

Overview of a Suggested Legal Structure for Establishment of Sleep Centers

The following overview is intended for informational purposes only and is not to be construed as legal advice. Those interested in establishing the legal framework for a Sleep Center should consult with a qualified attorney.

I. Introduction

Sleep Medicine is in many ways ahead of the law at this time. In other words, although there is an ever increasing body of laws and regulations which have been specifically created with Sleep Medicine in mind, there remain many unanswered questions at present.

One such question relates to how to establish physician owned Sleep Centers in a manner which complies with the federal anti kick-back law. In summary, the anti kick-back law provides for the imposition of substantial criminal and financial sanctions against physicians who are found to have participated in illegal patient referral arrangements.

Regulatory officials have provided guidance for compliance with the anti kick-back law in the form of what are known as Safe Harbors. Although there is at present no Safe Harbor specific to Sleep Centers, it appears that logical parallels can be drawn between Sleep Centers and Ambulatory Surgery Centers (or ASCs). Based on these parallels, a structure of developing Sleep Centers around the same basic legal framework as governs legally compliant ASC's is suggested as a means of striving for compliance with the federal anti kick back law, while at the same time offering a structure that also seeks to maximize legally compliant means of seeking to develop profitability for the member/owners of Sleep Centers.

II. Overview of Federal Ambulatory Surgery Center Safe Harbor

Prior to 1999 it was unclear whether physician ownership of ASCs violated the federal anti-kickback statute (42 USCS 1320a-7(b) which proscribes the offering or receipt of any remuneration in exchange for patient referrals covered by a Federal health care program such as Medicare or Medicaid. Violations of the anti-kickback statute can result in significant civil and criminal penalties, including imprisonment. Since most states have similar laws based on the federal regulations, compliance with anti-kick back rules and principals is of paramount importance.

In 1999 the Office of Inspector General (OIG) published a Safe Harbor applicable to ASCs. In essence, Facilities which meet each aspect of the Safe Harbor are 100% immune to the possibility of sanction under the federal anti-kickback statute.

On the other hand, the Safe Harbor is a legal guideline, not a mandate. Many ASCs are structured in a manner that meets many but not all requirements under the Safe Harbor. Structured properly, such Facilities are nonetheless completely compliant with applicable laws and regulations.

III. Specific Safe Harbor Provisions

Highlights of the above referenced Safe Harbor include the following provisions. This is not by any means a complete list. An experience health law attorney should be consulted when structuring provisions of this nature. Applying the following selected provisions to a Sleep Center will likely result in a structure which includes the following features, among others:

- a) The terms on which an investment in the Sleep Center are offered to investors must not be related to services rendered by the investors or the expected volume of referrals to the Center by investors.
- b) The Sleep Center and any person or entity connected to the Sleep Center must not loan investors the amounts (or any part thereof) needed to buy in to the Center. In other words, investors must be “at risk” in their investment.
- c) All distributions to investors must be directly proportionate to each investor’s capital investment in the Facility.

IV. Overview of How to Apply the ASC Safe Harbor to a Structure Designed to Create a Legally Compliant Sleep Center.

As outlined above, the ASC Safe Harbor presents one of the relatively rare instances where the law *requires* physicians to regularly use an entity, in this case an ASC, in which the physician has an ownership interest. The rationale for this is based on findings that ASCs often offer a number of benefits to patients including convenience, access to prompt care, and state of the art technology. These benefits are, however, illusory if physicians own interests in a Facility and do not regularly use the Facility to do cases. Not only do such owners increase the risk that the Facility could be found to violate anti-kickback statutes (state or federal), they also are an economic drain on the Facility by virtue of the fact that the physicians are taking profit distributions but not sufficiently adding to the economic viability of the Facility by regularly doing cases at the Facility.

The same concepts appear to be a logical fit with respect to Sleep Centers. Only those physicians who are active Sleep Medicine practitioners should be allowed to hold ownership interests in a Sleep Center which is designed to comply in concept with the ASC Safe Harbor.

Structuring a Sleep Center along these lines involves establishing an entity, such as a Limited Liability Company, and including a host of operating provisions designed to seek compliance with the Anti-Kick Back law based on application of the concepts found in the ASC Safe Harbor.

In addition, it is advisable that offering documents (and a subscription) agreement be properly prepared and utilized in a manner which complies with laws and regulations governing the sale of member interests in a Limited Liability Company or other entity.

V. Conclusion/Recap

In the absence of a Safe Harbor designed specifically for Sleep Labs, applying the framework of the ASC Safe Harbor to the legal structure of a Sleep Center appears to provide an appropriate mechanism for structuring a Sleep Center in a manner designed to comply with the Federal Anti-Kick Back Law.

With proper implementation, this structure also provides a framework for establishing other important aspects of the Center's governing documents, the end goal of which is creation of a Center which will provide excellent service to patients and allow physician Member/Owners to legally share in the facility fees associated with use of the Center.

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