KING & SPALDING

Health Headlines

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United States Supreme Court Strikes Down Vermont Prescription Confidentiality Law – On June 23, 2011, in *Sorrell v. IMS Health, Inc., et al.*, the United States Supreme Court struck down the Vermont Prescription Confidentiality Law (Vt. Stat. Ann., Tit. 18, § 4613(d), *amended by* H. 750) (the Law) as an unconstitutional restriction of First Amendment commercial speech. Subject to exceptions, the Law prohibits selling or using prescriber-identifiable prescription drug information to market or promote a prescription drug absent a prescriber's consent. It also specifically prohibits pharmaceutical manufacturers and marketers from using the prescriber-identifiable prescription drug information for marketing or promotional purposes without the consent of the prescriber.

Click **here** to read the King & Spalding LLP Client Alert issued by the FDA & Life Sciences Practice Group, which provides a more complete description of the case and the Supreme Court's rationale.

"Fighting Fraud To Protect Taxpayers Act Of 2011" Would, If Enacted, Change The Dynamic Of False Claims Act Settlements – On May 5, 2011, Senators Leahy (D-Vt.), Grassley (R-Iowa), Klobuchar (D-Minn.), and Coons (D-Del.), introduced a bill titled "Fighting Fraud to Protect Taxpayers Act of 2011," (the Bill) which would require the Attorney General to make annual reports to Congress summarizing False Claims Act, 31 U.S.C. § 3729 *et. seq.*, (FCA) settlements, including the details of damages calculations. The Bill also would allocate a percentage of FCA and other fraud recoveries to the Department of Justice (DOJ) to offset administrative costs of investigating fraud, and it includes miscellaneous fraud-fighting provisions. The Senate Judiciary Committee reported on May 19, 2011.

Section 9 of the Bill would require the Attorney General to report annually to the Senate and House Judiciary Committees settlements of FCA violations and violations of the Major Fraud Act, 18 U.S.C. § 1031, when the settlements result from a "claim for damages of more than $100,000." The annual report must include 14 elements for each settlement. These include, among others:

(1) the total amount of the settlement and portions allocated to various statutory authorities;
(2) the amount of actual damages as well as minimum and maximum potential civil penalties;
(3) the basis for any estimates of damages or civil penalties;
(4) the division of the settlement amount between damages and multipliers;
(5) the amount representing civil penalties and the percentage of maximum civil penalties;
(6) whether the defendant previously settled an FCA or Major Fraud Act matter;
(7) whether a Corporate Integrity Agreement (CIA) or Deferred Prosecution Agreement (DPA) has been negotiated in the instant matter and whether the defendant previously entered into a CIA or DPA;
(8) whether Civil Investigative Demands were issued in investigating the matter; and
(9) the percentage of the settlement amount awarded to the FCA relator.

The intent of the Bill is to place pressure on DOJ to drive harder bargains in resolving FCA suits. Senators Grassley and

Leahy's press release explains that the Bill's goal is to increase "accountability by requiring the Justice Department to better manage and account for key spending." Moreover, it seeks to ensure that "'False Claims Act lawsuits aren't being settled for pennies on the dollar.'"

If enacted, the Bill has the potential to significantly impact current FCA settlement negotiation practices in a number of ways. For example, the prevailing practice in settling FCA cases is that the act of entering into settlement negotiations takes off the table the potential for civil penalties of $5,500 to $11,000 per claim provided in the FCA, which can be particularly extreme in the healthcare industry due to the large volumes of claims. In light of the Bill's requirements to specify the upper and lower ranges of civil penalties, the amount of the settlement that constitutes civil penalties, and the percentage of the potential civil penalties the defendant ultimately paid, DOJ might feel compelled to raise the issue of civil monetary penalties in addition to damages in settlement negotiations. Additionally, the tax implications of FCA settlements would be changed in important ways. Currently, DOJ will not specify in settlement agreements the percentage of the payment allocated to base damages and the percentage allocated to multipliers, which the Bill would require. This is important for the settling entity's tax liability, as the repayment of the base amount of damages may be deductible as an offset to income, whereas penalties typically are not deductible. Finally, congressional oversight of the percentage of FCA settlements awarded to relators may have the effect of driving up the percentage paid to relators, which may be against the interest of a settling defendant that feels wronged by the relator's actions.

The Bill, Fighting Fraud to Protect Taxpayers Act of 2011, S.890, 112th Cong. (2011), is accessible by clicking **here**, and Senator Grassley's press release concerning the Bill is accessible **here**.

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Starting July 1, 2011, CMS Will Begin Using Predictive Modeling Technology To Fight Medicare Fraud – On June 17, 2011, the Centers for Medicare and Medicaid Services (CMS) announced that it will begin using predictive modeling technology to fight Medicare fraud. This is the latest of CMS's initiatives to shift from a "pay and chase" approach to a proactive fraud prevention model. According to the press release, this predictive modeling initiative builds on new anti-fraud tools and resources provided by the Patient Protection and Affordable Care Act. "President Obama is committed to hunting down and eliminating waste, fraud and abuse throughout the federal government," said Department of Health and Human Services (HHS) Secretary, Kathleen Sebelius.

Medicare claims will be analyzed using risk scoring technology that applies effective predictive models, according to the press release. CMS will now have access to real-time data to help identify suspicious claims. Northrop Grumman has been selected to develop CMS's national predictive model technology. Northrop Grumman has partnered with National Government Services, a Medicare administrative contractor (MAC), and Federal Network Systems, LLC, in order to leverage a wealth of claims data.

Given the importance of this initiative to CMS's overall anti-fraud efforts, Northrop will move rapidly to implement this new anti-fraud technology. According to the press release, Northrop Grumman will deploy algorithms and an analytical process that looks at claims by beneficiary, provider, service origin or other patterns in order to identify potential problems. In addition, based on the predictive modeling, Northrop Grumman may assign an "alert" and "risk scores" to claims. CMS will then review these claims to determine whether further investigation or other enforcement action is warranted.

To view the press release click **here**.

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Medicare Board Of Trustees Releases 2011 Annual Report; Predicts Widening Deficits For Trust Funds – Last week, the Medicare Board of Trustees (the Board) released its annual report on the fiscal condition of the Medicare trust funds: the Hospital Insurance ("HI") fund, which supports Medicare Part A, and the Supplementary Medical Insurance ("SMI") fund, which supports Medicare Parts B and D. The Board reports that although the federal health care reform legislation passed in 2010 has improved the short-term financial health of the funds, the funds still face substantial long-

term deficits based on current law and population projections.

According to the report, the financial status of the HI trust fund actually has improved in the short term as a result of lower expenditures and additional tax revenues caused by the health care reform legislation. Nevertheless, the Board estimates that HI expenditures will continue to exceed income, as they have since 2008, until the fund is exhausted in 2024, five years earlier than predicted a year ago.

The Board states that if health care reform is to have a long-term effect on the sustainability of the Medicare Part A program, future downward adjustments to payment increases for all categories of Part A providers will be necessary. According to the Board, however, "[w]ithout fundamental changes in today's health care delivery and payment systems, these reductions would probably not be viable indefinitely into the future and would likely result in HI payment rates that would eventually become inadequate to compensate providers for their costs of treating beneficiaries, with adverse implications for beneficiary access to care."

The Board found that the SMI trust fund appears adequately financed through the next ten years because premium and general revenue for the Part B and Part D programs are reset each year to match expected costs. However, Part B and D expenditures have increased over the last five years by an annual average of 6.9 percent and 9.7 percent, respectively. Part B expenditures were 1.5 percent of GDP in 2010 and are projected to grow to 2.4 percent by 2085. The Board expects Part D expenditures to increase from 0.4 percent of GDP to 1.7 percent by 2085. Even though the SMI trust fund maintains a balanced annual budget, the Board found that the fund's financing would have to grow more quickly than the overall economy to match the expected growth of long-term expenditures under current law.

Medicare expenditures totaled $523 billion in 2010. The Board report states that future expenditures projected under current law are likely to increase at a faster pace than either workers' earnings or the overall economy. By 2085, the Board predicts that Medicare expenditures will increase from 3.6 percent of GDP to 6.2 percent. According to the Board, "We believe that prompt action is necessary to address both the exhaustion of the HI trust fund and the anticipated excess growth in HI, SMI Part B, and SMI Part D expenditures."

The "2011 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplemental Medical Insurance Trust Funds" can be found **here**.

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