

SO YOU'RE THINKING OF GETTING INTO THE BUSINESS OF HEALTHCARE?

# HERE ARE THE TOP 5 THINGS YOU NEED TO KNOW.

Neda Mirafzali Clark Hill PLC

From an outsider's perspective, the healthcare industry appears to be a lucrative field upon which many would like to capitalize. That outsider is correct. In light of the new healthcare reform law, the majority of which the Supreme Court has upheld, the Federal government has been doling out huge sums of money as incentives to help achieve its "triple aim" of (1) better care for individuals, (2) better health for populations, and (3) lower growth in expenditures, and many are jumping at the opportunity to claim their share. However, a lucrative healthcare business comes at a price that is beyond capital contributions and investments.

The price in this industry is the countless landmine statutes and regulations dictating the formation of certain healthcare entities, relationships between members of the healthcare world, as well as a healthcare entity's workforce, to name a few. Naturally, with increased opportunity for money comes increased regulation as well as increased enforcement. Nevertheless, what entrepreneurs should remember is, if State and Federal laws are navigated properly, a healthcare business can become successful. This article, through a review of some of the most common Federal healthcare laws and regulations, provides the top five considerations for prospective healthcare-business

owners in working toward a successful healthcare business.

1.

## KNOWING HOW YOU CAN FORM YOUR ENTITY

First and foremost, before hitting the ground running with a new business venture, when incorporating professional services into the business model, it is important to determine *how* this entity may be formed. Beyond the limited liability company versus corporation debate, most states have a prohibition against the corporate practice of medicine ("CPOM"). While each state may define the term slightly differently, the general idea is that a general corporation, not owned by a physician, may not employ a licensed professional (*e.g.*, a physician) to perform professional services (*e.g.*, practice medicine). The impetus behind the CPOM doctrine is that physicians, and not corporations, should be practicing medicine. The doctrine aims to maintain the integrity of the delivery of medical services by eliminating competing interests in the outcome of the services being provided.

Notably, however, many common exceptions exist. For instance, the CPOM doctrine does not usually apply to hospitals. Hospitals may employ licensed professionals to provide their professional services because the hospi-

tal is in the business of providing healthcare services. Likewise, many states permit licensed professionals to perform their professional services through professional corporations or professional limited liability companies as, typically, each shareholder or member must be licensed in the professional service being rendered. Therefore, after identifying the service being provided, it is important to determine if the State has a CPOM doctrine and whether it applies.

2.

## KNOWING WHO CAN WORK FOR YOU

Healthcare entities that submit claims to Federal healthcare programs (*e.g.*, home health agencies, mental health organizations, etc.), like Medicare, have an obligation to perform certain background checks on those who provide services on behalf of those entities. Included in those background checks is ensuring that no person employed or contracted with the healthcare entity is excluded from participation in Medicare, Medicaid and all other Federal health care programs. Federal healthcare programs will not pay for any items or services furnished, ordered or prescribed by an excluded individual or entity. Likewise, entities submitting claims for healthcare items or services provided by an excluded provider or entity can

face enormous civil monetary penalties. As such, it is crucial to perform initial and periodic checks of all employees and contractors to ensure none are excluded.

### 3.

#### PROTECTING PATIENT INFORMATION (IT IS NOT ONLY FOR DOCTORS AND HOSPITALS)

Many know the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) as a prohibition against the release of medical records; however, HIPAA is much more than that. In fact, although HIPAA was enacted in 1996, in 2009, the Health Information Technology for Economic and Clinical Health (“HITECH”) Act, significantly amended HIPAA to instill a breach notification process and to increase penalties for violating HIPAA. The Department of Health and Human Services (“HHS”) Office of Civil Rights (“OCR”) enforces the HIPAA rules.

HIPAA, as a law, only applies to covered entities (i.e., health plans, health care clearinghouses, and healthcare providers). However, recognizing that covered entities do not perform all of their own healthcare functions or activities (for instance, billing and collections), the OCR drafted provisions of the Privacy Rule to permit covered entities to disclose patients’ protected health information (“PHI”) to business associates. Business associates are individuals or entities that provide a service to covered entities requiring the sharing PHI. Business associates can take a number of forms including, billing companies, consultants, independent transcriptionists, accreditation organizations, auditing companies, to name a few. HIPAA requires covered entities utilizing the services of business associates to enter into Business Associate Agreements, which set forth the parameters within which PHI may be used by the business associate. Failure to enter into, and abide by, a business associate agreement can result in significant fines.

penalties, depending on the violation.

Three Federal laws specifically govern referral relationships: the Anti-Kickback Statute (“AKS”), the Physician Self-Referral Law (“Stark”) and the Beneficiary Inducement Statute. The AKS is a criminal statute that prohibits knowingly and willfully soliciting, receiving, offering or paying anything of value to induce referrals of items or services payable by a Federal healthcare program. “Anything of value” includes cash, free rent, hotel stays, meals, concert tickets, excessive compensation, etc. Notably, one does *not* have to be a healthcare professional to violate the AKS.

Because almost any business relationship, especially a marketing relationship, could run afoul to the AKS, the HHS Office of Inspector General (“OIG”) has issued a number of regulatory safe harbors that protect relationships fitting squarely within the safe harbor. Some of these safe harbors include equipment or space rental agreements, employment agreements, and investments in ambulatory surgery centers.

In the most general terms, Stark relates to physicians referring patients to themselves. Specifically, Stark prohibits physicians from referring patients, who receive certain designated health services (“DHS”) payable by Medicare or Medicaid, to entities with which the physician, or an immediate family member, has a financial relationship, unless an exception applies. DHS includes certain clinical laboratory services, physical therapy, occupational therapy, speech therapy, radiology and imaging services, durable medical equipment and supplies, etc. Financial relationships can take a number of forms, including ownership and investment interests as well as compensation arrangements. For example, generally, providing gifts to a referring physician would constitute a compensation relationship. However, Stark, like the AKS, has certain regulatory exceptions, including the Non-Monetary Compensation exception, which permits the relationship so long as it satisfies the requirements of the exception.

The Beneficiary Inducement Statute prohibits a person from offering or transferring to a Medicare or Medicaid beneficiary any remuneration that the person knows or should know is likely to influence the beneficiary’s selection of a particular provider, practitioner or supplier of Medicare or Medicaid-payable items or services. The OIG has issued a number of exceptions to this statute, including the permissible provision of gifts with a value of not more than \$10 per item or \$50 in the aggregate to a single beneficiary annually. Therefore, unless it fits within an exception, offering a dis-

count to patients to induce the patient to purchase a service or supply from a particular provider is prohibited and can result in significant penalties.

Many impermissible relationships are not as obvious as the aforementioned examples; however, it is critical for healthcare business owners to have their relationships thoroughly evaluated by counsel to ensure full compliance with these laws.

### 5.

#### BEING COGNIZANT OF STATE LAW REQUIREMENTS

With the exception of the CPOM discussion, above, many of the laws introduced in this article have been Federal laws applying to Medicare and Medicaid beneficiaries and Federal healthcare monies. Before prospective healthcare business owners assume these prohibitions do not apply to private insurance, a review of State law is crucial. Many states have adopted laws very similar to the Federal laws noted above, which apply to private insurance. Moreover, many states have adopted laws *in addition to* the Federal laws that dictate the practice of a healthcare business, including fee-splitting laws and strict insurance fraud laws.

#### CONCLUSION

While the regulation of healthcare has been common since the 1990s, with the enactment of healthcare reform, and the availability of incentive payments, healthcare enforcement has increased dramatically. Healthcare professionals and non-healthcare professionals alike find themselves on the front page of the newspaper, faced with multi-million dollar fines and decades of jail time. As such, it is more important than ever for prospective healthcare-business owners to understand the landmines before them and to consult with qualified counsel to assist in navigating the Federal law issues as well as the many State law issues that may arise in forming and owning a healthcare business.

### 4.

#### UNDERSTANDING THE LIMITATIONS ON REFERRAL RELATIONSHIPS

Most typical business relationships thrive on rewarding a party for referring business. For instance, in many business ventures, it is common to offer a discount to an existing client or customer for referring a new client or customer. However, a person in the healthcare world engaging in a payment-for-referrals relationship could find him or herself in jail and/or facing colossal monetary



*Neda Mirafzali is an attorney with Clark Hill PLC's healthcare practice group. She regularly counsels healthcare providers, billing companies and management companies on corporate and healthcare compliance matters, reimbursement matters, audit appeals, litigation matters, and regulatory analysis. She may be reached at [nmirafzali@clarkhill.com](mailto:nmirafzali@clarkhill.com) or @nedazali.*