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In This Issue

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Faced with High Health Care Reform Costs, Congress and the Obama Administration Step Up Fraud and Abuse Enforcement Efforts

As recent events have demonstrated, one of the major challenges to health care reform is finding the money to pay for it. One potential source of funding is an acceleration of government efforts to pursue health care fraud and abuse that costs the health care system billions of dollars every year.[1] It comes as no surprise, therefore, that Congress and the Obama Administration are stepping up fraud and abuse oversight and enforcement activities in what might point toward an effort to curb the cost of health care reform.

Although the Obama Administration has not articulated a specific strategy for increasing fraud and abuse enforcement efforts, on May 20, 2009, Attorney General Eric Holder and Department of Health and Human Services (HHS) Secretary Kathleen Sebelius announced the creation of an interagency Health Care Fraud Prevention and Enforcement Team (HEAT) to combat abuses in the Medicare Program. HEAT consists of high-level officials from both HHS and the Department of Justice (DOJ) who are responsible for coordinating fraud and abuse enforcement efforts. To date, HEAT has uncovered fraudulent schemes in major cities, including Miami, Los Angeles, Detroit and Houston, that could result in significant government recoveries from penalties and settlements.

Congress' health care reform bill remains a work in progress, but there is little doubt that any health reform legislation will include enhanced fraud and abuse oversight and enforcement provisions. In fact, on July 14, 2009, the House introduced its tri-Committee health reform bill entitled "America's Affordable Health Choices Act of 2009." This bill provides for new tools to combat waste, fraud, and abuse within the entire health care system, and includes provisions for

pre-enrollment screening of providers and suppliers, as well as enhanced oversight of designated high-risk fraud and abuse areas (e.g., durable medical equipment and home health services). In addition, this bill requires health care providers and suppliers to implement compliance programs. The bill was approved today by the House Energy and Labor Committee and the House Ways and Means Committee, but is still awaiting approval by the House Energy and Commerce Committee.

Not to be outdone, the Senate Health, Education, Labor, and Pensions (HELP) Committee passed its health reform bill on July 15, 2009. This bill creates senior-level positions at HHS and DOJ to coordinate health care anti-fraud activities. Further, the proposed legislation establishes a Health Care Program Integrity Coordinating Council to coordinate strategic planning among federal agencies involved in fraud and abuse investigations and enforcement activities.

Regardless of whether comprehensive health reform legislation will succeed this year, the uptick in enforcement efforts may signify the government's intention to fund or offset some of the cost of health care reform through reducing waste, fraud, and abuse. As a result, health care providers and suppliers may face increased scrutiny. Providers and suppliers should review and adapt their compliance programs to comprehensively address areas where the risk for investigation and potential liability are increasing. Providers and suppliers that do not have a compliance program in place would be wise to consider investing now in risk-reducing policies and procedures. All providers and suppliers should make sure that these programs, policies, and procedures are consistently and effectively implemented. Finally, providers and suppliers should consider whether their existing policies and procedures for responding to government investigations should be modified or updated in light of the potential for increased government scrutiny.

HELP Committee Approves 12-Year Data Exclusivity for Biosimilars

Creating an approval pathway for follow-on biologic drugs (biosimilars) has been an important topic both in the last Congress and now in connection with the current health reform package. As explained in the *Washington Beat* in April, three competing bills on this topic were introduced in March alone. Both chambers of Congress are now considering additional amendments.

Of the several biosimilar proposals recently introduced in the Senate HELP Committee, the amendment proposed by Senators Kay Hagan (D-NC), Michael Enzi (R-WY), and Orrin Hatch (R-UT) was adopted by a vote of 16-7. This amendment provides for a 12-year exclusivity period for pioneer biologics, which offers significantly more protection for innovator companies than other proposals considered by the HELP Committee. For example, the amendment offered by Senator Sherrod Brown (D-OH) would have allowed for seven years of exclusivity (the period recommended by the Obama Administration), and the recent proposal by Senator Kennedy (D-MA) would have provided for a nine-year exclusivity period.

The final legislation needs to strike a delicate balance that takes into account both incentives to innovate and the cost to the patient. Those in the pioneer biologics industry and their supporters have been lobbying for a 12- to 14-year exclusivity period based on the amount of time it would

take to recoup the significant research and development costs associated with biological medicines (often well over $1 billion); a shorter period, they argue, would stifle innovation. The Biotechnology Industry Organization (BIO) hailed the HELP Committee's approval of the proposal as a "significant victory" for innovator companies, but is only cautiously optimistic because the amendment still faces hurdles in the House and on the Senate floor. Others think this exclusivity period is too long and will unduly restrict competition. AARP, for example, has called the 12-year period "unreasonable" and has indicated that the association would have trouble supporting legislation that would delay the entry of follow-on biologics for such a long period; AARP supported Senator Brown's seven-year proposal. A recent FTC report, which is summarized here, explains that the competition will be more akin to brand-to-brand competition and likely will not lead to immediate and drastic cost reductions seen when generic competitors introduce chemical drugs.

On the House side, a bill proposed by Representative Anna Eshoo (D-CA) has gained momentum. Representative Eshoo's bill would provide for an initial exclusivity period of 12 years, but could result in an additional two-and-a-half years for significant improvements and pediatric studies. A competing bill by Representative Henry Waxman (D-CA) would provide only five years of exclusivity. The House Judiciary Subcommittee on the Courts and Competition Policy held a hearing on the topic on July 14th but has not yet voted. At last count, Representative Eshoo's bill—the bill closest to the version adopted by the Senate HELP Committee—had considerably more sponsors and more support than the Waxman proposal.

Plan Finder: Misdirecting Seniors?

According to a recent report issued by the HHS Office of Inspector General (OIG), an online tool developed and administered by the Centers for Medicare & Medicaid Services (CMS) to help seniors compare the Part D plans best suited to their needs may do more harm than good. The report, entitled "Accuracy of Part D Plans' Drug Prices on the Medicare Prescription Drug Plan Finder," describes the OIG's methodology for determining whether CMS's Medicare Prescription Drug Plan Finder (the Plan Finder) accurately reflected the actual drug costs borne by beneficiaries during the period September 24, 2007-October 7, 2007 and its conclusion that it did not do so.

To use the Plan Finder, beneficiaries enter their ZIP codes and information about their prescription drug regimens. Beneficiaries may perform two types of searches: a general search to find the least expensive plan that suits their needs, and a more tailored search to determine the estimated drug costs for the specific pharmacy they intend to use to fill their prescriptions. During the period under review, CMS recommended that beneficiaries conduct a general, rather than pharmacy-specific, search when attempting to identify the least expensive plan.

To determine whether the drug prices returned by the Plan Finder approximated the beneficiaries' actual drug costs, the OIG chose 10 drugs commonly used by seniors and compared the plans' retail drug prices, as displayed by the Plan Finder, to the actual cost of the prescription drugs. During its review, the OIG conducted general, rather than pharmacy-specific, searches, in accordance with CMS's recommendation.

The OIG found that the drug prices returned by the Plan Finder "generally exceeded actual drug costs, frequently by large amounts." The OIG noted that, although the Plan Finder informs beneficiaries that "drug costs displayed are only estimates" and that "actual costs at the pharmacy may vary slightly," the Plan Finder provided inaccurate estimates of actual drug costs for the vast majority of reviewed claims. Specifically, the OIG found that the drug prices returned by the Plan Finder were higher than actual drug costs 92% of the time. The Plan Finder's estimated prices were over 100% higher than actual drug costs 19% of the time, meaning that, on average, almost one out of every five drugs purchased cost less than half the amount estimated by Plan Finder.

Although beneficiaries likely appreciated paying less than they had anticipated, the Plan Finder is intended to assist beneficiaries in comparing and selecting the Part D plans best suited to both their prescription drug needs and their budgets. For the Plan Finder to serve its intended purpose, it must accurately reflect beneficiaries' actual drug costs. If the Plan Finder continues to overestimate drug costs, the OIG believes that it may have the unintended consequence of causing beneficiaries to forgo Part D coverage under the misguided notion that they cannot afford it.

The OIG made two recommendations based on its findings. The first, with which CMS concurred, was that CMS consider using prescription drug event (PDE) claims to monitor the accuracy of the drug prices displayed on the Price Finder. The OIG acknowledged that the claims it reviewed had been incurred before CMS issued its April 2008 memorandum outlining the quality assurance checks it performs, and that it expects plans to perform, on the data submitted for inclusion in the Plan Finder. However, the list of quality assurance checks included in that memorandum did not include comparing plans' drug prices to actual costs on PDE claims.

The OIG's second recommendation was that CMS add a disclaimer stating that the Plan Finder's drug cost estimates may differ more than "slightly" from actual drug costs. CMS objected to this recommendation, arguing that the OIG's methodology was flawed because it did not use the pharmacy-specific search and because the drug prices and dispensing fees that plans negotiate with individual pharmacies can vary significantly. The OIG responded by citing to CMS's recommendation that beneficiaries conduct a general search. Although it disagreed with the OIG, CMS did indicate that it would revise the Plan Finder website to include language "encourag[ing] beneficiaries to select the pharmacy they currently use in order to get more precise [point-of-sale] pricing."

The full OIG report, including CMS's comments, may be found here.

Endnotes

[1] The National Health Care Anti-Fraud Association estimates that 3% of all health care spending is lost due to health care fraud perpetrated against public and private health plans every year. In 2008, this loss amounted to $72 billion. Other government and law enforcement agencies estimate losses from fraud to be as high as 10% of annual health care spending.

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