# ONCOLOGIST-HOSPITAL ALIGNMENT

in the Era of Health Reform

#### **ABSTRACT**

The trend in business alignment between oncology private practice and hospital oncology services in the community setting has been a significant one during the past seven to eight years and has experienced additional impetus as a result of federal health reform mandates of the Accountable Care Act. This article explores the predominant models for business alignment among oncologists and hospitals and the impacts that health reform may have on such models.



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The trend in business alignment between oncology private practice and hospital oncology services in the community setting has been a significant one during the past seven to eight years. The oncologist–hospital alignment dynamic, initially fostered by declining reimbursements coupled with concurrent increased costs of operation in the physician "office-based" setting, has experienced additional impetus as a result of federal health reform mandates of the Accountable Care Act [ACA, often referred to as "Obama Care." The ACA actually consists of two separate items of legislation, the Patient Protection and Affordable Care Act of 2010 (HR 3590) and the Health Care and Education Reconciliation Act of 2010 (HR 4872)].

Concerns about an uncertain future for both oncologists and hospitals under health reform mandates have sparked further interest in alignments designed to address the "triple aim" of the ACA, those aims being to: (1) improve the patients experience of care; (2) improve the health of populations; and (3) reduce per capita health-care costs.

In this article, we will first describe the predominant models of oncologist—hospital alignment and subsequently the impacts of health reform on the future of oncologist—hospital alignment initiatives.

### THE "FAMILY TREE" OF ALIGNMENT MODELS

Models of oncologist—hospital alignment relationships range from the informal and less aligned relationships to the more involved and advanced forms of alignment. Included in the former (less aligned) would be such traditional relationships as medical staff privileges, physician recruitment assistance, medical directorships, multidisciplinary care collaborations, facility/equipment joint ventures, and block lease arrangements.

While these less aligned forms do achieve a certain degree of oncologist—hospital collaboration, they generally fall short of truly aligning incentives between physician and hospital interests that are required in today's rapidly consolidating environment. Thus the evolution to the more involved and advanced forms of alignment models, which translate generally to the proposition that an oncology private practice converts its office-based services to hospital provider-based services and subsequently provides the professional services and program management of the hospital's expanded oncology service line for a fee.

Titles attached to such relationships include professional services agreement (PSA), management services agreement (MSA), and co-management agreement (CMA). Direct employment of oncologist by hospital is considered by some to be the highest form of alignment/commitment, at least from the hospital perspective (whereas physicians often perceive hospital direct employment as a form of "surrender"

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rather than a form of alignment). And a new kid on the block, the Oncology Accountable Care Organization (ACO) involves rationalization of services between physician office-based and hospital provider-based services with a payment redesign objective that involves participation of a commercial health plan(s).

The "family tree" of alignment models is depicted in Figure 1.

#### DESCRIPTIONS OF THE ALIGNMENT MODELS

We will provide only a cursory description of the traditional "legacy" forms of alignment relationship and then move on to a more detailed narrative on the more advanced models (PSA, MSA, CMA, Oncology ACO).

#### "Legacy" Alignment Relationships

The granting of hospital medical staff privileges, hospital providing assistance to medical practice for physician recruitment, and paid medical directorships are examples of traditional alignment relationships between physicians and hospitals. These forms do engender a certain amount of cooperation between oncologist and hospital, but are not sufficiently involved that they can much impact the economics or care process collaboration among the parties.

Compensating a physician for his or her advisory services as a part-time medical director of a hospital department or program does result in a professional medical contribution to a program, but does not address the potential competing economic interests between the physician medical director and the hospital. If the oncology program medical director is in private practice, say with an office-based chemotherapy/ infusion service that is competitive with the hospital outpatient infusion service, the economic incentives are simply not aligned.

#### **Multidisciplinary Care**

Multidisciplinary care clinics/collaborations stand for the proposition that cancer diagnosis and treatment requires an organized team approach – all disciplines represented in the full continuum of care for a particular cancer site should interact up front and during the care process such that all aspects of the patient's diagnose and treatment are considered. Sort of like a prospective tumor board on steroids. For example, a multidisciplinary care team for a newly diagnosed breast cancer patient might include medical, radiation, and surgical oncologists and support personnel, such as genetic counselor and social worker. The "multi-D" forum can be in one physical location and/or "virtual," with aid of telemedicine technology.

Formal, organized multidisciplinary care services tend to be sponsored by hospitals. In fact, one of the standards of accreditation for hospitals by the Commission on Cancer "While these less aligned forms do achieve a certain degree of oncologist—hospital collaboration, they generally fall short of truly aligning incentives between physician and hospital interests that are required in today's rapidly consolidating environment."

(CoC; American College of Surgeons, Commission on Cancer Accreditation. See www.facs.org/cancer/coc) is that the hospital cancer program offers a "multidisciplinary care approach."

While a patient-centered multi-D team approach sounds appealing, it requires a significant commitment of time on the part of participating physicians. Such physician time commitment is typically uncompensated and thus can become of limited interest to private practice physicians who can more productively utilize that time efficiently servicing patients.

In recognition of the physician time commitment requirements to effectively conduct a hospital-sponsored multidisciplinary care program, hospitals have begun to explore the application of the clinical co-management alignment model (discussed below) as an approach to compensating oncologist for participation in a hospital-sponsored multidisciplinary care program.

#### Facility/Equipment Joint Ventures

A popular physician—hospital alignment model involves co-ownership of medical facilities and/or medical equipment by physicians and hospital. In this model, the physicians and hospital, as joint venturers, lease out the facility and/or equipment at fair market value lease rates. Under Federal Anti-Kickback law, space or equipment lease rates associated with such ventures must be based on fair market value, fixed in advance, and not vary on the volume or value of any Medicare/Medicaid covered referrals that could be made by physician owners to the facility or equipment [42 C.F.R. Sec 1001.952 (b)-(d)]. "Per use" or "per click" fee arrangements would be impermissible. Such regulatory limitations on determining lease rates result in limited upside economic potential for straight facility/equipment leasing joint ventures, thus they are generally unappealing alignment vehicles

An example of a facility/equipment leasing joint ventures is provided as shown in Figure 2. In this particular example, a medical oncology group practice, a radiation oncology group practice, and a hospital form a development company (joint venture) which acquires and subsequently leases to the hospital's cancer center certain radiation and chemotherapy equipment.

Another form of oncologist–hospital joint venture is often referred to as a "clinical joint venture" or "operating joint venture," wherein the physician and hospital owners actually share in the net income generated from a jointly owned clinical business operation.

However, where such clinical/operating joint venture involves an ownership or other financial interest by any physician in a position to refer a designated health service (DHS) to the joint venture, such entity is prohibited from submitting claims to Medicare/Medicaid for the

services performed, essentially rendering such clinical joint venture economically nonviable (see generally Omnibus Budget Reconciliation Act of 1993, Pub L No.103-66 and subsequent amendments, Stark II and Stark III). Medical oncologists are considered referring physicians under Stark law and chemotherapy, radiation, imaging, and lab would be examples of prohibited DHS. Therefore, medical oncologists sharing in net income/profits generated by the operating joint venture would be an impermissible arrangement.

Interestingly, however, radiation oncologists are not considered to be referring physicians for purposes of Stark law and therefore it is not uncommon to find radiation therapy treatment services co-owned in joint venture among radiation oncologists and a hospital.

#### **Block Lease Arrangements**

A block lease arrangement is one in which a health-care provider leases a set block of time of health-care facilities and/or medical equipment during which such provider has exclusive use of such facilities and/or equipment to deliver services to its patients. If the lessee of the block time is by a physician/medical group, the physician/medical group can rely on the in-office ancillary exception to Stark law for the block time. In general, the in-office ancillary exception allows a physician or physician group practice to order and provide DHS in the physician office. The block time of facility and equipment is characterized as an extension of the physicians' office.

For example, a hospital owner of specialized radiation equipment (intensity-modulated radiation therapy – IMRT) finds that the medical equipment is being underutilized. Radiation treatments are amenable to block scheduling of patient flow, so the hospital offers to lease the IMRT facility and equipment to an oncology group for the group's exclusive use in the afternoons on Mondays, Wednesdays, and Fridays. The oncology group assumes possession of the facility and equipment during its reserved block lease time, performs radiation services for it patients and bills on its behalf accordingly.

Block lease arrangements can be advantageous in situations where costly plant and capital equipment is being underutilized. Refer to Figure 3 for functional diagram of a block lease arrangement.

Now we shall turn to the more involved and advanced forms of alignment models, which translate generally to the proposition of an oncology private practice providing the professional services and program management of a hospital's oncology service line for a fee.

#### Co-Management Agreement

The purpose of the co-management model is to engage and to appropriately reward participating physicians for their contribution as clinical leaders in developing, implementing, co-managing, and improving quality and efficiency of a hospital's service line.

Examples of physician duties under a CMA might include responsibility for assisting in the development and implementation and routine updating of policies and procedures and methods of operation of the cancer service line and assisting in the development and implementation of programs in response to value-based or pay for performance initiatives. A more complete listing of examples of physician duties under a CMA is provided as Figure 4.

Historically, co-management has been associated with the more "hospital proceduralist" specialties such as cardiology or orthopedics, but more recently has found application between oncologists and hospital oncology service lines.

In CMA alignments, there are typically two levels of compensation earned by the participating physicians. First

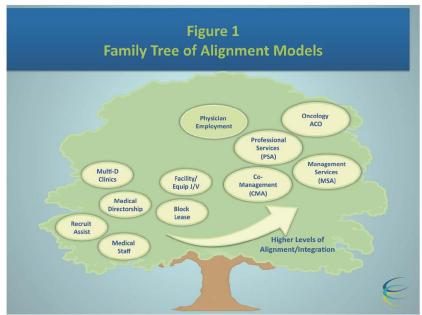


FIGURE 1. FAMILY TREE OF ALIGNMENT MODELS.

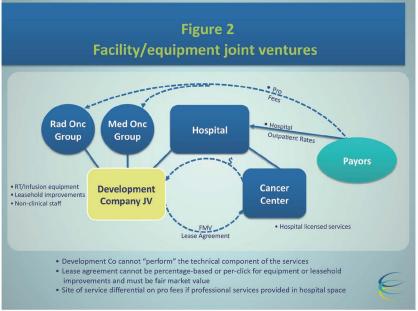


FIGURE 2. FACILITY/EQUIPMENT JOINT VENTURES

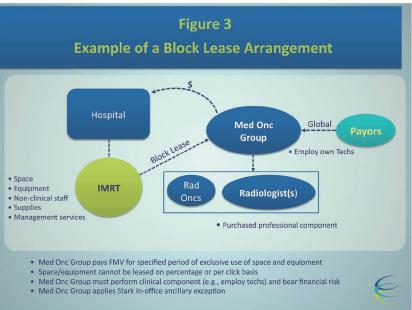


FIGURE 3. EXAMPLE OF A BLOCK LEASE ARRANGEMENT.

a fixed base fee consistent with the fair market value of the time and effort and professional expertise contributed by participating physicians to hospital service-line development, clinical management and professional oversight.

The second element of compensation in a CMA arrangement is a bonus fee, which is predetermined and contingent upon achieving specified, mutually agreed upon and objectively measurable program development, quality improvement, and efficiency goals. In a CMA arrangement, participating physician compensation can range from four to seven percent of service line net revenues under co-management.

A variant on the direct contractual CMA, described a bove, is a Co-Management Joint Venture Company. The Co-Management Joint Venture Company has the same purpose as the direct contractual variety, that is, to engage and to appropriately reward participating physicians for their contribution as clinical leaders in developing, implementing, co-managing, and improving quality and efficiency of a hospital's service line. However, forming a Co-Management Joint Venture Company adds a layer of organizational formality and sustainability (and cost) to the co-management relationship.

Schematic diagrams of the direct contract co-management alignment model and of the Co-Management Joint Venture Company are provided in Figures 5 and 6, respectively.

However, since community oncology, unlike hospital proceduralist specialties, is predominantly provided in the physician office setting, a stand-alone CMA arrangement can be compromised as long as the oncologist "co-managers" are competing with the hospital for ancillary services, chemotherapy, radiation therapy, and imaging in particular. Thus in CMA deliberations with oncologists, the dialog typically shifts to consideration of the consolidation of such ancillary services as hospital provider-based services which are then "turnkey" managed by the oncologists. This is the model contemplated below in the professional services arrangement (PSA) and management services arrangement (MSA).

#### **Professional Services Agreement**

In a PSA, a physician or physician group provides professional medical services to patients of another organization, a hospital for example. Physician(s) who provide professional medical services under a PSA are compensated for their services, typically on the basis of a work productivity formula, such as resource-based relative value units (RVUs), although there is a trend in substituting a pure RVU productivity compensation with a quality/value component. PSAs have been around for a long time as a mechanism for "hiring" a physician as independent contractor, particularly in jurisdictions which preclude direct employment of physicians by a nonphysician, the so-called "corporate practice of medicine doctrine," which is particularly restrictive in California and Texas.

A more current application of PSAs in the oncology alignment setting is one in which a hospital, as contractor, contracts with an oncology medical group practice, rather than a single physician, to provide the professional medical services on an exclusive basis. This application serves to preserve the practice entity and gives flexibility to the practice in assigning physicians to perform the work and in dealing with physician compensation issues associated with revenues generated under the PSA. In some instances, PSAs are drafted to include physician responsibilities and compensation in addition to patient care services, such as medical directorship and clinical program development.

In addition, PSAs are frequently found in situations where the alignment contemplated is one of converting the

### Figure 4 Examples of Oncologist Duties under a CMA

Administrative and Operational Services	Objective & Value Addressed
Assist in development & implementation and routine updating of Policies and Procedures and methods of operation of the Cancer Service Line and assist with the enforcement of compliance within the Cancer Service Line	Assure high quality patient care; warrant patient safety; maximize operating efficiency; manage operating costs
Assist in development & implementation of programs in response to value-based or pay for performance initiatives. Develop data analytic capabilities, outcome/cost metrics includes assisting in the development of shared savings (or similar) arrangements with Payors (Oncology ACO for example)	Promote patient-centered care - patient satisfaction

FIGURE 4. EXAMPLES OF ONCOLOGIST DUTIES UNDER A CMA.

### Figure 4 (continued) Examples of Oncologist Duties under a CMA

#### **Examples of Oncologist Duties under a CMA**

Financial Management Services	Objective & Value Addressed
Participate in the review of monthly reports of operational statistics, financial statements, and productivity reports and contribute the identification and implementation of any actions to be taken as a result of review.	Maximize operating efficiency; manage operating costs
Assist in development and implementation of long-term and annual capital budgets and annual operating budgets and measuring performance against such budgets with recommended actions to be taken as a result of budget variances. Advise re: opportunities for reductions in cost of care	Maximize operating efficiency; manage operating costs

## Figure 4 (continued) Examples of Oncologist Duties under a CMA

Medical Management Services	Objective & Value Addressed
Identification, development, documentation, implementation and ongoing updates of clinical pathways, clinical protocols and clinical care paths as appropriate	Assure high quality patient care; warrant patient safety; promote patient-centered care
Develop & implement quality assurance procedures and processes (QOPI for example); coordinate the utilization review and quality assurance of the Cancer Service Line.	Assure high quality patient care; warrant patient safety; promote patient-centered care
Responsible for all service line Accreditation (CoC, NAPBC, NCQA PCSP, etc.)	Assure high quality patient care; ; maximize operating efficiency

physician office-based ancillary services (chemotherapy, radiation and/or imaging) to a hospital provider-based service. In fact, a stand-alone PSA in oncology is not too compelling if the practice is to retain its ancillary service business independent of the hospital. The PSA model is depicted in Figure 7.

#### Management Services Agreement

The essence of the MSA is that one individual or organization contracts with another individual or organization to provide management services for all or a portion of the business of the contracting entity. In the case of oncologist—hospital alignment, this typically translates to hospital contracting with oncology medical group to provide routine day-to-day operational and managerial services to the hospital's oncology service line/cancer program. The MSA relationship is usually limited to outpatient services, but in some instances includes inpatient oncology services management as well.

Fundamental to a MSA arrangement, the hospital recognizes that the practice brings operational infrastructure and managerial value to the combined service which the hospital may not currently have in place. The theory is that since the oncology practice has been managing an outpatient business (their practice) successfully for the past 20 some odd years and has the preponderance of market share in outpatient oncology (probably 60%–80% in many markets), why not task them to provide day-to-day operational expertise to the expanded oncology enterprise?

In instances of a comprehensive alignment relationship between oncologists and hospital, where the oncology group is providing both professional and management services to the hospital service line, the applicable PSA and the MSA provisions are merged into a single document, a Professional Services and Management Agreement (PSMA). But whether two documents or one merged document, the context is the same; oncology medical group provides "turnkey" professional and managerial services to patients of the hospital for a fee (there are some regulatory limitations on the truly "turnkey" nature of the services to be provided under a MSA or PSMA by the physician group. For example, under Medicare regulations, in order to qualify for status as a hospital provider-based entity, for any service site "off campus" of the main hospital facility, the hospital would need to directly employ the clinical personnel providing services (nurses, pharmacist, etc.)).

So, what is the difference between a MSA and a CMA. The distinction between the two is subtle and the terminology is frequently used interchangeably. The distinction is that in a CMA relationship, physicians are typically less involved in routine service line operations. In the CMA, the role is more associated with providing clinical leadership and program development expansion than actually implementing and managing services.

However, in an MSA relationship, the physicians/physician practice assumes a much more active responsibility for routine day-to-day service-line operations. If a MSA relationship provides for a significant division of responsibilities between the physician practice and hospital personnel, such that the two parties are really co-managing the hospital service line, the subtleties between MSA and CMA get blurred. So just pick your label and move on. It is the substance of the agreement (MSA or CMA) that matters, not the label. See Figure 8 for diagram of the MSA model.

#### Comprehensive PSA + MSA + CMA

A recent trend in oncologist–hospital alignments has been to combine the features of all three advanced alignment models (PSA + MSA + CMA) into a single relationship. That is, an oncology medical group contracts with hospital/health

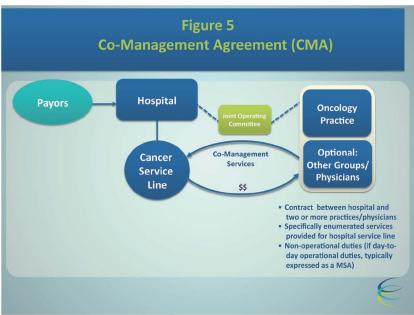


FIGURE 5. CO-MANAGEMENT AGREEMENT.

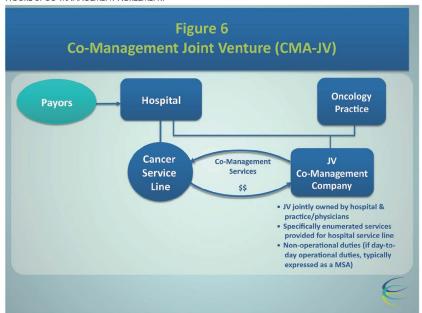


FIGURE 6. CO-MANAGEMENT JOINT VENTURE

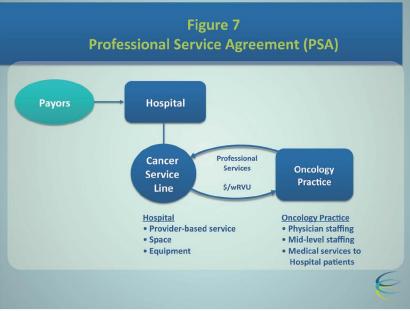


FIGURE 7. PROFESSIONAL SERVICE AGREEMENT.

system to provide a comprehensive package of professional medical services, day-to-day management services plus service line clinical program development leadership. Again, putting labels aside (PSA, MSA, CMA), it is the substance of the agreement that matters, not what you call it.

A schematic of the comprehensive PSA + MSA + CMA is provided in Figure 9.

Furthermore, see Figure 10 for a table of costing guidelines associated with each of the elements of the advanced alignment models.

#### The Oncology ACO

Is there a place for payers in the alignment dialogue? Often the primary objectives of an oncologist—hospital alignment are to incorporate consistency and evidence-based practice, workflow redesign and reduction of redundancies and costs across the full-continuum enterprise. And in achieving this goal, it has been demonstrated that the cancer spend can be reduced by 12–15%.<sup>1,2</sup>

However, if the providers of care – the oncologists and hospital in this case – work hard to bring about a reduction in cancer care costs ("spend"), without commensurate economic recognition from the payers for that care, it is the providers who lose (reduced revenue) and the payers (Medicare, Medicaid, commercial health plans) who win by virtue of markedly reduced medical cost for cancer services. A balance in the form of alternate payment methodologies to reward provider success is required. Otherwise why should providers – oncologists and hospitals – assume all this hard work and disruption? Solely for the benefit of payers who reap the windfall?

Enter a new model of oncologist—hospital alignment, the Oncology ACO, designed to address concept of accountability for reining in cancer costs without being compromised financially for doing so.

The Oncology ACO, pioneered through a collaboration among health system, oncology practice and payer in South Florida,<sup>3</sup> is a forum for cancer care process redesign and care coordination across the full continuum and for the implementation of alternate payment methodologies in oncology, bundled/episode-based pricing for example.

The model assumes participation from one or more health plan and most commonly is launched with a shared savings methodology with the participating health plan(s) transitioning to tumor-site-specific bundled prices within specified timeframe (two years). The features of the oncology medical home serve as the definitive care process construct, those core processes being pathways adherence, care coordination to minimize hospital emergency room, and inpatient activity and disciplined end-of-life counseling. And finally, the Oncology ACO model assumes that the organization will be supported via a robust data aggregation and analytics platform that is capable of producing meaningful clinical and cost outcomes data that documents a value proposition. See Figure 11 for diagram of the features of the Oncology ACO model.

#### Alignment Model Success Factors

Regardless of the form of oncologist—hospital alignment, the success factors listed below are common to all models. Without these features, the likelihood of forging a successful oncologist—hospital alignment is diminished.

- Both oncologist leadership and hospital C-level leadership committed to openly exploring the possibilities of meaningful business collaboration;
- Shared vision of the future state and a belief that things will be more sustainable working collaboratively;
- Trust level and mutual respect among the key stakeholders; and

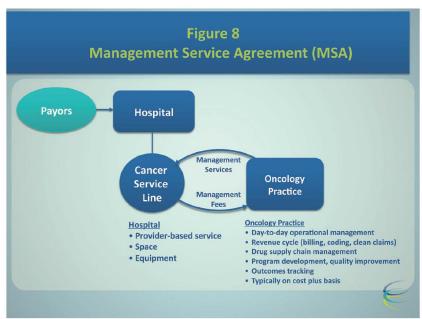


FIGURE 8. MANAGEMENT SERVICE AGREEMENT.

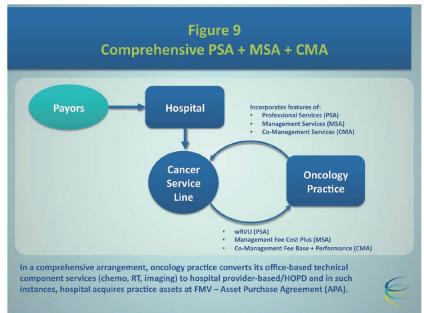


FIGURE 9. COMPREHENSIVE PSA + MSA + CMA.

Form	Element	Range of Fee
PSA	wRVU (with recognition of chemo admin and NP wRVUs)	\$85 to \$125 per wRVU
PSA	Optional: Medical Director duties, if not addressed elsewhere	\$180 to \$250 per hour
MSA	Day-to-day operations: personnel ("leased employees")	Cost + 7% to 11% or 2% to 4% net revenue/collections
MSA	Revenue cycle (pre-auth, coding, clean claim, billing & collections)	4% to 6% net revenue/collection
MSA	Program development: pathways, ACS CoC, PCSP, Quality (QOPI), etc.	Quality bonus comp at 10% to 15% of wRVU comp pool
CMA	Overall compensation	4% to 7% of net revenue under co-management
CMA	Base comp/performance comp	50%/50%

Figure 10

FIGURE 10. PSA + MSA + CMA COSTING GUIDELINES.

 Economic and transaction terms that make sense to both the physicians and the hospital.

#### CURRENT ISSUES IN ONCOLOGIST-HOSPITAL ALIGNMENT

Two major policy issues have surfaced, the resolution of which will likely have an impact on the current economics of oncologist—hospital alignment. One issue is the policy debate with regard to the cost differential between physician office-based services and its counterpart hospital provider-based (outpatient) services. The other major policy issue is the expansion of the 340B drug pricing program available to not-for-profit hospitals (and other qualified entities) servicing a disproportionate share of indigent/uninsured patients.

#### Site-of-Service Cost Differential Debate

First, a clarification: in this context, when we speak of "cost," we are actually referring to reimbursed medical costs from the payers perspective – the amount reimbursed – not actual operating costs. Probably no one really knows the situation-by-situation true cost differential between services provided in an oncologist office versus a hospital outpatient setting. The consensus wisdom is that physician offices are less expensive settings than hospitals for like care. And this may well be true – but where is the empirical evidence to prove it? There have been several recent credible studies of the reimbursement cost differential between physician office and hospital outpatient settings which found a 25%–53% of disparity.4–6

The site-of-care cost differential issue becomes visible in circumstances where oncologists and hospital are, in fact, pursuing an economically integrated business alignment, such as PSA/MSA combinations resulting from consolidating services to a hospital provider-based setting. While good for advancing care coordination and value-based ideals, the PSA/MSA may be not so good from a payer and patient co-pay perspective. Post-consolidation, payers can expect to see their medical costs increase 25–53% (or more depending on how you choose to slice the data).

The site-of-care differential issue becomes so visible, in fact, that legislation has been introduced in congress that would instruct the Center for Medicare and Medicaid Services to bridge the gap in Medicare reimbursement for oncologic services, that is to reimburse for services in hospital outpatient settings no more than that which is paid to physicians in the office setting. The proposed legislation is H.R. 2869, the Medicare Patient Access to Cancer Act of 2013. The American Hospital Association has responded to H.R. 2869 citing it as unfair to hospitals who invariably have a higher cost structure than physician offices due to the additional services required of a hospital.

In addition, a number of commercial health plans have simply taken the position that they will not reimburse hospitals more for like oncologic services when they are converted from physician office-based to hospital outpatient services. This then becomes a situation-by-situation negotiation between the hospital and the health plan.

One solution to the cost differential was the approach taken in one recent high-profile oncology practice-hospital alignment in the nature of a comprehensive PSA + MSA + CMA. That is, as part of the design of the consolidation, the hospital agreed to accept as reimbursement from the primary health plans affected by the consolidation, the rates that were being paid to the practice pre-consolidation. The alignment economics still worked despite the "haircut" in reimbursement rates. Problem solved (West Clinic and Methodist Le Bonheur Health System, Memphis form Partnership. January 2012).

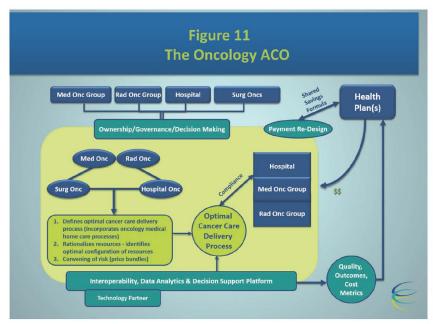


FIGURE 11. THE ONCOLOGY ACO.

#### 340B Drug Pricing Program

Initiated in 1992 under the Veterans Health Care Act Section 340B, this program discounts outpatient drug prices for nonprofit hospitals (and other qualified healthcare entities) that treat a disproportionate share (DSH; see generally Health Resources and Services Administration at www.hrsa.gov) of low-income Medicare, Medicaid, and uninsured patients.

A hospital becomes qualified for the 340B drug pricing program if it meets a threshold adjusted disproportionate share index of at least 11.75%. There are approximately 1,200 340B qualified hospitals in the USA, about 30% of all U.S. hospitals.

340B program discounts can range from 25% to upward of 40% below market basket rates. Applying these rates to an oncologist-hospital alignment involving, say 10 medical oncologists, that converts physician office-based chemotherapy to a hospital office-based setting that can result in an immediate reduction in operating costs for the consolidated program of perhaps \$7.5M annual (calculation of 340B savings: assumes 10 medical oncologists at average annual per oncologist drug buy at \$2.5M each = \$25M × estimated 340B drug price discount at 30% = \$7.5M). And isn't that one objective under health reform – to reduce costs of care? Yes, but as with the site-of-service cost differential issue, there are winners and losers in the 340 drug pricing program. Hospital wins an improved operating margin of \$7.5M. And pharmaceutical manufacturers lose \$7.5M in sales.

In addition, pharma does not think that this is fair. The argument is that the original intent of the 340 drug pricing program was to give a price concession to qualified entities for providing outpatient drug to indigent patients. In the example above, the \$7.5M drug cost savings is arrived at by applying the 340B drug discount to all outpatients of the qualified hospital, not just to the low income-uninsured portion of outpatients.

The 340B drug pricing program is administered by the Health Resources and Services administration (HSRA) of the U.S. Department of Health and Human Services. Regulations promulgated by HSRA do not make clear that 340B drug can only be used to treat the low-income/

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indigent class of outpatients, thus the interpretation by 340B qualified organizations has been that their 340B priced drugs can be administered and dispensed to all patients of the 340B qualified entity (insured patients or otherwise).

Under pressure from the pharmaceutical and drug supply distribution sector, this issue is undergoing scrutiny with the expectation that HSRA will issue by QTR 3 2014 regulations that clarify this matter and will put new limitations on the application of 340B priced drug to any but the originally intended low income/indigent/uninsured population served by 340B qualified entities.

Both of these controversial issues, site-of-care cost differential and 340B drug pricing, are anticipated to be clarified by the end of 2014 and with those clarifications may come economic impact to the efforts of providers to consolidate and rationalize oncology/cancer care services. In the meantime, those in the forefront of advancing oncologist–hospital alignment are building these variables into their planning budgets – one with a sensitivity to reduced reimbursement (site-of-service

differential) and the other a compromise to cost reduction (340B pricing restrictions).

#### **CONCLUSION**

Innovative and enlightened oncology providers remain keenly interested in undertaking to consolidate cancer care services for the purposes of care consistency, cost containment and value generation across the full continuum of cancer care.

The transactional, financial, and operational planning for such oncologist—hospital alignment undertakings has always required a disciplined attention to detail and no more so than now with such undertakings receiving a higher level of scrutiny.

But despite the regulatory and reimbursement unknowns, the basic proposition of system de-fragmentation as exemplified in the predominant oncologist—hospital alignment models remains valid — that through open and earnest collaboration among the providers of care — oncologists and hospitals — a superior and sustainable cancer care delivery system will emerge.

#### AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

The authors indicated no potential conflicts of interest.

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