Considerations of Volume or Value in Health Care Operations

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"Return on investment" are not dirty words. Whether a for-profit entity with an obligation to shareholders or a nonprofit health care provider with the obligation to be a good steward of a community asset, a positive margin is a necessity.

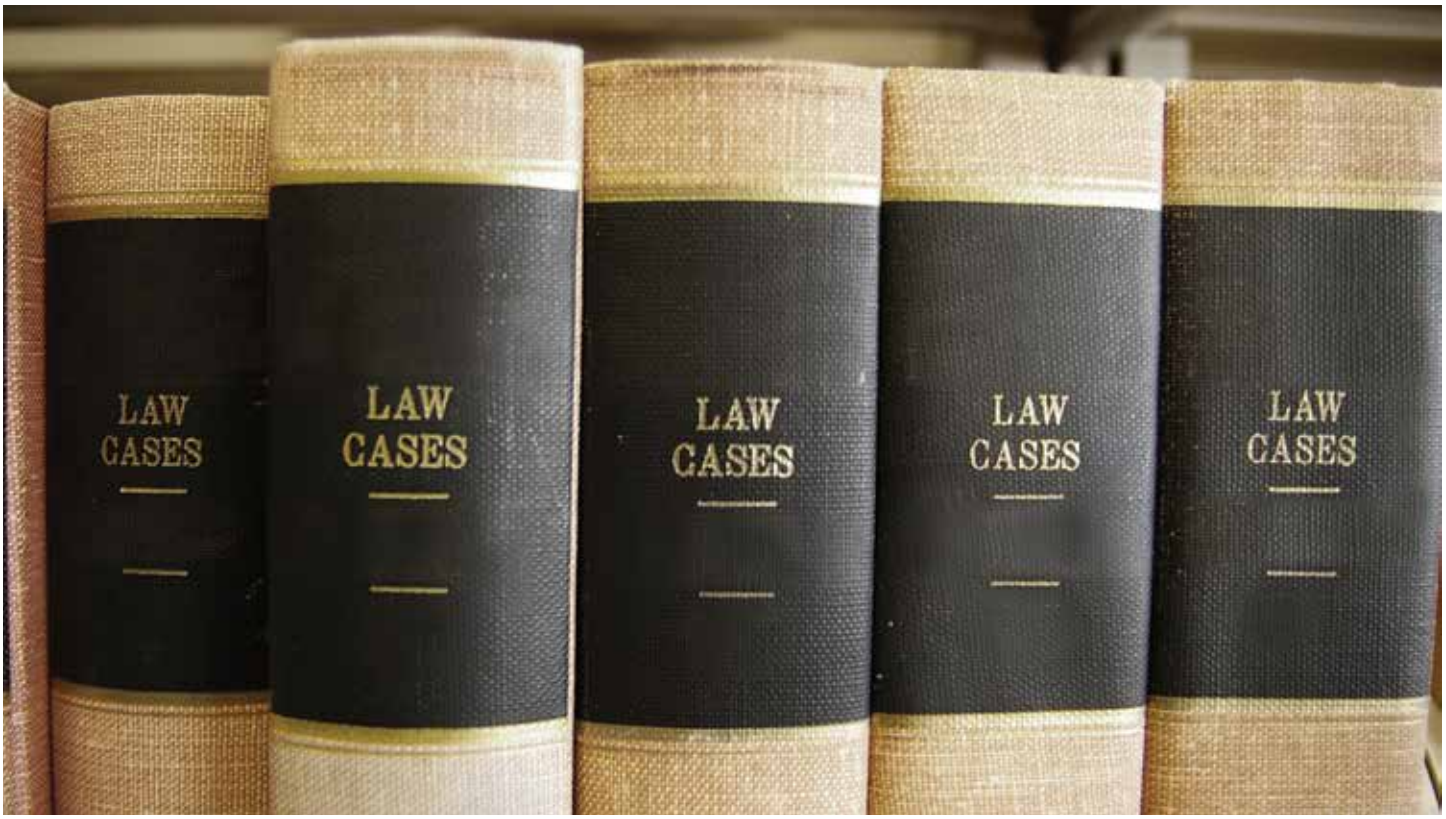
Traditional businesses can and do consider volume or value information in operational and transactional decision making. Health care providers, however, are not normal businesses and must proceed with caution in the consideration of such information. Recipients of federal health care money risk running afoul of the fraud and abuse laws, when considering volume or value information in some decision making. The Stark Law (Stark) exceptions and the Anti-Kickback Statute (AKS) Safe Harbors generally prohibit the volume and value of patient referrals or purchases from playing a role in many transactions. Nonetheless there are circumstances where such considerations are appropriate and necessary.

The Risk

The risk, of course, is that a decision or transaction that improperly utilizes volume or value data will lead to a Stark or AKS violation and/or a False Claims Act claim, with the corresponding need to return related federal health care program dollars and penalties. The following situations are illustrative of hospital management utilizing or considering volume or value data with a negative outcome.

Transactional Risk

In *United States ex rel. Singh v. Bradford Regional Medical Center,* an acute care hospital was found to have violated Stark as a matter of law and possibly the AKS through an equipment sublease agreement with a physician group.[1] Bradford subleased a nuclear imaging camera from a physician group, which the physician group had used in the office, rather than referring patients to the hospital, which had its own nuclear camera. The court looked beyond the four corners of the agreement and found that the hospital entered into the transaction considering the value of referrals from the physician group.[2] Although Bradford's arrangement "carefully sought to avoid requiring referrals and attempted to make a business decision based on [fair market value]," the court still found a violation where the hospital's decision to enter into the agreement—the sublease of equipment—was, as reflected in email by hospital management, driven by a desire to obtain referrals lost when the physician group purchased its own equipment.[3]



Compensation Risk

In *United States ex rel. Baklid-Kunz v. Halifax Hospital Medical Center,* the court found that an arrangement may not have fit within the Stark bona fide employment exception where Halifax paid doctors a bonus from a pool based on a percentage of the operating margin of a hospital program.[4] The physicians employed by Halifax were eligible to receive an incentive bonus from a certain compensation pool. The compensation pool was equal to 15% of the overall operating margin of the hospital program and Halifax admitted that this meant that the compensation pool contained revenue for "designated health services" not personally performed by the physicians. The court determined that revenue from referrals made by the physicians would flow into the bonus pool and therefore the physicians' remuneration was based at least in part on the value of referrals, and consequently did not satisfy the requirements of the Stark bona fide employment exception.[5] The court held that even if the share of the bonus was determined by the actual work performed by the physician, the overall funds to be divided were directly affected by referrals.[6]

Operational Risk

In May 2010 the Health Alliance of Greater Cincinnati and The Christ Hospital agreed to settle allegations that they violated the AKS and the False Claims Act by allocating time to physicians to sit on a reading panel based in part on the referral of cardiac patients to the hospital.[7] The government claimed that the cardiologists' allotment of panel time was tied to a corresponding utilization of the hospital. The problem was that the hospital allegedly used volume data in offering the opportunity for doctors to sit on a reading panel, putting at risk the Medicare reimbursement for hospital services to the cardiologists' patients.

Practice Considerations

There are a variety of consulting services and software tools that are marketed to health care providers to track referrals, physician profitability, and a host of related data. Similar tools are available to those that sell products reimbursed under federal health care programs. There is nothing illegal about collecting this data and using it in some contexts, but it can be evidence of bad intent if used improperly. All it takes is one email referencing return on investment on ancillary services revenue in connection with determining a physician's salary, or referencing the value of referrals or purchases in deciding which physicians should be provided certain opportunities, to create low-hanging fruit for regulators and qui tam counsel. To minimize the risk, controls should be in place when collecting and using volume and value data.

Factors to Consider in Assessing Risk

There are several factors that should be considered when assessing the risk involved with using volume or value data. What is the purpose of the use of the information? Is alternative information available, such as aggregated or blinded data, that could be used for the same purpose or to achieve the same objective? What is the precise nature of the volume or value information? What are the roles and functions of the persons within the organization who produce, have access to, or make decisions based on volume or value data? What is the nature of the financial or business relationship (or proposed relationship) between the organization or its affiliates and the physician, medical group, or other referral source whose volume, value, or purchase information is collected or analyzed? What is the temporal relationship between the production and/or use of the information regarding the volume or value of referrals, purchases, or other business generated (or that may be generated) by the physician, medical group, and other referral source and any financial transactions or arrangements with such persons or entities?

Risk Associated with Certain Activities

The risk associated with using volume and value data should be assessed based on the facts and circumstances of each operational decision or transaction. Some use of the data is safer than others.

Relatively Low Risk

The production and/or use of information regarding the volume or value of referrals presents a relatively low level of risk in situations in which: (1) there is a bona fide purpose or reason for the production; and (2) the use of the information is wholly unrelated to any actual or potential transaction or arrangement between the health care organization and the physicians, medical group, or others in a position to generate the volume or value of the referrals or purchases being assessed. Examples of low-risk activities include:

- Determining or projecting the volume of inpatient cases or outpatient ancillary services generated or projected to be generated by a particular physician or group of physicians solely for the purposes of determining the facility, equipment, or other capital needs for a particular department or division;
- Determining or projecting the volume of inpatient cases or outpatient ancillary services generated or projected to be generated by physicians in the aggregate (i.e., all members of the medical staff) solely for the purposes of annual budgeting or financial or strategic planning;
- Production and use of information regarding the volume of referrals or resource utilization by a particular physician solely for the purposes of bona fide quality of care and/or utilization review activities with respect to such physician;
- Production and use of aggregate patient or case volume data relating to hospital service lines or departments that does not reflect or reveal physician-specific or group-specific referral information to boards or committees

solely for the purposes of legitimate planning and oversight activities and functions;

- Production bonuses for services rendered consistent with the Stark bona fide employment exception; or
- Providing volume discounts consistent with the applicable AKS Safe Harbors.

Heightened Risk

The production and/or use of volume or value information presents a greater level of risk in situations in which: (1) the information is used to explain, justify, or compensate, in whole or in part, financial or business transactions involving physicians, medical groups, or others in a position to generate the volume or value of the referrals or purchases; or (2) is used in allocating benefits or preferences among physicians, medical groups, or other referral sources. Examples of heightened-risk activities include:

- Determining or projecting the volume or value of inpatient cases or outpatient ancillary services generated or projected to be generated by a particular physician or medical group in explaining or justifying (financially or otherwise) a proposed transaction or arrangement;
- Determining or projecting the volume or value of inpatient cases or outpatient ancillary services generated or projected to be generated by a particular physician in connection with the discussions or decisions regarding the recruitment of such physician to join the medical staff and/or become an employee;
- Determining or projecting the potential or expected return on investment associated with inpatient cases or outpatient ancillary services rendered in connection with the analysis or decision making regarding a transaction or arrangement between the organization and any physician, medical group, or other person or entity in a position to generate or otherwise influence inpatient cases or outpatient ancillary services being valued;
- Determining or projecting the volume or value of inpatient cases or outpatient ancillary services generated or projected to be generated by a physician or medical group in connection with the analysis or decision making regarding the compensation payable to such physician or medical group (except for professional medical services personally performed by the physician and/or medical group); or
- Determining or projecting the volume or value of inpatient cases or outpatient ancillary services generated or projected to be generated by a physician or medical group in connection with either the selection of a particular physician or medical group to provide services to the organization or its affiliates.

If a health care provider or supplier uses volume or value data for setting compensation, payment amounts, or the price of goods or services outside of a Stark exception and/or an AKS Safe Harbor, they are putting a target on their backs.

The Inherent Risk of Doing Business

To operate with a positive margin, volume or value information must be considered by health care providers and suppliers. There is an inherent risk in evaluating and using this information, and care must be taken so as not to run afoul of Stark and/or the AKS. As the *Bradford, Halifax,* and *Health Alliance* cases teach us, using volume or value data in operational, transactional, and compensation decision making is under great scrutiny by governmental authorities and qui tam relators. Health care providers and suppliers of certain health products should pause and take care if they decide to take volume and value data into account.

There is a tension between the needs of health care providers and suppliers to maintain positive margins and the restrictions on their ability to use volume and value information. It is a tension that must be reconciled.

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1 752 F. Supp. 2d 602 (W.D. Pa. 2010).
2 *Id.* at 623.
3 *Id.* at 643.
4 Case No. 6:09-cv-1002-Orl-31TBS, Dkt. No. 396 (M.D. Fla. Nov. 13, 2013).
5 *Id.* at 16-17.
6 *Id.* at 17.
7 Press Release, U.S. Department of Justice, *The Health Alliance of Greater Cincinnati and the Christ Hospital to Pay $108 Million* (May 21, 2010), *available at* www.justice.gov/opa/pr/2010/May/10-civ-602.html.