

CMS Seeks Comments on Anti-Kickback Statute Reform

The Trump Administration has continued to identify potential barriers to care coordination and value-based care incentives through changes to current regulation, as part of the Administration's "regulatory sprint towards coordinated care."¹ These changes have been primarily focused on modernizing fraud and abuse laws, as noted by the June 25, 2018 *Request For Information* (RFI) seeking public comments on reforming the physician self-referral law, commonly known as the *Stark Law*.² On August 24, 2018, the same day that comments were due for the Stark Law RFI, the *Office of Inspector General* (OIG) of the *Department of Health and Human Services* (HHS) published another RFI seeking public input on changes to the *Anti-Kickback Statute* (AKS) and beneficiary inducements in the *Civil Monetary Penalty* (CMP) Law.³

HHS has stated that updating fraud and abuse laws is key to facilitating innovation in coordination of care arrangements that ultimately underlie the healthcare industry's shift toward *value-based reimbursement* (VBR).⁴ As part of the most recently released RFI, HHS is seeking comments on ways that the agency could improve the safe harbors to AKS and the exceptions to the beneficiary inducements CMP definition of "remuneration."⁵ AKS "provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit, or receive remuneration to induce or reward the referral of business reimbursable under Federal health care programs."⁶ AKS safe harbors are available for providers who comply with their components in order to avoid criminal prosecution under AKS and the imposition of civil monetary penalties.⁷ The CMP Law, specifically the beneficiary inducement prohibition, authorizes imposing civil monetary penalties for offering or paying any remuneration to Medicare or Medicaid beneficiaries in efforts to influence the beneficiary's provider or supplier selection.⁸

The OIG states in the RFI that it is soliciting comments specific to four categories. One category on which the agency is seeking feedback is the promotion of care coordination and value-based care, including potential care and payment models which they are interested in pursuing, and how those models promote care coordination or value-based care, while preventing potential harms, e.g., increased costs.⁹ Additionally, the OIG requests commenters to identify any AKS safe harbors or CMP exceptions that should be added or modified related to coordinated care.¹⁰ The RFI also asks how "value" could

be defined and used in a safe harbor or exception such that OIG could evaluate 'value' within an arrangement to determine compliance."¹¹ Lastly, commenters are encouraged to provide thoughts on the potential definitions for a number of terms, as well as on where the OIG might "clarify its position through guidance as opposed to regulation."¹²

The second category for which information is requested is beneficiary engagement, including beneficiary incentives (e.g., the types of incentives in which providers and suppliers are interested, how they can affect quality of care and care coordination) and cost-sharing obligations (e.g., situations in which cost-sharing obligations are challenging, any financial or fraud and abuse risks to waiving cost-sharing amounts, and any potential risks to reducing/eliminating cost-sharing).¹³

The third category requests feedback regarding other regulatory topics, including information on current fraud and abuse waivers, cybersecurity-related items and services (including the donation or subsidization of same), and new exceptions required by the *Bipartisan Budget Act of 2018*.¹⁴

The fourth category for which the OIG seeks information from commentators is the intersection of the Stark Law and AKS.¹⁵ The agency is asking for feedback related to specific circumstances where Stark Law exceptions and AKS safe harbors should align to achieve the aforementioned goals of the RFI, as well as whether any Stark Law exceptions should not have a corresponding AKS safe harbor.¹⁶

Because many VBR models potentially implicate fraud and abuse laws, the OIG has recognized that they are significant hurdles for arrangements that may otherwise advance coordinated care efforts.¹⁷ Over the past few years, the OIG has received "an increasing number of comments" from industry stakeholders to its yearly safe harbor and special fraud alert solicitation.¹⁸ Perhaps in response to this increasing input from the healthcare industry, HHS has already issued this year an RFI on the Stark Law (as noted above) and a proposed rule (which is currently being reviewed by the Office of Management) entitled, "*Removal of Safe Harbor Protection for Rebates to Plans or PBMs Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection*."¹⁹ However, whether these RFIs on the "modernization" of fraud and abuse laws in the shift to VBR will ultimately result in any agency action remains to be seen.

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- 1 “Stark Law Reform Push Sees Movement on Multiple Fronts” By Steven Porter, Health Leaders, August 27, 2018, <https://www.healthleadersmedia.com/finance/stark-law-reform-push-sees-movement-multiple-fronts> (Accessed 8/31/18).
 - 2 “OIG Seeks Comments on Anti-Kickback Statute and Beneficiary Inducements as Part of its Regulatory Sprint to Coordinated Care” By Amy Hooper et al., McDermott News, August 27, 2018, <https://www.mwe.com/en/thought-leadership/publications/2018/08/oig-seeks-comments-on-aks> (Accessed 8/31/18); “Medicare Program; Request for Information Regarding the Physician Self-Referral Law” Federal Register Vol. 83, No. 122 (June 25, 2018) p. 29524. For more information on the Stark Law RFI, see “CMS to Review Stark Law Relevance Once Again” Health Capital Topics, Vol. 11, Issue 7 (July 2018), https://www.healthcapital.com/hcc/newsletter/07_18/HTML/STARK/convert_stark_reform_topics_article_7.24.18a_skr.php (Accessed 9/11/18).
 - 3 Hooper, August 27, 2018; Porter, August 27, 2018; “Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP” Federal Register Vol. 83, No. 166 (August 27, 2018) p. 43607.
 - 4 “HHS Asks for Stakeholder Input on Reforming Anti-Kickback Statute” American Health Lawyers Association, August 24, 2018, <https://www.healthlawyers.org/News/Health%20Lawyers%20Weekly/Pages/2018/August%202018/August%2024%202018/HHS-Asks-for-Stakeholder-Input-on-Reforming-Anti-Kickback-Statute.aspx> (Accessed 8/31/18).
 - 5 *Ibid*; Federal Register, August 27, 2018.
 - 6 Federal Register, August 27, 2018, p. 43608.
 - 7 *Ibid*.
 - 8 Hooper, August 27, 2018.
 - 9 Federal Register, August 27, 2018, p. 43609.
 - 10 *Ibid*.
 - 11 *Ibid*.
 - 12 *Ibid*.
 - 13 *Ibid*, p. 43609-43610.
 - 14 *Ibid*, p. 43610.
 - 15 *Ibid*, p. 43611.
 - 16 *Ibid*.
 - 17 Hooper, August 27, 2018.
 - 18 “OIG Issues Request for Information on Federal Anti-kickback and Beneficiary Inducement Issues” ReedSmith, Reed Smith Client Alerts, September 10, 2018, <https://www.reedsmith.com/en/perspectives/2018/09/oig-issues-request-for-information> (Accessed 9/11/18).
 - 19 *Ibid*.



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