Physician Investments – Make it Rain or Wear a Ball and Chain?

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(May 23, 2016) – RXpress, a Fort Worth compounding pharmacy facing federal scrutiny, is a cautionary tale of the intersection of physician investment opportunities, the deterioration of relationships and the significant danger when prudent structuring is ignored or deficient.

Physician investment models have become prevalent within the health care industry. Physicians face increasing financial pressure due to declines in reimbursements, difficulty in collecting out-of-network billings from payors, or increasing competition from non-traditional deliveries of medicine (i.e. telemedicine).

Aware of these pressures, non-providers are creating opportunities for physicians to participate in health care ancillaries, whether it is prescribing pain creams, ordering toxicology, DNA or genetic testing, or prescribing compound pharmaceuticals.

The RXpress case highlights the importance of careful, strategic planning in implementing physician-owned companies and marketing models within the health care industry.

RXpress is the subject of a federal investigation accused of paying kickbacks to physicians for writing prescriptions and paying sales reps commissions to market its services to physicians. RXpress came under the spotlight due to two factors.

First, Tricare (the military’s health insurance program) was involved, so Federal law is involved and the federal government is much more likely to investigate than a state government. Second, accusations stemmed from disgruntled business partners, so the problems came to light from an internal source.

While the factual details and legal positions for the RXpress matter are not known, it is not difficult to project the legal issues. The following synopsis of the law outlines the most common legal issues in physician investment arrangements.

The Federal Anti-Kickback statute, in general terms, prohibits knowingly and willfully soliciting or receiving any remuneration in return for referring a federal program patient to a person. Violations can result in both criminal and civil penalties, exclusion from Federal health care programs and loss of physician medical licenses.

The Office of Inspector General (“OIG”) enacted safe harbors so that transactions satisfying every element of a particular safe harbor would not be considered violations. When evaluating a model within the context of the Federal Anti-Kickback statute, each independent arrangement in the chain of relationships must be evaluated to determine if each, on their own, can withstand scrutiny.

The two most frequently relied upon Federal Anti-Kickback safe harbors in these scenarios are: (1) the Investments in Smaller Ventures safe harbor pertaining to the physician ownership; and (2) the Personal Services and Management Contracts safe harbor pertaining to the marketing arrangement.
The Investments in Smaller Ventures safe harbor generally is used in a physician-owned ancillary or physician-owned marketing/management service organization. The safe harbor requires eight elements be met including the often misquoted 60/40 bright line ownership and revenue tests. Because of the rigidity to meeting the tests, the 60/40 rules are difficult to satisfy.

In addition to the safe harbor, the OIG has expressed concern about these types of physician owned joint ventures. The OIG has provided several indicators regarding the operational structure of these models. Taken together, the safe harbor and the OIG's additional guidance require both proper structure and proper implementation of the physician-owned business.

The Personal Services and Management Contracts safe harbor generally applies to compensation arrangements (as opposed to an ownership arrangement). To satisfy the safe harbor, the marketing arrangement must meet six elements.

The most difficult to meet is the requirement that aggregate compensation paid over the term of the agreement must be set in advance and be consistent with fair market value. Most importantly, the compensation must not be determined in a manner that takes into account the volume or value of any referrals or business.

This requirement flies in the face of the typical sales commission compensation arrangement found in most any industry. The OIG has identified several suspicious characteristics of these arrangements. Again, prudent planning and structuring is needed to ensure these marketing arrangements can legitimately and effectively accomplish their intended business purposes.

The final piece of the regulatory puzzle for these types of arrangements is state law. In Texas, the state has a broadly written anti-kickback statute that applies even when federal programs like Medicare/Medicaid/Tricare are not involved.

Texas has provided an exception to allow any payment, business arrangement, or payment practice permitted by the Federal Anti-Kickback statute or any regulation adopted (i.e. safe harbors). Therefore, even if dealing with exclusively private pay or non-federal commercial payors, Texas physician-owned businesses must still follow the same rules and guidelines outlined by the Federal Anti-Kickback statute.

While the federal government is the 800-pound gorilla, Texas has been notoriously silent when it comes to regulatory oversight and enforcement. However, this silence should not be interpreted as a carte blanche invitation to structure arrangements that may run afoul of the Texas Anti-Kickback law.

Uncovering questionable arrangements and subsequent exposure comes typically not from the government itself but instead from reports or complaints filed by patients, former employees, competitors or, as evidenced by the RXpress case, jaded business partners.

The RXpress investigation can be traced to the apparent dispute among the partners. Proper planning to set expectations and partnership rules can significantly mitigate the risk that a business dispute will blow up the business or, even worse, expose a regulatory violation.

While there is comprehensive documentation needed to properly structure and define the relationships, the big risks can be simplified to four primary areas. The four C’s that tend to make or break a partnership are: (1) Cost, (2) Compensation, (3) Control, and (4) Contingencies.

The cost to buy into the partnership may seem simple at first blush. The cost issue is really just defining how much the purchaser will be
paying for ownership and how much ownership the owner is selling. However, in these physician-investment arrangements, the currency the sellers want is referrals which, as noted above, is illegal. Consequently, because referrals cannot be factored into the cost yet there may be unspoken expectations by both sides as it relates to referrals, conflict can arise. It is important with cost not just to set the price and amount to be sold, but to ensure it is set at fair market value and train the parties as to the importance of not being allowed to factor referrals into the expectations.

Compensation is another common issue that can lead to a business dispute. These arrangements typically have physicians and non-physicians as owners. The physicians do not typically have an active day-to-day role in the business, while the non-physicians tend to exclusively manage the daily operations. It is important to define up front the parameters for any compensation to be paid to a partner for the handling of such day-to-day operations.

Control is a third area to be defined to avoid business disputes down the line. It is common for the non-physicians and physicians to be aligned with their own group. The non-physicians want control because they generally own 60 percent and typically are in charge of the management of the business. The physicians want control because they feel like they are the engine that drives the business. This all can be alleviated with up front discussions and documentation of the decision making responsibilities and accountability among the partners.

The contingency planning is the final area to address to avoid a future business dispute. The contingency planning, or buy-sell planning, is defining what happens under various scenarios where a partner will leave. It is the last stop before litigation if a conflict leads to the point that a partner needs to leave the business. The contingency planning should address any other times a partner will voluntarily or involuntarily sell ownership. The planning should define the price or valuation process as well.

Traversing the health care industry can be an arduous task; a delicate balancing act between advantageous business terms and regulatory compliance.

For the non-providers seeking to gain access to the market and bring opportunities to providers, strategic alliances with advisors equipped with industry specific experience is key in navigating the complex rules and regulations governing these arrangements.

While most ventures and arrangements can be accomplished, some may require sacrifice to fall within the protection of applicable safe harbors and mitigate the risk needed to achieve a level of comfortableness for all those involved. This will also help mitigate potential issues that could arise upon deterioration of a business partner relationship.

However, creating opportunities that can withstand the spotlight of either the federal government or, eventually, the Texas government and other regulatory bodies can be a differentiating factor allowing a venture to stand out in an already-saturated market.

Careful analysis of each opportunity is required to identify viable, but most importantly, sustainable ventures that will survive the ever-present scrutiny that exists in the health care industry.

The life cycles of imaging centers, compound pharmacies, and physician-owned distributors have taught us that as the scrutiny intensifies, eventually those that remain do so because they were established from the beginning to adhere to, as close as possible, the applicable rules and regulations affecting such a venture. For physician investments, there is a fine line between profits and prison.

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