

Reed-DeGette Insulin Price Inquiry—Key Findings on Value-Based Contracts

On November 8, 2017, Diabetes Caucus Co-Chairs Tom Reed (R-NY) and Diana DeGette (D-CO) issued a Request for Information (RFI) on value-based contracts (VBCs) as part of their on-going insulin inquiry. Broadly speaking, the RFI covered areas such as the role of VBCs in insulin pricing, their prevalence in the general drug market, and the process used to implement them. The Co-Chairs were pleased to receive responses from a diverse set of stakeholders, including patients, researchers, innovators, and providers.

Value-based contracting is widely recognized as an umbrella term encompassing an array of different payment arrangements. Stakeholders, however, generally agreed on several features that are common to most VBCs. To begin with, nearly all VBCs involve a price or price concession linked to a *value*, with *value* being defined uniquely in each contract. VBCs use different arrangements to tie a price scheme with their concept of *value*, including: outcomes-based agreements, shared savings, risk-sharing, and indication-specific pricing. These pricing contracts are relatively new to the drug industry.

Of the respondents, just two stakeholders reported having VBCs for insulin products. Eli Lilly, a drug maker, is piloting an insulin VBC while Express Scripts, a pharmacy benefit manager, has implemented an insulin VBC as part of its Diabetes Care Value program. Stakeholders generally agreed that developing these contracts is challenging given the biology of diabetes and its typical care regimen. Unlike other chronic diseases, diabetes is a complex condition requiring multiple management strategies, including diet, exercise, and medication. Insulin, therefore, is just one of several clinical interventions a patient is prescribed as part of their diabetes care plan. As a result, insulin dosing is highly patient-specific, which makes measuring outcomes difficult.

Stakeholders also identified a number of administrative and operational barriers that often hinder or preclude the development of insulin VBCs. It was widely reported that the health care sector currently lacks the high-quality measures necessary for insulin VBCs. Additionally, some respondents said that the industry needs to improve its technological infrastructure before it can begin accurately collecting the patient data necessary for these contracts. Even if these challenges could be resolved, some stakeholders worry they could encounter legal barriers—particularly around patient privacy rights—in accessing and auditing relevant patient data.

Stakeholders also named several regulatory and statutory barriers that are potentially impeding the development of insulin VBCs. A diverse group of respondents noted that the Anti-Kickback statute (AKS) discourages VBCs since payers and drug makers are unsure if their pricing arrangements qualify as “remunerations.” To address this issue, some stakeholders suggested that the federal government should create new safe harbors for VBCs or issue guidance exempting VBCs from the AKS. Separately, some respondents worried about the negative impact that VBCs could have on government pricing programs, particularly the Medicaid Best Pricing Rule. Industry stakeholders said that VBC-triggered discounts could force some drug makers to sell their insulin products at unsustainable price points. As a result, some drug makers might have to discontinue their insulin products, creating potential drug shortages. In summary, there are several regulatory areas that need to be addressed before VBCs become an industry norm.

Given the rarity of these contracts, stakeholders were asked to describe hypothetical insulin VBCs. Some respondents said that an insulin VBC would likely be outcomes-based, involving metrics such as A1C levels. Others replied that this type of contract would be based on pre-specified endpoints such as insulin adherence or persistence thresholds. In either case, stakeholders reiterated that it would be difficult to develop an insulin specific VBC.

Going forward, Diabetes Caucus Co-Chairs Tom Reed (R-NY) and Diana DeGette (D-CO) will use this information to guide other facets of their insulin price inquiry.