February 23, 2018

By electronic submission via www.regulations.gov

Ms. Patrice Drew
Office of the Inspector General, Regulatory Affairs
Department of Health and Human Services
Attn: OIG-127-N
Room 5541C, Cohen Building
330 Independence Avenue SW
Washington, DC 20201

Re: OIG-127-N Solicitation of New Safe Harbors and Special Fraud Alerts

Dear Ms. Drew:

The Healthcare Leadership Council (HLC) appreciates the opportunity to submit proposals for new and modified safe harbor provisions under the Federal Anti-Kickback Statute (Social Security Act, § 1128B(b)).

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. Recognizing the transformational nature of the shift to value-based payment on the existing legal framework governing the U.S. healthcare system, the HLC has convened a broad group of organizations that advocate for a legal framework that aligns incentives to drive better value in 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 the HLC (the "Workgroup") includes a wide array of hospital, patient/consumer, physician, health insurance, medical device, pharmaceutical, information technology vendor, and supplier organizations.

As noted in the December 2017 solicitation, the Federal Anti-Kickback Statute's original safe harbor provisions were created to protect "relatively innocuous commercial arrangements" that would otherwise technically violate the "broad" language of the Statute from criminal and/or administrative penalties.[1] Additional safe harbors have been created to permit "certain non-abusive arrangements" and encourage "beneficial and innocuous arrangements."[2] The December 2016 Final Rule modifying the beneficiary inducement safe harbors references the need for such

modifications to allow for the "new and changing business relationships among health care providers" that may help to facilitate the shift from volume to value-based and patient-centered care.[3] Emerging arrangements and ongoing changes in the industry and technology warrant further expansion of the safe harbor framework in order to "foster high-quality, efficient, patient-centered care."[4] 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 system-wide improvement. HLC appreciates OIG's shared commitment to these goals and willingness to modify the Anti-Kickback Statute safe harbors as necessary in the changing healthcare payment and delivery environment.

Below is a summary of proposed changes to existing safe harbors as well as general proposals for new safe harbors; we note where a Special Fraud Alert could provide guidance in the absence of a new or modified safe harbor. We have also attached a white paper that provides further detail on the healthcare system changes that would benefit from these proposals, the process by which the proposals were developed, and other key issues to consider. We also highlight the protections against fraud and abuse that would remain should some or all proposals be adopted.

Organization-Based Waivers or Exemptions

The current Anti-Kickback Statute safe harbors do not address many types of possible arrangements among providers, payers, and pharmaceutical and medical device companies that would encourage greater care coordination and improve care quality and patient outcomes without involving fraudulent or abusive activity. While some safe harbors could protect certain value-based care models, application of their narrow requirements to new models of care delivery and payment is unclear. Safe harbors for personal services arrangements, fair market value compensation, warranties, and/or discounts, for example, potentially may combined to protect some arrangements that reward value and outcomes.[1] However, these safe harbors were designed for siloed care and payment settings and generally not with robust collaborative care model innovation in mind.[2] The failure to modernize the fraud and abuse framework threatens to impede meaningful progress. Uncertainty surrounding application of the Anti-Kickback Statute (including liability exposure) to new care models for which it was not designed, may discourage stakeholders from entering into arrangements that could help achieve better outcomes for patients and support public policy goals regarding healthcare system transformation. The following proposals would modernize this law and eliminate uncertainty about its potential application to beneficial organizational arrangements.

1. **Create safe harbor protecting all Accountable Care Organizations (ACOs) and other organizations implementing alternative payment models (APMs) that meet certain conditions, regardless of whether the organization is participating in a Medicare-sponsored program or project.[5]**

2. **Create safe harbor(s) effectively extending Federal Anti-Kickback Statute waivers for**

[1] *See, e.g.*, AHA Barriers to Care (2016).
[2] *See, e.g.*, AHA Barriers to Care (2016).

Medicare Shared Saving Program (MSSP) ACOs to activities or initiatives that involve care, item, service, and/or payment integration across stakeholders (i.e., providers, manufacturers, suppliers, and payers), that meet value-based healthcare criteria, and that are designed to improve patient outcomes and reduce the overall cost of providing care. Make such waivers available to stakeholders regardless of whether they are participating in a Medicare-sponsored demonstration project (e.g., ACO, APM, bundled payment initiative).[6]

3. **Create safe harbor(s) for clinically and financially integrated programs that allow all types of stakeholders to participate, give stakeholders flexibility in meeting those requirements as applicable, and allow financial savings distribution to support clinical and payment integration.[7]**

For example, new safe harbors could be created to protect: 1) bona-fide value-based arrangements, including those involving bundling services, data collection and analytics, and medtech arrangements to better determine whether clinical outcomes and cost-savings metrics are met and, 2) risk-sharing arrangements between manufacturers (e.g., pharmaceutical, device) and providers and/or payors that incentivize and reward improvements in clinical outcomes, care management, and/or reductions in cost. Should any of these safe harbors be implemented, the Anti-Kickback Statute would still prohibit inappropriate inducement of healthcare business. By specifying the approved activities/initiatives and the necessary value-based criteria and defining appropriate clinical and/or payment integration, these safe harbors would necessarily exclude any payment model that inappropriately takes into account volume or value of referrals.

Financial Arrangements

The electronic health record (EHR) safe harbor protects, through 2021, donation and partial financial support of EHR software, related technologies, and training.[8] Given the wide variation in provider timetables and resource availability for EHR technology acquisition, extending the timeframe for this safe harbor is warranted to ensure robust and widespread EHR implementation. Further, additional flexibility in defining covered technology is necessary to account for technological advancements not contemplated when the safe harbor was originally created. In light of these changes, we propose the following safe harbors:

4. **Revise and make permanent the [temporary] regulatory safe harbor for donation and financial support of EHR software, related technologies, and training,[9] as follows:**
    a. **Expand the scope of covered technology to encompass a broader range of health information technology:**
        i. **Technology related to information sharing;**
        ii. **Technology related to cybersecurity;**
        iii. **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**
        iv. **Industry-supported data collection, analytics, and other technology services as part of the exceptions.**
    b. **Remove the requirement that donated technology cannot replace something similar.**

Technical Guidance

As noted above, incentives for efficiency are built into value-based arrangements and mitigate the possibility of incentives to increase volume or use higher-level care settings or more complex services. However, uncertainty in applying the Anti-Kickback Statute provisions within a value-based system stifles innovation. The following proposals are suggestions that would offer clarity to stakeholders and facilitate continued progress toward a value-based care system:

5. **Issue guidance on how to apply the "volume or value of referrals" standard within the changing healthcare payment environment.** For example, this could clarify whether incentive payments to improve quality, even if they partially reflect the volume or value of a provider's referrals, are permissible.

6. **Issue guidance clarifying how to establish and document fair market value (FMV) in value-based payment settings and integrated care models (e.g., identify the type of data to use to determine FMV for a physician's participation in a pay-for-performance program or consulting arrangement between a physician and a medical device or pharmaceutical manufacturer).**

7. **Issue guidance expanding and revising definition of FMV to account for new payment models that incentivize performance and provide additional flexibility for collaboration among the various stakeholders to optimize the delivery of patient care to include improved outcomes and reduced costs (e.g., industry providing service line optimization support to a provider and obtaining compensation for that support from the provider through various risk-sharing arrangements).**

Issuing guidance on FMV would not impact the underlying protections against inducement, which would otherwise remain the same. New or clarified standards for documenting a definition of FMV can include safeguards relating to quality, payment caps, or similar criteria to ensure accurate assessment in a value-based environment without compromising program integrity.

8. **Eliminate or redefine the "one purpose" test for liability[10] and replace it with a balancing test that would require the OIG to prove that the transaction is likely to produce actual harm (either increased program costs resulting from overutilization or harm to a patient) and that this harm, if realized, would likely outweigh the actual or expected benefits to a patient (i.e., a harm standard). Transactions not meeting this harm standard would not give rise to liability.**

The breadth of the one-purpose test has created much uncertainty for stakeholders, which in turn may slow the progress of collaborative, patient-centered arrangements. A new harm standard could be narrowly tailored to better ensure that any remuneration that harms patients or inappropriately increases costs to the government falls outside the scope of permissible arrangements. This would potentially allow, for example, arrangements where providers and/or medical device or pharmaceutical manufacturers provide items or services of value to patients to assist with peri-operative regiment adherence, prescription medication adherence, or access to healthcare services.

The OIG could assess the arrangement's overall impact on quality of care and weigh these benefits against the potential risk of fraud and abuse to determine whether the transaction is permissible, regardless of whether one element of the arrangement is potentially problematic. The Anti-Kickback Statute would still prohibit inappropriate remuneration and arrangements that incentivize overutilization even if the "one purpose" requirement was modified to include a harm standard.

Thank you in advance for your consideration of the above proposals. Please contact Tina Grande at tgrande@hlc.org or 202-449-3433 with any questions.

Sincerely,

Mary R. Grealy
President

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[1] Department of Health and Human Services Office of the Inspector General (OIG). Notification of intent to develop regulations: "Solicitation of New Safe Harbors and Special Fraud Alerts," 82 Fed. Reg. 61229 at 61230 (December 27, 2017).
[2] 82 Fed. Reg. 61229 at 61230 (quoting 56 Fed. Reg. 35952).
[3] OIG. Final rule: "Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements," 81 Fed. Reg. 88368 at 88370 (December 7, 2016).
[4] 81 Fed. Reg. 88368 at 88370.
[5] 42 U.S.C. § 1320a-7b(b)(3) (2016).
[6] 42 U.S.C. § 1320a-7b(b)(3) (2016). Note that the language granting current waiver authority is in 42 U.S.C. § 1395jjj(f) and (i) (2016).
[7] 42 U.S.C. § 1320a-7b(b)(3) (2016).
[8] 42 U.S.C. § 1320a-7b(b)(3) (2016). Note that the current regulatory safe harbor for EHR donation is located at 42 C.F.R. § 1001(y) (2017).
[9] 42 U.S.C. § 1320a-7b(b)(3) (2016). Note that the current regulatory safe harbor for EHR donation is located at 42 C.F.R. § 1001(y) (2017).
[10] 42 U.S.C. § 1320a-7b(h) (2016). Note: the one-purpose test was created by the Third Circuit Court of Appeals in its decision in U.S. v. Greber, 760 F.2d 68 (3d Cir. 1985), widely adopted by courts interpreting the Anti-Kickback Statute.