The End of the Specialty Hospital Moratorium

How Hospitals Can Prepare for Changes

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The legal and regulatory environment of the healthcare industry is a web of complex rules suspended in a delicate balance. A change in any one of three interdependent factors—access, cost and quality—usually causes a wave of legal and regulatory activity.
Sometimes, legal and regulatory activity precedes a thoughtful wait-and-see approach, which is what happened with specialty hospitals, which increased dramatically in the 1990s. Although specialty hospitals have long provided various types of specialty care—such as women's health, children's health and cancer care—the specialty hospitals at the core of the controversy primarily provide services in cardiac care, orthopedics and surgery.

As physician-owned, for-profit specialty hospitals became more prevalent and attractive to the public, and began to adversely affect full-service hospitals, Congress and the federal government became increasingly concerned, and instituted a temporary moratorium in Nov. 2003, effectively halting their growth. The moratorium was intended to allow legislators and regulators an opportunity to analyze the impact of specialty hospitals on the healthcare industry, and to formulate legislative, statutory and regulatory responses.

On Aug. 8, 2006, the specialty hospital moratorium ended with the publication of the Center for Medicare and Medicaid Services' (CMS) final report to Congress on specialty hospitals, as required under the Deficit Reduction Act of 2005 (DRA). At the end of the moratorium, however, CMS implemented a strategic plan meant to minimize inequitable market advantage to specialty hospitals, and to discourage the formation of new specialty hospitals. This article discusses the practical impact of the final report; the applicable federal laws, regulations and policies; and how both specialty hospitals and traditional full-service hospitals can prepare for this dynamic change to the hospital service market.

Background: Controversy Surrounding Specialty Hospitals

Federal law defines a specialty hospital as one that is "primarily engaged in the care and treatment of cardiac, orthopedic, or surgical patients." It is interesting to note that other hospitals that do not provide a full array of medical/surgical services, such as cancer or long-term acute care hospitals, were not included in the definition of specialty hospitals. The rapid proliferation of these specialty hospitals aroused controversy because physicians were allowed to compete with traditional hospitals to provide cardiac, orthopedic and surgical services without providing all of the costly services required of traditional full-service hospitals.

The federal Physician Self-Referral Law (Stark law) prohibits a physician from receiving remuneration from referrals of Medicare patients for certain "designated health services" to those entities in which the physician or his or her immediate family members have a financial interest. However, under the "whole hospital exception" to the Stark law, physicians with a financial interest in specialty hospitals could refer Medicare patients to those hospitals.

Some critics have suggested that specialty hospitals do not meet the spirit and intent of the whole hospital exception. The whole hospital exception is one of many exceptions to the Stark law, and allowed physicians to refer Medicare patients to hospitals as long as:

1. the referring physician is authorized to perform services at the hospital; and
2. the ownership or investment interest is in the hospital itself, as opposed to a department within the hospital.

As a result, the number of specialty hospitals, most of which are for-profit corporations owned by physicians, multiplied from the early 1990s through 2003. The opponents of specialty hospitals insist that the whole hospital exception unintentionally created a loophole that allowed physicians to directly generate revenue for themselves. They argue that the physician owners and investors cherry pick and refer patients who need those specialty care services that provide a higher profit margin to their own specialty hospitals.

The diversion of more profitable patients from traditional hospitals in turn leaves the financial burden of caring for the indigent, underserved, and more cost-intensive patients to the traditional hospitals. Ultimately, this chain of events may cause financial distress for some traditional hospitals, and lead to:

1. closing emergency and trauma departments;
2. an increase in the number of unused hospital beds in the community; and
3. a reduction of specialists available for emergency department on-call services.

These factors, critics argue, have resulted in a reduction in the quality of care and an increase in healthcare costs.

Opponents also argue that if managed care organizations contract with specialty hospitals for the more profitable cases, traditional hospitals will be forced to close, and will eventually raise healthcare costs.

In response, the proponents of specialty hospitals argue that specialty hospitals provide patients with what they want: better service, higher patient satisfaction, state-of-the-art facilities that run more efficiently, improved clinical outcomes that result from streamlining specific services, and less expensive care. Advocates boast that specialty hospitals provide better customer service, with hotel-like accommodations. They also give physicians a sense of control over the operation and management of their practice without the usual bureaucratic interference from traditional hospital administration. In addition, specialty hospitals compel physicians to take
responsibility for the cost of providing healthcare, which contributes to more efficiency and lower costs.

In Nov. 2003, concerned about the potential impact of specialty hospitals on the healthcare system, Congress passed the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), which instituted a temporary 18-month moratorium on new enrollment applications of specialty hospitals. The MMA revised the whole hospital exception to prohibit physician owners and investors of specialty hospitals from referring Medicare patients to those hospitals, except for those specialty hospitals that were either already in operation or "under development" as of Nov. 13, 2003. The MMA also imposed restrictions on specialized services, the change in number of beds and physician investors for existing specialty hospitals. The MMA additionally required the secretary of Health and Human Services (HHS) and MedPAC to conduct studies of and make recommendations to address specialty hospital issues.

Although the moratorium expired on June 8, 2005, CMS extended its moratorium through Jan. 2006. Pursuant to the MMA, CMS announced its study recommendations, which included: 1) reformulation of payment rates for inpatient hospital services through diagnosis-related group (DRG) refinements and payment rates for ambulatory surgical centers (ASCs); 2) scrutiny of whether specialty hospitals meet the definition of a hospital under federal law; and 3) review of procedures for approval for specialty hospital participation in the Medicare program. CMS also stated that it would consider how provisions of the Emergency Medical Treatment and Labor Act (EMTALA)7 should apply to specialty hospitals.

Subsequently, Congress passed the DRA in Feb. 2006, which required the secretary of HHS to develop a strategic implementation plan regarding whether: 1) physician investments in specialty hospitals are proportional to investment returns; 2) the investment is a bona fide investment; and 3) the secretary should require annual disclosure of investment information. The DRA also required the secretary to consider the provision of care by specialty hospitals to Medicaid patients, patients receiving medical assistance under a state demonstration project, and patients receiving charity care. Additionally, HHS was required to draw up a strategic plan for enforcement of the specialty hospital moratorium.

CMS published its interim report in May 2006, incorporating its responsibilities under both the MMA and DRA. Then on Aug. 8, 2006, CMS published its final report to Congress on specialty hospitals, which includes a strategic implementation plan.

The most significant news in the final report is that the moratorium on new enrollment of specialty hospitals was lifted, effective Aug. 8, 2006, and CMS is now accepting new specialty hospital enrollment applications. CMS stated that it was unsure whether it had the authority to extend the moratorium. Regardless, CMS believes that a continued moratorium is unnecessary, because the three-year phase-in of the newly reformed inpatient DRGs is expected to reduce or eliminate the unfair incentives of physician owners and investors.

The other main initiative is that all hospitals will now be required to disclose physician investment and ownership information to CMS on a regular basis. Moreover, physicians referring patients to specialty hospitals may be required to disclose their ownership and investment interest in the hospital to patients. As explained in more detail below, the strategic and implementation plan is still being developed. Regardless, hospitals must be ready to comply with the strategic plan because some parts of the plan are already effective, and extensive changes may be necessary before the strategic plan is fully implemented.

**CMS's Strategic and Implementation Plan**

CMS's strategic plan for addressing the issues raised regarding specialty hospitals involves five basic components:

1. reformation and refinement of inpatient DRGs and ASC payment rates;
2. patient safety measures and EMTALA requirements;
3. promotion of transparency of investment by requiring the disclosure of financial information from hospitals and physicians;
4. enforcement actions emphasizing compliance with the Stark law, anti-kickback statute, and moratorium prohibitions; and
5. congressional consideration of a charity care mandate.

Of the strategies, CMS expects that the reformation and refinement of the inpatient DRG and ASC payment rates will have the greatest impact by decreasing or eliminating inequitable market advantage for specialty hospitals to cherry pick more profitable patients. In the end, CMS hopes that the new payment rates will discourage physicians and others from forming specialty hospitals that take advantage of the typically higher payments for certain inpatient and outpatient hospital services.

The FY 2007 DRG refinements include 20 new DRGs, modification of 32 others that better recognize severity of illness, and plans to phase-in a cost weighted system over a three-year period. These DRG refinements are expected to affect payments made to specialty hospitals. CMS also is working to close the gap between the payment rates for services provided at ASCs and hospital

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outpatient departments.

In addition, CMS will attempt to align the diametrically opposed financial incentives of the physician and the hospital. Currently, the payment system encourages physicians to perform as many services as possible, while hospitals strive to conserve resources and maximize profits. By establishing specialty hospitals demonstration projects in value-based purchasing, gain sharing and healthcare quality, CMS hopes to emulate the incentives that exist in specialty hospitals by encouraging physicians to actively participate in hospital governance and management, and by providing financial incentives for efficiency, quality and cost savings.

Second, CMS decided not to require all hospitals to have an emergency department, but has proposed that all hospitals, including specialty hospitals with specialized capabilities, must accept appropriate transfers of unstable patients under EMTALA. Moreover, CMS intends to require patient safety measures for all hospitals, regardless of whether they have an emergency department.

CMS also is developing specific guidelines and requirements within the Medicare conditions of participation for hospitals and specialty hospitals without emergency departments regarding patient appraisal, initial treatment and referral of emergency patients. In addition, CMS intends to take into consideration the recommendations regarding minimum patient safety standards from the Office of the Inspector General’s (OIG) on-going patient care and safety study.

Third, to promote the transparency of investment and ownership of hospitals, CMS will require all hospitals to periodically disclose ownership and investment interests, and compensation arrangements such as loans, profit distributions, dividends or other payments made between hospitals and physicians. CMS has not yet determined the scope of information for required disclosure, but will assess civil monetary penalties of up to $10,000 for each day past the deadline for failure to timely disclose requested information.

To curtail physician owners and investors from unnecessarily or inappropriately steering patients toward their specialty hospitals, CMS is contemplating having physicians disclose their financial interest to their patients. CMS also is considering ways to change the provider enrollment form to distinguish specialty hospitals from other types of hospitals.

Fourth, CMS plans to intensify its enforcement of the Stark law, federal anti-kickback statute, and False Claims Act to expose any financial arrangements between a specialty hospital and physicians that are not legitimately related to the physician’s level of ownership or investment. For example, CMS plans to take enforcement measures against entities that allow physicians to receive disproportionate returns on their investment or that sell interests to physicians on less than commercially reasonable, arms-length terms. These enforcement measures are intended to ensure the bona fides of physician investments in specialty hospitals.

CMS and OIG have clarified that they are suspicious of joint ventures because they might disguise inappropriate referrals among investors or between the investor and the venture. The OIG identified three areas of concern, including the manner in which: 1) the joint venture participants are selected and retained; 2) the joint venture is structured; and 3) the investments are financed and profits distributed. CMS also will continue its enforcement actions related to the MMA moratorium by investigating and recouping overpayments from specialty hospitals found to be in violation of applicable federal law.

Finally, CMS confirmed the results of the MedPAC and GAO studies that specialty hospitals provide proportionally less care to indigent, uninsured and underinsured patients in comparison to other reporting competitor hospitals, and that specialty hospitals had incurred much less bad debt from patient services. However, CMS avoids requiring minimum charity care at hospitals. It leaves it up to Congress to analyze the value of the community benefit of hospitals, both nonprofit and for-profit, and legislate accordingly.

In conclusion, CMS does not recommend that Congress amend the whole hospital exception to prohibit physician ownership of specialty hospitals. However, CMS continues to re-examine the definition of a hospital under federal law, which defines a hospital “as an institution that must primarily be engaged in furnishing services to inpatients,” to determine whether specialty hospitals meet this definition.

How Should Hospitals Prepare?

The final report neither directly alleviates the financial strain on traditional hospitals nor immediately prohibits specialty hospitals from taking advantage of inequitable market advantage. Rather, it establishes CMS’s general framework and approach toward specialty hospitals in the healthcare market, and foreshadows some issues that require more legislation and regulation. In the end, CMS’s message to Congress is that with a more sensitive payment system and continued regulatory oversight, natural market forces will equalize any perceived inequitable market advantage of specialty hospitals, and allow them to co-exist with traditional hospitals.

Traditional hospitals still must compete with specialty hospitals for patients requiring specialty services, and will continue to struggle with the financial burden of providing a disproportionate amount of care to underserved and high-cost patients. However, specialty
hospitals are not immune from financial risks. They must maintain a competitive edge by acquiring new technologies while balancing expenditures with their current and foreseeable financial status. Specialty hospitals also must overcome the unpredictability of market forces in niche specialties, emerging technologies, and changing reimbursement rates.

Still, the final report establishes some requirements and standards that will have an immediate impact on all hospitals. For example, the reformation of inpatient DRG and ASC payment rates affects all hospitals. CMS is relying heavily on the new payment rates to reduce the inequity between full-service and specialty hospitals.

It is unclear, however, whether the reforms will, in due course, have their intended effect. First, the new DRGs with cost-weighted adjustments will be phased-in over three years, while CMS has already started accepting enrollment applications of new specialty hospitals. Thus, the effect of DRG changes will not be evident immediately. Second, the phase-in may not effectively discourage the formation of new specialty hospitals, or eliminate inequitable market advantage, as expected. Even when the cost-weighted adjustments are in full effect, it is unclear whether the adjustment in payments would be enough to discourage the formation of new specialty hospitals.

Since all hospitals will be affected by the new rates, it is uncertain how traditional hospitals will fare. The new rates may not necessarily alleviate, but actually add to, their financial strain. However, given the time to mature, CMS’s strategy to reform the payments could allow for a more competitive, cost-efficient, quality hospital provider mix.

All hospitals will also be required to make physician investment and compensation relationship disclosures to CMS on a periodic basis. Even though CMS has not yet determined all of the elements for disclosure, hospitals can still prepare by establishing policies and procedures relating to physician investment and compensation relationships to ensure that the documentation and data are maintained to facilitate compliance. It is important that hospitals properly maintain and report all such documents for easy access, since a late response to a CMS disclosure request can result in substantial civil monetary penalties.

Similarly, all hospitals and healthcare joint ventures should reevaluate their compliance status under the Stark law and the anti-kickback statutes and their safe harbors. Since CMS has specifically directed attention to the issues of disproportionate returns on investment and non-bona fide or suspect investments, healthcare entities must take extra steps to re-examine every investment and compensation relationship with each physician, and re-structure under one of the applicable safe harbors any financial relationship that does not comply.

Furthermore, specialty hospitals must assess whether they are now required to accept appropriate EMTALA transfers of unstable patients. Each specialty hospital must first determine whether it indeed has an emergency department, and if not, whether it has specialized capabilities that will require it to accept patient transfers under the new EMTALA guidelines. It then must review and revise its policies and procedures for compliance with the new requirements.

Conclusion
The flurry of legislative and regulatory activity is not over yet. Although some aspects at the core of the specialty hospital controversy have been clarified, and hospitals can prepare for those changes, many initial concerns are still unresolved. It remains to be seen whether the unfair incentives will be eliminated by market forces, by recent regulatory initiatives, or by further legislative activity. 

Endnotes
5. Ed Silverman, No Easy Fit for Specialty Hospitals: Insurers Worry that These Facilities Will Ultimately Increase Costs at Nearby Community Hospitals, Managed Care (Sept. 2005).
8. Id. at 66-67.
9. Id. at 68-70.
10. Id. at 70-77.
11. Id. at 78-79.

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