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LEGAL



ASC REGULATORY AREAS THAT DEVELOPERS NEED TO PAY ATTENTION TO

Written by [Richard Romero](#) | Nov 9, 2016 | [0 Comments](#)



The Ambulatory M&A Advisor has written about urgent care business development and the legal steps that need to be taken into account during the start-up stages of the business. Although some regulatory issues may appear similar when it comes to hiring and the structure of an ASC, healthcare lawyers say that there are also some stark differences that make ASC regulations stand out from the usual crowd.

Mark F. Weiss, attorney, owner of The Mark F. Weiss Law Firm explains that many business practices which are completely legal in industry in general, constitute federal and/or state crimes or trigger significant penalties when engaged in in the context of a healthcare related-business.

A prime example of this would be the conduct barred by the federal Anti-Kickback statute which prohibits the offer, acceptance, payment or receipt of any remuneration in respect of the referral of a federal health care program inpatient, Weiss says. Additionally, the federal law commonly known as “Stark” prohibits physicians from referring Medicare patients for certain services (defined as “designated healthcare services”) to entities in which they have an ownership or investment interest.

“Those laws are merely examples. The important thing for the founders of healthcare related businesses to remember is that compliance issues are interwoven into the fabric of the business just as much as are issues of ownership, control, and so on,” he says.

Don Weinbren, Shareholder, Trenam Law says when discussing the top regulatory issues in ASC development, it depends upon who is developing the ASC, but from a legal standpoint, anyone developing an ASC would want to make sure that, whether it is single specialty or multi-specialty, hospital owned or physician partly owned, the entity is structured in a way that will comply with the ASC Safe Harbors under the Medicare Antikickback Statute. That makes things simpler for everybody involved in the long-run.

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Even though the federal government views the ASC as an extension of the physician's practice, which is why we have Safe Harbors in the first place, Weinbren says they still are an area in which there have been some unfavorable rulings.

"Let's say you are developing an Orthopaedic Surgery Center; you have a physician group that has a Physiatrist in it who is not going to be doing work in the ASC; or, there are Ophthalmologists who will be performing surgeries in the surgery center, but there also are Optometrists in the group. In structuring the entity to comply with the Safe Harbors, you will need to ensure that the only physicians who invest in the ASC are those who actually do work at the facility," Weinbren says.

"These examples show where the the government has ruled in a couple of Advisory Opinions. The government basically says that you cannot have the physician who will not be working in the ASC, but who will be referring business to those who do services there, being given an opportunity to invest in the entity. That is viewed as them receiving the investment opportunity in exchange for their referrals. Thus, the ASC developer would want to look out to ensure that they do not run afoul of the fraud and abuse laws."

Recruitment Regulatory Thoughts

Barry Rosen, attorney with Gordon Feinblatt says that when thinking about recruitment issues with a new ASC, often, the facility isn't really hiring the surgeon; the surgeon is actually hiring the facility.

"It is more like the ASC is a hotel. It is possible that an ASC would hire a surgeon, but it is just as likely that it is really the surgeon who may be investing in the ASC because the surgeon would like a dividend if they earn a profit," Rosen says.

"You do grant privileges to use the surgery center, because you want to make sure that surgeons that come to the ASC are licensed, and are not getting in trouble and hurting patients. If you don't go through a process of credentialing them, the ASC could get in trouble for letting an unqualified doctor touch the patient at the surgery center."

Weiss says when recruiting, first, it's important to consider that state law governs whether a lay-owned healthcare business can or can't employ physicians or even offer physician services rendered through subcontracted physicians.

Some states, California and Texas, for example, have prohibitions against that conduct, referred to as prohibitions on the corporate practice of medicine, he says.

"Of course, those restrictions don't apply to professional entities such as medical corporations which employ physicians, but we're not dealing with those entities here; rather, we're dealing with lay and other investor-owned businesses.

That said, there are literally hundreds of mistakes that can be made in engaging physicians. Here are a few questions and considerations: Are you hiring employees or future partners? This impacts the recruitment process in respect of the personality and drive that you must identify. What if any promises are being made as to future ownership, if any? In respect of the regulatory regime that I described as "Stark," above, and any state counterpart, you need to be careful to make certain that your relationship with engaged physicians falls into protected territory in order not to trigger a violation," Weiss says.

Finding Legal Counsel and Why it Matters

Weinbren says there is a lot of overlap between lawyers who develop businesses and those who do M&A work, but there are some issues on which M&A attorneys might not focus.

"For example, when you are structuring the entity, some of the considerations may be a little different than when you are structuring the purchase of an existing ASC. I would think that you would want to find a lawyer or a law firm that has multiple competencies. For number one, when you are structuring the creation of an ASC, you have to recognize, especially if you are going to be selling interest in the ASC to the physicians who are going to work there, you need an attorney who understands securities law, tax law and buy-sell planning, as well as federal, state and local laws as they relate to asset protection for the owners. All of these issues will come into play in drafting the documents for the entity and the ASC investment," Weinbren says.

Weiss says that if a business owner fails to obtain legal counsel or just ignore regulatory issues all together, at the extreme, the danger is that you're committing a crime.

"For example, over the past year or two, there's been an increase in reported and observed instances in which businesses have been set up to market pharmaceuticals, pain creams, for example, that violate the federal Anti-Kickback Statute (a criminal offense), violate physician licensing restrictions as well as other

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federal and state criminal prohibitions. Yet, on paper to the lay person, they might be mistaken as remarkable business ventures," Weiss says.

Weiss notes that the same range of regulatory issues applies as well to those who are acquiring an already existing healthcare venture. Unfortunately from that position, it's possible that a business has been operating "successfully," (at least from an accounting and general business perspective) for a number of years even though, from a regulatory perspective, the business is simply a time bomb waiting to explode. Whether the structure and be defused (and, actually, whether the danger would even be apparent from the due diligence process) depends on the sophistication of those assisting in that vetting process.

Weinbren and Weiss say that meeting with legal counsel on a scheduled basis during ASC development is the best way to check off the right marks on the regulatory list.

"I think there should be at least three initial meetings. The first meeting is to flesh out what the client's intentions and develop the structure of the entity. That will allow the attorney to start drafting the documents to create the entity, to develop its governing documents and the securities offering materials, etc.," Weinbren says.

"The second meeting would be to work through a check list of regulatory issues that the ASC needs to consider in its building and compliance with state and local laws and licensing, as well as the Federal requirements for conditions of participation in Medicare and Medicaid. This often takes two meetings. Then, I would think that you ought to be checking in with your attorney periodically just as a quality check. As you are going along and meeting with potential investors, it is prudent to go back and talk to your attorney to make sure that what you are doing is how he structured it. You could make inadvertent mistakes that could jeopardize the venture or cause unnecessary legal issues."

Weiss says in a sense, these meetings are like asking your doctor to confirm that you are absolutely healthy! Absence of evidence is not the same as evidence of absence.

"The most efficacious route is for business owners to obtain and involve their healthcare counsel at the earliest stage of the project. Mistakes made at the earliest stage can, and usually do, come back to disrupt the progress of a deal later in the process and may not become evident for some amount of time, after which they engender further delay or even abandonment of the project," Weiss says.

If you have an interest in learning more about the subject matter covered in this article, the M&A process or desire to discuss your current situation, please contact Blayne Rush, Investment Banker at 469-385-7792 or Blayne@AmbulatoryAlliances.com.

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