CMS Finalizes Rules Restricting Stark Whole-Hospital Exception

On November 2, CMS released a display copy of the 2011 Hospital Outpatient Prospective Payment System Final Rule. The display copy is available here, and the rule will be printed in the Federal Register on November 24.

Among many other provisions, the final rule implements provisions of the Patient Protection and Affordable Care Act (the "ACA") restricting the Stark law's whole-hospital exception. Much of the final rule follows the course that CMS charted in its proposed rule this summer. Key provisions of the final rule and CMS's preamble are:

- Definition of Procedure Rooms. CMS is limiting the definition of "procedure rooms" to the categories specified in the ACA (*i.e.*, only those rooms in which catheterizations, angiographies, angiograms or endoscopies are performed). Accordingly, physician-owned hospitals remain free to increase the number of procedure rooms in which other types of non-operative procedures are performed.
- Number of Operating Rooms, Procedure Rooms, and Beds. Absent a waiver, the ACA prohibits physician-owned hospitals from increasing the number of operating rooms, procedure rooms, and beds beyond that for which they were licensed on March 23, 2010. Recognizing that operating rooms and procedure rooms may not be separately licensed, CMS has instructed hospitals to count rooms that "were in existence and operational" on March 23. More significantly, CMS has interpreted the limitation as setting an aggregate cap — *i.e.*, that a hospital's *aggregate* number of operating rooms, procedure rooms, and beds cannot increase. Thus, a physician-owned hospital may, for example, retire an existing procedure room and open a new operating room. This interpretation may present an opportunity in particular for physician-owned hospitals with excess bed capacity.
- Relocation. CMS confirmed that physician-owned hospitals can relocate, in whole or in part, provided that the aggregate number of operating rooms, procedure rooms, and beds does not increase.
- Changes in Physician Ownership. CMS confirmed that the level of physician ownership may fluctuate over time, provided that it does not at any point exceed the March 23, 2010 level. This is the case even if the hospital itself redeems and reissues physician interests.
- Terms of Physician Ownership. In response to a comment, CMS stated that, "[d]epending on the facts," conditioning a physician's ownership on continued practice of medicine in the community "could implicate" the ACA's prohibition against conditioning ownership on a physician's ability to refer. Provisions similar to that described in the comment are not unusual. Physician-owned hospitals should review the terms of their operating, partnership, or shareholder agreements in light of this commentary.
- Patient Notification. CMS provided some guidance regarding the ACA's requirement for notification to patients of a hospital's physician ownership. CMS adopted a generally flexible approach, not imposing "any particular means of notification by a hospital of physician ownership." CMS was not flexible, however, in implementing the requirement for notification in advertising, and affirmed that

"*any*" (the emphasis appears in the preamble) public advertising for a hospital must disclose physician ownership.

CMS has not yet finalized the procedure for implementing the ACA's requirement that hospitals submit annual reports identifying each physician owner and describing the nature and extent of all ownership and investment interests in the hospital, but indicated that it would do so in a future rulemaking or guidance document. Similarly, CMS has not yet developed the process for physician-owned hospitals to obtain a waiver to permit expansion beyond the existing number of operating rooms, procedure rooms, and beds.

If you have any questions about these rules or any other changes brought about by health care reform, please contact your regular Ropes & Gray attorney.