Avoiding Red Flags in Medical Directorships – A Valuator's Guide

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The cornerstones of regulatory compliance, the concepts of commercial reasonableness and fair market value ("FMV") are integral to demonstrating that a compensation arrangement complies with the federal Anti-Kickback Statute ("AKS") and Stark Law. Specifically, unless covered by a "safe harbor," the AKS is a criminal statute that prohibits the knowing and willful payment of remuneration to induce patient referrals involving any item or service payable under a Federal health care program.[1] Likewise, the Stark Law prohibits physicians from referring patients for health care services payable by Federal health care programs to entities with which the physician has a financial relationship, unless covered under an "exception."[2] The applicable safe harbor (in the case of the AKS) or exception (in the case of the Stark Law) typically cited in support of medical director arrangements require that (i) the arrangement be consistent with FMV, and (ii) "[t]he aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services."[3]

Regulatory enforcement of medical directorships has historically been centered around either the FMV requirement or the identification of "sham" relationships.[4] However, though not an entirely new concept, examination into the reasonableness of total services hours may now be competing for center stage. Notably, in an action brought by way of a *qui tam* lawsuit[5] against SCCI Health Services Corporation ("SCCI") in 2001 and involving up to nine medical directors, the government's expert witness concluded that, given the hospital's bed-size, "[o]ne [m]edical [d]irector should be sufficient to cover medical direction, meet licensure requirements, physician staff needs and patient care requirements . . . ."[6] More recently, this indication of heightened scrutiny on duplicative services hours was included in commentary to the Stark Law Final Rule, whereby CMS, in expanding upon what might "further a legitimate business purpose," recited the following example: "[i]f the hospital needs only one medical director for the

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[1] 42 U.S.C. § 1320a-7b (2020).
[2] 42 U.S.C. § 1395nn (2020).
[3] 42 U.S.C. § 1320a. Note that the Stark law contains substantially similar text, which requires that "the aggregate services covered by the arrangement do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement…." *See* 42 U.S.C. § 1395nn(e)(3)(A)(iii).
[4] *See, e.g.,* U.S. Department of Justice (DOJ), Office of Public Affairs (Sep. 16, 2013) " 'No Show' Doctor Sentenced to 151 Months in Prison in Connection with $77 Million Medicare Fraud Scheme," *available at* https://www.justice.gov/opa/pr/no-show-doctor-sentenced-151-months-prison-connection-77-million-medicare-fraud-scheme. *See also* U.S. ex. Rel. Doe v. Doctor's Choice Home Care, Inc, *et. al.*, No. 8:15-cv-1044 (M.D.. Fla. Apr. 30, 2015) at ¶ 56. "According to the sham agreements, physicians were charged with performing a litany of services for Doctor's choice as medical directors. In reality, however, these services were not performed by the physician."
[5] U.S., ex rel Kaczmarczyk v. SCCI Health Services Corp., No. 4:99-cv-01031 (S.D. Tex. Jan. 17, 2001).
[6] *Id.*, Exp. Wit. Rep., July 12, 2005, ECF No. 217 at 9.

oncology department, but later enters into a second arrangement with another physician for oversight of the department, the second arrangement merely duplicates the already-obtained medical directorship services and may not be commercially reasonable."[7]

Since the concept of FMV first appeared within the Stark Law and AKS, valuation techniques and theory applicable to physician compensation arrangements have arguably evolved to the point where establishing FMV for certain arrangements connotes a fair bit of objectivity[8]. Determining commercial reasonableness, on the other hand, has remained a more subjective process, mostly relying upon detailed documentation of favorable facts and circumstances. While facts and circumstances are unique to each medical directorship, the following examples can help your organization identify potential areas of concern regarding legitimacy of medical director arrangements in light of the recent regulatory enforcement actions as well as published fraud and abuse regulations and texts.

Some Highlighted Examples

Medical Directorship Existing concurrent to a Management Agreement

In certain instances, just one medical director position can bring about compliance risk. This might occur when a medical director provides services related to a service line or department for which the hospital also maintains a management agreement with a physician-owned company. Typically, a management agreement delineates certain service line or department oversight responsibilities to the management company. While such services do not preclude the existence of a medical director, they call into question (i) how the duties are segregated and (ii) the legitimacy of the overall hours dedicated to the medical direction of a department. Medical directors may be provided under one of the following models:

Financially Responsible Party	Medical Director Compensation	Potential Compliance Risk
Management Company	Included in Management Fee	Minimal
Hospital	Compensated hourly to management company (reimbursed) or physician affiliated with management company, in addition to management fee	Services may overlap with management services and create an arbitrage opportunity for management company
Hospital	Compensated hourly to physician unaffiliated with management company	Services may overlap with management services and payment by hospital to dedicated medical director may reduce effort required by management company for actual compensated responsibilities

[7] 42 CFR § 411 at 77533.

[8] Although we note the Stark Law Final Rule does warn against viewing compensation arrangements in the vacuum of salary survey respondents (stating that FMV "may not always align with published valuation data compilations, such as salary surveys.") 85 Fed. Reg. 77658 (2020) at 77554.

Existence of Multiple Administrative Arrangements – One Physician

One physician having more than one medical directorship or administrative arrangement may bring about an increased compliance risk. Certain directorships and/or administrative roles are filled based on the careful consideration of physician qualities and qualifications other than specialty experience (*e.g.* utilization review, clinical integration, *etc.*) thereby enabling one physician to be the appropriate and desired choice for more than one administrative role. The number of positions held and/or combined potential hours associated therewith can contribute to the compliance risk. The below table describes examples of physician administrative roles and compensable monthly hours performing related responsibilities.

Hypothetical Position/Role	**Hypothetical Compensable hours per month**
Service Line Medical Directorship	44
Utilization Review Committee Chair	8
Pharmacy and Therapeutics Committee	6
Electronic Health Records Steering Committee	8
COVID Task Force	16
Diversity and Inclusion Committee	4
Total	86

While each of the positions individually appear reasonable, when combined, the associated hours total over 1,000 annually. If the physician fulfilling these roles is also a full-time clinician, let alone a full-time physician with a highly productive practice, it may call into question whether such total hours are in fact actually being worked, possibly further prompting a question into the validity of administrative time records (*i.e.* similar to circumstances published in a relatively recent Office of Inspector General ("OIG") fraud alert).[9]

Existence of Multiple Medical Directors – One Department

The vast majority of medical director arrangements are one-to-one (physician to department). However, there are instances when more than one medical director may be required (*i.e.*, co-medical directors) or when a department has more than one position due to legitimate subspecialty requirements. Compliance risk associated with these circumstances is greatest when there are no obvious contributing factors substantiating the additional need.

[9] Department of Health and Human Services. OIG. "Fraud Alert: Physician Compensation Arrangements May Result in Significant Liability" (June 9, 2015), *available at* https://f.datasrvr.com/fr1/015/37117/Fraud_Alert_Physician_Compensation_06092015.pdf (last accessed June 16, 2021).

Co-medical Directors

- Most appropriate when the hospital department is large compared to its peers.
- Another helpful factor is when hours per month for each of the positions are low.

Multiple Directorships in a Department

- Specialty training or external certification mandates the expertise (for example, cardiology sub-specialists such as electrophysiology, performing work within a broader cardiology program).
- The additional directorship is associated with common subspecialty.
  - The most common medical directorship position titles are noted in medical director surveys published by Medical Group Management Association (over 50 titles) and Integrated Healthcare Strategies (over 100 titles). If a named medical director title or specialty is not on either of those lists (or another reputable survey), compliance risk may be enhanced.

As a result of increased regulatory scrutiny and recent commentary published by CMS, it is more important than ever for hospitals and health systems to ensure that contracted administrative hours are reasonable and necessary to accomplish the commercially reasonable business purpose of the arrangement. Making such determination is not a simple task, and requires thoughtful documentation of facts and circumstances that lend themselves to a favorable finding of appropriate matching of hours and administrative services. Although each medical director arrangement is unique, the common circumstances described herein are intended to be thought provoking, and highlight potential areas of concern, which, if not properly considered, structured, and/or deployed, can give rise to unexpected regulatory risk.