



**Health System Transformation:  
*Revisiting the Federal Anti-Kickback Statute and Physician Self-Referral (Stark) Law to Foster Integrated Care Delivery and Payment Models***

February 2017

**EXECUTIVE SUMMARY AND PRIORITY OPTIONS**

The U.S. healthcare system continues to move toward quality-driven, value-based care delivery and payment models. These models could be interpreted to implicate the current federal fraud and abuse legal framework, creating policy and implementation challenges that impede delivery and payment reform. These new models align financial interests among providers to incentivize care coordination and improved quality, which may invite scrutiny under the outdated legal framework. The framework must allow appropriate patient-serving care delivery and payment models that encourage broader collaboration among stakeholders to accelerate ongoing improvements in care quality and patient safety while reducing the rate of cost growth. The federal government has issued waivers that protect certain arrangements from further scrutiny under the fraud and abuse legal framework, but the waivers are limited and only benefit a small group of stakeholders participating in Medicare initiatives. As such, stakeholders across the entire healthcare system are considering and advocating for changes to the current legal framework to make it more compatible with healthcare delivery system transformation while still retaining appropriate protections against fraud and abuse.

To facilitate the development of meaningful options to reform the Federal Anti-Kickback Statute and the Physician Self-Referral (Stark) Law, the Healthcare Leadership Council (HLC) through its National Dialogue for Healthcare Innovation initiative convened stakeholders and prepared a report released in January 2016 addressing these and other issues related to health system transformation.<sup>i</sup> Given the appetite for addressing challenges and concerns with applying the current fraud and abuse framework to new care delivery and payment models, HLC subsequently convened a broader workgroup of stakeholders representing both HLC members and other interested parties. This Workgroup, the Stark and Anti-Kickback Reform Workgroup, has continued the work of developing options to reform the Federal Anti-Kickback Statute and Physician Self-Referral (Stark) Law.

This white paper reflects the ongoing discussions of this Workgroup. It focuses on the Federal Anti-Kickback Statute and the Physician Self-Referral (Stark) Law, as primarily and respectively enforced by the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) and the Centers for Medicare & Medicaid Services (CMS), as well as the Department of Justice (DOJ).

The Physician Self-Referral (Stark) Law prohibits a physician from referring patients for services reimbursed by a federal healthcare program (i.e., Medicare) to a healthcare organization with which the physician has a financial relationship and prohibits the organization from billing for those services, unless an exception applies. The Anti-Kickback Statute prohibits the offer or receipt of anything of value in return for referring a patient for items or services reimbursed by a federal healthcare program (e.g., Medicare, Medicaid), unless an exception or safe harbor addresses the arrangement. The Anti-Kickback Statute applies to all healthcare industry stakeholders, including institutional and individual providers, medical device and pharmaceutical manufacturers, vendors, suppliers, and health plans. This white paper also addresses the relationship between the Federal Anti-Kickback Statute and the Civil Monetary Penalties (CMP) Law prohibitions related to beneficiary inducement (i.e., providing anything of value to a patient in order to encourage the patient to utilize a particular provider) and gainsharing (i.e., sharing savings among providers generated by limiting or reducing the provision of medically necessary services).

The options addressed in this white paper represent a working draft of potential regulatory and legislative modifications to the Anti-Kickback Statute and Physician Self-Referral (Stark) Law to better support innovative and integrated care delivery and payment models. A brief overview of priority options is identified here in the Executive Summary and discussed further alongside additional options in subsequent sections of this white paper. None of these options is, nor is intended to be, an exhaustive analysis of the universe of potential modifications to these laws. Rather, the priority and additional options addressed in this white paper are based on discussions with HLC, participants in the National Dialogue for Healthcare Innovation initiative, and members of the HLC Stark and Anti-Kickback Reform Workgroup.

### ***Priority Options***

The Workgroup considers the following, categorized as either Regulatory or Legislative alternatives and discussed more fully in the white paper, to be priority options. They have been selected based on the following criteria:

- *Feasibility:* Willingness of Congress, CMS and/or OIG to address

- *Impact*: Potential to alleviate or eliminate perceived and/or real barriers to developing and implementing new models of care delivery and payment based on fraud and abuse framework
- *Timeliness*: Whether meaningful action may/can be taken in the next 6-12 months

While this white paper categorizes the options as either regulatory or legislative, it is important to note that these options may be pursued independently or concurrently and some may lend themselves to both regulatory and legislative action.

### Regulatory Options

- Issue safe harbors, exceptions, or guidance that effectively extend existing Anti-Kickback Statute and Physician Self-Referral (Stark) Law waivers for Medicare Shared Savings Program (MSSP) Accountable Care Organizations (ACOs) to all ACOs and to other organizations implementing alternative payment models that meet certain conditions, regardless of whether or not they are participating in the MSSP or other Medicare-specific program.
- Revise and make permanent existing Anti-Kickback Statute and Physician Self-Referral (Stark) Law exceptions for donation and financial support of Electronic Health Record (EHR) software, related technologies, and training. Revisions should ensure a range of relevant and appropriate technologies (particularly information-sharing and cyber security technology) are included based on the evolving technological environment.
- Clarify how to establish, document, and apply the Anti-Kickback Statute and Physician Self-Referral (Stark) Law's prohibition on the use of "volume or value of referrals" to set payment within a changing healthcare payment environment oriented towards outcomes rather than volume of services delivered.
- Expand and revise application of fair market value standards to account for new payment models that are based on outcomes rather than productivity<sup>ii</sup> (e.g., by allowing incentives for efficiency and improved outcomes rather than basing fair market value on the number of hours worked).<sup>iii</sup>
- Eliminate or redefine the "one purpose" test for Anti-Kickback Statute liability and replace it with a balancing test that would require the OIG to prove either increased cost or actual harm to a patient.<sup>iv</sup> 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 prescription medication adherence, perioperative regimen 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 purpose of the arrangement is potentially problematic. Legislative action also may be appropriate to address this issue.

### Legislative Options

- Expand the parameters of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)-mandated alternative payment model report (due by April 16, 2017)<sup>v</sup> and require the HHS Secretary to review and assess the Anti-Kickback Statute, the Physician Self-Referral (Stark) Law, and the CMP Law in the context of the transformation of the healthcare system. This assessment should specifically address: (1) whether these laws create unnecessary barriers to integrated care delivery and payment models; (2) whether these laws are effective in limiting fraudulent behavior; and (3) whether these laws should be modified to more effectively limit fraud and abuse without limiting new care and payment models aimed at providing better care at lower costs. The review process for this report should include subject matter experts from CMS and the OIG; the Secretary also should consult with the Department of Justice (DOJ), Internal Revenue Service (IRS), and the Federal Trade Commission (FTC). The Secretary should also allow for opportunities for stakeholder input that would include medical practitioners and administrators, pharmaceutical and medical device manufacturers and suppliers, consumers, and legal and policy experts to review the Secretary's findings and assessment. The report could include findings from the assessment along with stakeholders' feedback, and should include plans of action to address any suggested changes to the legal frameworks that arise from the assessment, as well as a description of the actions needed to achieve those changes.
- Changes identified through the assessment and report noted above may yield opportunities for either legislative or regulatory action to amend the Anti-Kickback Statute, Physician Self-Referral (Stark) Law, and CMP Law to protect arrangements that promote increased quality and lower costs.
- Congress also may consider granting OIG and CMS enhanced regulatory flexibility/rulemaking discretion to develop exceptions/safe harbors that are consistent with broad policy objectives (e.g., increase efficiency and quality, decrease costs, and improve rate of information-sharing) and adapt the Anti-

Kickback Statute, the Physician Self-Referral (Stark) Law, and the CMP Law to the current healthcare environment.<sup>vi</sup> Note that OIG and CMS already have statutory authority to create safe harbors and exceptions, but Congress could either: 1) direct OIG to regulate in certain broad policy areas; or 2) establish new statutory safe harbors and exceptions to these laws that are consistent with policy objectives.



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**INTRODUCTION**

The U.S. healthcare system continues to move toward quality-driven, value-based care delivery and payment models. These models encourage integration and care and payment coordination between and among providers and other industry stakeholders using financial incentives, such as shared savings, bonus payments, or risk-sharing arrangements. While these models are designed to improve outcomes, reduce waste, and increase efficiency, they may align financial interests in ways that trigger fraud and abuse concerns. In general, the federal fraud and abuse legal framework penalizes arrangements between and among providers and other industry stakeholders that have the potential to encourage overutilization of healthcare resources, inappropriately influence provider decision-making, decrease competition among competitors, and/or harm patients. This framework was designed for a fee-for-service healthcare environment where volume was the leading payment incentive in a siloed payment structure (e.g., physician reimbursement separate from inpatient hospital reimbursement).

Congress, based on reports of Medicare program abuse, created the Anti-Kickback Statute and the Physician Self-Referral (Stark) Law to protect a volume-based payment system from overutilization and revenue-generating financial relationships that pose a risk of fraud and abuse. For example, the Physician Self-Referral (Stark) Law was originally passed to prohibit perceived overuse of lab services by physicians holding ownership interests in labs to which they were referring Medicare patients.

New delivery and payment models represent a shift to fee-for-value, designed to reward improved outcomes and efficiency and encourage cross-provider coordinated care across the care continuum. However, implementing these models within the confines of the current federal fraud and abuse framework is challenging. New delivery and payment models may trigger liability and require government protection (e.g., in the form of a waiver such as those offered to Accountable Care Organizations (ACOs) participating in the Medicare Shared Savings Program (MSSP)). Furthermore, the fear

of potential liability due to the complexity of the legal framework potentially stifles innovation and impedes progress toward a value-based system.<sup>vii</sup>

As such, stakeholders across the healthcare system as well as policymakers and legislators are considering and advocating for changes to the current framework to make it more compatible with healthcare delivery system transformation while retaining appropriate protections against fraud and abuse.

It is important to note that alignment of the fraud and abuse legal framework with new care delivery and payment models is being discussed at multiple levels across the healthcare system. The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) called for the HHS Secretary, in coordination with the OIG, to consider possible modifications to the legal frameworks to better align with integrated care delivery and payment models. As mandated by MACRA, CMS issued a report to Congress on the relationship between fraud and abuse laws and gainsharing or similar arrangements between physicians and hospitals (i.e., the gainsharing report).<sup>viii</sup> In addition, CMS solicited feedback on possible changes to the Physician Self-Referral (Stark) Law in the 2016 Physician Fee Schedule Proposed Rule, indicating that the agency is thinking about these issues and open to dialogue regarding modifications. In the 2016 Final Rule, CMS stated that it would consider the comments received when preparing MACRA-mandated reports to Congress.

### ***Purpose of White Paper***

This white paper represents the product of a working draft of potential regulatory and legislative options to modify two of the primary fraud and abuse laws (the Federal Anti-Kickback Statute and Physician Self-Referral (Stark) Law) to better support innovative and integrated care delivery and payment models. It is not intended to be, nor should it be construed as, an exhaustive analysis of the universe of potential modifications to these laws. Rather, the potential options are based on discussions with the Healthcare Leadership Council (HLC), its National Dialogue for Healthcare Innovation initiative, representatives from member companies, and the HLC Stark and Anti-Kickback Reform Workgroup.

These new models potentially implicate many other federal statutes and regulations, including the Civil Monetary Penalties (CMP) Law's beneficiary inducement and gainsharing provisions; the Civil and Criminal False Claims Acts (FCA); the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its implementing regulations; the off-label promotion regulations as enforced by the Food and Drug Administration (FDA) and Department of Justice (DOJ); the Veteran's Administration (VA) and Medicaid program's best price requirements for pharmaceutical companies;

antitrust and tax laws; and state laws that overlap with, mirror, or relate to these federal laws. However, the purpose of this white paper is to address the Federal Anti-Kickback Statute and Physician Self-Referral (Stark) Law as primarily and respectively enforced by the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) and Centers for Medicare & Medicaid Services (CMS), and the Department of Justice.

While this paper does not address the other federal and state laws noted above, it is important to note the relationship between the Federal Anti-Kickback Statute and the CMP Law as they relate to both beneficiary inducement (i.e., providing anything of value to a patient in order to encourage the patient to utilize a particular provider) and gainsharing (i.e., sharing savings among providers based on limited or reduced medically necessary services). For example, routinely waiving patient co-payments potentially implicates both the CMP Law's beneficiary inducement provisions as well as the Anti-Kickback Statute, which prohibits a copayment waiver because it constitutes something of value provided to a patient. As such, when considering potential changes to the Anti-Kickback Statute, stakeholders also should consider related changes to the CMP Law to ensure consistency in interpretation and application across both laws.

For reference, this white paper provides some background information on the Federal Anti-Kickback Statute and Physician Self-Referral (Stark) Law as well as an overview of recent regulatory and legislative changes that provide additional context for the discussion of possible options to modify these legal frameworks.

The options are organized into two main categories: Regulatory and Legislative. Within each category, the options are arranged into three subcategories: Organization-based (e.g., ACOs), Financial Arrangements, and Penalties. There are also two additional subcategories to the Legislative options category addressing a Report to Congress and expanding CMS/OIG authority to modify the existing regulatory framework. These changes may be pursued independently or concurrently and some of the options may lend themselves to both regulatory and legislative action. **Options identified in the Executive Summary as priority options are in bold below.**

## **THE CURRENT LEGAL FRAMEWORK**

### Federal Anti-Kickback Statute and Physician Self-Referral (Stark) Law

The Federal Anti-Kickback Statute and Physician Self-Referral (Stark) Law regulate arrangements between and among healthcare industry participants. The Anti-Kickback Statute prohibits any individual from knowingly and willfully offering, paying, soliciting, or

receiving anything of value in return for referring a patient for items or services or to induce the generation of business reimbursable by a federal healthcare program.<sup>ix</sup> This prohibition applies to all healthcare industry participants, including institutional and individual providers, medical device and pharmaceutical manufacturers, suppliers, vendors, and health plans. The Physician Self-Referral (Stark) Law prohibits physicians from referring Medicare patients for certain services to an entity with which the physician (or an immediate family member) has a financial relationship.<sup>x</sup> The Physician Self-Referral (Stark) Law also prohibits healthcare organizations from billing Medicare for services provided pursuant to an improper referral. The Federal Anti-Kickback Statute and the Physician Self-Referral (Stark) Law would both prohibit, for example, an arrangement in which a physician and a hospital shared in savings achieved through coordinating care delivered to Medicare beneficiaries unless a waiver applies.<sup>xi</sup>

The Anti-Kickback Statute is a criminal law, and intent is required for liability to attach; penalties for violating the statute include imprisonment and substantial fines. In contrast, the Physician Self-Referral (Stark) Law is a civil statute imposing “strict liability,” meaning that no intent to violate the law is required. Civil monetary penalties may be levied for violations of the Anti-Kickback Statute and the Physician Self-Referral (Stark) Law, and entities that violate either may be excluded from participation in federal healthcare programs.

There are exceptions to each law as well as “safe harbors” that protect certain arrangements under the Federal Anti-Kickback Statute. These exceptions and safe harbors protect certain types of business arrangements and transactions that are considered to present a minimal risk of fraud or abuse when appropriately structured (i.e., in accordance with the requirements of an exception or safe harbor). The exceptions and safe harbors and associated requirements are not the same across both laws, though there is overlap. Generally, exceptions and safe harbors address payments made in the course of everyday business dealings (e.g., salaries paid to bona fide employees) and payments made for services integral to healthcare delivery (e.g., personal services contracts).

When the Anti-Kickback Statute (1972) and the Physician Self-Referral (Stark) Law (1988) were enacted, the healthcare system provided little or no financial incentive to providers or patients to improve health or care delivery. Reimbursement models rewarded volume based on the number of services provided, rather than rewarding health promotion and maintenance. Volume-based reimbursement models risk incentivizing overutilization, which in turn increases costs. Congress sought to restrict financial arrangements that could lead to overutilization, inappropriately influence provider decisionmaking, and compromise patient care through the Federal Anti-

Kickback Statute and the Physician Self-Referral (Stark) Law. By prohibiting providers from benefiting from referring patients for services, Congress sought to formally discourage unethical behavior. Both laws are quite broad, prohibiting financial relationships and arrangements that are permitted in other industries, and the safe harbors and exceptions, though numerous, are extremely narrow in scope.

As reimbursement models have changed over time, the Anti-Kickback Statute, Physician Self-Referral (Stark) Law, and their implementing regulations have been modified in an attempt to keep pace with these changes. These piecemeal modifications have resulted in incredibly complex requirements and uncertainty regarding how to apply these requirements to arrangements not contemplated when these laws were enacted.

### Recent Legislative and Regulatory Changes

Significant changes in the healthcare marketplace have occurred since the Anti-Kickback Statute and the Physician Self-Referral (Stark) Law were enacted. As noted above, these changes are moving healthcare from a fee-for-service reimbursement model to a fee-for-value payment and care delivery model. Most recently, these changes include passage of the Patient Protection and Affordable Care Act of 2010 (ACA) and the creation of ACOs as well as the passage of MACRA, which will transform how Medicare compensates physicians and significantly expand the use of alternative payment models such as ACOs and bundled payments across providers.

- 1) *General Changes to Fraud and Abuse Laws:* MACRA contained several provisions relevant to the fraud and abuse laws in general, including requiring the Secretary of HHS, in consultation with the OIG, to:
  - a. Study the applicability of fraud prevention laws under alternative payment models (APMs), identify aspects of APMs vulnerable to fraud, and examine implications of waivers to APMs. The Secretary must report to Congress on its findings and provide recommendations on how to reduce APMs' vulnerability to fraud by April 16, 2017;<sup>xii</sup> and
  - b. Submit a report to Congress by April 16, 2016, with options for amending existing Medicare and Medicaid fraud and abuse laws and regulations through exceptions or safe harbors to permit gainsharing or similar arrangements between physicians and hospitals that would improve care while reducing waste and inefficiency.<sup>xiii</sup> CMS, in consultation with the OIG, submitted the report to Congress in 2016.<sup>xiv</sup> In the report, CMS noted that the Secretary of HHS had no legislative or regulatory options to consider, but made several observations about the application of the current fraud and abuse legal framework to gainsharing and similar relationships, including:<sup>xv</sup>
    - i. The fraud and abuse laws “may serve as an impediment to robust, innovative programs that align providers by using financial incentives

to achieve quality standards, generate cost savings, and reduce waste;” and

- ii. The Stark law is a “particularly difficult obstacle to structuring effective programs that do not run afoul of the fraud and abuse laws.”

MACRA also narrowed the CMP Law’s gainsharing provision<sup>xvi</sup> to prohibit hospitals from paying physicians to induce reductions or limitations of **medically necessary** services (compared to the previous language, which prohibited payments made to induce physicians to reduce or limit **any** service).<sup>xvii</sup>

2) *Physician Self-Referral Law Changes in Physician Fee Schedule*: CMS routinely uses payment rules to amend the Physician Self-Referral (Stark) Law regulations. In July 2015, CMS issued a proposed 2016 Medicare Physician Fee Schedule<sup>xviii</sup> in which it referenced its history of using such rulemakings to make changes to the Stark law, detailed proposed changes to the law, and requested public feedback about these changes, which included:<sup>xix</sup>

- a. Two new Stark law exceptions (covering payments to physicians to employ non-physician practitioners and timeshare arrangements for the use of office space, equipment, personnel, supplies, and other services that benefit rural or underserved areas);
- b. Guidance and clarification related to financial relationship documentation and requirements specific to certain financial relationships; and
- c. Clarifying ACA-mandated limitations on the whole hospital exception.

CMS finalized the proposed changes with minor modifications on October 30, 2015 in a final rule with comment period.<sup>xx</sup> In the proposed rule, CMS sought public comment regarding the impact of the self-referral law on healthcare delivery and payment reform and specifically asked for feedback on perceived Stark-related barriers to clinical and financial integration.<sup>xxi</sup> CMS also posed specific questions for stakeholder input regarding the need for guidance on the application of aspects of the Stark regulations to physician compensation unrelated to participation in APMs. In the final rule, CMS stated that it would carefully consider comments received in response to these questions when preparing reports to Congress as mandated by MACRA<sup>xxii</sup> and in determining the necessity of additional rulemaking on these issues.<sup>xxiii</sup>

In July 2016, CMS issued a proposed 2017 Medicare Physician Fee Schedule rule<sup>xxiv</sup> in which it noted that the Stark law “responds to the context of the time in which it was enacted” and includes flexibility to adapt to changing circumstances and healthcare industry developments.<sup>xxv</sup> The Final Rule issued in November 2016 reiterated these statements, and emphasized the Secretary’s authority (as granted

by Congress) to protect via regulatory exceptions beneficial healthcare industry arrangements not contemplated when the Stark law was enacted.<sup>xxvi</sup>

- 3) *Medicare Shared Savings Program*: The ACA made several changes that impact the fraud and abuse laws. One significant change was the creation of the Medicare “Shared Savings Program” (MSSP), which allows groups of providers to create ACOs and share in the savings generated by reducing the overall cost of providing care to an assigned population of Medicare beneficiaries. CMS and the OIG published interim final rules on November 2, 2011, waiving certain provisions of the Stark and the Anti-Kickback statutes that would limit ACO arrangements within the MSSP.<sup>xxvii</sup> A continuation notice published in 2014 extended these provisions, which were finalized in a joint rule issued by CMS and OIG in October of 2015.<sup>xxviii</sup> CMS has authority to issue waivers of the federal fraud and abuse laws as may be necessary to test models for improving care delivery or reducing expenditures.

Note that in CMS’ gainsharing report, it uses the OIG and CMS determination that these waivers were necessary as support for its assertion that the fraud and abuse laws may serve as an impediment to “robust, innovative programs” that use financial incentives to align providers and achieve quality standards.<sup>xxix</sup>

- 4) *The ACA made other changes to the fraud and abuse laws, including that it:*
- a. Lowered the Anti-Kickback Statute’s intent threshold,<sup>xxx</sup> specifying that an individual or entity need not intend to violate the statute or even know the statute exists to have the requisite level of intent; the individual or entity must just intend to induce the prohibited referral;
  - b. Established the Medicare Coverage Gap Discount Program, under which prescription drug manufacturers provide drug discounts to certain beneficiaries, and amended the Anti-Kickback Statute to exclude these discounts from its definition of remuneration.<sup>xxxi</sup> The OIG issued a final rule implementing this change to the Anti-Kickback Statute on December 6, 2017;<sup>xxxii</sup>
  - c. Added disclosure requirements to the Physician Self-Referral Law’s in-office ancillary services exception applicable to certain imaging services (e.g., physicians must disclose financial interests to patients); and
  - d. Removed the “whole hospital exception” (commonly referred to as the specialty hospital exception) to the Stark law, with limited grandfathering for existing arrangements.
- 5) *On December 6, 2016, the OIG finalized modifications to the Anti-Kickback Statute proposed in 2014.*<sup>xxxiii</sup> The final changes expanded the Anti-Kickback Statute’s regulatory safe harbor protecting waivers or reductions of beneficiary cost-sharing

amounts and established two new safe harbors protecting: (1) free or discounted local transportation services and (2) remuneration between a Federally Qualified Health Center (FQHC) and a Medicare Advantage organization in certain circumstances.

- 6) *E-prescribing and Electronic Health Records*: The Medicare Prescription Drug Improvement and Modernization Act (MMA) of 2003 mandated the development of an Anti-Kickback Statute safe harbor and a Stark law exception to promote e-prescribing technology adoption. In 2006, CMS and the OIG issued final rules furthering this mandate via two exceptions: (1) certain providers and health plans may subsidize 100 percent of e-prescribing system hardware, software, training, and support for certain related entities; and (2) through 2013, any provider or health plan may subsidize up to 85 percent of electronic health record (EHR) software and/or related technology and training services for any provider.<sup>xxxiv</sup> The preambles of both final rules provide an illustrative but nonexhaustive list of EHR software and related technologies that would be considered covered technology within the donation exception.<sup>xxxv</sup> These examples include connectivity services, clinical and information support services related to patient care, maintenance services, and secure messaging. The final rules specifically exclude certain items and services, including storage devices and software with core functionality other than electronic health records, such as payroll software. On December 27, 2013, the OIG and CMS issued joint final regulations extending the EHR exception through 2021 and modifying some of its requirements.<sup>xxxvi</sup> In response to stakeholder concerns about the scope of covered technology, the final rules note the importance of maintaining flexibility in the definition, particularly as health information technology evolves.<sup>xxxvii</sup> The rules declined to expand on the illustrative list provided in the 2006 final rule or to memorialize that list within the regulatory text and noted that revising the definition could inadvertently narrow the exception. The final rules emphasize that whether specific items and services are considered covered technology under the exception is dependent on the particular items or services. Specifically, donated items or services must be necessary and used predominantly to create, maintain, transmit, or receive electronic health records to qualify for the exception. The final rules suggest the possibility of expanding the scope of covered technology in the future.<sup>xxxviii</sup>

#### Recent Congressional Activity and Guidance

- 1) *Senate Finance Committee and Stark*: In response to increasing support for Physician Self-Referral Law reform, particularly following the passage of MACRA, the Senate Finance Committee held a roundtable with subject matter experts to discuss Stark law concerns in December 2015. The committee subsequently gave participants and other stakeholders the opportunity to submit comments on these

issues, which were summarized in a white paper published on June 29, 2016.<sup>xxxix</sup> Several of the recommendations and concerns highlighted in the white paper are mirrored here. The committee held a hearing on July 12, 2016, to examine current issues and opportunities related to the Physician Self-Referral Law, where experts in the field testified about the barriers to healthcare transformation the Stark law imposes and answered questions posed by committee members.<sup>xl</sup>

- 2) *Information Blocking*: The OIG issued an alert on October 6, 2015 addressing information blocking and the EHR safe harbor exception to the Anti-Kickback Statute.<sup>xli</sup> The alert notes that donation of EHR items or services that have limited or restricted interoperability due to action taken by the donor or anyone on the donor's behalf would not fall within the EHR donation safe harbor. OIG believes that charging fees to deter nonrecipient providers and suppliers and the donor's competitors from interfacing with the donated items or services would pose "legitimate concerns" that parties were improperly locking-in data and referrals and thus that the arrangement in question would not qualify for safe harbor protection.
- 3) *Medicare and Medicaid Discharge Planning Requirements*: CMS released a proposed rule on October 29, 2015 revising Medicare and Medicaid discharge planning requirements for acute care, long-term care, and critical access hospitals, inpatient rehabilitation facilities, and home health agencies.<sup>xlii</sup> The rule would implement the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014's discharge planning provisions, which modify conditions of participation (COPs) to require postacute care providers, hospitals, and critical access hospitals to account for quality, resource use, and similar measures in the discharge planning process. The rule would require these entities to use and share data on quality and resource use measures to assist patients in selecting postacute care providers.

## **POTENTIAL REGULATORY OPTIONS** (with priority options in **bold**)

Despite the healthcare payment and delivery system's continued evolution, changes to the fraud and abuse legal framework lag behind. The Stark law continues to restrict physicians' (and certain family members') financial relationships with entities to which the physician may make referrals. The 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 and exceptions could protect certain value-based care models, applying their narrow requirements to new models requires the expenditure of resources and a degree of risk tolerance that many stakeholders do not

possess. Safe harbors and exceptions for personal services arrangements, fair market value compensation, warranties, and/or discounts, for example, may be “cobbled together” to protect some arrangements that reward value and outcomes.<sup>xliii</sup> However, these exceptions were designed for siloed care and payment settings and generally cannot sufficiently enable robust collaborative care model innovation.<sup>xliiv</sup> The failure to modernize the fraud and abuse framework threatens to impede meaningful progress. Unwilling to risk penalty under the Anti-Kickback Statute or Physician Self-Referral (Stark) Law, stakeholders may be discouraged 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 these laws and eliminate uncertainty about their potential application to beneficial arrangements.

*Note: The U.S. Department of Health and Human Services (HHS) Office of the Inspector General (OIG) and the Centers for Medicare & Medicaid Services (CMS) have regulatory authority to create new and modify existing safe harbors/exceptions to protect arrangements that pose little threat of fraud and abuse.*

#### Organization-Based Waivers or Exemptions

- **Issue safe harbors, exceptions, or guidance that effectively extend Federal Anti-Kickback Statute and Physician Self-Referral law waivers for Medicare Shared Savings Program (MSSP) Accountable Care Organizations (ACOs) to all ACOs and to organizations implementing other alternative payment models that meet certain conditions, regardless of whether or not they are participating in the MSSP or other Medicare-specific programs.**
- Issue safe harbors, exceptions, or guidance that effectively extend Anti-Kickback Statute and Stark law waivers to activities or initiatives that involve the integration of care, items, services, and payment across stakeholders (i.e., industry, providers, and payers), that meet certain established value-based health care criteria and that are designed to improve patient outcomes and reduce the overall cost of providing care. These waivers would be available to stakeholders regardless of whether they are participating in a Medicare-approved program (e.g., ACO, APM, bundled payment initiative).

#### Financial Arrangements

- **Revise and extend the Anti-Kickback Statute and Physician Self-Referral exceptions for donation and financial support of EHR software, related technologies, and training, as follows:**

- Expand the scope of covered technology to encompass a broader range of health information technology:
  - **Specifically include technology related to information sharing** (e.g., application program interfaces, health information exchange networks, care coordination services, care management tools, population health management and quality management tools, and patient engagement and communication tools);
  - **Specifically include technology related to cybersecurity.** Because cyber security programs that protect patient records in EHR systems are often expensive and difficult to manage, recipients of donated EHR technology may not have adequate security systems in place.<sup>xlv</sup> This makes recipients vulnerable to security breaches as well as the providers with whom they exchange information;
  - Consider including technology such as cloud-based items and services, practice management and revenue cycle systems and services, EHR storage, as well as subscription fees related to the use and exchange of health information; and
  - **Include industry-supported data collection, analytics, and other technology services as part of the exceptions.**
- Remove the requirement that donated technology cannot replace something similar. This requirement limits the exception to those providers who have not implemented an EHR system, which by 2021, will likely be a vanishingly low percentage of providers.
- Make the exception permanent (currently, the exception expires in 2021).
- Create an Anti-Kickback Statute safe harbor and Stark exception for clinically and financially integrated programs that: (1) allow all the various types of stakeholders (i.e., industry, providers, payers) to participate as applicable; (2) give stakeholders flexibility in meeting those requirements to enable the program to achieve its goals, and (3) allow distribution of financial savings to support clinical and payment integration.<sup>xlvi</sup> Ensure that safe harbors and exceptions include the same provisions so that meeting one set of requirements achieves compliance under the federal Anti-Kickback Law, Stark, and the CMP Laws.

## Penalties

- Eliminate False Claims Act (FCA) bootstrapping to Stark law violations. The bootstrapping theory used by federal enforcement authorities makes a violation of the Physician Self-Referral law an automatic violation of the FCA (i.e., a claim for services provided by a physician who has an impermissible financial

relationship with the billing healthcare organization is tainted by the improper referral).<sup>xlvii</sup>

### Technical Changes/Guidance

- **OIG and CMS could issue regulatory 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.
- **OIG and CMS could clarify how to establish and document fair market value (FMV) through guidance** (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).<sup>xlviii</sup> **Alternatively, legislation could require the HHS Secretary to produce this guidance.**
- **OIG and CMS could expand and revise 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). **Alternatively, this also could be a legislative option;** the Anti-Kickback Statute does not statutorily define FMV (but the Stark law does) and both the OIG and CMS have released guidance expanding on the concept of FMV, but as care delivery and payment continue to evolve, additional clarification and flexibility is necessary.
- **OIG could eliminate or redefine the “one purpose” test for Anti-Kickback Statute liability 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).**<sup>xlix</sup> **Transactions not meeting this harm standard would not give rise to liability.** Replacing the “one purpose rule” with this harm standard would potentially allow, for example, arrangements where providers and/or medical device or pharmaceutical manufacturers and suppliers provide items or services of value to patients to assist with prescription medication adherence, perioperative regimen adherence,

or access to healthcare services (e.g., waiver of co-pays). The OIG could assess the 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 purpose of the arrangement is to increase referrals for an item or service reimbursable by a federal healthcare program. **The “one purpose” test is a product of case law, so a legislative solution may also be appropriate.**

- OIG and CMS could, through rulemaking, simplify exceptions and safe harbors, including:<sup>i</sup>
  - Eliminate and/or broaden the signature requirements in relevant exceptions/safe harbors;<sup>ii</sup>
  - Modify the written agreement requirements in relevant exceptions/safe harbors such that failure to put an agreement in writing would result in a lesser civil penalty and would not trigger Stark law or Anti-Kickback Statute liability;
  - Eliminate the commercial reasonableness requirement from relevant Stark exceptions;<sup>iii</sup>
  - Create a broad *de minimis* exception and adopt a technical violation exception to the Physician Self-Referral law that would protect innocuous issues, including:
    - Standard expense reimbursements;
    - Minor courtesies; and
    - Modest medical director or consultant fees.
- OIG and CMS could simplify the Stark exceptions and Anti-Kickback Statute safe harbors by eliminating cumbersome or unnecessary elements, streamlining definitions, and re-working some specific concepts that have grown unwieldy (e.g., the definition of “remuneration”).<sup>iiii</sup>

## **POSSIBLE LEGISLATIVE OPTIONS** (with priority options in **bold**)

### Reports to Congress/Stakeholder Input

- **Expand the parameters of the MACRA-mandated alternative payment model report (due by April 16, 2017)<sup>liv</sup> and mandate a new report that broadens the MACRA-mandated gainsharing report (issued by CMS in 2016)<sup>lv</sup>:**
  - These reports could be expanded to require the HHS Secretary to review and assess the Anti-Kickback Statute, Stark, and the CMP law in the context of the transformation of the healthcare system. The Secretary

could specifically address: (1) whether these laws create unnecessary barriers to integrated care delivery and payment models; (2) whether these laws are effective in limiting fraudulent behavior; and (3) whether these laws should be modified to more effectively limit fraud and abuse without limiting new care and payment models aimed at providing better care at lower costs. Both reports could include findings from the assessment.

- The review process for both reports should include subject matter experts from CMS and the OIG and the Secretary also should consult with the Department of Justice (DOJ), Internal Revenue Service (IRS), and the Federal Trade Commission (FTC).
- The Secretary should allow for opportunities for stakeholder input that would include medical practitioners and administrators, pharmaceutical and medical device manufacturers and suppliers, consumers, and legal and policy experts to review the Secretary's findings and assessment. Both reports could include stakeholders' feedback.
- The reports should include plans of action to address any suggested changes to the legal frameworks that arise from the assessment, as well as a description of the actions needed to achieve those changes.

**Potential changes to the fraud and abuse framework identified during the assessment and detailed in the Secretary's reports may yield opportunities for either legislative or regulatory action to amend the Anti-Kickback Statute, Stark law, and CMP law to protect arrangements that promote increased quality and lower costs.** Any such opportunities must be reviewed with care to ensure that existing exceptions that enable bona fide arrangements designed to improve patient care and reduce costs, such as the original exceptions to the Anti-Kickback Statute (i.e., discounts, employer/employee and group purchasing organization arrangements), are not compromised.

- **Congress also may consider granting OIG and CMS increased regulatory flexibility/rulemaking discretion to develop exceptions/safe harbors that are consistent with broad policy objectives (e.g., increase efficiency and quality and decrease costs) and adapt the Anti-Kickback Statute, Stark law, and the CMP law to the current healthcare environment.<sup>lvi</sup>** For example, new exceptions and 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 and providers and/or payers that incentivize and reward improvements in clinical outcomes and/or reductions in cost. Note that OIG and

CMS already have statutory authority to create safe harbors and exceptions, but Congress could direct them to do so regarding specific areas or in specific ways based on findings from the assessment and/or reports. Note also that CMS's authority to issue exceptions is limited to those situations where doing so would create "no possible risk of program or patient abuse."<sup>lvii</sup> This high bar limits the flexibility an exception can offer for innovative, effective alternative payment models (such as gainsharing and incentive compensation programs).<sup>lviii</sup>

- Congress could authorize a "fast track" guidance process, less formal than the current advisory opinion process, that would apply to all exceptions and safe harbors for value-based models.

### Financial Arrangements

- Amend the Physician Self-Referral law to permit ALL financial relationships EXCEPT those specifically prohibited based on their risk of fraud and abuse.<sup>lix</sup> Examples of continued PROHIBITED activities may include: 1) physician ownership of clinical and physiological laboratories, outpatient diagnostic imaging facilities, medical leasing equipment companies, and certain ancillary services (e.g., durable medical equipment); 2) physician financial relationships including under arrangements and per-click lease arrangements; and 3) physician compensation arrangements where payments vary with the volume or value of referrals.<sup>lx</sup>

### Penalties

- Remove strict liability from the Stark law. Replace with either an intent-based framework<sup>lxi</sup> or develop a sliding scale of penalties for violations to more closely align penalties with the severity of activity.

*Document Prepared for the Healthcare Leadership Council’s Anti-Kickback and Stark Reform Working Group by Jane Hyatt Thorpe, JD, and Elizabeth Gray, JD, MHA, Department of Health Policy and Management, Milken Institute School of Public Health, George Washington University.*

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<sup>i</sup> Healthcare Leadership Council (HLC). *Vlable Solutions: Six Steps to Transform Healthcare Now* (February 17, 2016). Available at: [http://www.ndhi.org/files/6414/5565/8017/Vlable\\_Solutions\\_Final\\_Report.pdf](http://www.ndhi.org/files/6414/5565/8017/Vlable_Solutions_Final_Report.pdf).

<sup>ii</sup> Public Interest Committee, American Health Lawyers Association (AHLA). White Paper: “A Public Policy Discussion: Taking the Measure of the Stark Law” (“AHLA White Paper”) at pp. 14-16, 21 (2009). Available at: <https://www.healthlawyers.org/hlresources/PI/ConvenerSessions/Documents/Stark%20White%20Paper.pdf>.

<sup>iii</sup> American Hospital Association (AHA). “Legal (Fraud and Abuse) Barriers to Care Transformation and How to Address Them” (“AHA Barriers to Care”) at p. 4 (July 5, 2016). Available from: <http://www.aha.org/content/16/barrierstocare-full.pdf>.

<sup>iv</sup> M.E. Paulhus. *The Medicare Anti-Kickback Statute: In Need of Reconstructive Surgery for the Digital Age*. 59 Wash. Lee L. Rev. 677, 706-07 (2002).

<sup>v</sup> Medicare Access and CHIP Reauthorization Act of 2015 (“MACRA”), Pub. Law 114-10, 129 Stat. 87, § 101(e)(7) (Apr 16, 2015).

<sup>vi</sup> Public Interest Committee, American Health Lawyers Association (AHLA). White Paper: “A Public Policy Discussion: Taking the Measure of the Stark Law” (“AHLA White Paper”) pp. 13, 21 (2009). Available at: <https://www.healthlawyers.org/hlresources/PI/ConvenerSessions/Documents/Stark%20White%20Paper.pdf>.

<sup>vii</sup> For example, stakeholders may consider entering into value-based arrangements that support improvements in care and better outcomes for patients (i.e., between and among private payers, providers, and biopharmaceutical companies related to the value of new medicines). In determining whether or not to enter into these arrangements, the parties must consider the application of fraud and abuse and other laws. Perceived or real ambiguity as to the application of the legal framework as it relates to value-based care delivery and payment models may create uncertainty and ultimately stifle willingness to pursue these arrangements.

<sup>viii</sup> CMS, Report to Congress: Fraud and Abuse Laws Regarding Gainsharing or Similar Arrangements between Physicians and Hospitals (“CMS Gainsharing Report”) (2016); MACRA § 512(b). Available from: <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/Report-to-Congress-2015.pdf>.

<sup>ix</sup> 42 U.S.C. § 1320a-7b(b) (2015).

<sup>x</sup> 42 U.S.C. § 1395nn(a) (2015).

<sup>xi</sup> Note that if stakeholders were part of an ACO participating in the MSSP, this financial arrangement could be permissible if those entities obtained a waiver.

<sup>xii</sup> MACRA, § 101(e)(7).

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- <sup>xiii</sup> MACRA, § 512(b) (i.e., “Gainsharing Report”).
- <sup>xiv</sup> CMS Gainsharing Report.
- <sup>xv</sup> CMS Gainsharing Report, pp. 7-8.
- <sup>xvi</sup> Social Security Act § 1128A(b)(1).
- <sup>xvii</sup> MACRA, § 512(a).
- <sup>xviii</sup> CMS, “Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016,” 80 Fed. Reg. 41686 (July 15, 2015).
- <sup>xix</sup> 80 Fed. Reg. at 41909-30.
- <sup>xx</sup> CMS, “Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016” 80 Fed. Reg. 70886 (November 16, 2015).
- <sup>xxi</sup> 80 Fed. Reg. at 41929.
- <sup>xxii</sup> APM report (MACRA §101(e)(7)) and Gainsharing report (MACRA § 512(b)).
- <sup>xxiii</sup> 80 Fed. Reg. at 71341.
- <sup>xxiv</sup> CMS, “Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017,” 81 Fed. Reg. 46162 (July 15, 2016).
- <sup>xxv</sup> 81 Fed. Reg. 46162 at 46452 (2016).
- <sup>xxvi</sup> CMS, “Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017” 81 Fed. Reg. 80170 at 80527 (November 15, 2016).
- <sup>xxvii</sup> OIG “Final Waivers in Connection With the Shared Savings Program” 76 Fed. Reg. 67992; CMS “Medicare Shared Savings Program: Accountable Care Organizations” 76 Fed. Reg. 67802.
- <sup>xxviii</sup> CMS and OIG “Final Waivers in Connection With the Shared Savings Program” 80 Fed. Reg. 66725 (October 29, 2015).
- <sup>xxix</sup> CMS Gainsharing Report, p. 7 (2016).
- <sup>xxx</sup> Following these changes, the Anti-Kickback Statute continues to include a ‘knowing and willful’ standard to determine a party’s intent. For an offer or payment of remuneration to violate the AKS, the offeror or payer must intend to induce a referral. See, e.g., United States ex rel. Ruscher v. Omnicare, 2015 WL 5178074 at \*13 (S.D. Tex. Sept. 3, 2015).
- <sup>xxxi</sup> ACA § 3301, adding § 1860D-14A to the Social Security Act (codified at 42 U.S.C. 1395w-114A) (2010).
- <sup>xxxii</sup> OIG “Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements” 81 Fed. Reg. 88368.

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<sup>xxxiii</sup> OIG “Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements” 81 Fed. Reg. 88368 (finalizing 79 Fed Reg 59717 (October 3, 2014)).

<sup>xxxiv</sup> OIG “Safe Harbors for Certain Electronic Prescribing and Electronic Health Records Arrangements Under the Anti-Kickback Statute” 71 Fed. Reg. 45110 (August 8, 2006); CMS “Physician Referrals to Health Care Entities With Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangement” 71 Fed. Reg. 45140 (August 8, 2006).

<sup>xxxv</sup> OIG, 71 Fed. Reg. at 45151-2; CMS, 71 Fed. Reg. at 45151.

<sup>xxxvi</sup> OIG “Electronic Health Records Safe Harbor Under the Anti-Kickback Statute” 78 Fed. Reg. 79202 (2013); CMS “Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships: Exceptions for Certain Electronic Health Records Arrangements” 78 Fed. Reg. 78751 (2013).

<sup>xxxvii</sup> OIG, 78 Fed. Reg. at 79216; CMS, 78 Fed. Reg. at 78765.

<sup>xxxviii</sup> OIG, 78 Fed. Reg. at 79216; CMS, 78 Fed. Reg. at 78766.

<sup>xxxix</sup> U.S. Senate Finance Committee Majority Staff. “Why Stark, Why Now? Suggestions to Improve Stark Law to Encourage Innovative Payment Models” (June 29, 2016). Available at: <http://www.finance.senate.gov/imo/media/doc/Stark%20White%20Paper,%20SFC%20Majority%20Staff.pdf>.

<sup>xl</sup> U.S. Senate Finance Committee. “Examining the Stark Law: Current Issues and Opportunities” (July 12, 2016). Video, Member Statements, and Witness Statements available at: <http://www.finance.senate.gov/hearings/examining-the-stark-law-current-issues-and-opportunities>

<sup>xli</sup> OIG. “OIG Policy Reminder: Information Blocking and the Federal Anti-Kickback Statute” (Oct 6, 2015). Available at: <http://oig.hhs.gov/compliance/alerts/guidance/policy-reminder-100615.pdf>.

<sup>xlii</sup> 80 Fed. Reg. 68126 (Nov 3, 2015).

<sup>xliii</sup> See, e.g., AHA Barriers to Care (2016).

<sup>xliv</sup> See, e.g., AHA Barriers to Care (2016).

<sup>xlv</sup> HITRUST. “Letter to Senator Lamar Alexander” (August 15, 2016). Available at: <https://hitrustalliance.net/content/uploads/2016/08/HITRUST-Stark-Exception-Congressional-Letter-Senator-Lamar-Alexander.pdf>.

<sup>xlvi</sup> AHA. “Trendwatch - Clinical Integration: The Key to Real Reform” (Feb 2010) (note: clinical integration defined as a spectrum from “bundled payments for single episodes of care” to “Medical Staff includes [almost] only fully-employed physicians,” Chart 4: Clinical Integration Spectrum, p. 7); AHA Trendwatch – The Value of Provider Integration (March 2014).

<sup>xlvii</sup> AHA White Paper, pp. 17, 22 .

<sup>xlviii</sup> AHA White Paper, p. 13.

<sup>xlix</sup> Paulhus, 59 Wash. Lee L. Rev. at 706-07.

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<sup>i</sup> AHLA White Paper, pp. 14-16, 21.

<sup>ii</sup> For example, the Physician Self-Referral (Stark) Law exceptions for office space rental, equipment rental, and personal services arrangements each require the written agreement to be signed by all parties. Failure to sign an agreement, even inadvertently, means that the agreement does not fit within an exception (and thus is a Physician Self-Referral (Stark) Law violation). CMS created a special rule allowing “temporary noncompliance” with the signature requirement for 90 days, but this grace period may be used by an entity only once every three years.

<sup>iii</sup> The commercial reasonableness requirement appears in the exceptions for office space rental, equipment rental, bona fide employment relationships, fair market value compensation, and inpatient hospital services. In general, the financial terms of the arrangement at issue (e.g., the lease or compensation amount) must be considered “commercially reasonable” even if the parties made no referrals to each other. CMS has not clarified the meaning of “commercially reasonable.” The Anti-Kickback Statute would prohibit sham arrangements even if the commercial reasonableness requirement is eliminated from the Physician Self-Referral (Stark) Law – as such, this requirement is unnecessary.

<sup>iiii</sup> AHLA White Paper, pp. 14-15, 21.

<sup>lv</sup> MACRA § 101(e)(7).

<sup>lv</sup> MACRA, § 512(b).

<sup>lvi</sup> AHLA White Paper, pp. 13, 21.

<sup>lvii</sup> 42 U.S.C. § 1395nn(b)(4).

<sup>lviii</sup> See, e.g., CMS Gainsharing Report, pp. 5-6 (2016).

<sup>lix</sup> AHLA White Paper, pp. 11-13, 21.

<sup>lx</sup> AHLA White Paper, p. 22.

<sup>lxi</sup> AHLA White Paper, pp. 12, 22.