KING & SPALDING

Health Headlines

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Federal Judge Stays Ruling Invalidating PPACA – On March 3, 2011, Judge Roger Vinson of the U.S. District Court for the Northern District of Florida stayed his own January 31, 2011 ruling invalidating the Patient Protection and Affordable Care Act (PPACA), pending resolution of appeals. In the earlier ruling, the court found that PPACA's individual mandate was unconstitutional, and that the remainder of the legislation was not severable from the individual mandate. Accordingly, the court invalidated the whole law. The stay granted on March 3 came in response to the government's February 17 motion for clarification, asking the court to explain the ruling's impact on the Obama administration's ongoing implementation of PPACA. The government argued that if the ruling were to have an "immediate injunction-like effect" on PPACA implementation, it would result in "a risk of substantial disruption and hardship for those who rely on the provisions that have already been implemented." In spite of the ruling, the Obama administration had continued to implement provisions of the legislation.

Judge Vinson confirmed that his ruling was intended to be the "practical" and "functional equivalent of an injunction" against further implementation of PPACA, and chastised the government for failing to abide by the ruling. Judge Vinson added two conditions to his grant of a stay: first, that the Department of Justice file its notice of appeal to the Eleventh Circuit within seven days, and second, that the government pursue expedited review at the appellate level.

The case before Judge Vinson was brought by elected officials in 26 states. Three other federal judges have declared PPACA constitutional. One other federal judge declared the individual mandate unconstitutional, but only Judge Vinson's decision invalidated the entire law.

The March 3 stay order is available by clicking here.

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D.C. District Court Upholds Constitutionality of Health Reform's Individual Mandate and Finds it Does Not Violate the Religious Freedom Act – In a memorandum decision dated February 22, 2011, Judge Gladys Kessler of the U.S. District Court for the District of Columbia granted the government's request to dismiss a case brought by several individuals challenging PPACA's mandate that individuals buy health insurance by 2014 or pay a penalty. *Mead v. Holder*, Civil Action No. 10-950 (D.D.C. 2011).

After finding in favor of all but one of the plaintiffs on the issue of standing and ripeness, Judge Kessler turned to the substance of the case. The judge held that the individual mandate was constitutional under both the Commerce Clause and the Necessary and Proper Clause, but rejected the government's argument that the individual mandate was also authorized under Congress' power to tax. On this last issue, the judge reasoned that the fee imposed upon individuals who fail to obtain minimum health insurance coverage by 2014 was categorized as a "penalty," not a tax, and was meant

as an inducement to obtain health insurance, not to raise revenue.

In addition to the constitutional challenges, two of the plaintiffs argued that the mandate to buy health insurance constitutes a "substantial" burden on their exercise of religion in violation of the Religious Freedom Restoration Act of 1993, 42 U.S.C. § 2000bb *et. seq.* (RFRA). In particular, the plaintiffs argued that being forced to purchase insurance "requires them to perform an act that implies that they doubt God's ability to provide for their health." The court, however, ruled that the plaintiffs' assertion, even if true, did not constitute a "substantial" burden under the RFRA, especially since plaintiffs have the option of paying a penalty instead of retaining health insurance. But, even if the mandate does constitute a substantial burden, the court ruled that the exception under the RFRA is met because the mandate is "in furtherance of a compelling governmental interest," namely reducing spiraling health care costs and premiums, and was the "least restrictive means of furthering that compelling . . . interest."

Judge Kessler's ruling marks the fifth time a federal court has weighed in on the constitutionality of the healthcare reform law with a tally of three courts supporting the law (U.S. District Courts for the Eastern District of Michigan, Western District of Virginia, and now the District of Columbia), and two against the law (U.S. District Courts for the Eastern District of Virginia and the Northern District of Florida).

The decision is available by clicking here.

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More Hospitals to be Scrutinized for Medicare Coverage of Implantable Cardioverter Defribillators (ICDs) – As previously reported in *Health Headlines*, the United States Department of Justice (DOJ) a year ago initiated a civil investigation into hospital billing for ICDs that has continued to broaden over time, sweeping hundreds of hospitals into its net. DOJ attorneys last week served a new request for information and documents on hospitals already under the microscope, and they informed defense counsel that another wave of letters targeting new hospitals for investigation will issue shortly. To date, there have been three waves of target communications going out to hospitals, starting with Civil Investigative Demands issued in Spring 2010. So it is too early for hospitals that have implanted ICDs to breathe a sigh of relief even if they have not yet been contacted by DOJ.

The DOJ inquiry focuses on whether hospitals submitted claims for ICD implantations since October 2003 that violated a National Coverage Determination (NCD) setting forth detailed coverage criteria for the devices. Implanted under the skin and connected to the heart, an ICD monitors and corrects life-threatening, fast heart rhythm. The NCD generally disallows Medicare coverage of an ICD implanted within 40 days of an acute myocardial infarction or within three months of coronary revascularization (CABG-coronary artery bypass graft, or PTCA-percutaneous transluminal coronary angioplasty). DOJ's inquiry focuses on claims for ICDs that appear to have been prematurely implanted based on the Department's initial claims analysis.

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CMS Issues Medicare Provider Compliance Newsletter with Guidance to Avoid Common Problems Identified by Recovery Auditors – CMS has issued its second Medicare Quarterly Provider Compliance Newsletter. Inside, CMS identified seven errors often found by Recovery Auditors and provided guidance to avoid those errors in the future. Of the seven common errors, two affect inpatient hospitals, two affect physicians, one affects both outpatient providers and physicians, and two affect durable medical equipment (DME) suppliers.

Both inpatient hospital errors involve incorrect coding. First, Recovery Auditors often found non-excisional debridement incorrectly coded as excisional debridement. The code for excisional debridement applies only to the "surgical removal or cutting away of devitalized tissue, necrosis, or slough." Non-excisional debridement is applicable for debridement using autolytic, enzymatic, or mechanical methods. Second, Recovery Auditors frequently found that inpatient hospitals inappropriately billed for the creation of a new tracheostomy when the patient merely underwent a revision to an existing tracheostomy, which has a unique code.

The two errors affecting physicians related to billing for evaluation and management (E/M) services. First, Recovery Auditors often found that providers billed E/M services the day before and up to 90 days after surgeries. The Global Surgical Package includes E/M services within a specific window surrounding surgery; thus, physicians may not bill separately for E/M services within that window. Second, Recovery Auditors frequently found that physicians billed "new patient" E/M services for existing patients. Medicare defines "new patient" as a patient who has not received any professional services, *e.g.* E/M, from the physician within the previous three years. Thus, Medicare may be billed only once for "new patient" E/M for the same beneficiary within any three-year period.

Recovery Auditors also noted that providers billed more than one initial infusion code per day. This problem affects both outpatient providers and physicians. Medicare will reimburse only one initial infusion code per day, unless two separate intravenous sites are necessary. If two sites are required, providers must append a modifier; otherwise, payment may not be made.

Finally, Recovery Auditors identified two problems affecting DME suppliers. First, suppliers often incorrectly billed for items and services relating to a hospice terminal diagnosis. Medicare will not reimburse these items and services because they are included in the hospice payment, and suppliers should bill the hospice. Second, suppliers often billed for quantities of budesonide greater than 62 units of service per month, which is the maximum amount reimbursed.

For each of the seven errors, CMS cited relevant manual provisions for quick reference. In general, providers can avoid these errors by following the guidance found in those provisions.

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Senator Grassley Proposes New Anti-Fraud Bill After Speaking Before Senate Committee on Finance – On March 2, 2011, Senator Charles Grassley (R-Iowa) proposed new efforts to enhance the federal government's authority to combat Medicare fraud in a bill to enact the "Strengthening Program Integrity and Accountability in Health Care Act of 2011." One of the bill's key provisions would require Medicare claims and payment data to be available to the public organized by provider name, similar to how other federal spending data is presently disclosed to the public.

Other provisions proposed by Senator Grassley's bill include:

- making Medicare payment suspensions of providers involved in a pending fraud investigation mandatory rather than discretionary;
- extending the time Medicare has to make prompt payment of claims to certain providers if the Secretary of Health and Human Services (HHS) makes a determination of a high likelihood of fraud or abuse;
- creating an information-sharing program between the Federal Trade Commission (FTC), which maintains a database of identity theft complaints, and the Social Security Administration (SSA);
- allowing the HHS Office of Inspector General (OIG) to exercise its permissive exclusion authority to exclude individuals from Medicare participation who have had past ownership or control interests with sanctioned entities;
- requiring state Medicaid agencies to exclude individuals or entities from participation in the state's Medicaid program if they own, control, or manage an entity that: has unpaid or unreturned overpayments during a period to be specified by HHS; is suspended, excluded, or terminated from any state's Medicaid program; or is affiliated with an individual or entity that has been suspended, excluded or terminated from Medicaid participation during a period to be specified by HHS;
- prohibiting state Medicaid agencies from providing reimbursement for covered outpatient drugs that are not approved by the federal Food and Drug Administration (FDA) unless the state first verifies with the FDA that such a drug is being legally marketed; and
- requiring all individuals or entities that participate in federal health care programs to comply with requests for documents, information, or interviews by the chairmen or ranking members of specified congressional committees.

Senator Grassley commented before the Senate Committee on Finance that the new bill contains many of the provisions that he proposed in S. 2964 (111th Congress, 2010) that were not integrated into PPACA. He told the committee: "the federal government needs to be more effective in combating fraud, waste, and abuse. The federal government has simply

made it too easy for bad actors to steal from these programs. It says a lot when you hear that organized crime groups have moved into health care fraud because it is profitable."

The text of Senator Grassley's proposed legislation is available by here. Senator Grassley's press release which accompanied the bill is available by clicking here. His comments before the Senate Committee on Finance on March 2, 2011 are available by here.

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