CMS Implements Stark Changes in Health Reform: In-Office Ancillary Services Exception & Whole-Hospital Exception

Through the Patient Protection and Affordable Care Act (PPACA), Congress has used health reform to make several changes to the federal Stark Law. Chief among these changes are (i) enhanced disclosure requirements under the in-office ancillary services exception and (ii) the sunsetting of the whole-hospital exception. CMS has now proposed new regulations to begin the process of implementing these changes.

In-Office Ancillary Services Exception

The PPACA requires physicians claiming protection of the in-office ancillary services exception to satisfy new disclosure requirements. Specifically, physicians:

- must inform patients that certain imaging services are available elsewhere, and
- must provide patients with a written list of alternate suppliers.

By statute, the new requirements became effective as of January 1, 2010—nearly three months *before* the law containing the new requirements was passed by Congress and signed by the President.

In the July 13 Federal Register, the Centers for Medicare & Medicaid Services (CMS), as part of its annual Physician Fee Schedule update, released a proposed rule implementing the new disclosure requirements. Click here to see the proposed rule.

Most significant, CMS states that the PPACA disclosure requirement "shall not be effective until [CMS] promulgates a final regulation implementing this new requirement and the new regulation becomes effective." CMS proposes a January 1, 2011 effective date for the new regulation. *Thus, while obviously at odds with Congress's intent, CMS's regulatory position is that physicians need not initiate disclosures until January 1, 2011.*

The proposed rule addresses other disclosure issues, answering some questions and leaving others unresolved:

- The PPACA allows CMS to apply the disclosure requirements to an array of imaging services. CMS proposes limiting such requirements to the three modalities of MRI, CT, and PET.
- The CMS rule would require a physician's disclosure "at the time of the referral," acknowledged by the patient's signature. The rule does not address what should happen when the patient and ordering physician are not in immediate proximity, nor (while perhaps infrequent in an office setting) when the patient is incapacitated. These questions are unresolved.
- The rule would require each physician's disclosure to identify ten alternate "suppliers"— *i.e.,* not hospitals—within a 25-mile radius. If there are not ten suppliers within this geographic radius, physicians would be required to identify all those located within 25 miles.

Comments to the proposed rule are due on August 24. A final rule is likely to be adopted in the fall. In the meantime—and while earlier disclosure certainly is permitted and, as a matter of prudence, may be continued—those relying on the in-office ancillary services exception can take comfort in CMS's proposal that the disclosure requirements will not be effective until January 1, 2011 at the earliest.

Whole-Hospital Exception

The PPACA precluded development of new physician-owned hospitals, and strictly limited the expansion and operations of existing physician-owned hospitals.

On July 2, CMS posted a display copy of its annual Hospital Outpatient Prospective Payment System update, slated for publication in the Federal Register on August 3. A copy is available here. In the update, CMS proposed the first of several rules implementing the PPACA's changes to the whole-hospital exception.

The proposed rule resolves some inconsistencies in the statute and outlines basic requirements, but leaves much for later. Of most immediate importance:

- The PPACA requires physician-owned hospitals to have physician ownership as of December 31, 2010, but then inconsistently prohibits physicians' aggregate percentage ownership from exceeding the level as of March 23, 2010. The CMS rule essentially picks the March date. Thus, hospitals not physician-owned as of March 23 cannot become physician-owned now or in the future.
- The PPACA prohibits any increase in "the number of operating rooms, procedure rooms, and beds for which the hospital is licensed" beyond the number as of March 23, 2010. The CMS rule applies the cap on operating rooms and procedure rooms "regardless of whether a State licenses these rooms." CMS limits its definition of "procedure room" to rooms "in which catheterizations, angiographies, angiograms, and endoscopies are performed." CMS has postponed until later the publication of proposed rules implementing the process by which hospitals can seek approval to expand beyond the March 23 levels.
- The PPACA requires physician owners to disclose their ownership interests to patients, and requires hospitals to disclose physician ownership on their web sites and in advertising. As with the in-office ancillary services exception, the CMS rule would require physicians' disclosure to be written and given "at the time the referral is made." The proposed effective date for the disclosure requirements is September 23, 2011.

Comments to the proposed rule are due August 31. In light of the strict approach emerging now from CMS as well as Congress, physician-owned hospitals should be cautious in taking any actions that could jeopardize their grandfathered status under the new regime.

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