HEALTH LAW AND COMPLIANCE

Legal Implications of Integration of Hospitals and Urgent Care Centers

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Urgent message: *As health systems and payors align their interests in the creation of accountable care organizations, hospitals that acquire or partner with urgent care centers must adopt a legal structure and an operating model that remain compliant with the federal Anti-Kickback Statute and the federal Stark law, and with other federal and state regulations.*

Introduction

With the advent of the Patient Protection and Affordable Care Act (PPACA), the government recognized that it could not continue to indefinitely pay for a majority of the medical care in the United States without providing sticks and carrots to encourage cost savings, improved outcomes, reduced use of hospital emergency departments as primary-care offices, and reduced hospital readmission rates.

The concept of the *accountable care organization* (ACO) was thus devised at the Medicare level to pay the highest-cost providers a share of the savings they could achieve by addressing these cost drivers, while requiring them to meet certain quality thresholds and qualitative metrics as a precondition to payment. In an ACO, a local network of providers work together to coordinate the full continuum of care for Medicare fee-for-service beneficiaries within their provider network. Providers that meet performance standards or quality benchmarks and reduce per-beneficiary spending below target are entitled to receive a share of the savings (the Shared Savings Program).[1]

Naturally, the highest-cost providers—hospitals—have the greatest to gain (and to lose) from ACOs, because they are the primary impetus for spending concerns. Second in cost is the physician fee-for-service payment system, which cannot be sustained indefinitely, given its built-in incentive to perform more and duplicate services across providers. Essentially, health care has become about controlling the greatest patient population by controlling the greatest number of physicians serving those patients—off the hospital site. Arguably, insurers led the charge, and states quickly followed suit by providing similar organizational certification as an ACO and incentives for the private insurance market. Among these incentives were limited exceptions to the imposition of Anti-Kickback Statute, the Stark law, and antitrust enforcement.[2] Nevertheless, because hospitals and health systems have sought to acquire off-site locations *without actually seeking ACO certification*, these laws still affect physician–hospital relationships:

- **The Anti-Kickback Statute:** The federal Anti-Kickback Statute[3] makes it a criminal offense to knowingly offer, solicit, or receive any remuneration—the transfer of value, cash, or otherwise, including payments for equipment and services—directly or indirectly, overtly or covertly, to induce referrals of items or services reimbursable by a federal health-care program. When remuneration is paid to induce or reward referrals of items or services payable by a federal health-care program (i.e., Medicare and Medicaid), the Anti-Kickback Statute is violated. State law equivalents apply to all payors, including insurance and private-pay, as well as to workers' compensation. The workers' injury payment program is increasingly recognized as a viable source of patients for the urgent care market.
- **The Stark law:** With some exceptions, the Stark law[4] prohibits physicians who have a financial relationship with an entity from referring certain types of items or services for which payment may be made under Medicare (referred to as Designated Health Services, or DHS), including radiology (e.g., x-rays and positron-emission tomography, computed tomography, and ultrasound images), clinical laboratory services, and inpatient and outpatient hospital services. State law equivalents apply to all payors for these

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[1] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/index.html
[2] https://www.ftc.gov/tips-advice/competition-guidance/industry-guidance/health-care
[3] http://oig.hhs.gov/compliance/physician-education/01laws.asp
[4] https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/index.html

types of services, including insurance and private-pay, and further prohibit the submission of claims resulting from such a referral. If the professional entity working out of the center wishes to continue to bill and earn income for DHS conducted on-site at the urgent care center, then the Stark law requires that it qualify as a *true group*, as that term is strictly defined under the Stark law. The definition requires, among other criteria, legal organization under a single tax identification number with common benefits and unified business structure. Additionally, service providers must be primarily physicians constituting bona fide employees or owners of the professional entity, rather than mere independent contractors if used.

Penalties for violation of these laws include large fines, imprisonment, recoupment of past claims' payments, and even triple damages, along with potential for debarment from the Medicare program.

Common Models

The following are examples of mechanisms for control and participation by hospitals in urgent care centers. How they operate varies on the basis on state law, state licensure requirements, and the individual state enforcement environment:

Employment Model

In the straightforward employment model, the hospital employs all of the physicians who operate out of the urgent care center.

Captive Model

As a threshold matter, direct ownership of professional entities by a hospital is prohibited in most states—these entities must be owned by a physician. In a captive model, the professional entity issues all of its ownership interests to a single physician who is also an employee of the hospital. The captive model enables a hospital to work with a friendly entity owned by a physician loyal to the hospital's mission of serving the community. Further, the model ensures that his or her successor is equally aligned with the hospital. It eliminates the licensing and legal uncertainties associated with employment of physicians in private-practice offices who further the hospital's mission and coordinate care but who may not necessarily render clinical services or coverage in licensed hospital facilities. Ultimately, captive models enable the hospital to provide financial support in order to recruit physicians in its community on behalf of the professional entity. The structural, operational, and, to some degree, financial control over the captive entity, its owners, and its managers is then conveyed to the hospital by means of any number of documents and agreements, which can include

- An administrative services agreement between the hospital and the captive entity to provide managerial support
- An employment agreement between the hospital and the physician-owner (pursuant to which the ownership of the captive entity can be transferred to another physician at any time, such as through a blank stock power or nominee agreement)
- A professional services agreement
- Staffing and coverage agreements and/or other relevant instruments

A hospital will charge a captive entity for any administrative services, personnel, space, equipment, and financing it provides.

Professional Services Agreement and Medical Directorship Models

The agreements just described can be coupled with any model. The professional services agreement (PSA) may constitute an agreement between the hospital or its captive professional entity and another physician or group providing staffing and services for the center. As a supplement to the PSA or in lieu thereof, the hospital or its captive entity may compensate a group or an individual physician for administrative and clinical oversight services involved in the day-to-day running of the center. The hospital will similarly charge for its own administrative services, personnel, equipment, space, and financing.

Comanagement Model

Under the comanagement model, the assets of the center, including space, leases, equipment, and nonprofessional personnel, will be contributed to a new joint-venture business entity in which the hospital will indirectly take ownership and contribute funds, and the founding members of the center will participate as owners. The purpose of such an arrangement is to recognize (and appropriately reward) medical groups and physicians for their efforts in developing, managing, and improving the quality and efficiency of a service line. Management service, leasing, financing, and other agreements may be entered into by the joint-venture entity, with the professional entity operating out of the center. PSAs and other agreements may also be contracted in accordance with the comanagement model. Comanagement services include

- Service line development
- Budget process management
- Business planning
- Medical director services
- Community relations and education
- Satisfaction surveys
- Clinical protocol development
- Ongoing assessment of the clinical environment
- Physician staffing
- Patient scheduling
- Staff scheduling and supervision

- Human resource management
- Case management
- Inventory management
- Credentialing

Legal Concerns

There is a risk of a finding of violation of the Anti-Kickback Statute by the Office of the Inspector General (within the U.S. Department of Health & Human Services), a determination that the professional entity does not constitute a true group under the Stark law, or an allegation that payments and reallocation of cost responsibility are meant to serve as inducements for referrals to the hospital.

The physicians may enter into an arrangement with the expectation that financial guarantees will be provided by the hospital. For example, if professional entity revenues are insufficient to cover budgeted and unanticipated expenses, the hospital will be expected to fund all necessary cost overruns. Accordingly, payment by the hospital will not be set in advance for the year (and will likely fluctuate in practice, notwithstanding written clauses stating the contrary), so as to cause the arrangement to fall outside of potential federal Anti-Kickback Statute safe-harbor protections. The "as-needed funding" could be alleged to be a kickback for referrals of services to the hospital. Though efforts might be made to qualify the additional funding as a financing arrangement, the issue then becomes whether such financing would be considered excessive or commercially reasonable, absent referrals to the hospital.

If the professional entity is entirely separate from the hospital (i.e., not captive), an agreement to share revenues or profits with such a noncaptive entity can potentially be challenged. The ability to seek or obtain a profit upside (i.e., a path to discrete profitability outside of the admission and referral of patients, services, and testing to the hospital) through the mere funding of the professional entity is threatened (if not nullified). As a catch-22, absent a path to profitability that is irrespective of referrals to the hospital, what would be the purpose of funding independent centers? This raises questions regarding the purpose of the arrangement. Further, any profit obtainable by leasing of personnel (including of physicians employed by the hospital), equipment, and space by a hospital to the professional entity is limited to fair market value (FMV). The profit margin for such business activities is relatively low.

To the extent that a physician or group is compensated for oversight of the center's office operations, rather than administrative functions for the benefit of hospital inpatient department and/or outpatient department, that compensation could be alleged to be a kickback to the professional entity, as a distinct independent entity unrelated to the hospital. Accordingly, any such compensation might instead be the sole burden of the professional entity payable directly out of its revenues, rather than part of the hospital's compensation to the managing physician or group. If the physician is engaged in administrative activities for the benefit of the hospital, FMV considerations still apply, and the conduct of such activities must be carefully documented and tracked. A regular performance review should also be conducted.

Additionally, there is a risk that payments made by the hospital to the physicians could be viewed as a means to offset the loss of Stark DHS, which would otherwise have been conducted on-site at the urgent care center had it not affiliated with the hospital, such as x-rays and clinical laboratory services—which are now farmed out to the hospital or its affiliates.

It is also possible that the government will not consider the physicians to be members of the true group practice if they concurrently hold employment status with the hospital (i.e., they are "leased" to the group as its employees as well). This could destroy the ability of the physicians to meet the *group practice* definition, such that Stark DHS may not be permitted to be rendered by the professional entity or billed under its tax identification number. Consequently, the physicians are not allowed to receive any DHS revenues or profits from the professional entity, and their DHS referrals (orders) to the professional entity will violate the Stark law. The government could unfavorably view physicians receiving any DHS profits (by claiming group-practice status under the Stark law) when the parties are also taking the position that such physicians are bona fide employees of the hospital in connection with the same or related services. This could also lead the government to challenge the physicians' employment status with the hospital, potentially resulting in significant Stark law penalties associated with hospital facility billings emanating from the physicians' referrals of inpatient and outpatient services and testing to the hospital.

Safe Harbors and Exceptions Protecting from Violation

Note that any agreement entered into should also comply with safe harbors under the Anti-Kickback Statute to the extent possible, as well as exceptions falling under the Stark law. Under these statutory and regulatory exceptions at the federal and state levels, the agreements must meet specific criteria, including that the term of the agreement not be less than 1 year; if an agreement is terminable within the year, the parties must not enter into the same agreement for the remainder of the initial 12 months. Further, services and items provided must clearly be delineated, and the payments associated with them constitute FMV. Additionally, the arrangement must be for a legitimate business purpose, and the compensation must not consider the value or volume of any referrals.

It is paramount that health-care counsel be consulted to ensure that the arrangement complies with legal guidelines and creates synergies through clinical integration, quality improvement, and reduction of hospital utilization, which will further bolster the justification for such a relationship. ■