December 20, 2019

By electronic submission via www.regulations.gov

Joanne M. Chiedi
Acting Inspector General
Department of Health and Human Services
Washington, DC 20201
Attn: OIG–0936-AA10-P

Re: Notice of Proposed Rulemaking to Revise the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements (OIG–0936-AA10-P)

Dear Acting Inspector General Chiedi:

The Healthcare Leadership Council (HLC) thanks the Department of Health and Human Services (HHS) Office of the Inspector General (OIG) for the opportunity to provide comments in response to the October 17, 2019 Notice of Proposed Rulemaking (NPRM) regarding the anti-kickback statute regulations and beneficiary inducements civil monetary penalty rule (CMP). HLC applauds OIG for proposing numerous changes to the Federal anti-kickback statute regulations and beneficiary inducements CMP to "remove potential barriers to . . . care that improves quality of care, health outcomes, and efficiency"[1] as it works to "accelerate the transformation of the healthcare system into one that better pays for value and promotes care coordination."[2]

HLC is a coalition of chief executives from all disciplines within American healthcare and the exclusive forum for the nation's healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century system that makes affordable, high-quality care accessible to all Americans. With the move toward a healthcare system based on providing better value, HLC has convened a broad group of organizations beyond its membership that recognize the transformational effect of this shift on the existing legal framework governing U.S. healthcare. In order to better coordinate and deliver patient care, the legal framework must allow appropriate patient-serving care delivery and payment models involving broader collaboration among stakeholders in order to accelerate ongoing improvements in care quality and patient safety while reducing the rate of cost growth. The Physician Self-Referral (Stark) Law and Federal Anti-Kickback Statute Workgroup of HLC (the "Workgroup") includes a wide array of hospital, physician, health insurance, medical device, pharmaceutical, information technology vendor, and supplier organizations.

As the October 2019 NPRM notes, there have been substantial changes to how healthcare is delivered and paid for across private and public healthcare programs, payors, and patients

since the enactment of the anti-kickback statute in 1972.[3] The original fraud and abuse framework that governs Federal healthcare programs was designed for the fee-for-service (FFS) payment model traditionally used in federal healthcare programs. FFS rewards volume and provides little financial incentive for providers or patients to improve the coordination of care delivery or focus on outcomes. In an effort to improve our healthcare system, there has been a continued push in the public and private delivery and payment sectors to move toward a value-driven system that pays for improved health and better outcomes and away from the traditional FFS approach. This shift requires an accompanying "transformation of established practices and enhanced collaboration among providers and other individuals and entities."[4] Up to this point, the fraud and abuse framework that governs Federal healthcare programs has often "inhibit[ed] beneficial arrangements that would advance the transition to value-based care and improve the coordination of patient care among providers and across care settings in both the Federal health care programs and commercial sectors."[5] Aligning the fraud and abuse framework with the current healthcare system is critical to ensuring that the system functions as efficiently and effectively as possible and supports stakeholder innovation and investment in systemwide improvement. HLC appreciates OIG's shared commitment to these goals and willingness to make significant modifications to the anti-kickback statute safe harbors and the beneficiary inducement CMP to better reflect the changing healthcare payment and delivery environment.

HLC also appreciates HHS' commitment to eliminating obstacles to care coordination and accelerating the transition to a value-based system through its Regulatory Sprint to Coordinated Care ("Regulatory Sprint").[6] In conjunction with the Regulatory Sprint, the Requests for Information (RFIs) issued by the OIG[7] and the Centers for Medicare & Medicaid Services (CMS)[8] in 2018 demonstrated a welcome and significant commitment not only to align the fraud and abuse legal framework with new care delivery and payment models, but to consider practical implications of the current framework from the perspective of multiple industry stakeholders.

We have organized our comment letter below in two parts. The first part highlights the proposals that we believe are most supportive of the transition to a value-based healthcare system as they are currently drafted, provides comment in response to several questions the OIG posed in the NPRM, and offers general recommendations for possible modifications to related proposals where relevant. The second part highlights key areas that remain unaddressed by this NPRM for consideration in making future, further changes to the Federal fraud and abuse framework.

PART 1: PROPOSAL HIGHLIGHTS AND CLARIFICATIONS

The most significant modifications proposed in this and the CMS NPRMs are those adding safe harbors and exceptions that protect value-based care and payment arrangements. While we discuss the specific and proposed provisions of these safe harbors below, their overall significance to healthcare transformation cannot be understated. The need for these safe harbors to be clear, comprehensive, and inclusive is critical if they are to have their desired impact of improving care coordination, quality, and patient outcomes while reducing costs. We recognize and support the effort that went in to crafting these new safe harbors and believe that what has been proposed is an excellent start. However, as written, we believe the safe harbors are too narrow to enable the healthcare transformation goals described in the NPRMs. Our primary concern is that the safe harbors will exclude several key stakeholders from protection, thus hampering the ability of the covered stakeholders to provide meaningful value-based care. We detail these concerns below as they apply to specific proposed provisions, but wish to emphasize here our support for an entity-agnostic approach that allows an array of stakeholders

to participate in value-based arrangements. Such an approach would allow the necessary flexibility for healthcare delivery and payment entities to create and implement innovative value-based arrangements while still maintaining existing protections against inappropriate financial relationships inherent to the Federal anti-kickback statute.

Modifying Safe Harbors

Electronic Health Record (EHR) Donation (1001.952(y))

We offer our enthusiastic support for the proposals modifying the electronic health record (EHR) donation safe harbor, including:

- Eliminating the safe harbor's sunsetting provision and making the safe harbor permanent;
- Expanding the scope of covered technology to include cybersecurity technology as part of an EHR arrangement; and
- Creating a new safe harbor protecting the donation of cybersecurity technology and services (1001.952(jj)) that does not include a contribution requirement.

In addition, we offer our enthusiastic support for the following additional proposed modifications to the EHR safe harbor and new cybersecurity safe harbor:

- Eliminating the 15% contribution requirement in the EHR safe harbor for all recipients;[9]
- Deleting the condition that prohibits the donation of equivalent items or services to allow donations of replacement EHR technology;[10] and
- Adding protection for specific hardware that is necessary for cybersecurity.[11]

We also support the alignment of these provisions to the parallel Stark Law provisions proposed by CMS.

Personal Services and Management Contracts and Outcomes-Based Payment Arrangements (1001.952(d))

We appreciate the expansion of the personal services and management contracts safe harbor to include protection for certain outcomes-based payments. However, we are concerned that this addition is overly complex and does not align with how these payments (e.g., shared savings or gainsharing), are currently made under alternative payment models. For example, entities would need to establish evidence-based valid outcome measures for individual participants. While savings to entities such as ACOs are often tied to outcomes or quality metrics as part of the methodology to determine savings from Medicare, savings paid to individuals through gainsharing in the ACO may not be. Measuring outcomes can be a challenging and resource-intensive process that may take time to evaluate (e.g., one or two years after an arrangement begins). As a result, this proposal could further perpetuate delays in distribution of shared savings and create an overly burdensome process for stakeholders.

New Safe Harbors

We offer our general support for safe harbors that protect:

- Care coordination arrangements to improve quality, health outcomes, and efficiency (1001.952(ee));
- Value-based arrangements that require the assumption of risk (1001.952(ff), (gg));
- Remuneration between and among parties to arrangements under a CMS-sponsored model and in the form of incentives and supports provided to patients covered by a CMS-sponsored model (1001.952(ii)); and

- Arrangements for patient engagement tools and supports to improve quality, health outcomes, and efficiency (1001.952(hh)).

We believe there is a significant need for safe harbors that protect activities and initiatives that involve the integration of care, items, services, and payment across stakeholders, including those participating in a Medicare-approved value-based payment program and those that are not. We appreciate OIG's recognition of the need for safe harbors that protect a variety of such arrangements. We particularly appreciate and support the new safe harbor for CMS-sponsored model arrangements and CMS-sponsored model patient incentives to reduce the need for waivers connected to CMS-sponsored models.

As a general matter, we believe that many of the definitions and frameworks proposed in the NPRM are too complex and depend on vague metrics that will be challenging for entities to navigate as they assess compliance. We are thus concerned that many entities will be unwilling to utilize the proposed safe harbors for value-based arrangements. Given the OIG's acknowledgement that industry stakeholders were "discouraged from entering into innovative arrangements that could improve quality and health outcomes, produce health system efficiencies, and lower costs (or slow their rate of growth),"[12] we believe that some of the proposals in the NPRM should be further modified to assure that the goal of a transformed healthcare system can be achieved. We have highlighted specific areas of concern related to these new safe harbors below.

Allocating risk in value-based arrangements (1001.952(ff), (gg))

We are concerned that a focus on full and substantial financial risk may make these safe harbors unworkable for all but the largest health systems, which in turn may drive further market consolidation and increased costs for the healthcare system. While we support the creation of safe harbors protecting risk-based financial arrangements, we believe that lower thresholds of financial risk will make participation in value-based enterprises easier and thus ensure that these safe harbors encourage improved coordination rather than provider consolidation.

We are concerned that the differing standards for assuming a threshold of downside risk – whether "substantial" or "meaningful" – will be confusing and pose a potential barrier to greater participation in value-based arrangements.

Irrespective of further modifications to the full and meaningful risk safe harbors, we urge the OIG to allow for a 1-year implementation period for these new safe harbors at minimum, rather than the 6-month period as proposed. Stakeholders already participating in value-based care arrangements will need sufficient time to modify those arrangements to fit within one of the proposed safe harbors, while others will require more time to develop arrangements that meet the requirements of the proposed safe harbors. Given the complexity of the requirements for these safe harbors, it is imperative that stakeholders have sufficient time and resources to identify and implement arrangements that are beneficial to the patients they serve. Providing at least one year before the safe harbors are implemented will give stakeholders more time to prepare and establish arrangements that can achieve the goals of value-based care in a meaningful way.

Arrangements for Patient Engagement Tools and Supports to Improve Quality, Health Outcomes, and Efficiency (1001.952(hh))

We appreciate and support this new safe harbor. We would request additional information related to its components, specifically regarding the definition of "patient engagement tool." It would be particularly helpful to have examples of such tools.

New or Modified Definitions and Terminology

Value-based enterprise (VBE) participants

As discussed above, we strongly believe that these definitions should be entity-agnostic and provide equal protection to all entities willing to bear risk for value-based arrangements. We would urge the OIG to allow for flexibility on who can be a VBE participant in order to ensure that non-traditional healthcare entities are eligible. Further innovation in the design, structure, and implementation of value-based arrangements must include an array of healthcare stakeholders to support sponsor and plan learning and to determine the range of potential benefits to diverse health systems and beneficiaries. Traditional healthcare entities may not have the capability to directly provide the services and supports envisioned in this safe harbor (e.g., services and supports to address social determinants of health, such as nutrition, physical activity, social connection or transportation). If these services and supports are supposed to be provided directly by the VBE participant, it is even more important that non-traditional healthcare entities are eligible to be VBE participants.

We strongly encourage the OIG to stand by its decision to **include** medical device manufacturers as VBE participants in the proposed safe harbors for value-based arrangements. Medical device manufacturers, including durable medical equipment, prosthetics/orthotics, and supplies (DMEPOS) manufacturers, bring an array of expertise to disease management, which when combined with their medical technology, creates additional value for patients and payers.[1] We appreciate OIG's inclusion of mobile health and digital technologies as VBE participants but believe that the value of medical technology in coordinating and managing patient care significantly exceeds these technologies alone. Digitization can help prove the value of a product, but a non-digital product such as an implant or disposable can be combined with the medical technology company's expertise to provide value across the care continuum.

We strongly encourage the OIG to **include** pharmacy benefit managers (PBMs) and DMEPOS suppliers and distributors in the definition of a VBE participant. These entities should be included in these arrangements to promote value-based care recognizing the important role they play in supporting all of the value-based purposes described in the NPRM.

We strongly encourage the OIG to explicitly **include** pharmaceutical manufacturers as VBE participants. Value-based arrangements can support aligning payments for medicines more directly with their value to improve meaningful health outcomes and reduce the need for other healthcare services. The ability to offer certain wraparound services (such as interventions to support patient adherence and appropriate diagnostic testing) within a value-based arrangement can help providers and payers realize the arrangement's value objectives, such as reducing the total cost of care. This ultimately benefits patients through improved outcomes and further benefits providers and payers through decreased administrative burdens.

[1] Examples include, among others: (1) robotic-arm assisted joint replacement for hip and knee surgery, which results in shorter hospital lengths of stay, quicker patient recovery times, and lower costs over a 90-day episode of care; (2) insulin pumps, continuous glucose monitors (CGM) – both covered under Medicare as Durable Medical Equipment (DME) – and emerging "artificial pancreas device systems" technologies that play a crucial role in reducing glycemic variability, helping prevent diabetes-related emergency hospitalizations and, in the longer run, development of diabetes-related complications, such as heart, eye, kidney, and nerve disease; (3) services that assist with preoperative planning and patient coaching to improve workflow, patient compliance with care protocols, and streamlining of care processes; and (4) technologies that combine the product with care protocols, ongoing training, and data tracking to improve population health outcomes, such as hospital-acquired infection or pressure wound rates.

Finally, we agree with the concerns OIG expressed in the NPRM regarding physician-owned distributorships (PODs). Consistent with the 2013 special fraud alert issued by your office, we agree that PODs deserve scrutiny in order to protect patients from inappropriate medical referrals or recommendations by health care professionals who may be unduly influenced by financial incentives. To address this, OIG could consider requiring certain conditions of all VBE participants that wish to sell or distribute medical devices within a VBE, such as a requirement to report under the Sunshine Act.

Value-based purpose
We seek clarification on how quality would be measured and applied and whether reductions in certain types of services might be considered reductions in quality. For example, would measures such as reducing admissions be seen as reducing quality?

Value-based activity
We note that the proposed definition does not include referrals. We question whether there may be a need for some flexibility for referrals in limited instances, such as for Accountable Care Organizations (ACOs).

Target Patient Population
We believe that the current definition in the NPRM should allow greater flexibility for changes in the target patient population over time. For example, the current definition does not appear to allow for expanding the patient population over the course of the value-based arrangement.

We also believe that limiting this definition to patients with chronic conditions and/or shared disease states is unnecessary and may hinder innovation in healthcare delivery. We suggest that the OIG maintain flexibility to allow providers to develop value-based arrangements that are in the best interest of the patient based on provider's clinical expertise. We note that there are several other safeguards proposed in this NPRM that will help ensure providers utilize this flexibility to support arrangements that are high-value and beneficial to beneficiaries.

Commercial reasonableness
We appreciate the modification to the commercial reasonableness requirement. However, we would still request more definition and clarity surrounding this term and how it applies, particularly in value-based arrangements.

Alignment with Stark Law

We also recognize and appreciate the OIG's efforts to align the proposed anti-kickback statute regulation changes with CMS' contemporaneous modifications to the Physician Self-Referral (Stark) Law regulations. However, we are concerned that the proposals are not sufficiently aligned. We believe that the differing standards that can be applied under each proposal would, if finalized, continue to pose a barrier to value-based care and care transformation. For example, both regulations utilize different metrics for determining downside financial risk and may require different conditions or standards for the corresponding exceptions and safe harbors. For example, CMS' proposed exception for value-based arrangements would protect both in-kind and monetary remuneration, while the safe harbor for care coordination would only protect in-kind remuneration. We encourage the OIG to adopt the broader exception proposed by CMS in this instance, but also offer it as an illustrative example of the differing standards for the same conduct proposed in both NPRMs.

We believe that the proposals would continue a dual regulatory environment where, for

example, an arrangement could meet the requirements of the Stark Law but violate the anti-kickback statute. While not all arrangements will implicate both the Stark Law and anti-kickback statute, there will be some arrangements that require compliance with both. Lack of consistency will make it even more challenging for entities to navigate this already complex regulatory framework as they design value-based arrangements. We strongly urge HHS to continue seeking opportunities to align the proposed changes to the federal fraud and abuse framework so that value-based entities do not face two regulatory constructs with different standards for compliance.

PART 2: OUTSTANDING ISSUES

We would strongly encourage the OIG to consider using this rulemaking opportunity to address a number of other issues and items, including:

- Consider expanding the scope of covered technology within the EHR safe harbor even further, to include:
    - Technology related to information-sharing including mobile applications, clearinghouse services, and other solutions enabling the sharing of healthcare information among patients, providers, and payers;
    - Cloud-based items and services, practice management and revenue cycle systems and services, EHR storage, and subscription fees related to the use and exchange of health information; and
    - Industry-supported data collection, analytics, and other related technology services
- A plan for or recognition of the need to issue more sub-regulatory guidance, such as in the form of FAQs, examples of allowable practices protected by the safe harbors, and other clarifying information on how the safe harbors apply. Issues for which sub-regulatory guidance would be most useful include how to apply the volume or value of referrals standard across safe harbors (existing and proposed) and how to establish and document fair market value.

Thank you for the opportunity to provide feedback and input on these proposals. Please contact Tina Grande at tgrande@hlc.org or 202-449-3433 with any questions.

Sincerely,

Mary R. Grealy
President

[1] U.S. Department of Health and Human Services Office of Inspector General. Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements ("NPRM"), 84 Fed. Reg. 55694, 55694 (October 17, 2019).
[2] NPRM at 55695 (2019).
[3] NPRM at 55694 (2019).
[4] NPRM at 55694 (2019).

[5] NPRM at 55695 (2019).
[6] *See, e.g.*, NPRM at 55695 (2019); OIG RFI at 43608 (2018).
[7] U.S. Department of Health and Human Services Office of Inspector General. Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP ("OIG RFI"), 83 Fed. Reg. 43607 (August 27, 2018).
[8] U.S. Department of Health and Human Services Centers for Medicare & Medicaid Services. Medicare Program; Request for Information Regarding the Physician Self-Referral Law (CMS "RFI"), 83 Fed. Reg. 29524 (June 25, 2018).
[9] NPRM at 55743 (2019).
[10] NPRM at 55743 (2019).
[11] NPRM at 55735 (2019).
[12] NPRM at 55695 (2019).