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Health Headlines

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Fourth Circuit Dismisses Challenges to PPACA on Procedural Grounds – On September 8, 2011, the Fourth Circuit Court of Appeals dismissed, on procedural grounds, two cases challenging the constitutionality of the Patient Protection and Affordable Care Act (PPACA). In the first case, *Commonwealth of Virginia ex. rel. Kenneth T. Cuccinelli, II v. Sebelius*, No. 11-1057, brought by the State of Virginia, the court held that Virginia lacked standing to challenge the requirement that all individuals carry health insurance, known as the "individual mandate," despite Virginia's argument that the mandate conflicted with state law. In the second case, *Liberty University Inc., et. al. v. Geithner*, No. 10-2347, brought by Liberty University and several individuals, the court held that the challenge to the individual mandate was premature because the federal tax Anti-Injunction Act (AIA) prohibits a pre-enforcement challenge to any "tax," which it held was defined broadly for purposes of the AIA. The Fourth Circuit is the third appellate court to consider constitutional challenges to PPACA. The other two circuits reached the merits of the challenges but arrived at opposite conclusions making it likely that the Supreme Court will have the last word.

In the Virginia decision, the court held that Virginia lacked standing because "the sole provision challenged -- the individual mandate -- imposes no obligations on the sole plaintiff, Virginia." The court reached this holding despite the fact that Virginia's General Assembly enacted the Virginia Health Care Freedom Act, which states that "[n]o resident of this Commonwealth . . . shall be required to obtain or maintain a policy of individual insurance coverage," the day after President Obama signed PPACA into law. Virginia argued that this conflict with state law was sufficient to create standing. The panel was unanimous in its rejection of this argument reasoning that "[u]nder Virginia's standing theory, a state could acquire standing to challenge any federal law merely by enacting a statute . . . purporting to prohibit the application of the federal law." This, in turn, would mean that "each state could become a roving constitutional watchdog of sorts; no issue . . . would fall beyond a state's power to litigate in federal court."

In the second case, brought by an employer, Liberty University, and several individuals, the court held that the challenge to the individual mandate was premature because the AIA controlled and barred pre-enforcement challenges to any tax. Although both the Secretary and the plaintiffs argued in their briefs that the AIA did not apply, the court disagreed. The relevant portion of the AIA states that "no suit for the purpose of restraining the assessment or collection of any tax shall be maintained in any court by any person." I.R.C. § 7421(a). The court held that "the term 'tax' in the AIA encompasses penalties that function as mere 'regulatory measure[s] beyond the taxing power of Congress' and Article I of the Constitution." Therefore, since the court decided that the term "tax" in the AIA encompassed taxes and penalties, the question of whether the fine individuals or employers must pay if they fail to maintain sufficient insurance coverage was a tax or penalty was largely superfluous. This decision had a two-to-one majority with the dissent arguing that the AIA did not control and that the court should have upheld the individual mandate as a valid exercise of Congress' powers under the Commerce Clause.

All three judges were appointed by Democratic presidents (two by Obama and the third by Clinton).

The 4th Circuit is the third court of appeals to rule on challenges to PPACA. The Sixth Circuit upheld the constitutionality of the individual mandate by a two-to-one majority, and the Eleventh Circuit ruled against the constitutionality of the law, also by a two-to-one majority. It is likely, therefore, that the Supreme Court will ultimately decide the issue.

A copy of *Commonwealth of Virginia ex. rel. Kenneth T. Cuccinelli, II v. Sebelius*, No. 11-1057, is available by clicking **here**, and *Liberty University Inc., et. al. v. Geithner*, No. 10-2347, is available **here**.

Reporter, *Daniel J. Hettich*, Washington, D.C., +1 202 626 9128, dhettich@kslaw.com.

House Democrats Outline Potential Healthcare Cuts for Supercommittee – On September 7, 2011, Democrats on the House Ways and Means Committee put forth a 13-page outline of potential cuts in healthcare spending for consideration by the deficit-cutting congressional "supercommittee," charged with proposing a $1.2 trillion savings plan. In addition to the two-dozen policy recommendations, the outline emphasizes the need to maintain (or accelerate) reforms included in the Affordable Care Act (ACA). The recommendations include:

- Raising the Medicare eligibility age to 67 by 2027 in two-month annual increments. The outline conditions this reform on retaining the ACA provisions designed to assist low-income Americans in purchasing insurance, warning that many near-elderly Americans without access to employer-based insurance would not otherwise be able to afford coverage.
- Increasing Part B premiums for high-income Medicare beneficiaries.
- The elimination or phase-out of Medicare bad debt reimbursement.
- Cuts to graduate medical education reimbursement.
- Reductions to reimbursement for Part B drugs administered in physician offices.
- A one- or two-year freeze on market basket adjustments for post-acute care providers (home health agencies (HHAs), skilled nursing facilities (SNFs), long-term care hospitals and inpatient rehabilitation facilities.
- A downward "rebasing" of HHA payments by 2015. The ACA implemented a four-year rebasing of HHA payments beginning in 2014. This proposal would implement the full rebasing two years ahead of the ACA.
- An increase in beneficiary cost-sharing obligations for SNF and HHA services, as well as for Medicare-covered clinical laboratory tests.
- Implementation of a non-budget neutral SNF value-based purchasing program.

The supercommittee has until November 23, 2011, to submit its recommendations to Congress as part of the August agreement to increase the Federal debt ceiling. If Congress fails to pass the supercommittee plan by December 23, 2011, Medicare providers will face across-the-board cuts of up to 2 percent beginning in 2013. The House Democrats' list of recommendations is available by clicking **here**.

Reporter, *Christopher Kenny*, Washington, D.C., +1 202 626 9253, ckenny@kslaw.com.

CMS Publishes Changes to Electronic Prescribing Incentive Program for CY 2011 – The Centers for Medicare and Medicaid Services (CMS) recently announced changes to the Medicare Electronic Prescribing (eRx) Incentive Program for Calendar Year (CY) 2011. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) authorized the establishment of a program to support the adoption and use of eRx technology. The program, implemented in 2009, offers financial incentives based on an eligible professional's or group practice's use of eRx technology. However, the program also requires payment reductions under certain circumstances; for example, beginning in 2012 a reduction in payment under the Medicare Physician Fee Schedule (MPFS) will be implemented for those eligible professionals or group practices who are not meeting requirements for electronic prescribing, as described in the CY 2011 MPFS final rule.

On September 6, 2011, CMS published a final rule (Final Rule) that modifies the 2011 eRx quality measure. Based on comments received by CMS that requirements under the eRx Incentive Program did not align with the Medicare Electronic Health Record (EHR) Incentive Program, CMS has revised the eRx quality measure so that eligible professionals or group practices now have the option of adopting either a qualified electronic prescribing system that performs four required functionalities or Certified EHR Technology as defined at 42 C.F.R. § 495.4 and 45 C.F.R.

§ 170.102. This change applies only in limited circumstances. It is only effective for the remainder of the reporting periods in CY 2011 for the 2011 eRx incentive and the 2013 eRx payment adjustment. *See* 76 Fed. Reg. 54956. CMS had also previously finalized two circumstances under which an eligible professional or group practice could request consideration for a significant hardship exemption for the 2012 eRx payment reduction. The Final Rule adds four additional hardship exemption categories. The Final Rule also extends the timeframe for submitting requests for a significant hardship exemption to November 1, 2011.

The Final Rule may be read **here**, and a summary of the rule with links to helpful information, including how to submit a hardship request, may be found **here**.

Reporter, *Christina A. Gonzalez*, Houston, +1 713 276 7340, cagonzalez@kslaw.com.

CMS Survey Shows that 72 Percent of Providers are Satisfied with their Contractor's Overall Performance – According to the Centers for Medicare and Medicaid Services's (CMS) Medicare Contractor Provider Satisfaction Survey (MCPSS or Survey) dated July 29, 2011, nearly three-fourths (72 percent) of providers are satisfied or very satisfied with their Medicare contractor's overall performance. The Survey shows that approximately 13 percent of providers are dissatisfied or very dissatisfied with their contractor's performance. According to the MCPSS, contractor satisfaction scores changed little between 2010 and 2011. The MCPSS elicits information from all provider types, including hospitals, physicians, skilled nursing facilities, and laboratories. The Survey noted that satisfaction with Part B Medicare Administrative Contractors (MACs) was lower than the other contractor types with 15 percent of providers expressing dissatisfaction.

The MCPSS includes satisfaction results for the following contractor types:

- Fiscal Intermediaries (FI);
- Carriers;
- Part A MACs;
- Part B MACs;
- Durable Medical Equipment (DME) MACs; and
- Regional Home Health Intermediaries.

Notably absent from the contractor types included in the Survey are Recovery Audit Contractors (RACs) and Zone Program Integrity Contractors (ZPICs). Among the various provider types participating in the Survey, home health agencies and hospices expressed the highest rates of satisfaction and the lowest rates of dissatisfaction. The Survey also shows provider satisfaction by business function for each of the six contractor types. The seven business functions reviewed were: (1) provider inquiries; (2) provider outreach and education; (3) claims processing; (4) appeals; (5) provider enrollment; (6) medical review; and (7) provider audit and reimbursement. Survey results indicate that typically contractor satisfaction exceeds 60 percent for the various business functions. However, provider satisfaction with Part B MACs for four of the six business functions was lower than 60 percent, with provider enrollment satisfaction being only 47 percent.

The Survey also identifies contractor activities with potential for improving provider satisfaction. According to the Survey, providers identified 13 elements of business-function performance as having the potential to increase provider satisfaction. For example, providers identified the following three items more than once as opportunities for improvement in overall satisfaction:

- Ability to fully resolve problems without a provider having to make multiple inquiries;
- Mechanisms offered for exchanging information about first-level appeals; and
- After leaving a message, the average time before receiving a return call.

A copy of the MCPSS is available by clicking **here**.

Reporter, *Stephanie F. Johnson*, Atlanta, +1 404 572 4629, sfjohnson@kslaw.com.

Pennsylvania Federal Judge Rules "Public Disclosure" Provision Bars FCA Suit Against Healthcare Provider – In a recently published decision favorable to False Claims Act (FCA) defendants, a federal district court dismissed FCA claims asserted against Pennsylvania-based Guthrie Healthcare System, Inc. (Guthrie) and other co-defendants. One of the bases for the district court's ruling was that certain information in plaintiff/relator's FCA *qui tam* action had already been made public in other lawsuits in which Guthrie and/or the co-defendants had been involved. This, the district court judge wrote, barred plaintiff's FCA lawsuit.

The case, *United States ex. rel. Rodney Repko v. Guthrie Clinic, P.C.*, et al., No: 304-cv-1556, involved allegations by Guthrie's former general counsel that Guthrie and the co-defendants had defrauded Medicare and Medicaid by setting up a scheme whereby clinics operating under one of Guthrie's arms were illegally paid by Guthrie to refer patients to its hospitals, thereby violating the Stark Law and Anti-Kickback Statute. Notably, around the time plaintiff filed his complaint in the Guthrie matter, he had recently been arrested on federal financial charges and entered into a plea agreement under which he agreed to provide information on the alleged criminal activities of Guthrie and the other defendants. Some of this information included the claimed FCA violations by Guthrie.

Before District Judge James Munley were defendants' motions to dismiss for lack of subject matter jurisdiction and for summary judgment, and plaintiff's motion for summary judgment. With respect to the issue of subject matter jurisdiction, the district court examined whether the FCA's jurisdictional bar provision had been triggered. That provision, 31 U.S.C. § 3730(e)(4)(A), prohibits courts from exercising jurisdiction over an FCA action "if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed" in certain other proceedings or "from the news media."

Citing *United States ex. rel. Paranich v. Sorgnard*, 396 F.3d 326 (3d Cir. 2005), the district court noted that the threshold for whether information is deemed "public" is whether it "would have been equally available to strangers to the fraud transactions had they chosen to look for it as it was to the relator." The jurisdictional bar, then, effectively boils down to a two-prong test: (1) whether the information was publicly disclosed via one of the sources set out in the statute (*e.g.*, a federal criminal, civil, or administrative hearing in which the government or its agent is a party); and (2) whether the relator's complaint is based on such information.

With respect to plaintiff's Stark Law and Anti-Kickback Statute allegations, defendants asserted that the information on which they were based—in particular, information regarding the alleged illegal financial transactions between defendants—was previously disclosed in prior litigation and on certain internet websites. The litigation at issue included a dispute over exemptions from Pennsylvania real estate taxes and a case filed in the Orphans' Court of Bradford County, Pennsylvania. Plaintiff, however, contended that this information was not "publicly" disclosed within the statute's meaning. Further, plaintiff argued, the financial transactions at issue could not lead to an inference of fraud because the fraud at issue did not simply involve the financial transactions themselves—they dealt, rather, with defendants' certifications that failed to acknowledge the illegal transactions (*i.e.*, the purported false claims).

The district court agreed with defendants, finding that, among other things, the information dealing with the financial and referral relationships between defendants had been publicly disclosed in accordance with the FCA's meaning because it could have permitted an "outsider to make an inference of fraud." The district court further found that plaintiff's claims were based on this publicly disclosed information because plaintiff's allegations of improper financial relationships between the defendants were "substantially similar" to the publicly disclosed information at issue. Accordingly, the district court granted defendants' motion to dismiss for lack of subject matter jurisdiction.

A copy of *United States ex. rel. Rodney Repko v. Guthrie Clinic, P.C.*, et al., No: 304-cv-1556 may be found **here.**

Reporter, *Gregory C. Sicilian*, Atlanta, +1 404 572 2810, gsicilian@kslaw.com.

HHS Issues Guidance on CMS Rule Requiring Equal Visitation Rights to all Hospital Patients – On September 7, 2011, the U.S. Department of Health and Human Services (HHS) issued interpretive guidance regarding the November 17, 2010 Centers for Medicare and Medicaid Services (CMS) regulation (the Rule) providing a hospitalized patient with the right to choose his or her visitors and to designate a person of choice to make medical decisions on his or her behalf should the patient become incapacitated.

The Rule followed an April 15, 2010 Presidential Memorandum, in which President Obama directed HHS to develop new standards regarding patient visitation rights and the right to designate surrogate decision makers regarding the patient's medical care. The President stated that denying patients access to their chosen visitors or decision-maker of choice can prevent doctors and nurses from having the best information about a patient's medications or medical history. HHS Secretary Kathleen Sebelius stated in a press release on September 8, 2011, that HHS is "releasing guidance for enforcing new rules that give all patients, including those with same-sex partners, the right to choose who can visit them in the hospital as well as enhancing existing guidance regarding the right to choose who will help them make medical decisions on their behalf."

Along with the HHS guidance, CMS issued a memorandum to all State Survey Agency Directors detailing the requirements of the Rule. State Survey Agency Directors are responsible for on-site inspections of hospitals on behalf of CMS.

Regarding visitation rights, the Rule provides that all Medicare and Medicaid participating hospitals, including critical access hospitals, must: (1) maintain written policies and procedures regarding patient visitation rights, including any "clinically necessary or reasonable restriction or limitation" that may be necessary, and the reasons for any such limitation; (2) inform all patients (or their designated representative) of their right to receive visitors of their choice, including a spouse, a domestic partner (including same-sex domestic partners), another family member, or a friend; (3) inform patients of their right to withdraw or deny consent at any time regarding authorized visitors; (4) not restrict visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability; and (5) ensure that all visitors have "full and equal" visitation rights that are consistent with the patient's preference.

The Rule further provides patients with the right to delegate to another person the ability to make medical decisions on his or her behalf as permitted under State law. According to the interpretive guidance, CMS expects hospitals to take reasonable steps to determine patients' wishes concerning the designation of a representative, and to give deference to patients' wishes concerning their designated representatives, whether expressed orally, in writing, or by other evidence.

In addition to the visitation and designated representative requirements, the Rule codifies a number of other patient rights addressed in the directive, including the right to participate in the plan of care, to formulate advance directives, and to receive notice of the patient's rights under the Rule when possible before providing or discontinuing care. As a condition of participation in the Medicare and Medicaid programs, hospitals must implement the Rule for all patients, not just those covered by Medicare or Medicaid.

The new Rule may be accessed by clicking **here**. The September 7, 2011 interpretive guidance is available **here**. CMS's memorandum to State Survey Agency Directors is available **here**.

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King & Spalding LLP Co-Sponsoring 4th Annual Healthcare Deal Making Summit – King & Spalding is co-sponsoring the 4th Annual Healthcare Deal Making Summit—dedicated to M&A deal making activity for non-profit and for-profit providers. The summit will be held at the Union Station Hotel in Nashville, Tennessee on October 3-5, 2011. Topics of the summit include:

- Implications of healthcare reform and industry consolidation of healthcare provider M&A transactions.
- Market intelligence on deal making activity and pricing from the leading equity investors, financiers, and investment bankers.
- Opportunities for non-profit and for-profit providers to facilitate deal making in a strategic business environment with the gathering of financiers and dealmakers under one roof.

For more information, please visit: **4th Annual Deal Making Summit**. To register, please visit **Healthcare Deal Making Summit Registration** and enter the number provided above.

Please contact **Jay Harris**, **Paul Quiros**, or **Bill Spalding** at +1 404 572 4600 for more information on this event.

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