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Health Law Washington Beat: Recent Health Industry News

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Mintz Levin's Health Law Practice has assembled the following overview of recent issues and developments that affect the health industry and that will continue to take center stage during the coming months.

In This Issue

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Senate Holds First Hearing on Daschle Nomination

The Senate Health, Education, Labor, and Pensions Committee held a hearing on January 8th regarding the nomination of Tom Daschle as Secretary of Health and Human Services (HHS). With President-elect Obama also naming Daschle to lead a new Office of Health Care Reform, the former Senate Majority Leader is expected to assume the role of "health czar" within the Administration.

The Senate hearing was largely free of contention, with members offering bipartisan praise for Daschle's knowledge of health care policy and depth of legislative experience. Several members across the aisle, including Chairman Kennedy (D-MA) and Senator Orrin Hatch (R-UT), stated their intent to fully support his nomination. In his testimony, Daschle pledged to carry through efforts to overhaul the country's health care system in a bipartisan manner and with Republican input. To this point, in questioning from Ranking Member Michael Enzi (R-WY), Daschle expressed support for moving reform legislation through the regular order rather than through the annual budget reconciliation process. The latter would effectively deny the GOP the opportunity to filibuster.

Daschle's proposals largely hew to the Democratic Party's health care platform, including the expansion of Medicare, Medicaid, and S-CHIP and government price negotiation on Medicare prescription drugs. He also spoke of instituting cost-containment measures, such as better incentivizing preventative care, and pursuing greater funding for HHS science agencies including NIH and FDA.

The Senate Finance Committee, which oversees Medicare and Medicaid, has principal jurisdiction over Daschle's appointment and will hold its own confirmation hearing at a date to be determined. That panel will likely also focus on the nominee's plans for jointly expanding access to health insurance coverage, containing costs, and improving the quality of care.

On a related note, congressional lawmakers have introduced a slew of health care reform proposals since the 111th Congress convened on January 6th. Though these are not likely to serve as the ultimate vehicles for an overhaul, several key lawmakers—including Senate Majority Leader Harry Reid—have sought to present their bills as markers on the issue and echo President-elect Obama's call that health care reform remains a high priority for 2009.

Plaintiffs File Summary Judgment Motion in Stark Law Case Against CMS

On December 17, 2008, a group of cardiologists, vascular surgeons, and cardiac catheterization laboratories filed a motion for summary judgment in an action against Michael O. Leavitt, Secretary of the HHS, in which they argued that the Centers for Medicare & Medicaid Services (CMS) exceeded its authority under the Stark Law and violated the Administrative Procedure Act when it made a change to the Stark Law in August 2008. The case, *Colorado Heart Institute v. Leavitt*,[1] was filed in the U.S. District Court for the District of Columbia.

The change at issue, which would become effective October 1, 2009, is CMS's recent decision to expand the definition of an "entity furnishing designated health services" under the Stark Law, which broadly prohibits physicians from referring Medicare patients to entities furnishing designated health services in which the physician (or an immediate family member) has an ownership or investment interest. The motion explains that the practical effect of CMS's new definition would be to force them and similarly situated physicians to cease operations, and, as a result, local hospitals would lose their ability to provide cost-effective, high quality care through these physicians. The motion also underscores that the new definition, among other things, is inconsistent with the Stark Law's structure and purpose.

According to lead counsel, Thomas S. Crane, who practices in Mintz Levin's Boston and Washington offices, "we are confident that a neutral court will understand that CMS's action amounts to regulatory overkill and is not supported by the law."

CMS Requires DMEPOS Suppliers to Post a Surety Bond for Medicare Participation

Suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) will soon be required to post a surety bond of at least $50,000 as a condition for participation in the Medicare program. DMEPOS suppliers must also post an extra $50,000 for each adverse legal action against them within the 10 years preceding Medicare enrollment, revalidation, or reenrollment. An adverse legal action includes any

- Medicare-imposed revocation of any Medicare billing privileges,
- suspension or revocation of a license to provide health care by any state-licensing authority,
- revocation or suspension by an accreditation organization,
- conviction of a federal or state felony offense, or
- exclusion or debarment from participation in a federal or state health care program.

CMS announced the surety bond requirement in a final rule issued on January 2nd but has not provided clear compliance deadlines. As of the date of this alert, CMS has not confirmed whether new DMEPOS suppliers must comply by May 4, 2009 (120 days from the published date of the rule) or by July 1, 2009 (120 days from the effective date of the rule). Similarly, existing DMEPOS suppliers have until either October 2, 2009 or December 3, 2009 to comply. CMS has promised it will clarify the compliance date for both on its website soon.

CMS explained that the surety bond coverage does not apply to certain entities, is tied to National Provider Identifiers (NPIs), and must be continuous. The rule is broad in its application to DMEPOS suppliers but exempts certain physicians and non-physician practitioners, physical and occupational therapists, state-licensed orthotic and prosthetic personnel, and government-owned suppliers. Existing DMEPOS suppliers must post a $50,000 surety bond for each assigned NPI to which Medicare has granted billing privileges. New DMEPOS suppliers must satisfy the surety bond requirements for each assigned NPI before receiving Medicare billing privileges. CMS has made clear that the surety bond coverage must be

continuous. If coverage lapses for any reason, the DMEPOS supplier will be considered immediately out of compliance with the rule and will not be able to receive payment from Medicare for DMEPOS supplied during the lapse.

The final rule is one of many steps that CMS has taken in recent years to combat fraud by DMEPOS suppliers. In March 2007, HHS and the Department of Justice established a team of federal, state, and local investigators (known as the Medicare Fraud Strike Force) to fight Medicare fraud through the use of real-time analysis of Medicare billing. The Medicare Fraud Strike Force has focused its efforts in Southern Florida and in the Los Angeles metropolitan area and has obtained hundreds of indictments and convictions. CMS believes that the surety bond is necessary to limit the number of improper and potentially fraudulent payments to DMEPOS suppliers—even if the rule forces some suppliers to reconsider their participation in the Medicare program. The surety bond requirement is also based, in part, on the 2007 Medicare error rate report, which revealed approximately $1 billion in improper payments for medical equipment and supplies.

CMS announced the surety bond requirement in a final rule that will go into effect on March 3, 2009. The rule is available here.

CMS Issues Draft 2010 Call Letter for Public Comment

Prescription drug plan sponsors and Medicare Advantage organizations have until 5:00 p.m. EST on January 30th to comment on the draft 2010 combined Medicare Advantage (MA), Medicare Advantage-Prescription Drug, Cost-Based Plan, and Prescription Drug Plan (PDP) Call Letter issued by CMS. The draft Call Letter focuses on new regulatory requirements and policy clarifications, including CMS's marketing rules and guidance from last year, along with the recent statutory changes that affect both the Medicare Advantage and the Prescription Drug Benefit programs. The Call Letter, which was released on January 8th, is available here.

CMS Sets Upper Limits to MA and PDP Agent and Broker Compensation

MA organizations and PDP sponsors may only pay their agents and brokers a set amount for initial enrollment in plans for 2009. On December 24, 2008, CMS issued a memorandum announcing that the fair market value (FMV) ceiling for MA organizations' and PDP sponsors' compensation to brokers and agents for initial enrollments in MA and cost plans was $400, and in prescription drug plans was $50. CMS will permit higher thresholds for certain regions. As a result, MA and cost plans may pay broker fees of up to $450 in Connecticut, Pennsylvania, and the District of Columbia, and up to $500 in California and New Jersey. CMS does not typically opine on FMV, so this announcement is unusual.

This announcement followed the release of a flurry of Medicare marketing rules and guidance, including CMS's November 10, 2008 regulation specifying that payments to brokers for initial enrollments must be FMV. According to the December memorandum, CMS determined the FMV amounts by analyzing broker fee compensation data taken from approximately 15,000 data records for 2009, and 4,000 data records from 2006 and 2007. The memorandum further states that 30% of MA and cost plans, and 50% of PDPs, must revise their existing compensation schedules to align with the FMV guidelines.

CMS's memorandum is available here.

CMS Posts Revised Disclosure of Financial Relationships Report Forms in Paperwork Reduction Act Notice

CMS posted the revised Disclosure of Financial Relationships Report (DFRR) forms and related materials in a Paperwork Reduction Act (PRA) notice on December 12, 2008. The 30-day notice is the next step in the Office of Management and Budget (OMB) clearance process required before CMS can conduct the DFRR information collection. The public has the opportunity to comment until 5:00 p.m. January 20, 2009.

CMS's DFRR initiative will require 400 hospitals to provide detailed information about their ownership, investment, and compensation arrangements with physicians. CMS will use the completed DFRRs both to identify arrangements that may not be in compliance with the Stark Law (which prohibits physician self-referrals) and to identify examples and areas of noncompliance that may affect future rulemaking. Hospitals selected for participation will have 60 days from the date on the cover letter or email transmission of the DFRR to respond, and completion is mandatory. Although CMS has the authority to impose civil monetary penalties of up to $10,000 per day for late submission, CMS has stated that it will contact noncompliant hospitals in writing to inquire why the hospitals did not return the completed DFRR in a timely way before taking further action. Additionally, a hospital may, for good cause, receive an extension of time to submit the DFRR.

Due to the level of detail the DFRR will capture, variations in hospital software and databases, and Privacy Act considerations, hospitals must submit the completed DFRR in hard copy. CMS does not plan to aggregate the collected data but rather will separately analyze each hospital's submission.

CMS has made it clear that hospitals should not construe its failure to find a Stark Law violation based on its review of the DFRR as an affirmative statement that the financial relationships are compliant, and that the government can later determine that a violation has occurred based on further review of the DFRR or on other information.

The OMB has 60 days to review the information collection (inclusive of the 30-day public comment period and a formal OMB 30-day review period). At the end of the review period, the OMB can approve, disapprove, or request that the information collection be withdrawn. It can also impose terms of clearance on an approval.

CMS is likely to move swiftly upon receipt of OMB approval. In the "Supporting Statement" included with the PRA notice, CMS indicated that it will contract with a payment safeguard contractor to collect and analyze the data from the DFRRs and that it expects the payment safeguard contractor to complete the project by September 30, 2009.

The revised forms are available here.

Mintz Levin's Related Advisories

CMS Proposes Mandatory Disclosure of Financial Relationships Between Hospitals and Physicians (Health Law Advisory, June 22, 2007)

CMS Moves Forward with a Modified Disclosure of Financial Relationships Initiative (Health Law Advisory, September 9, 2008)

OIG Approves Physicians' Investment in Group Practice

In an advisory opinion issued on January 9th, the Office of Inspector General (OIG) for HHS found that a physician and podiatrist group's investment proposal did not meet the requirements for the Anti-kickback Statute safe harbor for investments in group practices but nonetheless posed little risk to federal programs or beneficiaries. The OIG's advisory opinion can be found here.

Endnotes

[1] D.D.C., No. 1:08-cv-01626-RMC

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