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Health Washington Beat: Recent Health Industry News

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Mintz Levin's Health Law Practice has assembled the following overview of recent issues and developments that affect the health industry and that will continue to take center stage in 2009.

Obama Selects Daschle to Lead Health Care Reform

On December 11, 2008, President-elect Barack Obama chose former Senator Tom Daschle to head the new Office of Health Reform (OHR). With the naming of Daschle as the head of the OHR and the Department of Health and Human Services (HHS), Obama indicated that health care reform will be a top priority in his administration. In fact, because Daschle's nomination has been widely accepted by the health care industry and lawmakers, Daschle is expected to urge an overhaul of the health care system early in 2009.

Hoping to avoid the mistakes of the Clinton administration, Daschle favors a step-by-step approach to health care reform that will build on the existing employer-based insurance system. For example, instead of eliminating employer-based insurance altogether, he plans to encourage Congress to create a National Health Board (modeled after the National Reserve Board) that will be responsible for instituting guidelines to place new conditions and restrictions on insurers. In addition, Daschle has proposed the creation of a public insurance program for people who cannot afford private insurance. Stay tuned for further developments on President-elect Obama's health care reform initiatives.

HHS Secretary Proposes Consumer Role in Health Information Technology Privacy

On December 15, 2008, HHS Secretary Mike Leavitt announced that informed consumer choice should play a dominant role in health information technology (HIT) privacy. In a keynote address to the Nationwide Health Information Network forum, Leavitt outlined his suggestions for HIT privacy principles. Because he believes that consumers are comfortable with varying levels of privacy and access, Leavitt's privacy principles emphasize individual access and choice in allowing consumers to make informed decisions about their personal health records. In addition, Leavitt announced several tools to protect privacy and to permit consumers to access their health information. For example, the "Leavitt Label," modeled after the nutritional labels on food packaging, would allow consumers to quickly compare personal health record products.

HHS Advises on Application of HIPAA to Health Information Organizations

During the December 15, 2008 address, Secretary Leavitt released the HHS Office of Civil Rights (OCR) principles of the *Nationwide Privacy and Security Framework For Electronic Exchange of Individually Identifiable Health Information* (the "Privacy and Security Framework") that are intended to "establish a single, consistent approach" regarding the application of the Privacy Rule issued pursuant to the Health Care Portability and Accountability Act of 1996 (HIPAA) to protected health information (PHI) exchanged in a networked environment.

One of the primary goals of the Privacy and Security Framework is to resolve fundamental questions concerning the exchange of PHI between a HIPAA covered entity and other health information organizations (HIOs). HIOs typically are not covered entities for purposes of HIPAA compliance because the functions they perform do not make them a health plan, health care clearinghouse, or covered health care provider. However, HIOs frequently are business associates of covered entities and, as such, are permitted to create or receive PHI on behalf of the covered entity and to safeguard and appropriately protect the privacy of PHI in accordance with a business associate agreement. While there is no universal definition of an HIO, for purposes of the Privacy and Security Framework an HIO is "an organization that oversees and governs the exchange of health-related information among organizations according to nationally recognized standards." The Privacy and Security Framework addresses the application of HIPAA's privacy and security rules to HIOs under eight core principles:

- Individual Access;
- Correction;
- Openness and Transparency;
- Individual Choice;
- Collection, Use, and Disclosure;
- Data Quality and Integrity;
- Safeguards; and
- Accountability.

HIPAA covered entities and HIOs alike should review the Privacy and Security Framework in light of their own particular business arrangements, internal policies and procedures, and business practices to ensure that appropriate controls are in place for proper access to and protection of PHI exchanged electronically among health care entities.

The Privacy and Security Framework is available here.

OIG Asks for Proposals and Recommendations for Safe Harbors and Fraud Alerts

In accordance with Section 205 of the HIPAA, the HHS Office of Inspector General (OIG) recently issued its annual notice soliciting proposals and recommendations for developing new and modifying existing safe harbor provisions under the federal Anti-kickback Statute, as well as developing new OIG Special Fraud Alerts.

The Anti-kickback Statute prohibits individuals or entities from knowingly and willfully offering, paying, soliciting, or receiving remuneration in order to induce or reward business reimbursable under a federal health care program. Because the Anti-kickback Statute is, on its face, quite broad, the OIG developed safe harbor provisions to limit its reach and to specify payment arrangements that, although capable of inducing business referrals reimbursable by a federal health care program, would not be treated as a violation of the Anti-kickback Statute or serve as the basis for administrative sanctions. Similarly, the OIG periodically issues Special Fraud Alerts that offer guidance with respect to business practices that the OIG finds potentially fraudulent or abusive.

Proposals and recommendations are due to the OIG by February 17, 2009.

The notice is available here.

OIG Blesses Part-time Physician Employment Arrangement

On December 15, 2008, the HHS OIG posted Advisory Opinion No. 08-22, which relates to the federal Anti-kickback Statute and part-time physician employment arrangements. The nonprofit, tax-exempt corporation requesting the opinion plans to employ two physicians on a part-time basis to provide endoscopies, which are payable by a federal health care program. Each physician will also maintain a separate medical practice outside the arrangement. Relying on certifications that the physicians are in fact *bona fide* employees being paid salaries for personally provided professional services, the OIG concluded that the arrangement would comply with the employee safe harbor to the Anti-kickback Statute so would not generate prohibited remuneration.

The OIG explicitly expressed no opinion whether the arrangement complies with any other law, including the Stark Law, that "falls outside the OIG's advisory opinion jurisdiction." The OIG highlighted material differences between the Stark Law's employment exception and the Anti-kickback Statute's employee safe harbor. Specifically, the employment exception to

the Stark Law requires the remuneration to be consistent with fair-market value. Additionally, the remuneration can not be linked to the volume or value of referrals from the physician, and must be under an agreement that would be reasonable even without physician referrals to the employer.

The opinion is available here.

GAO Reports on MA Plans' Profits and Costs for 2006

Medicare Advantage (MA) plans may face heightened congressional scrutiny in 2009. On December 8, 2008, the GAO submitted a follow-up to its June 2008 report to the House Ways and Means Committee stating that, on average, MA organizations overestimated costs and underestimated profits in their bids to Medicare. More specifically, the GAO reported that MA organizations generally profited more and spent less than they claimed they would in their 2005 and 2006 bid submissions to contract with Medicare, resulting in profit margins exceeding their projections by 1.1 and 1.3 billion dollars, respectively. According to the GAO report, MA organizations could have provided beneficiaries more benefits and cost-sharing reductions if their predicted revenues and expenses were more accurate. The Centers for Medicare & Medicaid Services ("CMS") endorsed the GAO report but commented that the unexpected profits were largely due to the higher-than-expected number of high-risk patients enrolled in the MA plans. For example, because more patients than the MA plans predicted had potentially expensive health conditions, CMS paid the plans more money. As Congress begins to shape health reform in 2009, MA organizations should expect Congress to address these findings.

The report is available here.

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