HEALTHCARE**LEGAL**NEWS

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ENFORCEMENT ACTIONS AGAINST MANAGEMENT OF HEALTHCARE PROVIDERS

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In recent months, federal authorities have signaled a more aggressive approach in seeking to enforce the federal fraud and abuse laws against members of management of healthcare providers, drug companies and medical device manufacturers. In the past, regulatory enforcement authorities have been content to reach settlements with the affected organizations that required the payment of significant fines and the execution of agreements that require the organization to be "good citizens" and comply with the federal healthcare fraud and abuse, billing and other laws and regulations for periods of three years or longer.

The new "less kind, less gentle" approach has been to attempt to impose criminal charges on senior executives and/or to preclude their future involvement in companies that do business with government health programs, a death knell to the future careers of those affected. Moreover, prosecutors have sought to impose these draconian consequences on executives even if they did not have actual knowledge of the activities but could have stopped them if they knew that they were taking place. In the words of one top federal enforcement official, "[t]he behavior of a company starts at the top."

In response, individual executives at companies under investigation are attacking the legality of these governmental initiatives- especially if they were not aware of their organization's activities.

One successful defense effort took place earlier this year when a federal judge acquitted a former vice president and associate general counsel of a pharmaceutical manufacturer accused of interfering with a governmental investigation into off-label promotion of an FDA approved drug. In announcing his decision, the judge noted "I believe that it would be a miscarriage of justice to permit this case to go the jury." Critical to this successful defense was the defendant's reliance on outside counsel for advice and the judge's admonition of prosecutors for seeking access to (and being provided) communications with outside counsel that should have been subject to attorney-client privilege. This case points out the challenges in imposing individual liability on inside counsel of healthcare organizations; however, different factors that could lead to different results typically exist for investigations as to non-attorneys.

REIMBURSEMENT NEWS

CMS ANNOUNCES CHANGES IN REIMBURSEMENT FOR SEVERAL PROVIDERS

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On July 1, CMS announced proposed changes in 2012 reimbursement for physicians, hospital outpatient departments, ambulatory surgical centers and providers of dialysis services.

For physicians, the cuts will result in an overall 29.5% reduction in CMS payments for services provided to Medicare beneficiaries. While these cuts are required under the Sustainable Growth Rate (SGR) formula, Congress has acted in previous years to prevent the significant reduction in reimbursement rates. Furthermore, the President's budget proposal for the 2012 fiscal year would maintain the current payment rates to physicians until December 31, 2013.

With respect to hospital outpatient departments and ambulatory surgical centers, CMS announced a proposed increase in payments by 1.5% and 0.9% respectively. The proposed rule would also subject non-cancer hospitals to a 0.6% reduction to balance the increase in payments to cancer hospitals due to the budget neutrality requirement of the Affordable Care Act (ACA).

In sharp contrast to the announced cuts in reimbursement for physicians, CMS is proposing to increase payments for dialysis services by 1.8% for 2012, under the Prospective Payment System (PPS) that became effective on January 1 of this year. These proposed rules implement the annual adjustments required by the law that adopted PPS as the new reimbursement methodology for dialysis services. The 2012 year is the second year of a four year phase-in period for PPS. The "net" 1.8% increase is a combination of several adjustment factors that CMS is required to take into account annually to determine the 2012 reimbursement adjustment.

HEALTHCARE IT NEWS

A PARTIAL MEANINGFUL USE REPRIEVE

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Eligible professionals and hospitals that purchase and implement EHR systems are entitled to financial incentives to the extent that they can demonstrate "meaningful use" of these systems. CMS recently announced that during 2012, those participating in this program could continue to use attestation rather than direct electronic reporting to report clinical quality measure (CQM) results for that year.

Under its July 2010 Final Rule, CMS permitted eligible professionals and hospitals (Submitters) to use attestation to submit summary information on CQM to demonstrate meaningful use of certified EHR technology for the 2011 payment year. To attest, Submitters must log into the CMS Medicare & Medicaid EHR Incentive Program Registration and Attestation System, fill in numerators and denominators for the meaningful use objectives and CQMs, and legally attest that they have successfully demonstrated meaningful use. Generally, a complete EHR system will provide a report of the numerators, denominators and other information needed to attest.

However, for 2012 and future payment years, the Final Rule required that Submitters electronically submit CQMs to CMS as calculated by their certified EHR technology by uploading the data through a CMS-designated portal. The Final Rule also required that the certified EHR technology calculate the CQM results and transmit this information under the Physician Quality Reporting Initiative (PQRI) Registry XML specification.

In two Proposed Rules issued in mid-July of this year, CMS acknowledged what many in the industry argued: "that it is not feasible to receive electronically the information necessary for clinical quality measure reporting based solely on the use of PQRI 2009 Registry XML Specification content exchange standards as is required for certified EHR technology." The data elements required for the 2009 PQRI Registry submission are not well suited to allow compliance with the Final Rule. As a result, CMS has postponed the need for program participants to use direct electronic reporting of CQM results until 2013.

CMS also proposed a voluntary pilot program for the 2012 payment year through which the Submitters may report CMQs electronically using their certified EHR technology. However, CMS did not provide any financial incentives to participants in this pilot program.

OTHER NEWS

LITIGATION: EFFORTS TO CURB DATA MINING SUFFER A SETBACK

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Legislators across various states have been reviewing options to curb prescription data mining efforts to stem the tide of complaints from healthcare practitioners. The most recent effort in Vermont was struck down in June by the U.S. Supreme Court in *Sorrell v. IMS Health Inc*.

The Vermont law was designed to prevent data-miners from examining and selling prescriber identifying information to pharmaceutical companies which used information in their prescription drug marketing efforts.

Physicians may lament the decision as it exposes their patient prescription habits to data-miners and drug companies. The decision also strikes a blow to state government efforts to eliminate data-mining as part of an overall effort to reduce the cost of prescription drugs and to preserve doctor-confidentiality.

The Vermont law failed scrutiny under the First Amendment, however, not because it went too far in restricting speech, but because it did not go far enough. As surprising as that might sound, assuming physicians have a significant interest in keeping their patient prescription decisions confidential, the Supreme Court concluded that the Vermont law did not serve that interest because pharmacies "could share prescriber-identifying information with anyone for any reason except for marketing." Vermont would have furthered physician confidentiality more by narrowly limiting the use of prescription information to specific and justified circumstances. Essentially, by targeting only marketing related speech, the Vermont law drew too narrow a scope. Other states may well revise proposed laws to broaden their scope, preserving doctor patient confidentiality. The Vermont law also failed because it gave physicians the right to consent to the disclosure of prescriber identifying information. If a state's true goal is to preserve doctor patient confidentiality, then the prohibition on its use should not be limited to those who intend to use it for marketing efforts.

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