Anatomy of a Cancer Center Transaction: Part II

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This is the second of a two-part article comparing two models for structuring a community-based cancer center as a collaboration between oncologists and a hospital. The fact pattern on which the two models are based, along with a description of the first model—an on-campus private practice model—was published in the May 2010 issue of *Journal of Oncology Practice*.¹ In this issue, an alternative hospital-licensed service model and associated oncology service-line comanagement agreement are examined. This article is adapted from a session entitled "Anatomy of a Cancer Center Transaction" presented at the 2009 Cancer Center Business Summit.²

Model 2: Hospital-Licensed Service

The second model shifts provider status and business risk to the hospital. Infusion and radiation oncology services would be provided as hospital outpatient services. Under this model, the Highland Hospital, a 350-bed community hospital, would set aside on-campus space for the cancer center. The parties (ie, Medical Oncology Associates [MOA], a five-physician medical oncology group, and Radiation Oncology Associates [ROA], a three-physician radiation oncology group) would form a joint venture development company as a limited liability company (DevelopCo) to develop (ie, provide leasehold improvements), equip, and staff (with nonclinical personnel) the cancer center. The infusion, radiation therapy, and ancillary service areas would be licensed as hospital outpatient space, and the hospital would bill, under its provider numbers, for the technical/facility component of those services as hospital outpatient services. Payers would reimburse the hospital for those technical/facility component services at hospital outpatient rates. For reasons discussed below, this part of the transaction is referred to as a "modified under arrangements venture."

There are three billing options for the professional component of the oncology services in this model. MOA could lease space adjacent to the hospital-licensed infusion area and operate a private practice there, billing for evaluation and management services under its own provider numbers. In this case, MOA would be paid at physician-level reimbursement rates for those professional component services, with no site-of-service differential. In the second option, both oncology groups could provide their professional component services in hospital-licensed space (rather than in leased private-practice space) and bill separately for these services on a private-practice basis. In this case, MOA would be reimbursed with a site-of-service differential (ie, at a lower rate, because MOA is not incurring the overhead costs associated with its professional component services). There is generally no site-of-service differential for the professional component of radiation therapy services performed in a hospital outpatient setting. A third option would involve the hospital purchasing professional component services from the oncology groups (ie, on a work relative value unit basis) and billing for those services as hospital services.

This model also involves MOA and ROA entering into a service-line comanagement agreement with the hospital. Under a service-line comanagement arrangement, the oncology groups would be engaged by the hospital to serve as business partners in comanaging the hospital's oncology service line, and the oncologists would be rewarded for improving the quality, efficiency, and operations of that service line. Under the serviceline comanagement agreement, the oncologists could be assigned responsibility for all or part of the service line: infusion, radiation therapy (RT), outpatient services, inpatient services, and ancillary services (eg, oncology laboratory, pharmaceutical, and imaging services). The oncologists would become involved in all business decisions related to the service line, including strategic and business plans, budget recommendations, nonphysician staffing decisions (eg, job descriptions, scheduling, performance evaluations, and hiring, firing, and disciplining hospital personnel who staff the service line), service-line pricing, purchasing and materials management, development and implementation of quality and efficiency standards and clinical protocols, information systems, and re-engineering of workflow processes. The oncology groups would also provide an MOA medical director and ROA medical director to assist in the clinical oversight and medical direction of the service line.

Under the service-line comanagement agreement, the parties would form a joint operating committee consisting of representatives from both the hospital and oncology groups. The operating committee would make decisions by concurrent approval (ie, by vote of a majority of the oncologists and hospital representatives on the committee). The committee would meet regularly to comanage the service line and address service-line issues as they arise. It is assumed that recommendations of the operating committee would be adopted and implemented by the hospital. In this manner, the parties would comanage the oncology service line and be mutually accountable for its performance-but the hospital would, for legal reasons (ie, hospital licensure, accreditation, and Medicare certification purposes), have to maintain ultimate responsibility for serviceline decisions. Accordingly, all recommendations of the operating committee would be reported through the normal reporting chain of command of the hospital for final approval.

There would be two forms of compensation for the oncology groups under the service-line comanagement agreement: a base

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administrative fee and a series of bonuses contingent on meeting specified performance improvement targets. The base fee would pay for oncologist efforts and activities in comanaging the service line. It would reflect the projected number of hours of physician time needed to accomplish tasks assigned under the agreement at a reasonable hourly rate for oncologist administrative time (eg, \$200 to \$250 per hour per physician). In contrast, the performance bonuses would be distributed based on meeting specific quality and efficiency improvement targets agreed upon by all parties in areas such as completion of treatment plans before start of infusion (with staging, intent, and regimen documented); increased patient accrual for hospital-based clinical trials; on-time starts; reduced turnaround time between infusions and RT treatments; patient, employee, and physician satisfaction; employee turnover; use of less expensive but clinically equivalent drugs, devices, and supplies; reduction of adverse events; and compliance with programs such as the Physician Quality Reporting Initiative, the Quality Oncology Practice Initiative, and other clinical standards. Improvements would be measured over baseline performance. A fixed dollar amount could be earned by oncologists for achieving each specific performance goal (eg, \$25,000 for a 5% increase in timely completion of treatment plans over current baseline performance). Both the base fee and

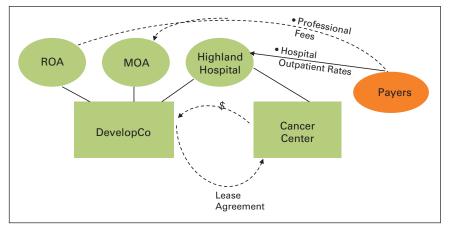


Figure 1. Hospital service and comanagement equity joint venture component. ROA, Radiation Oncology Associates; MOA, Medical Oncology Associates.

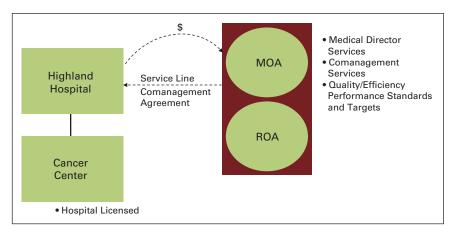


Figure 2. Hospital service and service-line comanagement component. MOA, Medical Oncology Associates; ROA, Radiation Oncology Associates.

performance bonuses would be established through independent valuation to ensure that no more than fair market value is paid for the comanagement services rendered and results achieved.

Under the service-line comanagement agreement, the oncologists could split as much as 3% to 6% of the service-line revenue in aggregate (for the combination of base and performance fees), but the fees would be expressed and paid on a fixed-fee (not a percentage of revenue) fair market value basis. For example, a hospital like Highland Hospital, with a \$40 million outpatient oncology service line, may be able to justify paying the oncologists up to about \$1.2 to \$2.4 million annually in comanagement fees if all performance targets are met. It is generally advisable to reset performance standards and targets and reappraise contracts every 2 years to ensure that there will be continuous quality and efficiency improvement and that payments remain within a fair market value range. Figure 1 illustrates the joint venture component of the hospitallicensed service model, and Figure 2 shows the comanagement component.

From a federal health regulatory perspective, counsel explains that all of the transactions in model 2 would need to be

commercially reasonable, fair market value transactions. Because of changes in the Stark Law3 that went into effect on October 1, 2009, amending previous exceptions,⁴ referring physicians like the MOA physicians would be prohibited from having an investment interest in a joint venture like DevelopCo, if DevelopCo is viewed as performing the technical/ facility component of hospital infusion or RT services (even though the hospital, and not DevelopCo, would bill for those services). The Centers for Medicare & Medicaid Services (CMS) has indicated that it will prohibit transactions "under arrangements" in which the referring physician has an investment interest in an entity that provides turnkey items and services to a hospital (ie, all of the space, equipment, clinical staff, nonclinical staff, management services, and supplies necessary for the hospital to provide the service).⁵ Such a turnkey underarrangement venture would be viewed as performing a hospital service. To complicate matters, CMS has expressly declined to provide guidance as to what lesser combinations or bundles of such items and services would or would not constitute performance of hospital services. Currently, it seems it would be legally defensible for physicians to have an investment interest in an entity like DevelopCo that does not provide some of the critical elements necessary to perform technical/facility components of oncology services. In this case, the hospital—not DevelopCo—would provide the space and all clinical staff (ie, technicians, technologists, nurses, laboratory personnel, and pharmacists). Because DevelopCo would not provide these key elements, it would have a legally defensible argument that such a modified under-arrangement venture would not have the capacity for service performance. However, parties should be prepared to modify their arrangements if CMS issues guidance or new regulations indicating a different position on such ventures.

Counsel also points out that because of the recent Stark Law³ changes, the hospital could not pay DevelopCo on a percentage or per-click basis for leasehold improvements and equipment it provides to the hospital in connection with oncology services.⁶ Additionally, the investment interest in DevelopCo would not meet the safe-harbor standards7 outlined in the Anti-Kickback Statute,8 because more than 40% of that interest would be held by persons deemed to be in a position to refer to the hospital for oncology services. (Certain legitimate business and financial arrangements are considered immune from prosecution under this statute. One of the safe harbors involves investment interests in small entities [ie, corporations that are not publically traded]. To qualify, among other criteria, no more than 40% of the investment interest can be held by persons in a position to refer Medicare or Medicaid business to the entity, and no more than 40% of the gross income of the entity can be generated by investors in a position to refer Medicare or Medicaid business to the entity.^{7,8}) In fact, CMS would view 100% of the investment interest in DevelopCo as tainted. This would not mean that the investment interest in DevelopCo is illegal; however, the parties would need to be able to prove that the investment interest is for legitimate business purposes (ie, to develop a new cancer center as a needed community resource) and that no purpose of the investment interest in DevelopCo is intended to induce referrals among the parties. The parties should be able to meet this burden of proof if DevelopCo were otherwise structured as a legitimate joint venture in accordance with applicable standards recognized by CMS and the Office of Inspector General.9

Counsel also explains that the service-line comanagement agreement could involve a number of federal laws, including the Civil Monetary Penalty Law,¹⁰ False Claims Act,¹¹ and prohibition on inurement and private benefit by tax-exempt organizations,¹² in addition to the Stark Law³ and Anti-Kickback Statute.⁸ Project counsel indicates that synthesizing these laws would yield the following principles for a legally compliant service-line comanagement arrangement:

- No stinting; oncologists cannot be rewarded for limiting or reducing items or services to Medicare patients under their care (eg, performance bonuses cannot be tied to generalized cost savings or beating cost budget).
- No steering; oncologists cannot hand off patients with more complex conditions to others for purposes of meeting performance standards (eg, to improve morbidity or survivorship statistics).

- No cherry picking; oncologists cannot be rewarded for accepting easier or better paying cases to meet performance standards.
- No gaming; hospital cannot use accounting tricks or fudge results to justify making payments to oncologists, if in fact oncologists have not met their contractual obligations.
- No payment for changes in volume or number of referrals; hospital cannot pay oncologists for increases in referral number, use, volume, revenue, or profit.
- No payment for quicker-sicker discharges; hospital cannot pay oncologists for reducing average length of stay for on-cology inpatients.
- Limited gain sharing permitted; hospital can share cost savings with oncologists generated by substitution or standardization of lower-cost items of equivalent quality (eg, substitute generic drugs for brand name pharmaceuticals, standardize use of lower-cost infusion supply packs).
- Must be fair market value, and independent appraisal strongly advised; fair market value is key to regulatory compliance for service-line comanagement agreements and necessary for meeting applicable Stark Law exceptions (ie, fair market value and indirect compensation exceptions).

Service-line comanagement agreements can be structured to be legally defensible, but they carry some irreducible legal risk, because they may be viewed as not meeting any safe-harbor standards7 of the Anti-Kickback Statute.8 The safe harbor that comanagement agreements most closely approximate is the personal services and management contract safe harbor. But that safe harbor requires "aggregate compensation" under the contract to be "set in advance." Under a comanagement agreement, minimum (base fee) and maximum (base plus all bonus fees) compensation are set in advance, but aggregate actual compensation to be paid to the oncologists under the contract cannot be known at the beginning of the contract, because performance results and the amount of performance bonuses that will be earned are not be known until year end. For this reason, aggregate compensation may not be viewed as having been set in advance in a comanagement agreement. Nonetheless, a comanagement agreement should be legally defensible as long as the parties obtain an independent fair market value assessment of payments under the contract to help negate any adverse inference that the payments are in part to induce referrals among the parties rather than solely to improve the quality and efficiency of the oncology service line.

It may also be advisable for the parties to engage an independent clinical monitor to validate that the performance standards included in the comanagement agreement are consistent with nationally recognized clinical quality standards. An independent clinical monitor could also objectively monitor the performance of the oncologists under the agreement and verify that they have met performance targets and earned their performance bonuses. Furthermore, an independent monitor could confirm that the comanagement agreement has not caused the oncologists inappropriately to change case or payer mix, increase volume, reduce care, or adversely affect quality. This

Financial Change	MOA	ROA	Highland Hospital
Old revenue	-MO/infusion professional fees	-MO professional fees	-MO/RO facility fees
New revenue	- DevelopCo joint venture distributions	- DevelopCo joint venture distributions	 Ancillary services (laboratory, imaging, pharmacy)
	-Comanagement fees	-Comanagement fees	
	-Elimination of drug/treatment nurse costs		
New costs	$- \ensuremath{DevelopCo}$ joint venture capital contribution	-DevelopCo joint venture capital contribution	-DevelopCo joint venture capital contribution
	-Loss of laboratory revenue		-Payment for DevelopCo items/services
			-Comanagement payments

Abbreviations: MOA, Medical Oncology Associates; ROA, Radiation Oncology Associates; MO, medical oncology; RO, radiation oncology.

should additionally minimize inherent legal risks associated with the agreement to an immaterial level.

Consultant Crunches the Numbers

Table 1 presents the model 2 scorecard showing potential new revenue opportunities and costs for each of the three parties in the scenario. The parties agree that there are certainly advantages and disadvantages to each model proposed and decide it would be useful to financially model both options to better understand the differing economic consequences for each party. This information could help the parties choose one model over the other. They agree to engage an oncology business consultant to run the numbers and report back to the group in approximately 30 days. Counsel suggests that the parties enter into a three-way confidentiality agreement so they can share data with each other and the consultant on a confidential basis. The parties also agree to share equally the predevelopment costs of the project, including project counsel and consultant fees.

Economic Comparison of the Two Models

To gauge the relative economic impact of the two models on both parties, the consultant assesses all relevant items of revenue and expense for each party. From this information, the consultant produces a comparison of the economic positions of stakeholders before and after the two transactions under consideration (Table 2). In both scenarios, the consultant assumes a 5% increase in new patient volume attributable to consolidated program synergies.

Key working assumptions for model 1 include:

- Highland Hospital acquires laboratory and miscellaneous equipment from MOA at a one-time purchase price of \$200,000.
- MOA is losing approximately \$300,000 annually from its laboratory operations.
- MOA and ROA are both paid annual medical director fees of \$75,000.
- ROA improves the revenue cycle for its professional fees from better contract rates and collections available through clinical integration with Highland Hospital.
- Highland Hospital anticipates a 5% increase in imaging use and 3% better contract rates for laboratory compared with existing MOA rates.

Table 2. Economic Comparison

Scenario	MOA (\$; No. of oncologists = 5)	ROA (\$; No. of oncologists = 5)	Highland Hospital (\$)
Current			
Net income/margin	2,725,000	1,485,000	7,932,500
Model 1			
Net income/margin	2,970,000	1,634,250	9,830,000
Enhanced position	245,000	149,250	1,897,500
Model 2			
Net income/margin	3,050,000	2,059,150	10,829,125
Enhanced position	325,000	574,150	2,896,625

NOTE. Enhanced position of Highland Hospital is expressed in terms of contribution margin.

Abbreviations: MOA, Medical Oncology Associates; ROA, Radiation Oncology Associates.

• MOA increases its space lease rental rate from \$28 to \$34 per square foot but gives up 2,000 square feet in laboratory and common areas.

Key working assumptions for model 2 include:

- The parties each contribute \$175,000 to DevelopCo, which leases equipment, facility leasehold improvements, and nonclinical staff to the hospital at cost plus a fair return on investment (eg, 15% to 25%).
- The business risk of chemotherapy drug purchasing and drug billing and collections is assumed by Highland Hospital.
- MOA is paid an annual fair market chemotherapy supervision fee.
- MOA and ROA receive service-line comanagement fees (base and bonus fees) of 3% to 6% of service-line revenues, translating to \$800,000 to \$1,500,000 for MOA and \$480,000 to \$845,000 for ROA.

Model 2 Preferred

The parties agree that model 2 better aligns their interests in improving the quality, efficiency, and operations of the cancer center. It also holds the potential for more favorable economics for each of the parties. Therefore, model 2 is tentatively selected as the preferred approach, subject to additional due diligence. The parties instruct project counsel to prepare a letter of intent incorporating their agreement to continue to assess model 2. They also agree to a standstill period for 90 to 120 days, during which they plan to complete their evaluation of the potential transaction while agreeing not to negotiate a cancer center deal with others. They ask project counsel to work with them during the standstill period to develop definitive documents for the potential transaction. Project counsel points out that there are a number of potential deal breakers that the parties will need to address and resolve for completion of definitive agreements, including:

- Governance/decision making.
- Deadlock/dispute resolution.
- Capital contribution and cost.
- Exclusivities and rights of first refusal.
- Covenants not to compete/restrictive covenants.
- Duration of arrangement.
- Termination/withdrawal rights.
- Buyout provisions.
- Operational integration (eg, staff, information technology platform/interfaces).
- Implications of existing commitments (eg, existing MOA space lease).

The parties schedule a series of regular meetings to work through these issues. They identify people within each organization who will work in parallel in subgroups to deal with operational, technologic, and financial issues. All agree to make their best efforts to try to resolve all issues, complete definitive agreements, and make a final go/no-go decision before the end of the standstill period.

Conclusion

The models compared in this two-part article are just two of many arrangements through which oncologists and hospitals can collaborate to better position themselves for future success while preserving an element of independent private practice for the physicians. As with the two models presented, all hospital-

References

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3. 42 USC §1395nn (2009)

4. 42 CFR §411.357(a), (b), and (p)

5. US Department of Health and Human Services: Centers for Medicare & Medicaid Services: Proposed rules. https://www.cms.gov/PQRI/Downloads/CMS_1413_P.pdf

physician collaborative arrangements have different advantages, disadvantages, and tradesoffs and carry different operational, financial, and legal risks. The tradeoffs and risks should be thoroughly evaluated so that parties can meaningfully assess their options and select the model that best serves their common business vision and objectives. To read the first installment¹ of the "Anatomy of a Cancer Transaction" series published in the May issue of *JOP*, visit http://jop.ascopubs.org.

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- 8. 42 USC §1320a-7b(b)

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10. 42 USC §1320a-7a

11. 31 USC §3729-3733

12. IRC 501 (c)(3)