Federal Safe Harbor for Value-Based Contracts Being Considered

P&T Committees Can Receive Data Beyond the Drug Label

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One of the major reasons value-based contracts between drug manufacturers and health insurers have been slow to develop is the looming barrier of the anti-kickback statute (AKS) in federal law established in 1972.

On February 26, 2017, Eli Lilly, the Academy of Managed Care Pharmacy (AMCP), the Pharmaceutical Research and Manufacturers of America (PhRMA), Prime Therapeutics, Teva Pharmaceutical Industries, and others responded to the Office of Inspector General’s (OIG’s) annual request for ideas on expanding safe harbors by endorsing consensus recommendations of an AMCP Partnership Forum, Advancing Value-Based Contracting (VBC), held in June 2017. “Thus far, to the extent that biopharmaceutical manufacturers and population health decision makers interested in entering a VBC have questions about the application of the Federal Anti-Kickback Statute, the only available option is to seek an advisory opinion from the Office of the Inspector General, which is a lengthy process.”

Drug manufacturers and health insurers have been pleading with the OIG for years for a VBC safe harbor. The AKS is a broad criminal and civil statute that prohibits the exchange of anything of value, in an effort to induce (or reward) the referral of federal health care program business. It comes into play when drug manufacturers offer rebates to various downstream players, such as pharmacy benefit managers (PBMs), insurers, and pharmacies, and get something in return.

But the OIG has rebuffed industry requests. Safe harbors listed by regulation include certain types of investment interests, personal services and management contracts, referral services, and space rental or equipment rental arrangements. OIG updates and amends current safe harbors under the AKS periodically, as well as adding new safe harbors through a public notice and comment rule-making process.

However, rules adding new safe harbors can be infrequent, with only three such rules having been finalized in the last 10 years, according to a memo from a House committee. It is worth noting that there is a safe harbor that allows some drug manufacturer discounts, such as the rebates offered to PBMs and health insurers.

But the OIG’s reluctance to countenance a VBC safe harbor may be eroding. On August 27, 2018, the OIG published a request for information (RFI), which said: “The Office of Inspector General (OIG) seeks to identify ways in which it might modify or add new safe harbors to the anti-kickback statute and exceptions to the beneficiary inducements’ civil monetary penalty (CMP) definition of ‘remuneration’ in order to foster arrangements that would promote care coordination and advance the delivery of value-based care, while also protecting against harms caused by fraud and abuse.”

There probably is emerging support from the higher reaches of the Department of Health and Human Services’ (HHS’s) executive suite for a VBC safe harbor. The OIG is part of the HHS. Earlier this year, Eric Hargan, Deputy Secretary at the HHS, established what is being called the Regulatory Sprint to Coordinated Care. Hargan expanded on the goal of the Sprint when he told the House Ways and Means Committee in July, “HHS is also looking at the anti-kickback statute and its intersection with the Stark Law to see if either law or the interactions between the two is stifling innovative arrangements that could result in better outcomes for patients.”

The Stark Law prohibits physicians from referring patients to facilities in return for something of value.

A PwC Health Research Institute from September 2017 shed some light on the hesitancy of drug manufacturers and health insurers to establish VBCs. PwC surveyed 101 pharmaceutical executives from 97 companies and 100 health insurance executives. PwC found limited participation in value-based contracts of any kind. Only a quarter of the pharmaceutical executives surveyed participated in a value-based contract. Eighty percent of those describe the contracts as successful. But PwC found considerable skepticism. Their report quoted Mona Chitre, Chief Pharmacy Officer and Vice President of Clinical Operations and Health Innovation at Excellus BlueCross BlueShield, a New York-based nonprofit insurer covering 1.5 million people, saying, “It’s too soon to tell whether value-based drug contracts can actually deliver additional value.”

Complaints about the negative impact of the anti-kickback statute on value-based contracts came up in numerous comments made in response to a June 2017 Centers for Medicare & Medicaid Services (CMS) RFI asking for comments on how to reduce drug prices. Not only was the AKS impediment mentioned, so was the Medicaid “best price” requirement. The Council for Affordable Health Coverage wrote: “Manufacturers and payers are reluctant to enter into value-based arrangements, in part, because of the challenge of squaring such innovative approaches with the inflexible complexities of rebate liabilities under Medicaid’s ‘best price’ reporting requirements. If a manufacturer offers a discount that is below the best price threshold, it triggers Medicaid rebate liability.”

The Council estimated that if VBCs were allowed more widely, including for prescription drugs and medication adherence, there would be an overall (private and public) health system continued on page 687
savings of nearly $50 billion, which would be coupled with significant gains in access to treatments. Federal budgetary savings would be about $3.7 billion over the 10-year budget window.

The writing appears to be on the wall. The OIG is likely either to approve a safe harbor for VBCs, though not one that is open-ended, or establish a new process where requests for advisory opinions that meet specified requirements are quickly approved or disapproved.