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Legal Alert
Health Care

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Legal Issues to Consider When Creating a Health Care Business Model

Business practices considered standard in other industries may in the health care industry be considered kickbacks for business or inducements to patients to choose a certain provider. To best demonstrate my point: in the beverage industry, if you want to get your product on a shelf in a supermarket, you must pay for "shelf space." Paying for referrals in health care may land you in jail. The minefield of federal and state regulations such as licensing, corporate practice of medicine laws, kickbacks, physician self referral (known as Stark), fee splitting, professional misconduct, anti-inducement or solicitation laws necessitate that a health care attorney, with expertise in these areas, counsel the creation, transactions, and business relationships of any health care provider. The stakes are too high to use an attorney without health care experience and expertise. When creating a new service line or product in any industry there are legal considerations to address. Health care is no different. However, the impact of existing laws should not be a barrier to innovation. With the correct legal counsel and advice the new service line or product usually can be created in a manner that does not violate existing laws. Business relationships among providers usually involve parties that can refer patients to each other for healthcare services or items. Many of the rules are federal and have parallel state laws. The main areas of concern are:

1. State License Laws
2. State Corporate Practice of Medicine Laws
3. Anti-Kickback – Federal and State Laws
4. Physician Self Referral – Federal and State "Stark"
5. Patient Inducement or Solicitations Laws
6. Fee-Splitting Rules – State
7. Cost Report Rules – Medicare and Medicaid
8. Complex Medicare/Medicaid Reimbursement Rules

The following is a brief explanation of each of these areas of laws.

1. State License Laws

The first place to start is state license laws. Are there state license requirements for the new "entity"? If the new service line or product is to be provided under the existing license of your current entity, is that service or product permissible?

2. Corporate Practice of Medicine

After the license question is resolved, you must consider the type of corporate entity to create. Choices vary depending on state requirements. Should the entity be a corporation – C or S, a limited liability company or a professional corporation. Some states require that all the owners of an entity that will provide professional services, such as physician services or legal services, be owned by individuals who hold the same professional license. The reason for this requirement is that these states prohibit a business corporation or lay person from controlling the medical decisions of a physician or professional staff. This legal concept is called the "corporate practice of medicine." The policy enforced in corporate practice of medicine states is to ensure that medical decisions are only made based on what is best for the patient. Some states have a clear prohibition against the corporate practice of medicine, such as New York. Some states don't follow the rule at all, such as Florida and Kentucky. In some states, the law is unclear.

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3. State and Federal Anti-Kickback Laws
The next law to consider is the State and Federal Anti-Kickback laws. This law is a broad prohibition of offer, solicitation, payment or receipt of anything of value, direct or indirect, overt or covert, in cash or in kind, intended to induce referral of patient for items or services reimbursed by all federal programs, including Medicare, Medicaid, and programs covering veterans' benefits. See Social Security Act § 1128B.

Remuneration is anything of value including money, rebates and free services. Both the offeror and recipient of a kickback violate the law. A kickback can exist if one purpose of the payment is to induce referrals, regardless of the legitimate reason for the payment.

The federal and some state anti-kickback laws are criminal laws, punishable by fines, imprisonment, and/or exclusion. However, there are "safe harbors" that describe 26 different types of business relationships. If you follow the requirements of the safe harbor, i.e., contracting for management or personal services, there is no criminal or civil sanction. Failure to meet the requirements of a safe harbor is not automatically a kickback arrangement. The facts of the business relationship must be evaluated to determine intent.

The 26 business relationships for which there are safe harbors include discounts, bona fide employment, space rentals, personal service and management contracts, co-insurance and deductible waiver, price reductions for eligible managed care organizations, and many more. Fair market value payment in business relationship, and reasonable business purpose of the relationship are legal concepts which must be evaluated. If your health care counsel is not sure whether a kickback exists, a request for an Advisory Opinion can be made from the Office of the Inspector General ("OIG") of the U.S. Department of Health and Human Services ("HHS"). There is a charge for the Opinion.

4. Physician Self-Referral – Federal and State Stark
Under the federal physician self referral law, a physician may not refer Medicare or Medicaid patients for designated health services ("DHS") to an entity with which the physician or an immediate family member has a financial relationship, unless an exception applies. An entity may not present a claim for reimbursement from Medicare or Medicaid for services provided as a result of a prohibited referral. Federal Stark is a civil law which imposes strict liability. The referral is not prohibited if an exception applies. If an exception is not met, the arrangement is unlawful. There are various exceptions that apply to ownership/investment and compensation arrangements 42 .CFR 411.358, ownership/investment interests 42 CFR 411.356, and purely compensation 42 CFR 411.357. A Stark analysis consists of three steps:

1. Is there a referral from a physician for a DHS?
2. Does the physician (or his immediate family member) have a financial relationship with the entity providing the DHS service?
3. Does the financial relationship fit an exception?

5. Patient Inducement or Solicitation
Anti-Inducement Provision, Section 1128A(a)(5) of the Act, provides for the imposition of civil monetary penalties against any person who offers or transfers remuneration to any individual eligible for benefits under [Medicare or a State health care program] that such person knows or should know is likely to influence such individual in order to receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, under [Medicare or a State health care program]. See also 42 C.F.R. § 1003.102(b)(13) "Anti-Inducement Regulations." The term "remuneration"

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under Section 1128A(i)(6) of the Act is defined to include "transfers of items or services for free or for other than fair market value." The legislative history to the Health Insurance Portability and Accountability Act of 1996 indicates that Congress did not intend for the Act to preclude "the provision of items and services of nominal value, including, for example, refreshments, medical literature, complimentary local transportation services, or participation in free health fairs." H.R. Conf. Rep. No. 104-736, at 255 (1996).

Items of nominal value which can be given to patients or potential patients are interpreted as having value of $10 per item or $50 in the aggregate on an annual basis per individual. There are five statutory or regulatory exceptions of permissible remuneration, which include:

1. Non-routine unadvertised waivers of co-payments or deductible amounts based on individualized determinations of financial need or exhaustion of reasonable collection efforts.
2. Properly disclosed differentials in a health insurance plan's co-payments or deductibles.
3. Incentives to promote the delivery of certain preventive care. Such incentives may not be in the form of cash or cash equivalents and may not be disproportionate to the value of the preventive care provided.
4. Any practice permitted under anti-kickback statute exceptions or regulatory safe harbors at 42 C.F.R. §1001.952.
5. Waivers of co-payment amounts in excess of the minimum co-payments amount under the Medicare hospital outpatient fee schedule.

If needed, your health care counsel can request an advisory opinion on whether a proposed business practice is a "kickback" or inducement or solicitation.

6. State Fee-Splitting Laws

The proposed business venture must also be examined to ensure that any state fee-splitting law is not violated. Not all states have fee-splitting laws. However, for those that do, usually the physician is at risk. For example, in New York State the Education Law § 6531 states that a physician's license may be revoked, suspended or annulled for professional misconduct if a physician requests, receives, participates in, or profits from "the division, transference, assignment, rebate, splitting or refunding of a fee" or "a commission, discount or gratuity" in connection with "providing professional care or services." For example, if your business model involves a physician paying a fee for administrative and billing services and that fee is determined as a percentage of the physician's revenue from billing for services, this arrangement may constitute a prohibited fee split. However, the problem may be solved by changing the fee to fair market value for the administrative and billing services. An experienced health care attorney can recognize these issues and address them.

7. Medicare and Medicaid Cost Report Issues

If the proposed business venture involves a provider that files cost reports with Medicare or Medicaid, you must be sensitive to the impact the business relationship will have on the cost report. It doesn't matter if the entity will be paid on a prospective payment basis. Cost reports have an "attestation" that must be signed, which states all laws were complied with. Examples of cost report rules that may come into play are home office, shared employees and/or office space, related party rules, Prudent Buyer rules, etc. These are set forth in Medicare regulations and the Provider Reimbursement Manual. Medicaid usually follows Medicare principles or they have their own set of rules. Once again, an experienced health care attorney can assist you in navigating these rules with the proper corporate structures, procedures, and prior approvals from applicable fiscal intermediaries.

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8. Medicare and Medicaid Reimbursement Rules
Once you've created your new business model, you need to identify revenue streams to pay for the services or items. Medicare and Medicaid have complex reimbursement rules applicable to each industry, which are too numerous to mention. For example, physician billing and coding rules, reassignment rules, nurse practitioner billing rules, etc.

Conclusion
A state or federal investigation is very costly to defend. The government has an arsenal of sanctions at the criminal, civil, and administrative level. The criminal laws include making a False Statement, Mail or Wire Fraud, False Claims in Medicare or State Health Programs, failure to disclose and repay an overpayment, and other state and federal sanctions. Civilly, there are the Civil Money Penalties ("CMP") laws, which impose an $11,000 fine for each claim. Anti-kickback laws impose fines up to $25,000, 5 years imprisonment, automatic exclusion, and CMP up to $50,000 and damages up to 3 times the amount of the illegal kickback. Penalties for violating the physician self referral law – Stark – include denied claims, overpayment, CMP up to $15,000 for each service a person knows or should have known was in violation of Stark, exclusion, and CMP up to $100,000 for attempting to circumvent Stark. The press is always reporting about overnight millionaires as a result of "whistleblower" or "relator" lawsuits. In this environment, it is wise to protect your business and yourself from corporate and personal liability by using the correct attorney with the correct expertise.

Change comes through challenges. Making an experienced health care attorney part of your strategic team in planning any new health care venture is wise. An experienced health care attorney can help you structure your business relationships without tripping any of these minefields of laws. What is a good health care attorney? I would define a good health care attorney as someone who has extensive experience working in your particular industry. An attorney who also has government regulatory experience is ideal because they know how regulators think and can identify the issues. For most work, the attorney does not have to be admitted in your state. Many of these issues are federal and those that are state are usually regulatory advice, which an experienced health care attorney can address by reviewing the state laws. How should you approach the attorney? Call him or her on the phone. Explain what you want to do. Don't expect answers immediately. Ask for information about the attorney's background.