KING & SPALDING

Health Headlines

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Proposed Rule Would Require Most Providers and Suppliers to Give Medicare Beneficiaries Written Notice of Right to Contact Quality Improvement Organization – On February 2, 2011, the Centers for Medicare and Medicaid Services (CMS) published a proposed rule in the *Federal Register* that would require most providers and suppliers participating in the Medicare program to give all Medicare beneficiaries written notice about their right to contact a Quality Improvement Organization (QIO) concerning the quality of care that they receive and to provide contact information for the local QIO. Under current rules, CMS only requires that Medicare beneficiaries receiving inpatient hospital services be informed of their right to contact the QIO concerning their quality of care. The new notice requirement would apply to the following types of providers and suppliers:

- Ambulatory surgical centers
- Hospices
- Hospitals
- Long term care facilities (LTCs)
- Home health agencies (HHAs)
- Comprehensive outpatient rehabilitation facilities (CORFs)
- Critical access hospitals (CAHs)
- Clinics and rehabilitation agencies
- Portable x-ray services
- Rural health clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

In addition to notifying Medicare beneficiaries of their right to contact the QIO, the proposed rule would also require the following types of providers and suppliers to furnish contact information to patients on how to contact the State survey agency: hospices, hospitals, CORFs, CAHs, clinics and rehabilitation agencies, portable x-ray services, RHCs and FQHCs. Comments on the proposed rule must be received by CMS no later than 5:00 on April 4, 2011. The full text of the proposed rule is available by clicking here.

Reporter, *Harry Richards*, Washington, D.C., +1 202 626 9126, jrichards@kslaw.com.

Florida Court Invalidates Entirety of PPACA; States' Responses to Decision Vary – On January 31, 2011, a fourth federal district court ruled on the constitutionality of the Patient Protection and Affordable Care Act (PPACA or the Act). *See Bondi, et al., v. U.S. Dept. of Health & Human Services*, Case No.: 3:10-cv-91-RV/EMT (N.D. Fla. 2011). The court addressed two questions: (1) whether the Act's expansion of the Medicaid program to include a larger eligible population violated the Spending Clause of the Constitution and principles of federalism protected by the Ninth and Tenth Amendments (the "Medicaid expansion issue"); and (2) whether the mandate that all individuals purchase health insurance by 2014 or pay a penalty violates the Commerce Clause of the Constitution (the "individual mandate issue"). With respect to the Medicaid expansion issue, the Court ruled that because state participation in the Medicaid Program

"is--as it has always been--voluntary," the provisions of PPACA expanding Medicaid coverage are not unconstitutional. With respect to the second issue, however, the court found that because the Commerce Clause does not extend the power to Congress to regulate "inactivity" (*i.e.*, the failure to purchase health insurance), the individual mandate is unconstitutional. This ruling is consistent with the ruling issued in the Eastern District of Virginia, but contrary to decisions issued by the Western District of Virginia and the Eastern District of Michigan, which both upheld the Act in its entirety. However, the *Bondi* decision took its ruling one step further than the Eastern Virginia district court, finding that because the individual mandate is "inextricably bound together in purpose" with the other provisions of the Act, it cannot be severed, and *the entire Act* is therefore unconstitutional. However, the court's boldness ended with its declaration of the Act's unconstitutionality; it refused to issue an injunction against the Act's continued implementation, prompting confusion as to the practical effect of the ruling.

The *Bondi* case involved 26 states: Alabama, Alaska, Arizona, Colorado, Florida, Georgia, Idaho, Indiana, Iowa, Kansas, Louisiana, Maine, Michigan, Mississippi, Nebraska, Nevada, North Dakota, Ohio, Pennsylvania, South Carolina, South Dakota, Texas, Utah, Washington, Wisconsin, and Wyoming. In the decision's aftermath, state officials in at least Florida, Idaho, and Wisconsin have made public statements regarding their belief that the ruling permits them to abandon further implementation of PPACA immediately. *See* Amy Goldstein and N.C. Aizenman, "States Divided on Meaning of Health Care Ruling," (Washington Post), January 26, 2011, available online at CBS News. On the other hand, officials in Georgia, Iowa, and Mississippi have indicated that preparations for the Act's implementation will continue while the legal challenges inevitably proceed to the Supreme Court, because to cease preparations while awaiting a final ruling would be "irresponsible," and leave the states too far behind in the event that the Supreme Court finds the Act to be constitutional. The federal government is currently considering whether it is necessary to seek a stay from a higher court, ordering the continued implementation of PPACA while the legal challenges proceed to the Supreme Court.

Reporter, *Krista Barnes*, Houston, +1 713 751 3273, kbarnes@kslaw.com.

Fraudulent Research Applications Submitted to IRBs – Fictitious research applications have been submitted to several institutional review boards (IRBs) for a fake clinical study of a cancer drug to treat recurrent or neoplastic polyps in patients with a history of colorectal adenomas. In a notice issued by the FDA, the agency notes that the fictitious research applications resemble the phony applications that were used in an undercover investigation conducted by the Government Accountability Office (GAO) two years ago.

The March 26, 2009 GAO study, available by clicking here, found that IRBs reviewing proposals for human subjects research are vulnerable to unethical manipulation. In that investigation, GAO succeeded in getting approval from one IRB to conduct human tests of a fictitious medical device.

FDA is investigating these new, fictitious research applications and requests that any information concerning the false submissions be reported to FDA. FDA is alerting IRBs of the phony applications "to remind them of their responsibilities under FDA regulations to protect the safety and welfare of research participants by conducting careful review of research." FDA's notice is available by clicking here.

Reporter, *Susan Banks*, Washington, D.C., +1 202 626 2953, sbanks@kslaw.com.

King & Spalding Upcoming Roundtable to Discuss Medicare and Medicaid Program Contractors – On February 23, 2011, King & Spalding will be hosting a Roundtable in its Atlanta office entitled "Taking Charge of Contractor Chaos." The Roundtable will offer a discussion of the various Medicare and Medicaid program contractors (including RACs, MACs, MICs, PSCs and ZPICs) and how they operate, overlap and differ, as well as how providers can prepare themselves for contractor audits. Please be on the lookout for additional communications regarding further program details and registration information.

King & Spalding 20th Annual Health Law and Policy Forum – King & Spalding's 20th annual Health Law and Policy Forum will be held this year on March 14 at the Four Seasons Hotel in Atlanta. Please be on the lookout for additional communications soon that will provide details on the specific content of the program.

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Dennis M. Barry
dbarry@kslaw.com
+1 202 626 2959