KING & SPALDING

Health Headlines

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Circuit Court Invalidates Affordable Care Act Individual Mandate, Upholds Remainder of Act – On August 12, 2011, the U.S. Court of Appeals for the Eleventh Circuit declared the individual mandate provisions of the Affordable Care Act (the Act) to be unconstitutional. *See State of Florida v. U.S. Dep't of Health and Human Servs.*, No. 3:10-cv-00091-RV-EMT (11th Cir. 2011). In a 2-1 decision, the three-judge panel upheld in part an earlier district court decision striking down the individual mandate as a violation of the Commerce Clause of the U.S. Constitution. Unlike the district court, however, the circuit court upheld the remaining provisions of the Act.

The attorneys general of 26 states had challenged the constitutionality of the Act, arguing that the individual mandate exceeded Congress's power to regulate interstate commerce, and that its expansion of the Medicaid program to include a larger patient population effectively "coerced" states into participating in a voluntary program. In a 304-page decision, the circuit court held that the individual mandate exceeded the bounds of the Commerce Clause, stating that while Congress has broad authority to regulate interstate commerce, "what Congress cannot do under the Commerce Clause is mandate that individuals enter into contracts with private insurance companies for the purchase of an expensive product from the time they are born until the time they die." Calling the mandate "breathtaking in its expansive scope," the circuit court went on to state that Congress cannot regulate the health care market by regulating individuals who have not yet entered it. But the circuit court overturned the district court's decision to invalidate the entire Act, including the Medicaid expansion provisions.

The Eleventh Circuit's decision follows a June decision by the U.S. Court of Appeals for the Sixth Circuit, which upheld the individual mandate. A decision from the Fourth Circuit is expected later this year. That at least two circuit courts have reached different conclusions on the Act's constitutionality increases the likelihood that the issue will reach the U.S. Supreme Court. The Eleventh Circuit's decision is available by clicking **here**.

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Congressional Leaders Finalize Membership of Twelve-Person Joint Committee on Deficit Reduction – On August 11, 2011, House Minority Leader Nancy Pelosi (CA) finalized the composition of the Joint Committee on Deficit Reduction by naming Democratic Representatives Xavier Becerra (CA), Chris Van Hollen (MD), and Jim Clyburn (SC) to the so-called Congressional "super committee" eight days after the Budget Control Act of 2011 (BCA) was signed into law by President Barack Obama establishing the committee. On August 10, 2011, House Speaker John Boehner tapped Republicans Dave Camp (MI), Fred Upton (MI), and Jeb Hensarling (TX) for membership on the committee. Senate Majority Leader Harry Reid picked Democrats Patty Murray (WA), Max Baucus (MT), and John Kerry (MA), and Senate Minority Leader Mitch McConnell's Republican choices were Jon Kyl (AZ), Pat Toomey (PA), and Rob Portman (OH).

The Congress passed the BCA in order to increase the nation's debt ceiling limit while also creating mechanisms to reduce the deficit by establishing spending targets over the next ten years, between fiscal years 2012 and 2021. The BCA

specified $917 billion of spending cuts over this ten year period and established the Joint Committee on Deficit Reduction to identify an additional $1.5 trillion worth of cuts. The committee is tasked with identifying these spending cuts by November 23, 2011 through additional legislation to be passed by December 23, 2011.

If the committee cannot agree upon additional spending cuts of at least $1.2 trillion through entitlement reform or by raising tax revenue, the BCA includes a "sequestration" procedure that automatically cuts certain mandatory and discretionary spending equal to the difference between $1.2 trillion and the amount of reduction agreed upon by the committee. Exemptions in the law protect Social Security, Medicare, and Medicaid *beneficiaries* from cuts to those programs, but the sequestration procedure could include up to a two percent uniform reduction in payments to providers for services under Medicare Parts A, B, and C.

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HHS OIG Decides Not to Exclude Forest Laboratories CEO From Federal Healthcare Programs – According to a press release issued by Forest Laboratories, Inc. (Forest), the Office of the Inspector General, Department of Health and Human Services (HHS OIG) informed Forest's Chief Executive Officer and President, Howard Solomon, in a letter dated August 5, 2011, that it had decided not to exclude him from participation in federal healthcare programs. The agency's decision is significant as this case was one of HHS OIG's leading exclusion actions brought against an individual.

Social Security Act Section 1128(b)(15) authorizes HHS OIG to exclude an officer, officer or managing employee of an entity that has been either excluded from participation in federal healthcare programs or convicted of certain offenses. Perhaps signaling an intent to pursue more exclusion actions against such categories of individuals, on October 20, 2010, HHS OIG released guidance explaining the factors it would consider in deciding whether to exclude an officer or managing employee under Section 1128(b)(15). Among the factors to be considered, in addition to the circumstances surrounding the underlying misconduct and seriousness of the offense, are the positions held by the individual with the sanctioned entity, particularly during the time of the underlying misconduct; the degree of authority associated with the individual's position; whether the individual took steps to stop the misconduct or mitigate its effects; and whether the individual disclosed the misconduct or cooperated in the investigation.

The HHS OIG letter to Solomon does not detail why it elected not to pursue his exclusion. According to a Forest press release, the August 5, 2011 HHS OIG letter provides a brief one sentence explanation. That letter states that the HHS OIG has decided to close the case "based on a review of the information in our file and consideration of the information that your attorneys provided to us, both in writing and during the in-person meeting." Although the decision does not provide detailed insight into HHS OIG's application of its October 2010 exclusion guidance, the decision is encouraging for the healthcare industry and healthcare company officers to the extent it demonstrates the opportunity for advocacy before the HHS OIG regarding the interpretation and application of the general criteria set out in its exclusion guidance.

A copy of Forest's August 5, 2011 press release is available by clicking **here**. A copy of the OIG 2010 exclusion guidance is available by clicking **here** and a copy of the OIG's Fact Sheet is available by clicking **here**.

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Peninsula Regional Medical Center Agrees to Pay $1.8 Million to Settle FCA Allegations – On August 10, 2011, the Department of Justice (DOJ) issued a press release stating that Peninsula Regional Medical Center (Peninsula) has agreed to pay $1.8 million to settle allegations that it failed to take action to prevent medically unnecessary cardiac stent procedures by Dr. John R. McLean. It was also alleged that the senior medical staff at Peninsula failed follow up on evidence presented to them that Dr. McLean was performing unnecessary procedures for federal healthcare program beneficiaries.

As part of the settlement, Peninsula has entered into a Corporate Integrity Agreement (CIA) with the Department of Health and Human Services, Office of Inspector General. According to the press release, the CIA requires, among other things, that Peninsula ensure accurate billings and appoint physician executives to oversee medical staff quality-of-care matters.

A copy of the DOJ press release is available by clicking **here**.

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CMS Issues Medicare Provider Compliance Newsletter with Guidance to Address Billing Errors – CMS has issued its fourth Medicare Quarterly Provider Compliance Newsletter. Inside, CMS identified seven common hospital billing errors with respect to coding that affects DRG assignment.

CMS noted the MS-DRG codes that its recovery auditors targeted for validation:

- 040: Peripheral/Cranial Nerve and Other Nervous System Procedures with Major Complication and Comorbidity (MCC)
- 064: Intracranial Hemorrhage or Cerebral Infarction with MCC
- 065: Intracranial Hemorrhage or Cerebral Infarction with Complication and Comorbidity (CC)
- 066: Intracranial Hemorrhage or Cerebral Infarction without CC or MCC
- 189: Respiratory Failure
- 237: Major Cardiovascular Thoracic Aortic Aneurysm Repair Procedures with CC or MCC
- 252: Other Vascular Procedures with MCC
- 377: Gastrointestinal Hemorrhage with MCC
- 378: Gastrointestinal Hemorrhage with CC
- 379: Gastrointestinal Hemorrhage without CC or MCC
- 467: Revision of Hip or Knee Replacement with CC
- 481: Hip and Femur Procedures except Major Joint with CC
- 486: Knee Procedures with Principal Diagnosis of Infection with CC
- 488: Knee Procedures without Principal Diagnosis of Infection with CC or MCC

For each of the errors, CMS cited relevant manual provisions for quick reference. In general, providers can avoid these errors by following the guidance found in those provisions. The Quarterly Provider Compliance Newsletter is available by clicking **here**.

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