Ambulatory Surgery Center
Transactional, Regulatory and Compliance Legal Practice

Ruder Ware has developed an active practice counseling ambulatory surgery center providers and has served as special counsel in several cases involving ambulatory surgery center exclusions. The firm's health care and compliance attorneys are knowledgeable on the numerous legal and regulatory requirements that are applicable to ASCs. The regulations applicable to these entities are complex and nuanced. The consequences of failing to comply or with taking improper steps to exclude providers can be very costly.

Some of the issues that our health care practice has recently addressed include the following:

- Counseling ASC's on the application of the Stark law, Anti-Kickback Statute, and ASC safe harbor issues.
- Advising and representing providers on issues relating to conditions of participation and governmental surveys.
- Representing organizations in preparing and submitting self-disclosure to the government.
- Development of ASC investment entities.
- Establishment of ASC compliance programs
- Decisions regarding exclusion of "under-performing" providers.
- Structuring exclusion provisions to minimize risk of violating regulations or enhancing the risk of litigation.
- Sale and purchase of surgery centers.
- ASC licensure and governmental approval.
- Compliance with patient confidentiality and privacy laws.
- Risk assessment, audits, compliance work plans, staff compliance training.
- Contractual relationships with outside parties.
The Importance of Specific Experience with ASC Matters

Over time, we have seen many ambulatory surgery centers that were structured in ways that expose the participants to unacceptable levels of legal risk. This often occurs when an attorney, consultant, or owner tries to structure the organization without a complete understanding of applicable regulatory requirements. Some structures that we have seen are based on operating agreements that are similar to those used in other types of businesses, such as real estate companies or other business types. We find that even a simple knowledge of applicable regulatory safe harbors can result in an organizational structure that leave participants open to risk. These organizations can go along quite nicely until there is an event. That event might be an audit, a whistleblower, a departing owner, or an under-performing provider who is removed using the process established under the operating agreement. This often results in a great deal of turmoil for the center and significant costs associated with negotiation, settlement, and litigation. Not all of the risks associated with these organizations can be avoided, but having seen a number of structures and disputes, it is clear that risk can be greatly reduced if a proper structure is adopted from the beginning.

Similar issues arise in connection with the purchase or sale of an ASC or an ownership position in an ASC. The purchaser needs to conduct appropriate due diligence of the target organizations. This due diligence must include the legal structure but should also extend to past activities that could result in post-acquisition risk. Failure to conduct knowledgeable due diligence can completely change the financial outlook of a contemplated investment because of the risk of regulatory and legal risk. It is important to note that not all issues that are discovered through due diligence necessarily result in rejection of a transaction. Knowledge of potential risks affords the opportunity to address these issues through the negotiation and acquisition process.

Our health care team includes an attorney who is certified in health care compliance and who has focused much of his activity on addressing compliance issues for surgery centers. Contrary to popular belief, surgery center compliance programs cannot simply "parrot" the safe harbor regulations. This will inevitably result in risk to the organizations. An ASC must be prepared in the overall context of the Anti-kickback Statute as well as other applicable regulatory requirements. This requires attention to certain nuances that can only be identified and addressed through experience handling ASC divestiture and regulatory cases. We have seen several surgery center that have been subject to conflict and unnecessary expense because they simply reiterated the ASC safe harbor provisions in their operating agreement and/or compliance program. We have also seen cases where unnecessary and large expense was incurred addressing issues caused by inconsistent use of terms and reliance of regulatory comments that ultimately create ambiguity.
National Consulting Practice and Litigation Expertise Support

Our experience in compliance and ambulatory surgery center regulatory issues has resulted in being retained by local litigation counsel from various parts of the country to provide support on the unique regulatory issues involving ASCs. National support in legal disputes and ASC compliance program issues has become the center of our ASC practice. Unlike some of the larger national firms, we work cooperatively with our local counsel partners, without risk of interfering with existing relationships that local counsel may have built with ASC participants over long periods of time. Business or litigation counsel often finds that the expert on ASC law in their area is stationed at a large, national health care law firm. Our smaller "boutique" firm is much less threatening. Additionally, our practice and reputation in this area results from our working relationship with other lawyers. We do not and cannot see these relationships as "predatory" in nature.

Our Ambulatory Surgery Center Attorney

**John H. Fisher** has practiced health care law for over 25 years. One of John’s significant areas of expertise involves the regulatory and business aspects of ambulatory surgery centers. Over the years, John has represented numerous clients on legal and compliance issues related to ambulatory surgery centers. John consults as a subject matter expert and provider legal backup to other attorneys and law firms from around the country on issues relating to ambulatory surgery centers. Some of John’s more recent ASC related projects include:

- Representation of an ASC in connection with the exclusion of non-complying owners.
- Representation of excluded providers in litigation and settlement.
- Creating operating documents that comply with ambulatory surgery center safe harbors and other applicable regulatory requirements.
- Creation of policies and procedures required to gain certification as an ASC.
- Consultation with local litigation attorneys regarding regulatory issues relevant to ASC litigation.
- Consultation with ASCs on establishment of compliance programs and identification of related risk areas.
- Assisting ASC providers in addressing detected deviations in operating and compliance requirements.