ML STRATEGIES

Are Exchange Health Plans Federal Health Care Programs, and Therefore Subject to Anti-Kickback Statutes?

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- Industry stakeholders were generally surprised to recently learn that health plans offered on the health care exchanges may not be considered "federal health care programs" and therefore may not be subject to certain fraud and abuse laws.
- Despite a letter from HHS Secretary Kathleen Sebelius stating that the exchange plans were not federal health care programs, a subsequent letter from CMS and the absence of additional guidance from DOJ has created confusion amongst lawmakers and the health care sector.
- While the Sebelius letter could mean higher enrollment and greater access to premium assistance and brand name drug coupons that lower the cost for individual consumers, some stakeholders such as pharmacy benefit managers and health plans believe there will be a rise in health care costs and a shift in utilization away from generic drugs.

Background

As **we reported earlier this week**, Rep. Jim McDermott, the ranking Democrat on the Ways and Means Health Subcommittee in the House of Representatives, received a response to his August 6 letter to Secretary of Health and Human Services, Kathleen Sebelius, on whether Qualified Health Plans (QHPs) sold on the new health care exchanges were considered "federal health care program[s]" under Section 1128B(f) of the Social Security Act. Sebelius responded that the QHPs were not considered federal health care programs and, as such, not subject to the provisions of the anti-kickback statute.

This is relevant because "federal health care programs," as defined in the Social Security Act, are subject to the anti-kickback statute, which makes it a crime to pay or receive anything of value in return for the referral of patients or as an inducement for people to buy goods and services reimbursed by the programs (health plans). This was surprising news for most health care industry stakeholders who interpreted that the nearly $1 trillion in exchange subsidies (over the next decade) to help defray premium costs on the health exchanges, constituted a "plan… that provides health benefits… which is funded directly, in whole or in part, by the United States Government," which would meet the definition of "federal health care program" as defined by law.

As a result, hospitals, branded pharmaceutical manufacturers, and some consumer groups hailed the decision. Exclusion from the anti-kickback regime could mean a green light for hospitals to sign up uninsured patients after presenting in the emergency department in order to be reimbursed by commercial health plans. In another instance, drug manufacturers could potentially provide coupons that would defray out-of-pocket costs for consumers on their branded drugs. However, if the QHPs were considered federal health care programs, then anti-kickback laws would apply, restricting these in-kind or monetary contributions.

On the other hand, a host of industry stakeholders, such as pharmacy benefit managers, generic drug manufacturers, and commercial health plans expressed concern at the new policy. These stakeholders fear that exempting subsidized health insurance from laws that ban rebates or kickbacks would shift utilization away from generic drugs to branded drugs. For example, though drug coupons would drive down copayments for brand-name drugs, often insurers will still pay much more for brand-name drugs than for their generic counterparts – a situation feeding fears that this change will cause health care spending to rise and shift utilization away from generic to branded drugs.

Then, on November 4, 2013, the Center for Consumer Information & Insurance Oversight (CCIIO), which is the component of CMS that regulates QHPs, issued a Q&A document, entitled "**Third Party Payments of Premiums for Qualified Health Plans in the Marketplaces**," which "discourage[d]" cost-sharing and

premium payment support, but did not reverse the assertion that QHPs were not federal health care plans as defined under 1128B of the Social Security Act.

Confusion Persists

What is most perplexing for lawmakers and industry stakeholders alike, is that even as recently as a Senate Hearing on Wednesday morning (November 6), Secretary Sebelius again stated in response to questioning from Senator Charles Grassley (R-IA) that QHPs were not "federal health care programs" but that HHS would continue to monitor the plans for potential fraud and abuse. She did not directly address the CCIIO memo. Adding to the confusion is that the vast majority of stakeholders did not consider this a contentious issue and thus the impetus for the McDermott letter and ensuing response from HHS is yet unclear.

As a result of the HHS response, stakeholders may need to change their strategies going into 2014. However, the CCIIO memo and lack of concurring opinion from the Department of Justice (DOJ) has given most companies and organizations reasons to move with caution as HHS and the Obama Administration work to coordinate both their interpretation of the statute and ensuing enforcement.

Congressional staff seem similarly perplexed as to why and how HHS came up with this determination and the nature of coordination between HHS and CMS in crafting the response to McDermott, much less other federal government entities such as the Department of Justice or the White House. Clearly, there is a public perception benefit in distinguishing plans on the exchange from traditional federal health programs like Medicare. However, the resulting pushback from commercial health plans, generic drug manufacturers, pharmacy benefit managers and others that claim health care costs will rise if anti-kickback does not apply to QHPs, is sure to be a thorn in the side for many Congressional Democrats who are fighting to improve the image of the health care exchange rollout.

Further, Senator Grassley continued his investigation into the matter via a formal letter to HHS and DOJ on November 7, requesting more information about how and when the decision was made, whether DOJ will decline to intervene in *qui tam* suits, and other information surrounding the issue. Grassley's letter requested a response to his questions by November 13.

Conclusion

The only thing for certain in the past several days is that stakeholders, lawmakers, and industry analysts alike are still unclear as to whether QHPs are, indeed, not "federal health care programs," and what activities will be permissible that would otherwise have been illegal under the anti-kickback statute. It is also not widely settled that the Secretary of HHS necessarily has the power to decide what "is" or "is not" a federal health care program as defined, which means this issue could be decided by the courts. Further, because Attorney General Eric Holder has not issued a concurrent statement of how DOJ intends to enforce the law, experts are unclear as to the ultimate impact of the HHS letter to McDermott without additional information.

Although the Obama Administration clearly has its hands full with website troubles and other ACA implementation issues, the implications of this interpretation of the law cannot be overstated and industry stakeholders will have to weigh the risks in making significant business decisions before the Administration clarifies the law going forward.

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