

## Health Law Washington Beat: Recent Health Industry News

2/9/2009

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### Obama Administration Supports Inclusion of a Public Plan Option in Health Care Reform Legislation

On February 2, 2009, Jeanne Lambrew, Deputy Director of the White House Office of Health Reform, stated that the Obama Administration supports the inclusion of a public insurance plan option in health care reform legislation. Speaking at the National Health Policy Conference in Washington, D.C., Lambrew said that the President believes in giving people a true choice, which would include offering a public plan option to operate side-by-side with private insurance options on a level playing field. Although no specific details were provided, Lambrew noted that a public plan option could be modeled after state employees' health benefits plans through which the government pays private health insurers to provide coverage and assumes the financial risk involved in providing that coverage.

Lambrew's remarks came on the heels of a January 29, 2009 statement by House Energy and Commerce Committee Chairman Henry Waxman, who declared that health reform legislation should include a public plan option to compete with private plans and to draw support for those in favor of a single-payor health care system. Many other congressional Democrats believe that a public plan option is crucial to health care reform. Proponents argue that a public plan would help drive down overall health care costs by competing with private plans and lowering administrative costs. Most importantly, a public plan would provide coverage options for certain segments of the population that have not been well-served by private health plans.

Arguments in favor of a public plan option were bolstered by a recent report by the Institute for America's Future entitled *A Public Health Insurance Plan: Reducing Costs and Improving Quality*. According to the report, public health insurance plans are superior to private insurance at controlling costs while, at the same time, preserving access to care. As an illustration, the report noted that between 1997 and 2006 private insurance spending per enrollee increased 59% faster than Medicare spending.

Although President Obama wants bipartisan support for health care reform, his stance on public plan options is controversial. Many congressional Republicans as well as the health insurance industry oppose a public plan option. Opponents believe that the government would set rules favorable for the operation of public plans at the expense of private plans. And they argue that a public plan would ultimately lead to higher costs for private insurers because the government would underpay providers and private insurance would be left to "pick up the slack."

The inclusion of a public plan option in health care reform legislation is shaping up to be a major battlefield in the coming months. Even though the country appears ready for health care reform, the administration faces an uphill battle in light of the worsening economy and the loss of Tom Daschle to head the health care debate. The Obama Administration will likely introduce details regarding the public plan option in health care reform legislation following the passage of the economic stimulus package.

### SCHIP Expansion Bill Signed into Law

On February 4, 2009, President Obama signed a bill into law that reauthorizes the State Children's Health Insurance Program (SCHIP) and increases funding for the program by \$32.8 billion over the next four and a half years. With this increased funding—a cost that will be financed by raising the federal cigarette tax—approximately 4 million additional children will receive health care coverage. Opponents of the bill claim that the expansion goes too far because it will cover middle-class families who would otherwise be covered by private health insurance as well as children of legal immigrants who have lived in the country for less than five years. Supporters disagree, citing the importance of expanding affordable healthcare coverage, particularly at a time when people are losing their jobs and health insurance.

The 2009 SCHIP bill, which looked very similar to the 2007 bill vetoed by President Bush, easily passed both the Senate (66-32) and the House (290-135). When signing the bill into law, President Obama called it a "down payment" on his commitment to ensure access to affordable health care for all Americans. The text of the bill is available [here](#).

### CMS Rescinds Draft Call Letter

On January 22nd, just two days after President Obama took office, the Centers for Medicare & Medicaid Services (CMS) rescinded the draft Medicare "call letter" originally posted on the CMS Web site on January 8th. CMS reasoned that it sought "an opportunity for further review of the document" and pledged to re-post the call letter for public comment once the agency has made any revisions. CMS acknowledged that Medicare Advantage (MA) organizations and prescription drug plan (PDP) sponsors require guidance in order to prepare bids for 2010, and therefore assured MA organizations and PDP sponsors that a revised draft call letter will be released for comment as soon as possible. Applications for new health plans are due on February 26th, and the final call letter was due to be released on March 30th. Bids for MA and Part D plans are due June 1st.

### State Enforcement of Federal Privacy Rule Proposed in House Bill

Section 4410(e) of the American Recovery and Reinvestment Act of 2009 (H.R. 1), which is included among H.R. 1's provisions related to the privacy and security of health information, would expand the Health Insurance Portability and Accountability Act of 1996 (HIPAA) enforcement authority by permitting the 50 states' attorneys general to enforce the HIPAA privacy rule. If passed, this provision would represent a vast change because enforcement authority currently resides at the federal level only.

In a January 30, 2009 letter to Senate Majority Leader Harry Reid (D-Nev) and Senator Mitch McConnell (R-Ky), the U.S. Chamber of Commerce Institute for Legal Reform (ILR) urged the Senate to oppose Section 4410(e) of H.R. 1 and any companion legislation in the Senate bill and to retain the current HIPAA enforcement structure. The ILR expressed concern that the provision would lead to "a patchwork of potentially conflicting authorities and interpretations" and encourage "a multitude of civil actions." The ILR also pointed out that the Department of Health and Human Services (HHS) has developed substantial expertise in administering and interpreting the HIPAA and has worked closely with covered entities to foster compliance. Further, the ILR is concerned about the time, energy, and resources necessary to comply with the varying interpretations of state authorities who may lack the expertise to interpret and enforce the law. This issue is especially important in this economy because many American businesses are "struggling to survive."

### Legislation Introduced to Ban "Pay-for-Delay" Deals for Pharmaceuticals

Legislation to ban "pay-for-delay" agreements that postpone the entry of generic drugs to the market was introduced on February 3, 2009 by the new chairman of the Special Committee on Aging, Senator Herb Kohl (D-Wisc.).

Pay-for-delay agreements are used to settle patent litigation between brand-name and generic drug companies and typically involve payments made by the brand-name companies to the generic companies for delaying the introduction of generic drugs to the market. Senate Bill 369<sup>1</sup> states that “consumers and the health care system would benefit from free and open competition in the pharmaceutical market and the removal of obstacles to the introduction of generic drugs ... [and that] the Federal Trade Commission [(FTC)] has determined that some brand name pharmaceutical manufacturers collude with generic drug manufacturers to delay the marketing of competing, low-cost, generic drugs.” The legislation would amend the Clayton Act to explicitly prohibit any agreement resolving or settling a patent infringement claim in which the generic manufacturer is paid to delay the research, development, manufacture, and market of a generic drug.

The Senate Judiciary Committee held a hearing last week to examine the issue. FTC Commissioner Jon Leibowitz, among others, discussed the impact of pay-for-delay agreements on the pharmaceutical market. FTC representatives have previously informed Congress that eliminating these deals is a priority for antitrust enforcement. Commissioner Leibowitz has noted that “delaying generic entry on even a single drug can cost consumers billions of dollars.”

## Senate Considers Physician Payment Sunshine Act of 2009

Recently, Senators Grassley and Kohl introduced a new version of the Physician Payment Sunshine Act (the “Act”) with sharper teeth than the version they introduced in 2007. Generally, the law would require manufacturers of drugs, devices, biologicals, or medical supplies reimbursable by Medicare, Medicaid, or SCHIP to submit a “transparency report” to the Secretary of HHS if they provide anything of value to “covered recipients” (a physician or group practice). The proposed legislation would apply to payments or transfers of value of \$100 or more (yearly aggregate) and would require that the reports, which would be submitted beginning March 31, 2011, and annually thereafter, contain the following:

- name and address of recipient;
- value of the payment or transfer;
- date of payment or transfer;
- description of the form of the payment or transfer;
- description of the nature of the payment or transfer indicated as: consulting fees, compensation for other services, honoraria, gifts, entertainment, food, travel, education, research, charitable donations, royalty/license fees, ownership of investment interests, CME speaker fees/grants, and anything else HHS requires;
- if the payment or other transfer of value is related to marketing, education, or research specific to a covered drug, device, biological, or medical supply, the name of that covered drug, device, biological, or medical supply;
- information regarding any ownership or investment interest of the manufacturer held by a physician (or immediate family member of the physician); and
- anything the Secretary of HHS deems appropriate.

The law would preempt any state law or regulation that requires similar disclosures but would have no effect on any state law or regulation that mandates the reporting of information over and above that required by federal law. This provision represents a retreat from the broad preemption provisions in the 2007 version of this legislation.

For unintentional failure to report, penalties would include fines from \$1,000 to \$10,000 for each payment not reported, with a cap of \$150,000 per year. For intentional failure to report, the fines would be from \$10,000 to \$100,000 for each payment not reported with a cap of \$1 million per year.

Exclusions include the following:

- payments of less than \$100 to a covered recipient (yearly aggregate);
- product samples;
- patient education materials;
- the loan of a device for less than 90 days;
- warranty replacements (devices);
- items for use as a patient;
- discounts and rebates;
- in-kind items used in charity care; and
- dividends or distributions from a publicly traded security and mutual fund.

If passed, the Act could have a significant impact on how the public views providers and the income they generate, but, surprisingly, it has met with little resistance from affected parties, including physicians and manufacturers. In fact, industry associations, such as AdvaMed and the American Association of Medical Colleges, have commended the Act’s sponsors for taking steps to achieving a more ethical and transparent way of doing business in the industry.

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## Endnotes

<sup>1</sup> S. 369, 111th Cong. (2009).

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*For assistance in this area, please contact one of the attorneys listed below or any member of your Mintz Levin client service team.*

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