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Health Headlines

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Federal Court Strikes Down Health Reform Mandate for Individuals to Maintain Health Insurance – Today, the Eastern District of Virginia issued a memorandum opinion striking down Section 1501 of the Patient Protection and Affordable Care Act (Act), also referred to as the Minimum Essential Coverage Provision (Provision) or as the "individual mandate." *Commonwealth of Virginia v. Sebelius*, Civil Action No. 3:10CV188-HEH (Dec. 13, 2010).

The Commonwealth of Virginia brought a lawsuit against the Secretary of the Department of Health and Human Services seeking to, among other things, declare the Provision—which requires that every citizen maintain a minimum level of health insurance coverage and penalizes citizens who fail to obtain such coverage—unconstitutional. Both parties filed motions for summary judgment on the issue of whether the Provision exceeded Congressional authority under the Commerce Clause and General Welfare Clause of the United States Constitution. The Court granted summary judgment in favor of the Commonwealth. The court concluded that Congress lacked authority under the Commerce Clause, and associated Necessary and Proper Clause, to compel individual citizens to purchase health insurance. Finding that the portion of the Provision penalizing citizens for failing to obtain health insurance was not intended by Congress as a *bona fide* revenue raising measure, the court also held that the Provision could not be construed as a tax under the General Welfare Clause. Accordingly, the court granted summary judgment in favor of the Commonwealth and declared the Provision invalid. The court, however, elected to sever the Provision from the remainder of the Act as opposed to striking the Act down in its entirety as the Commonwealth argued should be the case. It is very likely that the United States Department of Justice will appeal to the Fourth Circuit Court of Appeals.

The court's decision is available by clicking here.

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Bill to Extend Medicare Physician Payment Fix Goes to President's Desk for Signature – On December 9, 2010, the U.S. House of Representatives voted 409 to 2 to pass legislation extending through 2011 a fix for Medicare payments to physicians. Because the House bill was identical to a Senate bill passed the day before, it now awaits President Barack Obama's signature. President Obama had previously urged Congress to enact the legislation, calling it "an important step forward to stabilize Medicare."

Without the fix, Medicare payments to doctors would face a 25 percent cut, amounting to $15 billion, on January 1, 2011. The bill's supporters warned that as many as two-thirds of doctors would stop accepting new Medicare patients, and the military's Tricare health system would suffer as well because its payments are tied to Medicare's. The cut stems from a 1997 law requiring automatic reductions in doctor pay if limitations in a "sustainable growth rate" formula would be exceeded. Since its passage, Congress has voted numerous times to extend a fix that avoids the cuts.

The fix will be paid for by a shift in funds from the recently enacted health care overhaul program. In particular, the overhaul's tax credits to help pay insurance premiums will be slightly less generous in order to offset the cost of continuing Medicare's current levels of doctor pay. President Obama and Secretary of Health and Human Services Kathleen Sebelius have signaled a desire to enact a permanent fix in 2011.

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NY OMIG Issues 2011 Medicaid Work Plan – On December 6, 2010, the New York State Office of the Medicaid Inspector General (OMIG) issued its 2011 Medicaid Work Plan (the Work Plan). In support of its vision of the New York OMIG as "*the* national leader in promoting and protecting the integrity of the Medicaid program," the Work Plan identifies the following "Executive Initiatives":

Compliance
According to OMIG, its "most significant executive initiatives relate to implementation and oversight" of the compliance obligations imposed on October 1, 2009 which require every major health care provider receiving more than $500,000 annually in New York Medicaid reimbursement to have an effective compliance program. (A copy of the corresponding New York statute and regulations is attached to the Work Plan.) Covered providers were required to certify to OMIG by December 31, 2009 that they adopted and implemented effective compliance programs. In its Work Plan, OMIG stated that it has been "following up" with providers (and in some cases, going door-to-door) which were required to certify but failed to do so and will conduct compliance program effectiveness reviews. It also indicated that it "has begun to identify providers who need additional direction in their compliance efforts." According to the Work Plan, "[s]everal hundred providers" subject to the certification requirement had failed to file a certification as of July 1, 2010, six months after the deadline. OMIG also indicated that it had begun using data mining to identify the following compliance weaknesses: billings for deceased patients; billings for services ordered or provided by excluded persons; double billings for services provided to hospital inpatients; and failure of providers to make required disclosure of payments by third parties and third-party obligations.

Governance and its Relationship to the Compliance Function
Based on its finding that governance weaknesses contribute directly to compliance failures, the Work Plan indicates that OMIG "is and will be conducting investigations of significant compliance failures to determine the potential governance weaknesses, and to determine appropriate action . . . OMIG will also be evaluating board responses to identified compliance failures . . ." Consistent with New York Medicaid Inspector General James Sheehan's prior statements, the Work Plan suggests that, under appropriate circumstances, individual board members will be held responsible for compliance failures.

Payments Due from Third Parties
In 2009, New York State enacted changes to the Social Services and Insurance Law based on the Deficit Reduction Act of 2005 which expanded the definition of "insurers," expanded the "retrospective" time period for third-party liability from two years to three years, required insurers to provide information on "benefits paid" and prohibited "insurers" from denying claims based on reasons which are issues in the "retrospective" TPL environment (*i.e.*, carrier timely filing and missing prior-authorization). According to the Work Plan, "OMIG has emphasized and will continue to enforce the requirement that Medicaid providers identify and bill other payers first where Medicaid enrollees have other insurance coverage . . . OMIG will focus during FFY 2011 on the obligation of payers to provide information and to honor and pay claims due providers where a patient has other coverage."

Reporting, Refunding and Explaining Overpayments by Providers within 60 Days
The Work Plan states that beginning January 1, 2011, OMIG will begin enforcing Section 6402 of the Patient Protection and Affordable Care Act. "Providers who retain overpayments more than sixty (60) days after identifying the payment will be reviewed for enforcement action . . . Providers who show up in other OMIG and Department of Health (DOH) projects, but have never reported an overpayment through the disclosure protocol or identified and reversed a payment through the void process will [also] be identified and reviewed."

Pharmacy, Device and Prescription Drug Issues
The Work Plan indicates that OMIG established a new pharmacy unit within the Division of Medicaid Investigations

(DMI) and will utilize this unit to manage investigations concerning: (1) utilization patterns by individual nursing homes concerning off-label use of atypical antipsychotics for Medicaid enrollees; (2) "brown-bagging" (*i.e.*, the practice of requiring patients who receive certain costly drugs as part of an inpatient or outpatient treatment to obtain the drugs from an outside pharmacy and bring the drugs with them for their treatment); and (3) kickbacks and incentive payments to nursing homes, pharmacy consultants, and physicians in connection with prescription drugs and medical devices.

Home Health and Personal Care Issues
Because "OMIG's audits have disclosed significant disparities between services ordered by treating physicians for home health patients, services contained in the patient evaluation and nursing treatment plans, and services actually provided by home health staff," OMIG indicated that it will use data mining to identify specific geographic and referral relationships for further review.

Evaluation and Review, Employee Training and Professional Standards, and Outreach to Beneficiaries and Beneficiary Organizations
In FFY2011, OMIG will continue and expand its efforts with respect to all three of these initiatives.

A copy of the Work Plan is available by clicking here.

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D.C. Circuit Rejects Government's Collective Knowledge Theory of Intent and Aggressive Damages Calculation in False Claims Act Case – On December 3, 2010, in *United States v. Science Applications International Corp.*, No. 09-5385, the D.C. Circuit vacated a judgment of False Claims Act (FCA) liability and remanded the case for a new trial based on errors committed by the district court in jury instructions that permitted scienter to be established through collective knowledge of corporate employees and based on a jury instruction that improperly relieved the Government from establishing its burden of proof on damages. *Id.* at 33 & 39. The court also discussed the contours of the implied certification theory of falsity under the FCA. *Id.* at 18.

Science Applications International Corporation (SAIC) contracted with the Nuclear Regulatory Commission (NRC) to provide "technical assistance and expert analysis" in support of potential rulemaking by the NRC. *Id.* at 3. The United States later brought suit, alleging that the contracts between SAIC and the NRC and certain federal regulations required SAIC to disclose conflicts of interest, and that SAIC had failed to do so. The United States contended that SAIC's alleged failure to do so amounted to violations of the FCA and breach of contract. The case was tried to a jury, and the jury returned a verdict in favor of the Government for "the full amount of payments made by the government for the claims the jury concluded were knowingly false." *Id.* at 9. SAIC moved for judgment as a matter of law or a new trial, both of which the district court denied.

On appeal, the D.C. Circuit first considered the scope of the implied certification theory. Implied certification permits a plaintiff to establish the FCA's requirement of "falsity" when a claim for payment "rests on a false representation of compliance with an applicable federal statute, federal regulation, or contractual term" and the "certification was a prerequisite to the government action sought." *Id.* at 13 (citation and quotation marks omitted). The court rejected SAIC's position that the implied certification theory requires an "express condition precedent to payment" in the relevant statute, regulation or contract. Instead, the court provided the following formulation:

[W]e hold that to establish the existence of a "false or fraudulent" claim on the basis of implied certification of a contractual condition, the FCA plaintiff—here the government—must show that the contractor withheld information about its noncompliance with material contractual requirements. The existence of express contractual language specifically linking compliance to eligibility for payment may well constitute dispositive evidence of materiality, but it is not, as SAIC argues, a necessary condition. The plaintiff may establish materiality in other ways, such as through testimony demonstrating that both parties to the contract understood that payment was conditional on compliance with the requirement at issue.

*Id.*at 18. The court noted the risk of an excessively broad interpretation of the implied certification doctrine and suggested this could be "addressed through strict enforcement of the [FCA]'s materiality and scienter requirements." *Id.* at 21. The D.C. Circuit declined to vacate the judgment on grounds concerning the implied certification theory.

The court did hold, however, that the district court's instruction permitting the jury to find scienter established based on the collective knowledge doctrine was in error and required that the judgment be vacated. The collective knowledge doctrine "allows 'a plaintiff to prove scienter by piecing together scraps of 'innocent' knowledge held by various corporate officials, even if those officials never had contact with each other or knew what others were doing in connection with a claim seeking government funds.'" *Id.* at 29 (citation omitted). The D.C. Circuit concluded, "We nonetheless believe that under the FCA, 'collective knowledge' provides an inappropriate basis for proof of scienter because it effectively imposes liability, complete with treble damages and substantial civil penalties, for a type of loose constructive knowledge that is inconsistent with the Act's language, structure, and purpose." *Id.* at 28.

The D.C. Circuit also vacated the judgment on the ground that the district court's jury instruction on damages was in error. The Government essentially sought to "adopt an irrebuttable presumption . . . that treats services involving expert advice and analysis affected by potential organizational conflicts as categorically worthless." *Id.* at 39. The D.C. Circuit held that in a case in which a "defendant agreed to provide goods or services to the government," the "benefit of the bargain measure" is the proper test to calculate damages. *Id.*at 36. "[T]he government will sometimes be able to recover the full value of payments made to the defendant, but only where the government proves that it received no value from the product delivered," *id.* at 37, and the defendant must be entitled to offer countervailing evidence of the value provided to the government, *id.* at 39.

The court's decision is available by clicking here.

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House Approves Bill to Narrow Applicability of FTC Red Flags Rule – On December 7, 2010, the House voted to pass legislation previously approved by the Senate that would narrow the applicability of the Federal Trade Commission's (FTC) Red Flags Rule, which requires "creditors" to implement measures to prevent identify theft by the end of this year.

The Red Flags rule seeks to prevent identify theft by requiring covered creditors to implement programs that would flag practices prone to identify theft. The broad definition of creditors by the FTC includes those that "advance funds on behalf of a person for expenses incidental to a service provided by the creditor to that person." By definition, physicians and other healthcare providers were included in that group. The bill passed last week, named the Red Flag Program Clarification Act of 2010 (the "Clarification Act," S.3987), amends the definition of "creditor" under the Fair Credit Reporting Act to exclude those that "advance funds on behalf of a person for expenses incidental to a service provided by the creditor to that person." Instead, the definition of "creditor" is limited to those that (1) obtain or use consumer reports, directly or indirectly, in connection with a credit transaction; (2) furnish information to consumer reporting agencies in connection with a credit transaction; or (3) advance funds to or on behalf of a person, such as payday lenders. The bill, which is available by clicking here, must now be signed by the President.

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CMS Announces Results from HQID, PGP and MCMP Demonstration Projects – According to the Centers for Medicare and Medicaid Services (CMS), results from three key demonstration projects provide support for the contention that offering financial incentives to providers to improve patient care increases the quality of care and can reduce growth in Medicare expenditures. The results, released in a December 9, 2010 press release (the Press Release), are from the Hospital Quality Incentive Demonstration (HQID), the Physician Group Practice (PGP) Demonstration and the Medicare Care Management Performance (MCMP) Demonstration.

The Hospital Quality Incentive Demonstration

The HQID is a demonstration program sponsored by Medicare in partnership with Premier Healthcare Alliance designed to test whether paying hospitals for performance based on quality measures associated with certain clinical conditions

would improve the quality of inpatient care. CMS announced that $12 million in incentive payments is being awarded to 212 hospitals. The 212 hospitals are receiving the incentive payments for top performance, top improvements and overall attainment in six clinical areas: heart attack, coronary bypass graft, heart failure, pneumonia, hip and knee replacements, and the Surgical Care Improvement Project (SCIP). CMS has awarded more than $48 million through the first five years of the HQID.

The Physician Group Practice Demonstration

The PGP Demonstration creates incentives for physician groups to coordinate the overall care delivered to Medicare patients, rewards physician groups for improving the quality and cost efficiency of health care services, and creates a framework for collaboration with providers. Physician groups earn incentive payments based on both the quality of care they provide as well as the estimated savings they generate in Medicare expenditures.

During the fourth year of the demonstration, all 10 participating physician groups achieved benchmark performance in 29 of the 32 measures, and three out of those 10 physician groups achieved benchmark performance on all 32 measures, according to CMS. Each of the 10 physician groups achieved benchmark performance on the 10 heart failure measures and seven coronary artery measures. Over the first four years of the PGP Demonstration, the physician groups increased their quality scores an average of 10 percent on 10 diabetes measures, 13 percent on seven heart failure measures, 6 percent on seven coronary artery disease measures, 9 percent on two cancer screening measures and 3 percent on three hypertension measures.

CMS announced that five physician groups will receive $31.7 million in payments as part of their share of $38.7 million in savings generated for the Medicare Trust Fund in performance year for of the PGP Demonstration.

The Medicare Care Management Performance Demonstration

The MCMP Demonstration aims to promote the use of health information technology to improve the quality of care for beneficiaries with chronic conditions. Physicians practicing in small to medium-sized practices in California, Arkansas, Massachusetts and Utah who meet clinical performance standards on specified measures are eligible to receive financial rewards, and can receive an additional bonus for reporting data using an electronic health record certified by the Certification Commission for Health Information Technology.

CMS is awarding approximately $9.5 million in incentive payments to more than 500 small and solo physician practices in the participating states for providing high quality preventive care and care for chronically ill patients. CMS reported that the average payment per practice is $18,100, although some practices earned as much as $62,500.

Additional information on Medicare demonstrations is available by clicking here.

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