PUBLICATION

HHS's Regulatory Sprint Continues: OIG Releases RFI Focused on Removing Barriers to Value-Based Care

September 19, 2018

The Department of Health and Human Services, Office of Inspector General (OIG) recently released a request for information (RFI) seeking public input on "how to address any regulatory provisions that may act as barriers to coordinated care or value-based care." The scope of the RFI is far-reaching, and goes well beyond promoting care coordination and value-based arrangements. It applies to both the Anti-Kickback Statute and the beneficiary inducement civil monetary penalty (CMP) law, and seeks comments on matters ranging from potential alternative payment model (APM) safe harbors to new "care coordination" focused exceptions to the beneficiary inducement CMP. Comments are due by October 26, 2018.

The RFI, published on August 27, 2018, comes on the heels of a Centers for Medicare and Medicaid Services (CMS) June 25, 2018 RFI on the same. In combination, the RFIs reflect growing HHS momentum (and indeed, "sprint") to revamp the physician self-referral law and Anti-Kickback Statute to facilitate value-based and APM arrangements. The OIG seeks input to evaluate how to provide additional flexibility for such arrangements while also protecting against the harms caused by fraud and abuse.

Below, we provide a sampling of areas the OIG is seeking comment on. Of note, and per the RFI, individuals and organizations that previously submitted comments to CMS's June 25, 2018 RFI should resubmit any relevant comments to the OIG to ensure OIG consideration.

- APM focused arrangements that the industry is interested in pursuing (e.g., value-based arrangements or arrangements involving "innovative technology"), for which the Anti-Kickback Statute and/or the beneficiary inducement CMP may pose barriers.
- Additional or modified safe harbors to the Anti-Kickback Statute and/or exceptions to the definition of "remuneration" under the beneficiary CMP that may be necessary to protect APM focused arrangements;
- Definitions of health care payment and delivery reform terminology, like "alternative payment models," "care coordination," "clinical integration," "gainsharing," "value-based care," "incentive payments," etc.;
- The types of incentives providers, suppliers, and others are interested in providing to beneficiaries, and how providing such incentives would contribute to or improve quality of care, care coordination, and patient engagement;
- Input on whether the OIG should amend its "Policy Statement Regarding Gifts of Nominal Value to Medicare and Medicaid Beneficiaries" to increase "nominal value" from no more than $15 per item or $75 in the aggregate per patient on an annual basis;
- Feedback on how relieving or eliminating beneficiary cost-sharing obligations may improve the delivery of care and enhance value-based arrangements. The OIG is particularly interested in input regarding scenarios where cost-sharing obligations are an impediment and the financial impact on providers, suppliers and other entities. Furthermore, the OIG seeks comment regarding the financial impact on providers, suppliers, and other entities, as well as the fraud and abuse risks, if cost-sharing amounts could be waived for beneficiaries participating in a care coordination or value-based arrangements;

- Feedback on the current waivers developed for the purposes of testing models by the Center for Medicare and Medicaid Innovation and carrying out the Medicare Shared Savings Program;
- Information about the types of cybersecurity-related items or services that entities may wish to donate or subsidize, and how existing fraud and abuse laws may pose barriers to such arrangements;
- Input on implementation of new safe harbors associated with exceptions incorporated in the Bipartisan Budget Act of 2018, including (1) incentive payments made to Medicare beneficiaries under the Medicare Shared Savings Program; and (2) the provision of telehealth technologies to end-stage renal disease (ESRD) patients who are receiving home dialysis under Medicare Part B; and
- How best to align physician self-referral law exceptions and Anti-Kickback Statute harbors focused on APM arrangements.

This RFI, as part of HHS's Regulatory Sprint to Coordinated Care, presents a key opportunity for health care industry stakeholders to potentially shape and influence the form of new APM focused Anti-Kickback Statute safe harbors and beneficiary inducement CMP exceptions. As noted previously, comments are due **October 26, 2018**.

If you have any questions about the content of this alert, please contact any member of the Baker Ober Health Law Group.