orators with primary care medical homes—the building block of ACOs.

- Trend 3. Expect to see renewed interest in compatible oncology practices organizing to scale as clinically integrated oncology networks, with common treatment pathways and health information exchange capabilities bringing data connectivity and advanced informatics and reporting capabilities to such networks.
- Trend 4. Expect to see increased interest and even experimentation in bundled pricing arrangements for oncology care as the final outcome of the payment redesign dialogue. As an example, the CMI Healthcare Innovation Challenge program⁶ could become a proving ground for oncology bundled pricing methodologies.

Accepted for publication on January 25, 2012.

Acknowledgment

The 2011 Cancer Business Center Summit research survey was successfully conducted through the persistence of Amy Wyeth, MS, Cancer Business Center Summit Research Associate.

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Author's Disclosures of Potential Conflicts of Interest

Although all authors completed the disclosure declaration, the following author(s) indicated a financial or other interest that is relevant to the subject matter under consideration in this article. Certain relationships marked with a "U" are those for which no compensation was received; those relationships marked with a "C" were compensated. For a detailed description of the disclosure categories, or for more information about ASCO's conflict of interest policy, please refer to the Author Disclosure Declaration and the Disclosures of Potential Conflicts of Interest section in Information for Contributors.

Employment or Leadership Position: Ronald R. Barkley, Cancer Center Business Summit (U) **Consultant or Advisory Role:** None **Stock Ownership:** None **Honoraria:** None **Research Funding:** None **Expert Testimony:** None **Other Remuneration:** None

Corresponding author: Ronald R. Barkley, Cancer Center Business Development Group, 49 Perry Rd, Bedford, NH 03110; e-mail: rbarkley@ccbdgroup.com.

DOI: 10.1200/JOP.2012.000550

Oncology Professional Services Agreements: A Model for Hospital Affiliation That Preserves Private Practice

By Michael L. Blau, Esq

Foley & Lardner, Boston, MA

Integration Trends

By way of background, there is currently a distinct trend in the health care industry toward increased integration and consolidation among providers. From the hospital perspective, the preferred model for integrating with oncologists is to directly employ them (at least in those states that permit hospitals or their affiliates to employ physicians). According to a recent study, 50% of hospitals are currently employing oncologists, and an additional 25% plan to begin employing oncologists in the near future.¹

Hospitals have good business and legal reasons for preferring an employment model. From a business perspective, employment permits the hospital to better control its destiny in the marketplace. Under an employment arrangement, the hospital can negotiate with payers for both hospital and oncologist payment rates, can bargain for bundled or capitated payments, and can determine how those payments will be internally allocated between the hospital and oncologists (and/or other providers).

Under an employment arrangement, the hospital can also largely dictate the terms of employment, including physician duties; clinical, quality, and efficiency standards; service levels; and compensation methodology. In addition, the hospital can change compensation arrangements over time (as employment contracts expire or are terminated) to adjust to evolving third-party payment methods and economic conditions.

Moreover, as a result of current economic and regulatory pressures on oncologists, senior oncologists today are increasingly willing to consider becoming employed by a hospital. This is because payments for oncology services are not keeping up with the pace of inflation in practice costs; drug profit margins have eroded by approximately two thirds since Medicare implemented the average sale price (ASP) methodology in 2005,² and Medicare payments for oncology (and related ancillary services) were cut significantly in both the 2010 and 2011 Medicare physician fee schedules.³ In addition, physicians graduating from oncology training programs are increasingly

willing to become hospital employees, for reasons of work-life balance and changed expectations about the relative burdens and benefits of independent private practice.

From a legal perspective, the employment model also has distinct advantages. The hospital can collectively bargain with commercial payers for both hospital and employed physician rates, without engaging in illegal price fixing in violation of federal and state antitrust laws.⁴ This is because employment involves sufficient financial and clinical integration to permit the employer and employee to jointly price and collectively bargain with payers and vendors.⁵ The hospital can also require employed oncologists to make in-network referrals to the hospital, where appropriate, without violating federal or state antikickback statutes that prohibit paying for patient referrals.^{6,7} Furthermore, ancillary revenue from pharmacy, laboratory, imaging, and radiation therapy services can be shared between the hospital and employed oncologists without violating the Stark Law prohibition against self-referrals for “designated health services” (as long as the ancillary revenue is not allocated to the referring physician on the basis of volume or value of referrals to the hospital).⁸ In addition, nonprofit hospitals can employ oncologists for competitive purposes, and not just for community benefit purposes.⁹ These particular legal advantages may not be available to a hospital that enters into an independent contractor arrangement with an oncologist or oncology group, such as through the professional service agreement (PSA) arrangements described in this article.

However, for many independent private practice oncology groups, employment is simply not an acceptable option. The owners of strongly independent oncology groups generally have operated successful small businesses for many years. They have developed valuable infusion, radiation, and cancer centers. They have assembled talented and loyal workforces, and they have earned a good living. They treasure their autonomy and independence and are not interested in selling out to, or being taken over by, a hospital. These professionals, rightly or wrongly, may be concerned that if they become hospital employees they would be subject to more bureaucratic hospital processes, as well as slow and not particularly physician-friendly institutions; they may also believe that oncology-focused interests would be lost, diluted or unduly compromised along the way.

On the other hand, the good news for independent oncology groups is that there is also a pronounced trend toward hospital-oncologist collaborative arrangements that do not involve employment. In a recent study,¹⁰ hospitals were found to have implemented (or to be in the process of implementing) a greater percentage of alignment ventures with independent oncology groups of virtually all types, including comanagement, equipment lease, and joint venture arrangements. More recent experience suggests that the PSA model is a preferred hospital affiliation model for an increasing number of oncology groups that are interested in preserving an independent (but hospital-aligned) status. According to a recent report,^{1,11} 42% of hospitals surveyed are currently using a PSA model, and an additional 14% are considering implementing one within the next 12 months.

The PSA Model

The PSA model provides a means by which a community oncology group can maintain a significant modicum of independent private practice and stem financial hemorrhaging of the group, while aligning in a meaningful way with a preferred strategic hospital partner. The PSA model involves converting the oncology group’s existing practice site to a hospital-licensed facility that continues to be principally staffed by the oncology group. Alternatively, the PSA may involve (1) developing a new cancer center (either on or off the hospital campus) that is principally staffed by the oncology group, or (2) staffing of an existing on-campus cancer facility.

If the facility is not located on the campus of the hospital, then the oncology group can provide or lease to the hospital physicians, nurse practitioners, and physicians assistants to staff the facility; however, the oncology group cannot provide or lease to the hospital other clinicians who provide direct patient care (eg, treatment or support nurses and technicians). Otherwise, the off-campus facility will not qualify to be paid at hospital outpatient rates by the Medicare program.¹² If the facility is located on the hospital’s campus, then the oncology group can provide all staffing for the center, including physicians, other clinicians, and nonclinical staff.¹²

In any of these scenarios, some or all of the services performed at the site are hospital-licensed services that are billed under the hospital’s provider numbers and are paid by payers at hospital outpatient rates.¹³ Hospital outpatient rates, particularly for medical oncology services, may be 30% to 150% higher than payments by the same payers for such services at physician fee schedule rates. Oncology services billed by the hospital at outpatient rates may include not only the facility component of medical and radiation oncology services, but also the professional component of those services (including examination, management, consultation, chemotherapy administration and interpretation services). It may also include associated pharmacy, laboratory, and imaging services. If the hospital would qualify for 340B pricing on drugs, there is a further economic advantage to the hospital in billing for oncology pharmaceuticals at hospital outpatient rates. (Note though, that the hospital does not become eligible for 340B pricing of drugs until it files its first cost report after the PSA becomes effective. This may be up to a year after the hospital begins operating the oncology group’s practice sites as provider-based facilities.)¹⁴ The availability of hospital outpatient rates for some or all of these services provides an economic foundation by which a PSA arrangement can be financially beneficial for both the oncology group and the hospital.

In exchange for the oncology group converting its practice sites to hospital-licensed status, or staffing the hospital’s existing or new cancer facility, the oncology group remains intact and, under the PSA (and ancillary agreements), can receive the following economic benefits:

- Avoidance of reduction in aggregate physician compensation for a defined period based on a fair-market work relative value unit (wRVU) rate for oncologist services.
- Fair market employee lease and management fees for the administrative services of nonphysician or nonclinical staff provided by the group.
- Fair market medical director fees (on an hourly basis) or comanagement fees (which may be on an efforts and task completion basis) for comanaging the hospital's oncology service line and meeting mutually agreed quality, efficiency, and operational improvement targets.

Fair market value of medical director and comanagement fees should be determined by independent appraisal. Medical director fees are typically determined on an hourly basis, with the hourly rate determined by reference to benchmarks for medico-administrative (but not clinical) services. In contrast, comanagement fees may be either hourly or task based (or a combination of the two), depending on the valuation method and comparability benchmarks used by the valuation firm. These fees, combined, may in certain instances increase current physician compensation and benefits by 5% to 10% (or more) for the duration of the PSA.

Potential Pitfalls

Although PSAs have the potential for tangible benefits to both hospitals and oncology providers, they are not without drawbacks. The following are some of the principal business and legal constraints related to PSA arrangements.

Physician Compensation

Generally, under a PSA, the oncology group is paid on an aggregate wRVU basis. For health regulatory compliance reasons, the wRVU rate (and any other financial arrangement with the oncology group) must be set at fair market value through an independent appraisal process. Hospital payments to physicians are governed under federal law by the Stark Law¹⁵ and the Anti-Kickback Statutes.¹⁶ The applicable Stark Law direct compensation exceptions for PSA arrangements are those related to personal services and fair market value.^{17,18} These include a requirement that payments be fair market value, set in advance, and not vary with the volume or value of referrals or other business generated between the parties. Fair market per unit of service payments, such as wRVU-based payments, are also defined as payments that are “set in advance” and do not “vary with the volume or value of referrals” or “other business generated” for Stark Law purposes.¹⁹ There is also an Anti-Kickback safe harbor for personal services and management contracts that such a PSA approximates but does not fully satisfy.²⁰ The PSA arguably does not meet the safe harbor standard that aggregate compensation be set in advance. Under a wRVU payment arrangement, the per-unit payment amount is set in advance, but the aggregate compensation varies with the number of work units and so is arguably not set in advance. This risk can be mitigated, but not eliminated, by obtaining an independent fair market value appraisal of the compensation arrange-

ment to evidence the parties' intention to pay fair market compensation for actual services rendered, and to negate any adverse inference that oncologists are being overpaid to improperly induce them to refer to the hospital. This will also help a nonprofit hospital to demonstrate that it is only paying reasonable compensation under the PSA and is not misusing charitable funds—engaging in a prohibited inurement, private benefit, or excess benefit transaction—in violation of tax exemption or intermediate sanction standards.^{21,22} Typically, fair market value will approximate the physician compensation and benefit pool generated by the number of wRVUs performed by the group during the immediately preceding 12-month period. The wRVU payments are made to the group as a whole, and the group, in turn, remains free to set individual compensation for its members.

However, there are limits on the duration of fair market value opinions. If the PSA is a long-term agreement (eg, 5 or more years), then the wRVU rate will probably need to be reassessed periodically during the term of the PSA and will change with the market on revaluation.

Medicare Provider–Based Status

To qualify to be paid by Medicare at hospital outpatient rates, the group's practice sites must meet the Medicare provider–based status rules.¹³ Under those rules, the sites must meet state law requirements for hospital licensure, as well as applicable Joint Commission accreditation standards.²³ These standards may include physical space requirements, such as corridor widths for ambulance stretchers, number of wash basins per square foot, size and/or separation of areas for infusion chairs, building code compliance, and so on. Accordingly, there may be leasehold improvements to the practice sites that are necessary to bring them up to licensure standards, unless these physical space requirements are waived by the applicable state Department of Public Health. The cost of renovations to meet these physical space requirements will need to be considered in assessing the feasibility of a PSA arrangement.

The Medicare provider–based status rules also require that the hospital outpatient oncology services at the site be integrated with and under the ultimate clinical, administrative, and financial control of the hospital.^{24–27} Consistent with this requirement, under the PSA, the oncology service line at the sites can generally be overseen by an operating committee composed of designees of the oncology group and designees of hospital administration, so that there is shared input into the operations of the hospital's oncology service line. While retaining its ultimate decision-making authority, the hospital could agree under the PSA that reasonable recommendations made by the operating committee would be approved and implemented by the hospital.

The Medicare provider–based status rules would also preclude the oncology group from leasing nonphysician clinicians (other than nurse practitioners or physician's assistants) to the hospital at any off-campus location (ie, any site that is located more than 250 yards from the main hospital), and would require that any off-campus site be located within 35 miles of the main hospital.²⁵ Thus, treatment nurses; support nurses; pharmacy, laboratory, and radiation technicians; physicists; and do-

simetrists would need to be directly employed by the hospital at any off-campus site. This, in turn, may change existing working relationships with these employees, subject them to different salary and benefit levels, and in some circumstance potentially cause them to be covered by the hospital's collective bargaining contracts.

Repercussions

It can be expected that commercial payers will react to converting oncology group sites to hospital outpatient rates by trying to renegotiate their payer contracts with the hospital when the opportunity arises (ie, when the existing agreement expires or is up for renewal). The outcome of such renegotiations will depend on the relative bargaining strength of the parties at that juncture.

It should also be noted that after converting an oncology group site to hospital outpatient services, patients may be subject to higher copay amounts (based on hospital facility fees and higher hospital rates). This may be an issue for some patients, particularly for low-income patients who are involved in a continuing course of treatment at the time of the conversion.

Duration

Although the oncology group may want to lock in a good PSA deal for as long as possible, there are limits to the duration of PSA arrangements and to the financial terms of those transactions. One limiting factor is the duration of the independent fair market appraisal. Valuation opinions for PSAs may be good for as little as 1 to 3 years, depending on the valuation firm and nature (and perceived economic volatility) of the arrangement being valued.

Another limiting factor for tax-exempt organizations may be Internal Revenue Service statute Rev. Proc. 97-13, which limits the duration of use of tax-exempt bond-financed property under agreements, such as certain PSAs, to as little as 2 to 3 years, depending on the structure of the financial arrangement.²⁸ For these reasons, the PSA agreement may have a relatively long-term framework (eg, 5-10 years), but may need to be revalued, or the hospital may need to have a without-cause termination right after only a few years.

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Unwind Rights

In part because of the above duration issues, oncologists entering into a PSA are well advised to request unwind rights. These would permit the oncology group to fully reconstitute itself and remain whole and intact at the end of the PSA arrangement. Accordingly, at the end of the PSA, the oncology group may want the right to regain any space or assets that have been leased or sold to the hospital; redeploy its staff; and have access to all books, records and data necessary for the group's ongoing operations. The oncology group may also want to avoid any post-termination noncompetes or restrictive covenants. Otherwise, at the end of the PSA arrangement, the participating oncologists may, as a practical matter, have no option left but to become hospital employees or relocate.

There are other business and legal considerations to take into account in assessing the feasibility of PSA arrangements in particular situations. Appropriate financial, legal, and valuation consultations should be obtained, as necessary, in the feasibility assessment process.

Conclusion

The imperative of national health reform is to slow the rate of growth of health care spending to a sustainable level. PSA arrangements, in the short term, may cost payers and employers more, but they may provide a needed bridge to a new generation of aligned arrangements in which providers can share financial risk for quality and efficiency improvements and take responsibility for providing increasingly patient-centered, accountable care.

Accepted for publication on January 24, 2012.

Author's Disclosures of Potential Conflicts of Interest

The author(s) indicated no potential conflicts of interest.

Corresponding author: Michael L. Blau, Esq, Foley & Lardner LLP, 111 Huntington Avenue, Boston, MA 02199; e-mail: MBlau@foley.com.

DOI: 10.1200/JOP.2011.000506

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