

Frequently Asked Questions on the Certificate of Need Process for Surgical Services

By ROSE WILLIS

Michigan is among many states that require entities to obtain a Certificate of Need ("CON") before performing most surgical services. While a CON is just one out of several legal and regulatory requirements that must be addressed in these situations, the process of applying for and winning approval of a CON from the Michigan Department of Health and Human Services' CON Program ("CON Program") can be time consuming and challenging. However, failure to properly comply with the CON process can result in unnecessary liability, additional costs, and delays to the project. Some of the frequently asked questions relating to CONs for surgical services include:

1. Do I need a CON for this type of surgery? Only those surgical services that would be performed in an operating room, and more particularly, in a freestanding surgical outpatient facility, certified ambulatory surgical center and licensed hospital site are covered by the CON Program. Surgeries that may be performed in the physician's

office are expressly excluded from the services covered by the CON Program. The state defines "surgery" broadly to include among other things cutting into any part of the body, reducing fractures or dislocations, repairing malformations or defects, and endoscopic procedures. With such a broad definition, when determining whether a CON is required, the focus is really on the location in which the service would be performed, and not on the type of surgery being proposed.

2. What is a surgical commitment? Written commitments from physicians are essential requirements under the CON Program in order to show "need" exists for the service. The number of cases that must be committed in order to secure a CON for the surgical service varies based on a number of factors specific to the project. For example, if the surgical facility is new, it must project at least 1,128 per proposed operating

room using available surgical case commitments from physicians. Whether a physician's cases are available to be committed can be a technical analysis that depends on, among other things, (1) where the cases were performed and (2) whether those cases were already committed during the prior 3 year period.

3. Can I purchase a surgical commitment? Securing a sufficient number of cases in physician commitments can be a challenging process. Generally, parties should not pay physicians, and physicians should not accept payment, specifically in exchange for issuing a physician commitment. Such payments may place the parties at risk of legal liability, including but not limited to risk of liability under the Federal Anti-Kickback Statute. If a physician engages a third party to assist with securing the necessary commitments, the physician must ensure the third party does not utilize improper methods to secure the commitments on the physician's behalf.

4. How long does it take to obtain a CON for surgical services and how can I speed up the process? Parties should estimate approximately 5-6 months from the filing of the Letter of Intent with the CON Program to the issuance of a CON. This timeframe may be longer if the CON Program reviewers have questions on any of the CON documents submitted, or if those documents were not accurately completed. This timeframe may be shortened if expedited review is requested from the CON Program for an additional fee. Availability of expedited review is subject to the CON Program reviewers' availability and schedule. However, if granted, expedited review could shorten the review period by at least 30 days. Finding the right counsel to organize the process from the start will avoid unnecessary delays. Before any CON Letter of Intent is submitted with the CON Program, the parties should have determined most of the information necessary to complete the CON application, including the availability of commitments and financing details.



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Rose Willis' practice focuses on healthcare regulatory, transactional and corporate law in her representation of healthcare providers and suppliers and other current or prospective participants in the healthcare industry. Rose regularly counsels healthcare industry clients.

5. Can I purchase a CON? A CON is an "asset" which may be acquired. However, the ease of which it can be purchased depends on the structure of the acquisition and the status of the CON proposed to be acquired. The acquisition of a CON as an asset requires that the purchaser seek approval through submitting a CON application and accompanying forms. Critical details in determining whether an acquisition CON would be successful include whether or not the CON was meeting its minimum volume requirements or has ever been acquired in the past. In contrast, the acquisition of the ownership interests of an entity that owns the CON does not itself require approval from the CON Program so long as the location of the service remains the same.

The CON process is information driven and can be challenging for the parties involved. However if the parties are properly prepared and have a good understanding of the requirements to win a CON, it should not unnecessarily delay the overall project nor should it place the parties at risk of unnecessary legal liability or cost.

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