PUBLICATION

CMS Advisory Opinion 2019-01: CMS Approves Physician-Owned Hospital's Plan to Use Dormant Remote Operating Rooms

September 20, 2019

A physician-owned hospital with operating rooms at a second campus that have been inactive since before March 23, 2010 received approval from CMS to include such spaces within the hospital's aggregate capacity limits, according to Advisory Opinion 2019-01. Although the "remote operating rooms" would require some modifications to return to full service, CMS concluded the hospital could count them in its baseline. Based on specific information certified by the hospital, CMS concluded that the rooms both "existed" and were "operational" on March 23, 2010.

Because of its physician ownership or investment interest, the hospital must satisfy certain requirements of the whole hospital exception to the Stark Law (Social Security Act § 1877(d)(3)) if it wishes to submit claims to Medicare for designated health services (DHS) referred by its physician owners/investors. As amended by the Affordable Care Act (ACA), the whole hospital exception also restricts the hospital's expansion so its capacity does not exceed the aggregate number of operating rooms, procedure rooms, and beds for which the hospital was licensed on March 23, 2010. Absent the satisfaction of these conditions for the exception, the hospital would be prohibited from presenting such claims for DHS to Medicare.

The circumstances of the remote operating rooms were the result of a 2007 hospital merger, through which the hospital acquired a facility with eight licensed beds and four operating rooms. Sometime between 2007 and 2010, the hospital discontinued scheduling surgical procedures at the smaller facility because patient volumes could not support dual-campus operations. However, the hospital maintained and certified to CMS that on March 23, 2010, the remote operating rooms were:

- Fully operational and available for use, if needed;
- Not used for any other clinical activities and did not undergo any structural modifications as a result of the merger;
- Fully equipped to support patient care, including the presence of required medical gases, vacuum, electrical, mechanical, lighting, and a fully operational pre-operative assessment area and post-anesthesia care unit;
- In full compliance with all federal and state requirements for operation, including safety and environmental standards; and
- At a facility fully accredited by the Joint Commission.

Subsequently, because the operating rooms in use at the hospital's main campus required lighting updates, lights from the latent remote operating rooms were removed in late 2011 to complete the main campus lighting updates and were never replaced. Thus, since that time, the remote operating rooms have not been fully equipped for patient care. Further, the hospital advised it currently utilizes the space for the provision of therapy services. Nevertheless, the hospital asserted that, if needed, it could restore the space to fully operational surgical rooms in a matter of a few days, mainly through undertaking lighting replacement and sterilization measures. The hospital also certified that its governing state agency confirmed, following state verification of compliance with current ventilation standards, that it could replace the lighting and begin use of the remote operating rooms for surgical procedures.

CMS determined the remote operating rooms could permissibly be included in the hospital's "baseline number of operating rooms, procedure rooms, and beds" (42 C.F.R. § 411.362(a)) for the purposes of complying with the regulatory prohibition against facility expansion (42 C.F.R. § 411.362(b)(2)) based on its interpretation of the limitation on expansion as applied to operating rooms. Citing its prior interpretive guidance with respect to applying these expansion limits, CMS noted the limits apply to "the number of operating … rooms that existed at the hospital and were operational on March 23, 2010 (or December 31, 2010, if applicable).

Because *exist* is not a defined term under the Stark regulations, CMS applied the common dictionary meaning to reason that the remote operating rooms existed if they "occurred or were found, especially in a particular place," on March 23, 2010. And with respect to *operational*, CMS applied the applicable regulatory definition found in 42 C.F.R. § 424.502, wherein to be operational a provider or supplier, inter alia, has a qualified physical location, open to the public and fully equipped (as applicable to the provider or supplier specialty) to furnish the intended health care services.

Based upon the above-referenced certifications by the hospital, CMS believed there was adequate evidence the remote operating rooms existed and were operational to the extent required for the operation rooms to be included in the hospital's baseline on March 23, 2010. CMS pointed out that the hospital's certifications of the facility's full accreditation by the Joint Commission and the remote operating rooms' full compliance with all federal and state requirements for operation were important to its analysis. Finally, CMS addressed the lack of lighting equipment since 2011 and the current utilization of the space for therapy services. In CMS's view, its analysis of the remote operating rooms should only turn on their state of existence and operation on March 23, 2010 for the determination of inclusion, so these subsequent circumstances had no bearing on its conclusion.

Connecting the Dots

Prior to this Advisory Opinion, CMS last issued an advisory opinion in September 2017 (CMS-AO-2017-01). CMS last addressed physician-owned hospital expansion limits when it discussed unlicensed observation beds in 2016 (CMS-AO-2016-01) and concluded an increase in observation beds was compliant with Stark law based on certification that the state's approval process for the observation bed unit would not have resulted in additional "licensed" beds at the hospital.

Request for Information Regarding the Physician Self-Referral Law seeking public recommendations for improvement, CMS received comments on various areas of concern in its approach to advisory opinions. In light of those comments, on August 14, 2019, CMS published proposed changes and solicited comments regarding its advisory opinion regulations. Proposals for change under consideration include items such as broader consideration for the types of requests accepted, scope of individuals and entities that can rely on advisory opinions, permissible uses of advisory opinions, as well as other substantive and administrative issues. Comments for consideration on the proposals are due to CMS by September 27, 2019.