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## Reverse Migration?: A Trend of ASC Conversion to HOPD

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Over the past 30 years, the health-care industry has witnessed the birth and growth of the ambulatory surgery center (ASC) industry, and a great migration to an ASC setting of procedures that previously were performed in hospitals.<sup>1</sup> Today, procedures performed in ASCs are broad in scope, including shoulder, hip, knee and spine surgeries, as well as many pain management and diagnostic services. For example, more than 50 percent of colonoscopy services performed in the United States are completed in ASCs.<sup>2</sup> Over the past decade, surgeries and procedures performed at ASCs have risen drastically, along with the number of ASC locations. According to the Medicare Payment Advisory Commission (MedPAC), in 2010, ASCs served 3.3 million fee-for-service Medicare beneficiaries, an increase of 0.9 percent from 2009.<sup>3</sup> Moreover, there were 5,316 Medicare-certified ASCs in 2010, an increase of 2.6 percent over the previous year.<sup>4</sup> In all, Medicare spent roughly \$3.4 billion on ASC services in 2010 alone.<sup>5</sup>

Although the number and types of procedures that are performed in an ASC setting continue to expand, studies and reports indicate a slower growth in the number of ASCs and volume of services performed at ASCs compared to previous years.<sup>6</sup> Furthermore, the health-care industry has experienced a reverse migration of sorts in the increasing acquisition by hospitals of freestanding ASCs and their conversion to hospital outpatient departments (HOPDs). This paper will discuss several areas related to conversion of ASCs to HOPDs. First, it will examine factors driving conversion of ASCs to HOPDs. Then, it will explore various legal considerations for hospitals considering converting an ASC into an HOPD. Finally, it will discuss co-management agreements and their place in the conversion of an ASC to an HOPD.

## I. FACTORS DRIVING CONVERSION

### A. Higher Reimbursement for Services Performed at HOPDs.

A primary factor driving conversion of freestanding ASCs to HOPDs is the great differential in reimbursement rates between the two facilities. Hospitals view freestanding ASCs as an avenue to return patients and revenue streams that were previously “lost” to ASCs. Beginning in 2007, Medicare payments to ASCs were lower than or equal to Medicare payments to HOPDs for comparable services for 100 percent of procedures.<sup>7</sup> Although HOPDs historically had always received higher reimbursement from Medicare than freestanding ASCs, this disparity grew larger when Centers for Medicare & Medicaid Services (CMS) implemented a revised ASC payment system effective Jan. 1, 2008, in accordance with the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003.

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<sup>1</sup> ASC to HOPD Conversion: Costly Consequences, Ambulatory Surgery Center Association.

<sup>2</sup> Ambulatory Surgery Center; A Brief History, Ambulatory Surgery Center.info, available at [www.ambulatorysurgerycenter.info](http://www.ambulatorysurgerycenter.info).

<sup>3</sup> Report to Congress: Medicare Payment Policy, Chpt. 5 Ambulatory Surgical Center Services, p. 115, Medicare Payment Advisory Commission (2012).

<sup>4</sup> Report to Congress: Medicare Payment Policy, Chpt. 5 Ambulatory Surgical Center Services, p. 115, Medicare Payment Advisory Commission (2012).

<sup>5</sup> Report to Congress: Medicare Payment Policy, Chpt. 5 Ambulatory Surgical Center Services, p. 115, Medicare Payment Advisory Commission (2012).

<sup>6</sup> See Report to Congress: Medicare Payment Policy, Chpt. 5 Ambulatory Surgical Center Services, p. 115, Medicare Payment Advisory Commission (2012); see also Intelligmarker 2011: Multi-Specialty ASC Study, VMG Health (2011) available at [http://www.vmghealth.com/Downloads/VMG\\_Intelligmarker11.pdf](http://www.vmghealth.com/Downloads/VMG_Intelligmarker11.pdf).

<sup>7</sup> Testimony on HB 2522 Physician Self-Referral Legislation, Monica M. Ziegler, (June 8, 2010), Pennsylvania House of Representatives Insurance Committee.

The revised payment system greatly expanded the types of services eligible for payment in the ASC setting to cover roughly 3,500 surgical procedures and excluded from eligibility only those procedures that pose a significant safety risk to beneficiaries. However, the reformed policy also caused significant variation between ASC and HOPD reimbursement rates in the past several years. In 2003, Medicare paid hospitals 16 percent more, on average, than it paid ASCs.<sup>8</sup> Today, on average, Medicare pays ASCs 56 percent of the amount paid to HOPDs for performing the same procedure.<sup>9</sup> For example, Medicare pays \$362 for a colonoscopy surgery performed at an ASC, and \$643 for the same service performed in an HOPD.<sup>10</sup>

This growing divergence in payments is driven, in part, by differences in how the payment systems are updated each year to account for inflation. Despite the fact that ASCs and HOPDs offer the same services, the CMS applies two different measures of inflation to update the payment systems for the two surgical providers. For ASCs, that measure is tied to consumer prices. For HOPDs, it is tied to medical costs. The ASC inflation update based on consumer prices is unrelated to changes in medical costs and is historically lower than the inflation update based on medical costs.

Defenders of the disparity in reimbursement contend that the variance in payment is reasonable because ASCs are likely to incur lower operating costs than HOPDs and because HOPDs must meet additional regulatory requirements and treat patients who have more complex cases.<sup>11</sup> According to a comparison between ASC and HOPD costs conducted by the Government Accountability Office, ASC costs are, on average, lower than HOPD costs.<sup>12</sup> Moreover, MedPAC claims patients treated in HOPDs are typically more medically complex than patients treated in ASCs, and these more complex patients are therefore more costly.<sup>13</sup> Lastly, unlike ASCs, HOPDs are subject to the Emergency Medical Treatment and Active Labor Act (EMTALA), which mandates HOPDs to stabilize and transfer patients who are believed to be experiencing a medical emergency when presented at the facility, regardless of the patient's ability to pay for services.<sup>14</sup>

While the defenders of the reimbursement disparity can point to factors to support the different treatment of ASCs and HOPDs, the fact remains that the lower reimbursement rates for procedures performed in an ASC can result in significant cost savings to the party responsible for paying for the patient's health-care. For example, coinsurance payments are typically less for procedures performed at ASCs rather than at HOPDs.<sup>15</sup> A beneficiary could pay as much as \$496 in coinsurance for a cataract extraction procedures performed in a HOPD, whereas that same beneficiary's copayment in the ASC would be only roughly \$195.<sup>16</sup> By having procedures completed in an ASC rather than an HOPD, a patient may save as much as 61 percent compared to

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<sup>8</sup> ASC to HOPD Conversion: Costly Consequences, Ambulatory Surgery Center Association.

<sup>9</sup> ASC to HOPD Conversion: Costly Consequences, Ambulatory Surgery Center Association.

<sup>10</sup> ASC to HOPD Conversion: Costly Consequences, Ambulatory Surgery Center Association.

<sup>11</sup> Medicare Payment Advisory Commission 2003, Medicare Payment Advisory Commission 2004.

<sup>12</sup> Government Accountability Office 2006.

<sup>13</sup> Medicare Payment Advisory Commission (2004).

<sup>14</sup> 42 USC § 1395dd.

<sup>15</sup> Testimony on HB 2522 Physician Self-Referral Legislation, Monica M. Ziegler, (June 8, 2010), Pennsylvania House of Representatives Insurance Committee.

<sup>16</sup> Testimony on HB 2522 Physician Self-Referral Legislation, Monica M. Ziegler, (June 8, 2010), Pennsylvania House of Representatives Insurance Committee.

their out-of-pocket coinsurance for the same procedures in an HOPD.<sup>17</sup> Overall, Medicare and its beneficiaries save more than \$2.5 billion each year from procedures performed in ASCs rather than at HOPDs.<sup>18</sup> It is not surprising that the Office of the Inspector General (OIG) has included in its work plan this year an examination of the conversion of ASCs to HOPDs, as discussed more fully below. This reverse migration of cases back to a hospital setting has the potential to cost the federal government a significant amount of money.

### ***B. Physician Alignment.***

The conversion of an ASC to an HOPD can also be an effective physician alignment tool for hospitals. While many hospitals still joint venture with physicians in a freestanding ASC to create physician alignment, conversion of an ASC to an HOPD provides many benefits to physicians that investment in a freestanding ASC cannot provide. The main benefit of a freestanding ASC joint venture between physicians and a hospital is that the parties' financial interests are strongly aligned. Each party has a financial incentive to operate the facility as effectively and as efficiently as possible to increase the overall profits. Physician investment in an ASC, however, carries financial risk for physicians. Although investment in a freestanding ASC has the potential for higher returns and overall compensation, there is also a risk of loss of the investment. This is especially true in light of the growing disparity in reimbursement between ASCs and HOPDs, and the overall trend in the slowing growth of the ASC industry. Additionally, many start-up ASCs require debt guarantees from individual investors, which puts their personal assets at risk if the ASC does not perform as expected.

There are several benefits to physicians when a hospital purchases their ASC and converts it to an HOPD. One is the proceeds from the sale of the ASC, which can result in a large payout for the physicians. Another is the elimination of the risk of loss of a physician's capital investment or payment of a guarantee of debt of a freestanding ASC. Finally, many times a hospital will enter into a co-management agreement with the physicians to manage the ASC after it is converted to an HOPD, which has many benefits for physicians. First, management payments have a high degree of certainty and predictability. Moreover, physicians can have direct involvement and control of the surgery process even though they are no longer owners.

Co-management arrangements do have some limitations. Although HOPDs allow for more predictable fees paid to physicians under a management agreement, such agreements must reflect fair market value, which may be much less than what physicians could earn in an ASC joint venture. For example, a highly successful ASC can generate a much higher return on investment for its physician owners than a management agreement would pay. Further, because there is no direct equity physician ownership in an HOPD, there is not always a true congruence of interest between the hospital and the physicians. As a result, despite the management arrangement, some parties have found the physicians do not have strong incentives to operate in the most efficient way possible. In addition, compared to an equity investment, a co-management arrangement is a relatively short-term relationship.

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<sup>17</sup> Testimony on HB 2522 Physician Self-Referral Legislation, Monica M. Ziegler, (June 8, 2010), Pennsylvania House of Representatives Insurance Committee.

<sup>18</sup> ASC to HOPD Conversion: Costly Consequences, Ambulatory Surgery Center Association.

## II. OIG WORK PLAN

The growing trend of ASC conversion to HOPDs has caught the attention of the OIG. The OIG's Fiscal Year 2013 Work Plan indicated several areas of review related to ASCs, including a review of hospital acquisition of ASCs and the impact such acquisitions have on Medicare spending, specifically on Medicare payments and beneficiary cost sharing.<sup>19</sup> Investigations will focus on the extent to which hospitals acquire ASCs and convert them into HOPDs, causing Medicare to reimburse at higher rates for services performed in HOPDs rather than ASCs.<sup>20</sup> The OIG will also review the appropriateness of Medicare's methodology for reimbursing ASCs under the revised payment system<sup>21</sup> and compare payment rate disparities within ASC and HOPD settings for similar surgical procedures.<sup>22</sup> Lastly, the OIG plans to review the quality of care and safety of Medicare beneficiaries obtaining surgeries and receiving care in ASCs and HOPDs.<sup>23</sup> Investigations will focus on assessing pre-operative care and care during surgeries and procedures, and will indicate adverse events identified in each setting.

## III. LEGAL CONSIDERATIONS

A hospital's acquisition of a freestanding ASC and conversion to an HOPD implicates a number of regulatory and other legal considerations, especially if the conversion involves a co-management agreement with the former physician owners of the ASC. Therefore, the hospital and physicians involved need to be mindful of these considerations when structuring these transactions, particularly in light of the OIG's focus on these transactions in this year's work plan. The OIG recently issued Advisory Opinion 12-22, which can help guide physicians and hospitals in structuring the co-management element of these transactions.

### A. Purchase/Sale Agreement.

The hospital's purchase of the ASC and the payment of the purchase price to the physician owners of the ASC will need to fit within an exception to the Stark Law<sup>24</sup> assuming that the physician owners make referrals to the hospital. Generally, these transactions can fit within the isolated transactions or fair market value exceptions to the Stark Law.

To meet the fair market value exception, the compensation paid to a physician must be pursuant to an arrangement that (1) is set forth in writing, signed by all parties and covering items or services specified in the agreement; (2) is for a specified time period; (3) specifies the compensation that will be provided under the arrangement (the compensation must be set in advance, consistent with fair market value, and not determined in a manner that takes into account volume or value of referrals or other business generated by the referring physician); (4) is commercially reasonable and furthers the legitimate business purpose of both parties; (5) does not violate the Anti-Kickback Statute; (6) and does not include counseling or promotion of a business arrangement that violates the law in the services performed. 42 C.F.R. § 411.357(l).

The transaction must meet the following conditions to qualify for the isolated financial transactions exception: (1) The amount of remuneration must be both (i) consistent with the fair

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<sup>19</sup> OIG Work Plan 2013, p. 7.

<sup>20</sup> OIG Work Plan 2013, p. 7.

<sup>21</sup> Federal law required the secretary to implement a revised payment system for payment of surgical services furnished in ASCs, beginning Jan. 1, 2008. *See* 42 C.F.R. § 416.171.

<sup>22</sup> OIG Work Plan 2013, p. 22.

<sup>23</sup> OIG Work Plan 2013, p. 22.

<sup>24</sup> 42 U.S.C. § 1395nn.

market value of the transaction and (ii) not be determined in a manner that takes into account volume or value of any referrals by the referring physician or other business generated between the parties; (2) the remuneration must be provided under an agreement that would be commercially reasonable even if the physician made no referrals to the entity; and (3) there are no additional transactions between the parties for six months after the “isolated transaction” (except for those that meet another exception) and except for commercially reasonable post-closing adjustments that do not take into account (directly or indirectly) the volume or value of the referrals or other business generated by the referring physician. 42 CFR § 411.357(f).

Both of these exceptions require that the purchase price reflect fair market value. Accordingly, the hospital should obtain a valuation from a third-party appraiser experienced in health-care transactions.

There is no safe harbor to the Anti-kickback Statute that applies to the sale of an ASC to a hospital. Unlike the Stark Law, there is no isolated transaction safe harbor or fair market value safe harbor under the Anti-Kickback Statute. Therefore, it is important that the hospital’s purchase of the ASC not be conditioned in any way to the physician’s referrals to the hospital.

## ***B. Provider-Based Regulations.***

1. *Requirements Applicable to all Provider-Based Facilities.* Hospitals interested in converting an ASC into an HOPD should also review and follow Medicare’s requirements for provider-based entities found at 42 C.F.R. § 413.65. All provider-based facilities are required to be operationally, clinically and financially integrated with the main hospital provider. Accordingly, HOPD must satisfy the following requirements:
  - a. *Licensure and Operations.* The location must be operated under the same license as the hospital. Additionally, The Joint Commission should be notified about the existence of the hospital’s off-campus location for survey purposes.
  - b. *Clinical Integration.* The location must be clinically integrated with the hospital, as evidenced by the following:
    - i. All professional staff providing professional services at the HOPD must have clinical privileges at the hospital;
    - ii. The hospital must maintain the same monitoring and oversight at the HOPD as it does for any of its other departments;
    - iii. The medical director of the HOPD must maintain a reporting relationship with the chief medical officer or other similar hospital official that has the same frequency, intensity and level of accountability that exists in the relationship between the medical director of a department of the hospital and the chief medical officer or other similar official of the hospital, and must be under the same type of supervision and accountability as any other director, medical or otherwise, of the hospital;
    - iv. Medical staff committees or other professional committees at the hospital must be responsible for medical activities at the HOPD (i.e., quality assurance, utilization

review, and the coordination and integration of services, to the extent practicable, between each location and the hospital);

- v. Medical records of patients treated at the HOPD must be integrated (or cross-referenced) into a unified hospital retrieval system; and
  - vi. Inpatient and outpatient services provided at the HOPD and the hospital must be integrated, and patients treated at the HOPD requiring further care must have full access to all inpatient and outpatient services of the hospital.
- c. *Financial Integration.* The financial operations of the HOPD must be fully integrated within the financial system of the hospital, as evidenced by shared income and expenses between the hospital and the HOPD. The costs of the HOPD must be reported in a cost center of the hospital and the financial status of the HOPD must be incorporated and readily identified in the hospital's trial balance.
- d. *Public Awareness.* The HOPD must be held out to the public and other payors as being part of the hospital (i.e., by including such locations in phone books, websites, marketing and hospital brochures). Patients must be made aware when they enter the HOPD that they are entering an outpatient department of the hospital and must be billed accordingly.

The government has indicated that satisfying each of these requirements is an important part of demonstrating that a HOPD is an integral part of the hospital.

2. *Requirements Applicable to Off-Campus Locations.* Medicare requires the HOPD to be located on the main hospital's campus, defined as an area within 250 yards of the hospital's main campus,<sup>25</sup> or the HOPD must be located within a 35-mile radius of the main provider.<sup>26</sup> If the HOPD's location falls within 250 yards of the hospital's main campus, the facility is essentially considered an on-campus entity. If, however, the ASC is located farther than 250 yards from the hospital campus, but within a 35-mile radius, the facility is an off-campus entity and may qualify for HOPD designation. If the HOPD is off-campus, it will also need to satisfy certain requirements applicable to off-campus facilities.

- a. *Ownership and Control by the Hospital*
  - i. The HOPD must be wholly-owned by the hospital and must operate under the hospital's governing body and in accordance with the hospital's bylaws, rules, regulations and operating decisions. It is not necessary to establish a new holding company to own the off-campus locations; and
  - ii. The hospital must also have final responsibility for administrative decisions, final approval for contracts with outside parties effecting the location, final responsibility for personnel policies and final approval for medical staff appointments.

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<sup>25</sup> 42 C.F.R. §413.65(a)(2).

<sup>26</sup> 42 C.F.R §413.65(e)(3)(i).

b. *Administration and Supervision by the Hospital*

- i. The HOPD must have a reporting relationship with the hospital that has the same frequency, intensity, and level of accountability that exists in the relationship between the hospital and an existing department — in essence, direct supervision;
- ii. The administrator of the HOPD must maintain a reporting relationship with a manager at the hospital that is the same as the relationship between the manager and other hospital departments and be accountable to the hospital's governing body; and
- iii. Administrative functions of the HOPD must be integrated with the hospital, including billing, records, human resources, payroll, employee benefits, salary structures, and purchasing services. Either the same employees must handle these administrative functions for the HOPD and the hospital, or the administrative functions for both entities must be contracted out under the same contract agreement, or the administrative functions must be handled under different contract agreements but the HOPD's contract be managed by the hospital.

3. *Requirements Applicable to Hospital Outpatient Department.* The location, and the physicians providing services at such location, will also need to meet the following requirements applicable to HOPDs.

- a. *Site-of-Service Codes.* Physicians would be required to bill Medicare Part B physician services using the correct site-of-service code (e.g., hospital code POS 22, instead of physician office code POS 11).
- b. *Medicare Provider Agreement.* The location must comply with the hospital's Medicare Provider Agreement.
- c. *Civil Rights Act Compliance.* Physicians would be required to comply with the non-discrimination provisions of the Civil Rights Act.
- d. *Treatment as Hospital Outpatients.* The hospital must treat all Medicare patients receiving services at the HOPD, for billing purposes, as hospital outpatients (i.e., the hospital cannot treat some Medicare patients to which it provides services as physician office patients and other Medicare patients as hospital patients).
- e. *Patient Notice.* The hospital must provide written notice to Medicare beneficiaries, prior to the delivery of service, of the amount of the beneficiary's potential financial liability (i.e., the co-insurance liability amounts for an outpatient visit to the hospital and for the provision of physician professional services).
- f. *Payment Window Requirements.* If a patient is admitted to the hospital as an inpatient after receiving care in the HOPD, payments for services provided in the HOPD are subject to the three-day payment window provisions such that outpatient diagnostic services related to the admission furnished by the admitting hospital within three days immediately preceding the Medicare beneficiary's admission are deemed to be inpatient services and included in the inpatient payment.

- g. *Incident-To Services.* A physician must be present (on campus or within the same building) and immediately available to furnish assistance and direction throughout the performance of procedure performed by mid-level practitioners. This does not mean that a physician must be present in the room when the procedure is being performed.
- h. *Conditions of Participation.* The location would also be required to comply with all health and safety rules for Medicare hospitals and to satisfy Medicare hospital conditions of participation (including hospital building code requirements).

If the location can satisfy all these requirements, it is likely the hospital will be able to qualify the location as an off-campus provider-based HOPD.

4. *Requirements Applicable to Off-Campus Facilities Operated Under Management Contracts.* If a provider-based HOPD is not located on the main campus of the hospital but is operated under a management contract, it must also meet the following criteria:

- a. *Staff Employment.* The hospital must employ the staff of the HOPD who are directly involved in the delivery of patient care, except for management staff and certain other staff. The hospital may not otherwise utilize the services of “leased” employees (i.e., personnel who are actually employed by the management company but provide services for the hospital under a staff leasing or similar agreement) who are directly involved in the delivery of patient care.
- b. *Control.* The administrative functions of the HOPD must be integrated with the hospital, and the hospital must have significant control over the HOPD’s operations.
- c. *The Management Contract.* The management contract must be held by the hospital, not by a parent organization that controls both the hospital and the HOPD, if applicable.

### **C. Licensing and Certificate of Need.**

Hospitals converting an ASC into an HOPD also need to consider various licensure and permit requirements. For example, if the hospital is located in a Certificate of Need state, it may need to obtain approval from the state Certificate of Need board before the ASC can be sold and converted to an HOPD. In addition, depending on the state licensure requirements, the facility may be required to obtain health-care facility licenses maintained through the state’s Department of Health.<sup>27</sup> Various notices and forms must be filed with Medicare and the state’s Medicaid programs. A hospital will also need to examine the various accreditation and local, state and federal licenses and permit requirements for the conversion.

### **D. Co-Management Agreements.**

Co-management arrangements are frequently used to align and reward physicians for assisting in managing a surgery center and often include incentive compensation to improve the facility’s quality and efficiency. A typical co-management relationship involves an agreement between a hospital and a specialty physician group, such as a cardiology or orthopedic group, whereby either

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<sup>27</sup> E.g. see S.C. Code 44-7-260 (2011), South Carolina facility license.

the physician group alone, or the physician group in partnership with the hospital, manages the operational and clinical activities of a hospital-based specialty service line. Generally, the co-management agreement provides for fair market value compensation in exchange for the provision of management services. Under a typical co-management agreement, the compensation includes an annual base fee and a quality-based incentive fee. The base fee is pre-determined, consistent with the fair market value of the services provided, and includes compensation for management and oversight in addition to service line development activities. The incentive fee is typically structured to include a series of pre-determined payments that are contingent on the achievement of specified, mutually agreed-upon quantifiable targets based on quality improvement and efficiency. Such arrangements, however, implicate a unique combination of regulatory issues.

#### ***E. The Anti-Kickback Statute.***

Payments under a co-management arrangement implicate the federal Anti-Kickback Statute because they could be interpreted as remuneration to physicians in exchange for referrals to the hospital. The personal services and management contracts safe harbor is the most applicable safe harbor to a co-management relationship. In order to qualify for safe harbor protection, the arrangement must: (i) be set out in writing and signed by the parties; (ii) specify the services to be provided; (iii) if the agreement is intended to provide for services on a periodic, sporadic or part-time basis, the agreement must specify the exact schedule of such intervals, their precise length, and the exact charge for such intervals; (iv) the term must be for not less than one year; (v) the compensation must be set in advance, consistent with fair market value, and not determined in a manner that takes into account the volume or value of referrals; and (vi) the services performed under the agreement must not involve the counseling or promotion of a business arrangement or other activity that violates any state or federal law. 42 CFR 1001.952(d).

A co-management arrangement providing for a percentage-based compensation structure (for example, with an incentive fee that varies based on achievement of certain clinical quality improvement metrics) likely would not satisfy the personal services and management contracts safe harbor. The personal services and management contracts safe harbor requires “aggregate compensation” to be set in advance, and the OIG’s position is that percentage compensation is not “set in advance.” However, a co-management arrangement can meet many of the other elements of this safe harbor. Specifically, a co-management agreement should be set forth in writing and include all the services to be provided; the term of the agreement should be for a duration of one year or greater; any contracted services should be reasonably necessary to accomplish the business purposes of the agreement; and the compensation should be consistent with fair market value in arms-length transactions and not take into account the volume or value of referrals.

As is the case with the purchase price paid to physicians in the hospital’s acquisition of the ASC, the hospital’s payments under a co-management arrangement should be supported by an independent third-party fair market valuation. The compensation and incentive payment structure should be revisited throughout the course of the relationship to ensure that incentive payments are being provided only for performance improvements and to ensure that the compensation is still fair market value. If compensation provided is not commensurate with fair market value, such compensation could be construed as a kickback from the party paying greater than fair market value for the services actually provided.

## ***F. Stark Law.***

Payments under a co-management arrangement also implicate the Stark Law. The Stark Law personal service arrangements and fair market value exceptions are potentially applicable to co-management agreements. Both of these exceptions contain a requirement that the compensation must be consistent with fair market value, set in advance, and not vary with the volume or value of referrals. The “set in advance” requirement permits a specific formula that is set in advance, can be objectively verified and does not vary with the volume or value of business generated. For example, an incentive fee based on achievement of objectively verifiable clinical quality improvement metrics should be acceptable. In 2009, CMS proposed a new Stark Law exception<sup>28</sup> for incentive plans/shared service plans. However, the exception was never finalized.

## ***G. False Claims Act.***

Co-management agreements can also lead to liability under the False Claims Act (FCA). Liability under the FCA occurs when (1) a person or entity knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; (2) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; or (3) conspires to commit a violation of any of certain provisions of the False Claims Act (including the two listed above). Violations of the FCA are punishable by penalties of not less than \$5,500 and not more than \$11,000 per claim, plus treble damages for the amount of damages the government sustains. FCA actions can be based on Anti-Kickback Statute and/or Stark Law violations. If a claim that a hospital submits to Medicare was improperly induced or violated the Stark Law, then it may also be a false claim.

## ***H. Civil Monetary Penalties Law.***

A co-management structure that incentivizes behavior to reduce costs could run afoul of the Civil Monetary Penalty (CMP) statute<sup>29</sup>. The CMP statute prohibits a hospital from knowingly making a payment, directly or indirectly, to a physician as an inducement to reduce or limit services to a Medicare or Medicaid beneficiary. A physician who knowingly accepts payment in violation of the CMP could be fined up to \$2,000 for each such individual with respect to whom the payment is made. In addition, violators face potential exclusion from federal and state health-care programs.

Since 2001, the Office of Inspector General (OIG) has issued favorable advisory opinions on gainsharing and performance-based compensation arrangements, and recently issued Advisory Opinion No. 12-22 specifically addressing a co-management arrangement.

## ***I. Advisory Opinion No. 12-22.***

Recently, the OIG issued new guidance on co-management agreements in an advisory opinion. On Jan. 7, 2012, the OIG published Advisory Opinion No. 12-22, which addressed a co-management agreement between a hospital and physicians that was designed to align incentives by offering compensation based on quality, service, and cost cost-saving measures. This is the first time the OIG has specifically addressed a co-management arrangement of this nature, but the OIG’s analysis mirrors concepts from other advisory opinions regarding gainsharing and performance-based compensation arrangements. The OIG analyzed the arrangement under both the CMP and the Anti-kickback Statute. The OIG concluded that the agreement could constitute improper

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<sup>28</sup> 73 Fed. Reg. 38502, 38604-05.

<sup>29</sup> 42 U.S.C. § 1320a-7a.

payment to either reduce or limit services or induce referrals under the CMP law; however, the OIG did not impose any sanctions due to several safeguards in the arrangement. These safeguards included the following:

- i. Both the fixed fee and incentive fees under that arrangement reflected fair market value as supported by an independent, third-party valuation. Further, the arrangement provided that the physician group would provide substantial services to earn the fees.
- ii. The fee paid to the physician group did not increase as a result of an increase in the number of patients treated at or referred to the hospital. Further, the incentive fee was capped at a certain amount each year and did not fluctuate based on the number of patients treated.
- iii. The physician group agreed that the compensation received under the arrangement would be distributed to its member physicians pro rata based upon the amount of ownership interest in the group practice and not in any way based upon individual participation under the arrangement.
- iv. The physicians agreed that they would not (a) stint on care of patients; (b) increase referrals to the hospital; (c) cherry-pick healthy patients with desirable insurance for treatment at the hospital; or (d) accelerate patient charges to earn the performance fee.
- v. The hospital used an independent utilization review body to review the cost-savings measures implemented under the arrangement. In addition, the employee satisfaction, patient satisfaction, and quality components of the arrangement were monitored on multiple levels by a performance improvement committee, a peer review committee, the medical executive committee, and the hospital's board of directors.
- vi. The arrangement allowed for flexibility in physician decision-making. The arrangement encouraged physicians to efficiently manage the use of supplies and products, but did not limit or restrict the physicians' abilities to offer patient services or have access to any supply or device that a physician considered clinically appropriate for patient care. In addition, the hospital used an independent, third-party utilization review body to analyze the clinical appropriateness of procedures performed in the facility. Further, the cost-savings benchmarks were based on the "aggregated performance" of the physician group so that earning the incentive fee was not dependent upon meeting a specific standard for each particular patient.
- vii. The performance measures were very detailed and based on national standards, independent utilization reviews, and employee and patient satisfaction measures.
- viii. The physician group could not receive the incentive fee if it did not satisfy the baseline measure for the various components so that the physician group was not rewarded for maintaining the status quo.
- ix. The term of the arrangement was limited to three years.

- x. The hospital notified patients and their families in writing of the arrangement prior to patients' receiving services.

## **VI. CONCLUSION**

While the ASC industry has experienced tremendous growth over the past three decades, that growth has slowed in recent years. One factor contributing to the slowing growth may be the recent trend of hospital acquisitions of ASCs and their conversions to HOPDs. These types of transactions are appealing to hospitals and physicians for a number of reasons, including increased reimbursement for hospitals, and less risk for physicians. However, the result of these transactions is an increase in cost to Medicare, patients and other payors. Further, they involve a complex set of regulatory issues that physicians and hospitals must navigate. Physicians and hospitals should pay careful attention to structuring these transactions, especially in light of the OIG's focus on them in this year's work plan.