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Are We Clear Now? CMS Issues Proposed Rule Implementing Health Reform's "Whole Hospital" Restrictions

August 3, 2010

In the Hospital Outpatient Prospective Payment System Proposed Rule for calendar year 2011 ("OPPS Proposed Rule"), which appears in today's Federal Register,¹ the Centers for Medicare & Medicaid Services ("CMS") proposes changes to the Stark Law regulations to implement the amendments contained in the recent health reform legislation (the "Health Reform Law") to the Stark Law's "whole hospital" exception. In our earlier issue of *Health Reform IMPACT* addressing this topic,² we noted that various provisions of the amended whole hospital exception, including the interplay of certain dates set forth within the legislation, would remain unclear until Congress or regulators provide additional guidance. That guidance, which we will summarize below, has now arrived in the form of the OPPS Proposed Rule. However, despite the guidance offered in the OPPS Proposed Rule, much uncertainty remains, and additional rulemaking is anticipated.

What About The Confusing Interplay of Dates?

The Health Reform Law introduced three separate compliance dates relating to the whole hospital exception — March 23, 2010, December 31, 2010, and September 23, 2011 — but failed to explain the interplay among them. For example, it was unclear whether a hospital under development as of March 23, 2010 (the enactment date of the Health Reform Law) would be required to have physician ownership as of March 23 (the date beyond which aggregate physician ownership could not increase) or whether it could finalize its physician ownership sometime prior to December 31, 2010 (the date by which a physician-owned hospital must have in place both physician ownership and a Medicare provider agreement). Furthermore, it was unclear what Congress intended by establishing an over-arching compliance deadline of September 23, 2011.

In the OPPS Proposed Rule, CMS acknowledges that it received numerous inquiries regarding the significance of these dates. CMS proposes to reconcile these dates by requiring a physician-

¹ See [75 Fed. Reg. 46170](#) (Aug. 3, 2010).

² See "Closing the Whole Hospital Window: Impact on Hospitals and Physicians," April 6, 2010, [available here](#).

owned hospital to have had physician ownership in place as of March 23, 2010, in order to qualify for the whole hospital exception. Additionally, a physician-owned hospital must have a Medicare provider agreement that is effective on or before December 31, 2010. Finally, CMS states that the compliance deadline for all other provisions of the amended exception that do not contain an explicit deadline, including many of the requirements intended to ensure bona fide investments by physicians, will be September 23, 2011. A hospital may request an advisory opinion from CMS for a determination of whether an existing or proposed arrangement meets the requirements for bona fide investments.

Additional Ownership Hazards

Even if a hospital has physician ownership in place by March 23, 2010, there are additional hazards to navigate. Because the amended whole hospital exception prohibits an increase in "the aggregate percentage of ownership or investment interest held by physicians," hospitals with physician ownership must use extreme caution in any transactions involving the sale or transfer of units of ownership. For example, this prohibition could be violated, perhaps inadvertently, by redeeming ownership units held by non-physicians. In other words, if the number of units held by physicians remains unchanged, but the overall number of units held by investors decreases, the percentage of ownership held by physicians will automatically increase. As an illustration, if a hospital has 100 ownership units outstanding — 35 owned by physicians, five owned by the CEO, and 60 owned by Company A — and the hospital redeems and retires the CEO's units, then without changing the number of units owned by the physicians, the physicians' aggregate percentage of ownership has increased from 35% to 36.8%, resulting in potentially massive numbers of unlawful referrals.

Operating and Procedure Rooms

The Health Reform Law also amends the whole hospital exception such that, subject to limited exceptions, a physician-owned hospital cannot increase the number of operating rooms, procedure rooms, and beds for which it is licensed above the number as of March 23, 2010 (its "baseline" number). As written, the statute is unclear as to whether it would allow a physician-owned hospital that was under development as of March 23, 2010 (and, therefore, not yet licensed), to be completed and license its operating rooms, procedure rooms, and beds if completed by December 31, 2010.

In the OPPI Proposed Rule, CMS proposes to specify that a hospital will be limited to the number of operating rooms, procedure rooms, and beds for which the hospital is licensed on March 23, 2010, or if the hospital did not have a provider agreement in effect as of that date, but does have an agreement in effect on December 31, 2010, the effective date of such provider agreement. Thus, a physician-owned hospital that was under development on March 23 will be allowed to license its beds, operating rooms, and procedure rooms between March 23 and December 31, 2010, and comply with the amended whole hospital exception. CMS also notes that the limitation on expansion applies to operating rooms and procedure rooms regardless of whether a state licenses these rooms.

CMS limits the definition of procedure rooms to rooms in which catheterizations, angiographies, angiograms, and endoscopies are performed, but has solicited comments on whether the definition should be expanded to include rooms where additional services, such as CT or PET scans, are performed. Furthermore, CMS clarifies that, for those limited situations in which a

physician-owned hospital is granted an exception to this rule and permitted to expand, only those referrals made after the exception is granted will be protected (details on the exception process are forthcoming in additional rulemaking).

Notice Provisions

CMS also proposes regulations to implement two provisions of the amended whole hospital exception that require physician-owners to provide advance notice to patients. The first provision requires that physician-owned hospitals maintain procedures requiring referring physicians to disclose to patients, "by a time that permits the patient to make a meaningful decision regarding the receipt of care," their ownership interests and, if applicable, the ownership interests held by treating physicians. In the OPPS Proposed Rule, CMS proposes to clarify that the physician must provide written disclosure of the ownership interest at the time the referral is made. Pursuant to the Health Reform Law, CMS also proposes to add a regulation stating that, in the case of a hospital where a physician is not present in the hospital 24 hours per day, seven days per week, the physician-owned hospital must receive a signed acknowledgment from the patient prior to admitting, or providing an outpatient service to, the patient stating that the patient understands that a physician may not be present during all hours services are rendered to the patient.

Conclusion

CMS indicates in the OPPS Proposed Rule that it will issue additional proposed rules relating to the amended whole hospital exception at a subsequent date. Specifically, CMS states that it will propose rules relating to: the exception process whereby physician-owned hospitals can expand beyond their baseline number of beds, operating rooms, and procedure rooms; annual reporting of owners and investors in physician-owned hospitals; and publication of physician ownership information on the CMS Web site. Any comments on the OPPS Proposed Rule are due to CMS by August 31, 2010.

Based on the restrictive view of the amendments to the whole hospital exception evidenced in the OPPS Proposed Rule and because the OPPS Proposed Rule has not yet been finalized and additional regulations will be forthcoming, we are advising clients to exercise caution in implementing changes at syndicated hospitals that might affect their grandfathered status. If you have any questions about any aspect of the whole hospital exception, including CMS' proposed regulations to implement the Health Reform Law's amendments, please contact any of the attorneys in our Healthcare Practice Group listed below.

Also, please [click here](#) to visit our special Web page for Health Reform IMPACT.

Bass, Berry & Sims Healthcare Attorneys

H. Lee Barfield, II
(615) 742-6202
lbarfield@bassberry.com

Philip F. Berg
(615) 742-7908
pberg@bassberry.com

Krista Thornton Cooper
(615) 742-7734
kcooper@bassberry.com

Meredith Edwards
(615) 742-7823
medwards@bassberry.com

Mary Beth Fortugno
(615) 742-7739
mfortugno@bassberry.com

Valere Fulwider
(615) 742-7822
vfulwider@bassberry.com

Lauren Gaffney
(615) 742-7824
lgaffney@bassberry.com

Pooneh Ghiassi
(615) 742-7782
pghiassi@bassberry.com

Anna Grizzle
(615) 742-7732
agrizzle@bassberry.com

Elisa E. Harris
(615) 742-6553
eharris@bassberry.com

Angela Humphreys
(615) 742-7852
ahumphreys@bassberry.com

J. James Jenkins, Jr.
(615) 742-6236
jjenkins@bassberry.com

Seth A. Killingbeck
(615) 742-7707
skillingbeck@bassberry.com

David King
(615) 742-7890
dking@bassberry.com

Claire F. Miley
(615) 742-7847
cmiley@bassberry.com

T. Scott Noonan, Co-Chair
(615) 742-6273
snoonan@bassberry.com

Shannon Pinkston
(615) 742-7727
spinkston@bassberry.com

Cynthia Y. Reisz
(615) 742-6283
creisz@bassberry.com

Brian D. Roark
(615) 742-7753
broark@bassberry.com

Catherine J.B. Sloan
(615) 742-7789
csloan@bassberry.com

Danielle M. Sloane
(615) 742-7763
dsloane@bassberry.com

Nesrin Garan Tift
(615) 742-7903
ntift@bassberry.com

Leigh Walton, Co-Chair
(615) 742-6201
lwalton@bassberry.com

Elizabeth S. Warren
(615) 742-7719
ewarren@bassberry.com

Douglas M. Wolford
(615) 742-7917
dwolford@bassberry.com

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