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CMS Clears Up Stark Deadline Confusion and Proposes Implementing Regulations for Whole Hospital and Rural Provider Stark Exceptions

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Clearing up some of the confusion surrounding deadlines for compliance, CMS issued proposed rules for implementation of the health care reform legislation changes to the whole hospital and rural provider exceptions to the Stark Law as part of the Cost Year (CY) 2010 OPPS/ASC Proposed Rule. The health care reform legislation amended the rural provider and "whole hospital" ownership exceptions to effectively bar future physician investment in hospitals, while providing a limited grandfathering provision for existing hospitals that have physician investment and a provider agreement by December 31, 2010.

CMS notes that it received numerous inquiries regarding how the following various deadlines in the statute work together.

- The hospital must have physician owners and investors, and a Medicare provider agreement in effect as of December 31, 2010.
- The percentage of the total value of ownership or investment interests held in the hospital, or any entity whose assets including the hospital, by physician owners and investors in the aggregate must not exceed such percentage in effect on March 23, 2010.
- With limited exception, a hospital cannot expand the number of operating rooms, procedure rooms or licensed beds that were in place as of the March 23, 2010
- The hospital must not have been converted from an ASC on or after March 23, 2010
- Compliance with the exception by September 23, 2011.

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CMS takes the position providers must comply with all of the requirements including disclosure by September 23, 2011 and failure to satisfy the individual earlier deadlines will preclude the use of the revised exceptions after the earlier deadline has passed. For example, the exception requires that the percentage of total value of physician ownership in the hospital, in the aggregate, must not exceed such percentage as of March 23, 2010; therefore, if a hospital had no physician ownership as of March 23, 2010, the hospital will not satisfy the revised whole-hospital and rural provider exceptions.

In addition to clarifying deadlines, CMS proposes promulgating a new regulatory provision, 42 C.F.R. § 411.362, to implement the statutory requirements. Aside from merely incorporating the statutory requirements, CMS makes the following substantive proposals:

- **Limitation on Expansion of the Facility**

- The health care reform legislation limited the number of operating rooms, procedures rooms and beds at a physician-owned hospital to those that were licensed as of March 23, 2010; however, the statute was somewhat ambiguous with respect to the application of this limitation to facilities that obtain their provider agreement after March 23, 2010, but before the December 31, 2010 deadline. CMS states that these provisions must be read "harmoniously" and proposes regulatory language specifying that if a hospital did not have a provider agreement in effect as of March 23, 2010, the limitation on the number of licensed operating rooms, procedure rooms and beds will be set as of the effective date of the provider agreement.
- The limitation on expansion of operating rooms and procedure rooms will apply regardless of whether a State requires such rooms to be licensed.
- "Procedure rooms" is defined in the statute to include rooms in which catheterizations, angiographies, angiograms, and endoscopes are performed, except the term does not include emergency rooms or departments. CMS has discretion to include additional rooms by regulation, but has chosen not to as of this time. CMS is soliciting comments regarding whether "procedure rooms" should include additional

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rooms where procedures are performed, such as CT or PET scans.

- CMS states that it will promulgate regulations concerning the process for hospitals to apply for exceptions to the expansion limitations in a later rulemaking.

- **Preventing Conflicts of Interest**

- The health care reform legislation requires a hospital to submit an annual report to CMS identifying all physician and non-physician owners and investors in the hospital. CMS states that proposals regarding the reporting process will be part of a later rulemaking.
- Under the health care reform legislation, hospitals are required to develop procedures to necessitate physicians referring to the hospital to disclose to patients their ownership or investment interests in the hospital and, if applicable, the treating physician's ownership and investment interest.
 - CMS proposes that hospitals meet this requirement by requiring referring physician owners and investors to agree to provide such disclosure as a condition of continued appointment to the medical staff or for admitting privileges. CMS is soliciting comments on the benefits and drawbacks of this proposal.
 - Noting that a patient may see multiple specialists responsible for his or her care at the hospital, CMS states that it will not define "treating physicians" and will consider treating physicians to be any physician responsible for any aspect of the patient's care or treatment. CMS is soliciting comments on this approach.
- Under the health care reform legislation, a hospital must disclose the fact that it has physician owners and investors in any public advertising and on its public website. CMS seeks public input on the methods a hospital should be required to use in disclosing the information. For example, CMS would like comments on whether the disclosure should be made on a particular page within a hospital's website (i.e., home page, "About Us" page) and whether a minimum font size should be required.

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- **Ensuring *Bona Fide* Investment**

- The health care legislation enumerated seven requirements related to ensuring that physicians have *bona fide* investment interests in order for hospitals to qualify for the whole hospital or rural provider exception. Included among these requirements is the limitation on the aggregate percentage of physician ownership or investment interest in the hospital as of March 23, 2010 and other requirements to ensure that physician owners and investors do not receive more favorable investment terms, distributions or other benefits for the hospital or other owners/investors in the hospital. CMS proposes to incorporate these provisions in their entirety into the regulations and will issue further clarification in a later rulemaking *only if* CMS determines such guidance is necessary.

- **Patient Safety**

- To meet the requirements of the whole-hospital and rural provider exceptions, the health care legislation requires that a hospital that does not have a physician on the premises during all hours during a patient's stay must disclose that fact upon admission and obtain a written acknowledgement from the patient. In addition, hospitals must also have capacity to: (1) provide assessment and initial treatment for patients; and (2) refer and transfer patients to a hospital capable of treating a patient, where the hospital lacks such capability.
- CMS proposes that these requirements will apply to both inpatients and outpatients. Hospitals must meet these requirements no later than September 23, 2011.

- **Conversion from an ASC**

- Under the health care legislation, a physician-owned hospital will not qualify to use the whole hospital or rural provider exceptions if it was converted from an ASC on or after March 23, 2010. CMS proposes incorporating this requirement directly into the regulations.

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- **Publication of Information Reported**

- CMS is delaying any rulemaking with respect to the requirement that the Secretary publish and, update on an annual basis, the ownership and investment interest information reported by physician-owned hospitals.

- **Enforcement**

- CMS states that it will comply with the requirement that it establish and implement policies and procedures to ensure compliance with the new physician-owned hospital provisions by May 1, 2012. CMS does not propose any regulations on this topic at this time.

In addition to proposing amendments to the Stark regulations, CMS also proposes conforming amendments to the provider agreement regulations, 42 C.F.R. Part 489. The provider enrollment regulations were amended in prior rulemakings to incorporate patient disclosure requirements for physician owners and investors of physician-owned hospitals (including critical access hospitals). CMS proposes incorporating additional requirements that parallel the Stark regulations, including, among other things, the requirement for disclosure of physician-ownership on the hospital's website and other patient disclosures. CMS is soliciting comments as to whether amendments to the provider agreement regulations are necessary or whether the amendments to the Stark regulations, discussed above, are sufficient to provide guidance regarding the new physician-owned hospital requirements.

Ober|Kaler's Comments

Comments regarding the proposed rule are due to CMS by August 31, 2010. Physicians that currently hold an ownership or investment interest in a hospital, and hospitals with physician owners, should consider how the proposals will effect their continued compliance with the rural provider or whole-hospital ownership exceptions to the Stark law. Moreover, providers should be on the look out for upcoming rulemakings regarding other aspects of the exceptions not addressed in this rulemaking, including the process for reporting physician ownership to CMS and the means by which a hospital can seek an exception to the limitation on expansion of the number of operating rooms, procedure rooms and beds.