities, less well understood is clinical

Five Principles to Enhance the Physicians' Business Case for Quality

1) Standardize to the science.
2) Simplify the working environment.
3) Make administrative processes and payment clinically relevant.
4) Engage the patient in the process.
5) Fix accountability in report cards at the locus of control.

From Gosfield AG and Reinertsen JL: Doing well by doing good: Enhancing the business case for quality. http://www.ufi-a.com, 2003.

integration, which can offer protection from otherwise violative behavior while it improves quality.

Taken together, these three areas of the law have been unduly daunting to hospitals and physicians seeking to collaborate. Set forth in this article are four specific strategies that can help oncologists and hospitals work together within the boundaries of these laws.

Strategies

Complying With Stark

Amazingly, there is a specific provision in the Stark regulations that allows a hospital to provide compliance training to a physician or the physician's office staff when the physician practices in the hospital's local community. The training must be held in the local community. The definition of compliance training for these purposes includes training regarding the basic elements of a compliance program, specific training regarding the requirements of federal and state health care programs, including billing, coding, reasonable and necessary services, documentation and unlawful referral relationships, or training regarding other federal, state, or local laws, regulations or rules governing the conduct of the party for whom the training is provided.[3] Many of these matters, though, are also implicated in efforts to improve quality and enhance efficiency. Under this rubric, therefore, hospitals can teach physicians how to (a) organize themselves to standardize their documentation in accordance with clinical practice guidelines, thereby avoiding false claims liability; (b) use such guidelines to establish the highest and best use of ancillary personnel in the physician's practice so as to maximize legitimate reimbursement opportunities; (c) become more efficient in the way care is delivered and billed; and (d) adopt formal compliance mechanisms to further these goals. By understanding that the impetus to improvement in quality and efficiency also speaks directly to fraud and abuse avoidance, this regulation allows hospitals to pay for resources that will help physicians help themselves.

Providing Staff

With Medicare's better recognition of the use of nonphysician practitioners (NPPs), such as nurse practitioners, physicians' assistants, and clinical nurse specialists, Medicare now will pay for the services of such NPPs (who have their own provider numbers) at 85% of the physician fee schedule. NPPs are covered under Medicare to do anything that a physician would be allowed to do in Medicare, provided that the activity is within the scope of the NPP's license. Although NPPs may not supervise other individuals in providing diagnostic services, they may perform diagnostic services, as well as many other activities, themselves. Therefore, to the extent that oncologists use these individuals in their practices, they can enhance efficiency, potentially increase revenues, and better meet patients' needs. However, many physician practices that would like to hire these individuals do not believe the volume of potential NPP activity generated in their practice would make it financially worthwhile, given the salaries these highly valued practitioners can command.

Today, it is entirely possible for a hospital to function, in effect, as a staffing service by hiring nurse practitioners, physicians' assistants, and clinical nurse specialists for whom the hospital pays full-time wages and benefits. The hospital then leases these individuals, on a fair market value hourly rate and on an agreed-upon schedule, to physician practices for far less than full time on an independent contractor relationship. When those individuals work in the physicians' practices, they may reassign their right to payment (even to multiple practices), so that the physician practice for which they are working can be paid at 85% of the fee schedule for their services, which they provide without physician involvement, and sometimes at 100% of the fee schedule when their services meet the Medicare definition of services incident to the physician. In addition, these individuals can perform many other activities that are not billable, but can enhance the efficiency of an oncology practice.

Medical Staff Initiatives

As a practical matter in most hospitals, 20% of the physicians on staff do 80% of the work in the hospital. It also has become increasingly difficult to generate much physician enthusiasm for participation in the organized medical staff. As all physicians are beleaguered by the increasing demands on their time, the value to them of medical staff activity has diminished. However, for oncologists, the hospital remains significant. If the medical staff were to focus its activities around enhanced efficiencies for physicians, including saving them time by simplifying their environment, quality of care would improve as would the quality of their own professional lives. By adopting clinical practice guidelines that are consistent with what oncologists do in their offices as a basis for standing order sets, proper flow of patients and enhanced use of the hospital's personnel to facilitate the physicians' clinical work, for example, the organized medical staff could perform vital activities to improve the business lives of the physicians who use the hospital's resources.

Clinical Integration

One of the major challenges to oncologists has been inadequate reimbursement to cover the totality of their services. In fact, it is the failure of Medicare to acknowledge and pay for the true cost of delivering proper oncology services that has led to the oncology business model reliant on pharmaceutical revenues. Today, oncologists would be well advised to increase their financial margins by lowering their expenses. Standardization in accordance with clinical practice guidelines—of documentation, equipping examination rooms, and how NPPs and other staff can save physicians for their highest and best uses, for example—would significantly enhance the oncologist's business case. Another technique to

respond to increasing demands for performance measurement and efficiency would be through clinical integration. This is an opportunity made available by the Department of Justice and the Federal Trade Commission, where otherwise competing physicians come together, without merging their practices or taking joint financial risk,[4] and bargain collectively with managed care organizations.

Clinical integration requires the application of several bedrock principles, including (1) the use of standardized processes in the form of clinical practice guidelines, pathways, or protocols; (2) internal profiling and monitoring of physician performance in accordance with guidelines; (3) investment in infrastructure to make these activities happen; (4) corrective action taken with regard to those physicians who are not performing effectively; and (5) sharing of data with payers. When such activities are undertaken for purposes other than merely bargaining over payment, it is permissible to bargain collectively for fees in a way that would otherwise be considered impermissibly collusive.[5]

Clinical integration offers a significant chance for oncologists to do better by doing the right thing to improve patient care.

The description of this type of joint venturing by the Federal Trade Commission and the Department of Justice in its 1996 safety zone statements does explicitly address the role of hospitals in such activities. Hospital facilitation of physician clinical integration, and, further, direct hospital clinical integration with physicians, is also another opportunity that provides a chance for oncologists and hospitals to work together and improve the business case for both.

Conclusion

The hospital is a business "significant other" to most oncologists. Hospitals are increasingly eager to undertake legally permissible activities that will further their own business case while helping physicians whose loyalty is critical to their own success. The four strategies set forth above, albeit described very briefly, are significant possibilities that both partners should consider.

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