

**PROPOSED BOARD OF MEDICAL EXAMINERS RULE  
COULD CLOSE MANY AMBULATORY SURGERY CENTERS**

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The proposed change in the New Jersey Board of Medical Examiners' ("Medical Board") rules regarding Ambulatory Surgery Centers will create new hurdles for these centers that could result in divestiture of physician and non-physician owners and closure of many centers.

New Jersey law, as with federal law, prohibits referrals by physicians to entities in which they have a financial interest. This prohibition is expressed in both an anti-referral prohibition and an anti-kickback provision. Under state law and regulation, there is an exception to the anti-referral prohibition if the service is provided at the practitioner's medical office for which the patient is billed directly by and in the practitioner's name, the so-called "private practice" exception. No definition of "medical office" or "billed directly by and in the practitioner's name" exists in current Medical Board rules. In fact, the current Medical Board rule's only reference to ASCs is a statement of what type of entity can bill a facility fee. (The proposed rules do not even mention facility fee billing.) ASCs have relied on numerous advisory letters issued by the Medical Board generally stating that the Board considers an ASC to be an extension of the physician owner's private practice, thus protecting the ownership interest under both the anti-referral and anti-kickback prohibitions.

Those ASCs that bill Medicare or another federal health care program are aware that a referral to your own ASC is a technical violation of the federal anti-kickback statute, which makes it a criminal offense knowingly and willfully to offer, pay, solicit or receive remuneration to induce or reward referrals of items or services reimbursable by a federal health care program. This is because the referrer's receipt of a portion of the facility fee is considered remuneration for the referral. While there is a federal ASC safe harbor that would provide protection from prosecution for the referral, many ASC owners recognize that the federal safe harbor is not mandatory and choose not to comply with every requirement of the ASC safe harbor. Under federal anti-kickback rules, failure to qualify for the ASC safe harbor does not mean the arrangement is unlawful. Rather, if such an arrangement came under scrutiny, it would be reviewed on a "case-by-case" basis, and the physicians involved know that they would have the chance to defend their ASC referrals as medically necessary, unrelated to the value or volume of their referrals, and without illegal intent.

Under the Medical Board's proposed rules, however, which has no "knowingly and willfully" requirement, there would be no option but to meet the federal ASC safe harbor and strict compliance is required with no opportunity to "defend" an arrangement that does not quite meet all of the criteria. And because the Medical Board's rules apply regardless of whether a federal healthcare program is the payor for the service, ASCs that do not bill federal healthcare programs no longer are exempt from meeting the federal ASC safe harbor. Because the Medical Board has chosen to use the federal ASC safe harbor as the litmus test under both the anti-referral and anti-kickback prohibitions, the ASC safe harbor would apply to all ASCs.

As a result, physicians who have operated under the understanding that compliance with the federal ASC safe harbor is preferable--but not mandatory--could no longer operate in New Jersey

without restructuring.

#### Federal Safe Harbor:

The federal ASC safe harbor, 42 C.F.R. §1001.952(r), has four different categories of exception depending on the type of owners involved. The criteria for the “multi-specialty” ASC safe harbor, which is the one the Medical Board uses as the basis for its ASC exception, follows this article.

In addition to physicians who are in a position to refer patients to the ASC and perform procedures there and hospitals which are owners with such physicians, the federal ASC safe harbor only allows other investors in an ASC under very limited circumstances. Such an investor cannot be employed by the entity or by any investor, cannot be in a position to provide items or services to the entity or any of its investors, and cannot be in a position to make or influence referrals directly or indirectly to the entity or any of its investors. Notwithstanding, under federal rules, investments by these parties are not necessarily unlawful, provided that payments made in return for their investment are not for the purpose of inducing or rewarding referrals. But the Medical Board rule makes compliance with this provision mandatory, resulting in divestiture of any investors who do not meet these criteria. Also, the federal ASC safe harbor is only available to certified ASCs. It is unclear, then, whether the safe harbor would even be available to a one-OR surgical practice that is not Medicare certified. In fact, the Medical Board does not define ASC, so it is unclear if the proposed rules apply equally to licensed ASCs and to one-OR surgical practices.

The federal multi-specialty ASC safe harbor also includes the “one-third” rules. The Medical Board’s proposed rule attempts to mirror these “one-third” rules in the federal safe harbor but is so inartfully worded that it results in confusion. Assuming the Medical Board intends to impose the “one-third” rules verbatim, this would require that: 1) each physician investor must derive at least one-third of his or her medical practice income from all sources for the previous fiscal year or previous 12-month period from his or her own performance of procedures that require an ASC or hospital surgical setting in accordance with Medicare reimbursement rules and 2) at least one-third of each physician's procedures that require an ASC or hospital surgical setting under Medicare reimbursement rules must be performed at the ASC in which he or she is investing. The “one-third” rules are perhaps the most difficult criteria of the federal ASC safe harbor to meet, but full compliance would be required under the proposed Medical Board rule.

The Medical Board has also added its own additional requirements and modifications to the ASC safe harbor that make meeting the exception even more difficult.

Unlike the federal safe harbor, the Board’s rule makes no provision for an owner of an ASC to be a group practice made up of physicians who would qualify as individual owners. The Board’s rule would result in forced divestiture of any owners who are not individual, qualifying physicians.

In addition, the Medical Board’s proposal appears to state that a practitioner owner can only refer patients to the ASC for procedures performed on those patients *by that practitioner*. If there are current instances where a physician owner refers a patient for a procedure but the procedure will be performed by a different physician, such a referral would no longer be allowed. The federal

ASC safe harbor, on the other hand, only states that physician owners must be physicians “who are in a position” to refer patients directly to the entity and perform procedures on such referred patients. It does not expressly prohibit the physician owner from occasionally referring the patient to another physician at the ASC for the performance of the procedure if that makes good clinical sense. Instead, the “one-third” rules are intended to curb any increased risk of remuneration for referrals among different specialists at the ASC.

Finally, the proposed rule follows federal law in requiring that a physician “fully inform” a referred patient of the physician’s financial interest in the ASC. However, under the Medical Board’s rule, a physician owner would not only have to provide notice to referred patients of his/her financial interest in the ASC, the notice would have to advise the patient that it might cost the patient more to have the procedure performed at that ASC and that the patient should consult his/her carrier to determine if, in fact, the patient will incur a higher cost.

If the Medical Board’s ASC rule becomes effective, nearly every ASC in the state will have to reassess its structure. Many will have to divest certain investors and, possibly, unwind completely or face penalties for violating the Medical Board’s prohibition on self referrals and kickbacks.

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