

August 3, 2018

Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
Hubert H. Humphrey Building  
202 Independence Avenue, S.W., Room 445-G  
Washington, DC 20201

***RE: CMS-1720-NC, Request for Information Regarding the Physician Self-referral Law***

Dear Ms. Verma:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, our clinical partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) Request for Information (RFI) on reducing regulatory burdens of the Stark Law.

We welcome the Department of Health and Human Services' (HHS) launch of its "Regulatory Sprint to Coordinated Care," making removal of unnecessary government obstacles to care coordination a key priority. The AHA and America's hospitals and health systems stand ready to assist the Department and CMS in tackling a major obstacle – the barriers created by the physician self-referral law compensation regulations.

As recognized in your June 20 blog, *Working Together for Value*, the Stark Law was enacted years ago and in its current form may prohibit relationships that are designed to enhance care coordination, improve quality, and reduce waste. Every day, hospitals and health systems – and the patients they serve – experience the frustration of working to coordinate care and improve the health of their communities while continuously encountering the obstacles of existing rigid compensation regulations. We strongly endorse your view that "to achieve a truly value-based, patient-centered health care system, doctors and other providers need to work together with patients."



Our response to the RFI highlights the obstacles hospitals and physicians face in moving to a value-based system while navigating the Stark Law compensation regulations that were built for the very different fee-for-service model. We also recommend specific changes to remove barriers and drive patient-centered care. **We urge that no changes be made to the regulations implementing the Stark Law's ownership ban. That ban is a carefully developed policy that is working as Congress intended.**

We believe meaningful changes to the regulations can achieve significant improvements to patient care. We previously discussed the adverse impact the Stark requirements have on patient care in AHA's report, [Legal \(Fraud and Abuse\) Barriers to Care Transformation and How to Address Them...Wayne's World](#). That is why we recommend specific changes to the compensation regulations that will foster and enable the relationships between hospitals and physicians necessary to achieve value-based care and a patient-centered system, and to remove unnecessary and burdensome requirements that do not advance coordinated care. Our recommendations are followed by amended regulatory text to accomplish each of the proposed changes.

Our recommended changes include:

- Protection for value-based payment methodologies – specifically, a new exception for value-based payment arrangements, and modifications to the personal services and risk sharing exceptions.
- Clear, authoritative, and timely guidance – specifically, define key elements of compensation exceptions and revise the Advisory Opinion process.
- Refocus regulations on arrangements that produce overutilization by eliminating provisions that do not address overutilization yet add unnecessary complexity and ambiguity, specifically, add an alternative method for demonstrating compliance with documentation requirements, modify the payment-by-physician exception, and de-couple compliance with Stark from compliance with the Anti-Kickback Statute.

Again, we thank you for your focus on this critical issue and for your consideration of our comments. Our detailed comments and suggested regulatory text are attached. Please contact me if you have any questions at [mhatton@aha.org](mailto:mhatton@aha.org) or (202) 626-2336.

Sincerely,

/s/

Melinda Reid Hatton  
General Counsel

## AMERICAN HOSPITAL ASSOCIATION DETAILED COMMENTS ON STARK RFI

### ACCELERATE TRANSFORMATION TO A VALUE-BASED SYSTEM OF COORDINATED CARE AND IMPROVED PATIENT OUTCOMES

HHS, CMS, hospitals and health systems all agree that the Stark Law often stands as an impediment to the development and implementation of value-based payment models that reward providers for delivering higher quality, cost-effective care with better outcomes. **We urge that compensation exceptions to the Stark Law be created or adapted to enable hospitals and physicians, working together, to coordinate care and improve patient outcomes. We urge that no changes be made to the regulations implementing the Stark Law's ownership ban. That ban is a carefully developed policy that is working as Congress intended.**

For providers, the problem is designing flexible payment terms that reward physicians who help them achieve care coordination and improved patient outcomes. CMS has implemented new payment methodologies in the context of traditional Medicare fee-for-service reimbursement that can only be implemented effectively if physicians, hospitals and other caregivers actively collaborate toward a shared goal of high-quality, low-cost care. At the same time, CMS's current Stark compensation regulations constrain innovation. They discourage the development and adoption of rewards that encourage change on a broad scale, across all patient populations and payer types, and over indefinite periods of time. The regulations also fail to recognize that relationships between payers, providers, physicians, and patients have transformed significantly over time and that those new relationships already address many of the risks the Stark Law was enacted to prevent.

Outside of Medicare, many health systems and other providers are exploring partnerships with physicians to develop new payment and delivery models that encourage the same kinds of improvements in the quality and efficiency of care for all patients and communities. Yet, due to the broad definition of "financial relationship" under the Stark Law, providers are concerned that even innovative payments based solely on the delivery of high-quality, cost-effective care to self-pay or commercial insurance patients can run afoul of the Stark Law's payment and referral prohibitions. Uncertainty about the application of the Stark Law and the potentially devastating consequences it imposes for being wrong have impeded those efforts.

The need for change is clear and the failure to make changes will have an increasingly negative effect on transforming to a value-based system. Congress has repeatedly recognized that new models for delivering health care cannot go forward under the current Stark Law regime. Congress authorized waivers from the Stark Law for the Medicare Shared Savings Program (MSSP), and authorized the Secretary to create waivers for any programs initiated through the Center for Medicare and Medicaid

Innovation (CMMI). Waivers, however, are insufficient – they protect only arrangements specific to the waived program and are limited in duration.

Outside of the waived programs, hospitals every day face challenges meeting the demands of Medicare program initiatives that require joint efforts by hospitals and physicians to care for patients, efforts that are inhibited by existing Stark regulations. Today Medicare imposes financial penalties if hospitals do not meet targets related to readmissions, quality metrics, and meaningful use. Yet, for all of these initiatives, the active participation of physicians is needed.

**To reach the full potential of a value-based system, the Stark compensation regulations must be reframed to meet the objectives of the new system, through the creation of a new exception designed specifically for value-based payment methodologies, and reforms to the personal services, employment, and risk sharing exceptions.**

#### **New Value-based Payment Exception**

**We believe an exception specific and dedicated to value-based arrangements is the most effective and efficient way to provide the certainty and protection hospitals, health systems, and physicians need to join forces in achieving a patient-centered and value-based health system.** The substance of the exception should be driven by a hands-on, bottom-up approach – providing protection for what is practically needed to achieve the care coordination underpinning a value-based system. The new exception should cover only those arrangements with a declared objective of achieving one or more of the pillars of coordinated care:

- Promoting accountability for the quality, cost, and overall care for patients;
- Managing care for patients across and among other providers; and,
- Encouraging investment in infrastructure and redesigned care processes for high-quality and efficient care delivery for patients.

We urge that the new dedicated exception protect financial arrangements that include various types of remuneration, so long as the remuneration is reasonably related to, and used to achieve, one or more of the pillars of coordinated care described above. Remuneration falling within the exception should include incentive payments, shared savings payments based on actual cost savings, and infrastructure payments or in-kind assistance (including, but not limited to, electronic health records (EHRs) technology, cybersecurity resources, data or clinical analysis tools, and start-up support).

The exception also should establish the basic accountabilities for the use of financial incentives or in-kind assistance:

- *Transparency.* Documentation of the use of incentives or other assistance must be maintained and available to HHS upon request.

- *Recognizable improvement processes:* Any performance standards used (e.g., required care protocols, metrics used to award performance bonuses) must be consistent with accepted medical standards and reasonably fit the purpose of improving patient care.
- *Monitoring:* Performance under improvement processes must be internally reviewed to guard against adverse effects and documentation of those reviews must be maintained and available to HHS upon request.

We expect that as a result of the new exception we propose, hospitals and health systems will be able to implement practical and positive improvements for patients, providers, and the Medicare program. We provide examples of these improvements below. For each we also illustrate direct benefit to beneficiaries using "[Wayne](#)," a 75-year-old male with multiple chronic conditions and who has limited support at home, as an example.

Shared EHR infrastructure to coordinate care. Under new models of payment, hospitals and health systems are financially responsible for creating an efficient care team that achieves lower costs and higher quality, enabling patients to achieve and maintain the best possible health outcome. To do so, care teams need ready access to the information necessary to make informed decisions about patient care. In today's world, that requires building and maintaining electronic systems for securely transmitting information and making it available to support those caring for the patient across sites of care, among professionals and over time. Care teams also need access to current and authoritative information to support a physician in diagnosing and ordering treatments for a patient. This requires both the data and the analytical tools to support a physician's decision-making, as well as ongoing quality assurance and quality improvement programs.

**Current regulations place unreasonable constraints on how hospitals finance needed infrastructure, and there are no exceptions for a hospital to provide data analytic tools to assist physicians in making treatment decisions for patients. Investing in needed infrastructure is a pre-condition for implementing new payment models and accountability.**

***Beneficial impact on beneficiaries:*** For [Wayne](#), shared electronic systems across his care team would mean no longer answering the same questions or completing duplicate paperwork every time he has an appointment or contact with someone on his care team.

Incentives for care redesign to improve outcomes. Hospitals want to implement incentive programs to encourage and reward physicians who adhere to defined care pathways in treating their patients, as consistent use of these pathways improves patient outcomes. The physicians evaluate relevant research and data and, through a consensus process, develop care pathways to achieve the best outcomes for patients.

**However, under current regulations, the only protections available to hospitals and health systems for incentive arrangements are haphazard combinations of exceptions originally designed for functionally independent providers, not collaborators.** Existing exceptions are anchored in an “hours worked” or “resources expended” approach, while the objectives of new models are outcomes-based, such as following care pathways to most efficiently achieve the best outcomes for patients. In many models, it is impossible to attribute specific savings to specific actions by specific physicians. In addition, linking incentives to whether a care pathway was appropriately followed for individual patients can be interpreted as running afoul of the prohibition on compensation being related to the value or volume of services ordered by a physician, depending on the circumstances. Yet rewarding a physician who did the right thing for a patient by following the care pathway can be the most effective means to achieving the goals of quality and efficient patient care.

***Beneficial impact on beneficiaries:*** For [Wayne](#), care pathways would mean having the most current treatment options available to meet his particular needs.

Incentives for more efficient treatment options. In order for hospitals and health systems to drive reductions in unnecessary health care expenditures, they need the ability to encourage the physicians who are responsible for making key medical decisions to select the most efficient (and effective) treatment options, including those that are less expensive for the patient. One primary tool for achieving this objective is sharing a portion of bottom-line cost savings with physicians who help reduce overall costs in collaboration with hospital staff, while maintaining or improving the clinical outcomes for patients. For example, hospitals would like to establish programs with specific cost-saving actions – such as promoting the use of standardized devices or drugs from a formulary list that are available to the hospital at a lower cost – and then share a portion of the cost savings with groups of physicians responsible for achieving lower costs. Such programs would include hospital and physician collaboration on determining the most efficient care in specified circumstances, ensuring that patient care continues to meet objective clinical standards

**There is uncertainty in the field about the parameters for implementing these programs. The absence of a specific exception that expressly protects cost-saving financial arrangements between hospitals and health systems and physicians inhibits achieving reduced costs through collaboration.**

***Beneficial impact on beneficiaries:*** For [Wayne](#), a formulary would mean he is prescribed a drug that is best suited to his needs and the most cost-effective for him.

Team-based approach that includes non-physician practitioners. Increasingly, care for a patient in the community includes a physician, as well as other clinical staff, such as advance practice nurses, dietitians, and social workers. While the physician establishes, and has overall responsibility for, the entire care plan, success of the plan

can be achieved most effectively when all members of the team fulfill their specific roles, whether monitoring medications, counseling for dietary needs or ensuring appointments for other services are made and kept. The team approach also provides a patient or family with ready access to a knowledgeable professional with awareness of their medical history when a question or concern arises. With this approach, the physician remains accountable for the overall care provided by the team and her or his compensation should recognize this additional accountability.

**However, no exception exists to allow a hospital to reward achievements, such as those that result from a team effort. The fair market value (FMV) time-spent and resources-expended test is not readily applicable because the objective is whether the patient's needs were better met, not how much time was spent with or on behalf of the patient. Providing financial rewards to physicians for care coordination and care management of individual patients could be seen as running afoul of the volume/value prohibition, as it arguably links payment to the volume of potential referrals for hospital services.**

***Beneficial impact on beneficiaries:** For [Wayne](#), having a care team means he can make a call to multiple team members to discuss his concerns and avoid an unnecessary trip to the emergency department or prevent a cascade of difficulties that would land him back in the hospital.*

We believe that value-based arrangements protected by the new exception will not carry the risk of overutilization addressed by the Stark Law. Our proposed exception draws on safeguards included in the Waivers for the MSSP, as well as certain other requirements intended to protect the Medicare and Medicaid programs against abuse in the fee-for-service context. Together, all of these guardrails will assure that these value-based incentive payment arrangements do not give rise to new risks of overutilization or unnecessary care. In addition, the care provided patients served through any value-based arrangement would be part of the existing quality oversight programs of the Medicare program, which will guard against underutilization. New quality programs also have placed greater emphasis on treatment outcomes and efficiency.

The regulation text for the new exception is included, beginning on page 15.

### **Modify Personal Services and Risk-sharing Exceptions**

With respect to the request for comments on the personal services and risk sharing exceptions, we believe these exceptions currently protect some limited arrangements and could be improved. Specifically, **we urge that these two exceptions be modified to protect arrangements that cover services to Medicare fee-for-service patients.** This will support care coordination efforts of hospitals and physicians to a broader group of patients. Even with the proposed changes, however, the modest effects are not a substitute for the value-based exception's specific and comprehensive protection for value-based arrangements.

Personal services arrangement exception. The personal services arrangement exception specifically permits physician incentive plans, which are defined as compensation arrangements that may incentivize physicians to reduce or limit care to enrollees of a plan. Currently, the definitions of enrollees and health plans do not cover Medicare fee-for-service patients. **We recommend that the exception be expanded by removing the current restriction that limits application to only patients enrolled in commercial plans.** The protected payment models would still have to comply with the existing safeguards in the current regulation, creating no additional risk.

**The regulations also should affirm that the exception can protect non-monetary compensation provided by a hospital or health system to participating physicians necessary to implement a new payment model.** Investments in infrastructure that is used in the redesign of care that leads to quality improvement and/or lower costs can reasonably constitute FMV compensation. Similarly, innovative payments tied to the achievement of quality goals or adhering to clinical protocols can readily be considered FMV in light of physicians' contributions, even if the value of participation is not measured by traditional metrics such as time spent on related tasks.

The amended regulation text is included, beginning on page 15.

Risk-sharing exception. The risk-sharing exception also is available to providers serving patients of commercial plans, when the plan puts the providers at financial risk for their services (e.g., hospital inpatient payment models based on diagnostic-related groups (DRGs)). **We urge that this exception similarly be expanded to include arrangements involving Medicare, Medicare Advantage, and Medicaid, and their beneficiaries.** The proposed extension would give providers flexibility in meeting the coordinated care goals of the financial risk payments.

We note that the proposal would not increase the risk of program or patient abuse. The focus of the Stark Law is payment arrangements that incentivize utilization, raising the potential for overutilization, unnecessary and increased program costs, and patient exposure to unnecessary care and its attendant risks. Risk-sharing arrangements pose no such risk. Rather, the concern with such arrangements has historically been underutilization. The risk of payments to reduce medically necessary care is already adequately addressed by the civil money penalty law, 42 USC § 1320a-7a(b). Similarly, the risk that such payment arrangements might be an unlawful inducement to physicians to refer patients to the entity is adequately addressed by the federal Anti-Kickback Statute (AKS). 42 USC § 1320a-7b(b).

The amended regulation text is included, beginning on page 15.

Conforming changes to the employment exception. The employment exception is silent on the use of physician incentive plans. **We recommend that the exception expressly permit employers to adopt physician incentive plans for their employees.** Hospitals and health systems should have the same latitude to use incentive plans with

their employed physicians as with independent contractor physicians. We see no evidence that Congress intended to make a distinction. It is more likely that Congress assumed no express authority was required.

The amended regulation text is included, beginning on page 15.

## **REMOVE REGULATORY OBSTACLES TO CARE COORDINATION**

The definitions of critical terms used in nearly all the compensation exceptions have been the subject of conflicting and ambiguous interpretation and judicial decisions. As a result, hospitals spend enormous resources – time and dollars – attempting to fathom where the line will be drawn for any particular prohibition or mandate at any point in time. Because Stark is a strict liability statute, getting it exactly right is the difference between being compliant or facing demands for distorted repayments and potentially ruinous false claims exposure. Hospitals are entitled to know, in advance, exactly what is required so they can operate in compliance with the law. **We urge the agency to provide clear, authoritative, and timely guidance.**

The self-referral law was intended to regulate compensation arrangements that improperly encourage utilization (resulting in increased program costs and potentially exposing enrollees to harm from medically unnecessary services). Any requirement imposed should serve that purpose or be eliminated. Hospitals and health systems are spending more and more resources on complying with the Stark Law. Every physician contract requires a thorough analysis which often necessitates regular engagement of valuation consultants to ensure minimal Stark risk. Engagement of consultants can cost in excess of \$20,000 to review a single physician compensation agreement to ensure compliance. The costs can become astronomical – the number of contracts a hospital or health system enters into can range from hundreds to thousands. For a small or rural hospital, the expense for even a few contracts is a significant diversion of resources from patient care.

### **Definitions of Certain Critical Elements of Compensation Exceptions**

Most of the self-referral compensation exceptions include three substantive requirements: (1) the aggregate compensation must be FMV; (2) the compensation may not be determined in a manner that takes into account the value or volume of Medicare referrals; and (3) the arrangement must be commercially reasonable even if the physician makes no Medicare referrals. We propose specific modifications to remove ambiguity and limit the diversion of resources away from coordinated care.

**The first step in clarifying these three critical elements is to acknowledge that they are *separate and independent* concepts.** The FMV requirement addresses the *aggregate compensation* paid to the physician. The requirement that the compensation not be determined in manner that takes into account the volume or value of referrals addresses the *methodology* used to determine the compensation. The commercial

reasonableness of the arrangement addresses the *need for or utility of the items or services* to be provided regardless of Medicare referrals.

**Fair market value. The definition of “fair market value” should be returned to the statutory definition, the same as was adopted in the original rulemaking in 1995.** A change made in 2001, without public notice or explanation, inserted a poorly worded definition of “general market value” that has caused confusion among regulators and the regulated. It caused at least one court to incorrectly conflate the determination of FMV with the determination of whether the methodology for payment took into account the volume or value of referrals (a separate and independent prohibition). The 2001 insertion should be deleted.

**We also urge that a rebuttable presumption be created to provide greater certainty for the contracting parties.** Compensation should be presumed to be fair market value if the hospital or health system has received a valuation from a qualified valuator (a person or entity that has certified their qualifications and training to provide an opinion) prior to entering into the arrangement that the compensation (or the methodology used to establish the compensation) is within the range of fair market value.

The amended regulation text is included, beginning on page 15.

**When compensation does not vary with or otherwise take into account the volume or value of referrals.** The commentary that accompanied publication of regulations in 2001 has created confusion about the meaning of the phrase “takes into account” in the statute, leading many, including courts, to consider a provider’s subjective intent as potentially relevant in determining whether the manner in which the compensation was established took into account value or volume.

**The regulations should make clear that the volume/value test is a bright line, objective test. That is, by the plain terms of an arrangement, does the methodology used to set physician compensation utilize the value or volume of the physician’s referrals.** The volume/value element of the statute requires that the *manner*, i.e., the methodology, used to formulate the amount of compensation paid must not take into account referrals. The focus of the statute is on arrangements that incentivize referrals in plain terms; it does not look to the parties’ state of mind.

**In addition, we recommend the regulations confirm that a fixed payment per service is deemed not to vary or take into account the volume or value of referrals as long as the amount is determined initially by a methodology that does not take into account referrals and is not subsequently adjusted during the term based on referrals.** While a payment is made each time the service is provided, the amount of the payment does not change.

**The regulations also should clarify and reaffirm that the volume/value prohibition is not implicated where the payment is based on a physician’s personally performed services notwithstanding a correlation with services being performed by the hospital.** For example, surgeons and other physicians who primarily perform procedures in hospitals should be able to be compensated in the same manner as other physicians, including based on personal productivity.

These clarifications are particularly important for quality improvement and care redesign efforts that require greater cooperation between hospitals and physicians. Hospitals and physicians should not have to be concerned that the volume/value requirement can be implicated by innovative arrangements related to a clinical integration initiative. More specifically, hospitals should not have to worry that such efforts will be seen as “anticipating” referrals.

The amended regulation text is included, beginning on page 15.

**Commercial reasonableness. We urge that an arrangement should be treated as commercially reasonable if the items or services being purchased are useful in the purchaser’s business and are purchased on terms and conditions typical of similar arrangements between similarly situated parties.**

Ambiguity in the regulation has resulted in interpretations that go beyond the plain meaning of the statute. It should be made clear that commercial reasonableness does not relate to the compensation paid by the parties. The level of compensation is addressed by the FMV requirement; commercial reasonableness is focused on the need for and utility of the items or services purchased.

The amended regulation text is included, beginning on page 15.

**Referral. We recommend that the definition of a referral in the regulations be modified to clarify that a “referral” under Stark must result in either an additional payment or an increase in payment.** Many interactions that qualify as a referral under the current definition do not actually result in any payment by Medicare. For example, an attending physician may order a consultation by a specialist for an already admitted inpatient. The specialist’s consultation may result in an order for additional testing but will not affect the DRG payment to the hospital.

The overutilization concern underlying Stark is not present in this situation. However, under the current regulations, if the specialist has a financial relationship with the hospital that does not qualify for an exception, arguably the hospital’s claim for the entire inpatient stay is subject to denial. That cannot be what Congress intended since there is no risk of increased costs if the referral does not result in an increase in payment.

The amended regulation text is included, beginning on page 15.

### **Timely Guidance**

The current advisory opinion (AO) process has not lived up to its potential. During the 20 years the regulations have been in place, CMS has issued approximately 15 opinions related to compensation issues. **We recommend two changes to improve the process:**

- **Questions of interpretation and hypotheticals should be accepted and addressed through the AO process; and,**
- **If an opinion is not issued within the required 90 days of the completed request, the requester will be deemed to have received a favorable determination and may rely on it until such time as CMS formally issues an opinion.**

The paucity of opinions is largely due to the unreasonably limited type of questions that may be posed and the extended wait time for a response to questions that are accepted. General questions of interpretation and hypotheticals are out of bounds. However, these are exactly the kind of inquiries that would be particularly useful as a hospital considers potential arrangements. This is especially the case for small or rural facilities trying to navigate within the complexity of Stark while minimizing the diversion of resources to legal and compliance costs and away from patient care.

The fundamental problem with the process is that it is modeled on the HHS Office of Inspector General's (OIG) advisory opinion process and regulations, which are designed for opinions related to a felony criminal statute enforced by the Criminal Division of the Department of Justice, often secretly through a grand jury. The process is intentionally narrow and limited out of concern that it could be misused and an opinion would immunize the requestor from criminal prosecution. The limitations of the OIG's model are wholly inappropriate for a payment regulation, especially in light of the Stark Law's regulatory complexity and the need for certainty before arrangements are initiated and claims submitted.

The amended regulation text is included, beginning on page 15.

### **Eliminate Provisions that Do Not Address Overutilization and Add Unnecessary Complexity and Ambiguity**

Alternative method of satisfying documentation requirements. Many of the compensation exceptions also contain writing and signature requirements at the inception of the arrangement. These documentation requirements do not add any additional substantive protection against problematic arrangements. Instead, they serve as an audit trail to assess if there is a binding agreement. In practice, these paperwork requirements subject providers to potentially catastrophic payment denials for clerical errors even when an arrangement actually satisfies the substantive elements of an exception.

**We urge a different approach: a hospital should be deemed to satisfy the writing and signature requirements when it demonstrates the existence of a binding, enforceable contract under applicable state law.** This will avoid the problems created when a regulation attempts to micro-manage how to demonstrate the existence of a binding agreement. There will not be any increase in the risk of problematic arrangements because the substantive protections are intact. There will be a significant reduction in the potential for disallowances based on paperwork mistakes.

The victims of such mistakes are often smaller hospitals and providers, especially in more rural areas. Such entities often do not have the resources for in-house legal staff. Importantly, the failure to satisfy the documentation requirements is obviously inadvertent. If the entity entering into an otherwise legitimate arrangement had realized the failure to have a writing would cause huge disallowances, the entity undoubtedly would have done so.

The amended regulation text is included, beginning on page 15.

Compensation arrangement end-date. We urge the regulation be modified to create a fixed date for when an improper arrangement ends: **a compensation arrangement should terminate 30 days after the physician or family member last receives compensation from the entity or items or services are provided under that arrangement.** Currently, there is no fixed end-point for purposes of setting the period of disallowance on claims to Medicare for services referred by a physician who is a party to the arrangement. As a result, the potential is great for large disallowances that are wholly disproportionate to the non-compliance. The fixed date will provide certainty to hospitals and the health care field, while maintaining a period of disallowance that will impose significant penalties and incentive to self-police.

The amended regulation text is included, beginning on page 15.

Payments by a physician exception. **We urge that the regulation text be returned to the language of the statute that broadly protected any payments made by a physician so long as the payment was consistent with the fair market value for the items or services.** The agency's regulations unreasonably narrowed application of the exception and as a result, innocuous arrangements that are not structured to incentivize utilization can result in large payment denials. There is no reason to deny hospitals the benefit of the breadth of Congress' exception. To the extent the same arrangement also might be covered by another exception, that should not prevent a hospital from relying on the payment-by-physician exception that provides a less cumbersome method of complying.

The amended regulation text is included, beginning on page 15.

Eliminate requirement of compliance with Anti-Kickback Statute. The regulatory requirement that a compensation arrangement not violate the federal Anti-Kickback Statute (AKS) should be eliminated from all Stark exceptions in which it appears. The requirement places an unreasonable burden of proof on entities seeking payment with no offsetting benefit or protection to the Medicare program. It is at odds with the way Congress structured the statute – turning a strict liability statute into an intent-based one – and it is unnecessary. The self-referral law and the AKS are independent laws imposing independent obligations. Congress was clear that compliance with the self-referral law did not relieve entities from their obligations to comply with the AKS.

**For the same reasons, the requirement that arrangements must not violate any federal or state billing or claims submission rules also should be removed.** Providers have an independent obligation to comply with such rules. Inclusion of pre-existing legal requirements as an additional element for a self-referral exception provides no additional protection to federal health care programs or patients.

The amended regulation text is included, beginning on page 15.

## MODIFICATIONS TO REGULATORY TEXT

### New Value-based Payment Exception

New Language: [42 CFR § 411.357]

(\_\_\_) Any remuneration provided pursuant to a value-based payment arrangement that meets the following conditions:

(1) The arrangement is for one or more of the following purposes—

- (i) Promoting accountability for the quality, cost, or overall care for patients;
- (ii) Managing and coordinating care for patients; or
- (iii) Encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery for patients.

(2) The remuneration is provided directly or indirectly by a provider of services or a supplier (including a hospital) in a value-based arrangement to a provider of services or a supplier (including a physician or physician practice) that is participating in the clinical integration arrangement.

(3) The remuneration consists of (i) incentive payments, (ii) shared savings payments based on actual cost savings, or (iii) infrastructure payments or in-kind assistance (including, but not limited to, electronic health records technology, data or clinical analysis tools, and start-up support) reasonably related to and used in the implementation of a value-based arrangement.

(4) The remuneration under an incentive-payment or shared-savings program must be paid in accordance with performance standards that –

- (i) Use an objective methodology for evaluation, are documented and verifiable, and are supported by credible medical evidence;
- (ii) Are separately identified and measured;
- (iii) Are reasonable for patient care purposes;
- (iv) Are monitored throughout the term of the arrangement to protect against reductions or limitations of medically necessary patient care service; and
- (v) Reflect the achievements of the participant receiving payment under the arrangement (or the achievements of another provider of services or supplier under that participant's oversight) or of the program.

(5) An officer, director, or authorized representative of the party making infrastructure payments or providing in-kind assistance and of the party receiving the

payment or assistance must certify in writing that the remuneration is reasonably related to and used in the implementation of a value-based arrangement.

(6) The remuneration (or the formula for determining the specific remuneration to be provided) must be set in advance in writing. Records of remuneration paid or provided must be maintained.

(7) Documentation maintained pursuant to this section shall be made available to the Secretary upon request.

### **Modifications to Personal Services Exception**

#### **New Language [42 CFR § 411.357(d)]**

(d) Personal service arrangements. (1) General—Remuneration from an entity under an arrangement or multiple arrangements to a physician or his or her immediate family member, or to a group practice, including remuneration for specific physician services furnished to a nonprofit blood center, if the following conditions are met:

...

(v) The compensation to be paid over the term of each arrangement is set in advance, does not exceed fair market value, and, except in the case of a physician incentive plan (as defined at § 411.351 of this subpart), is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

...

(2) Physician incentive plan exception. In the case of a physician incentive plan (as defined at § 411.351) between a physician and an entity (or downstream contractor), the compensation may be determined in a manner (through a withhold, capitation, bonus, or otherwise) that takes into account directly or indirectly the volume or value of any referrals or other business generated between the parties, if the plan meets the following requirements:

(i) No specific payment is made directly or indirectly under the plan to a physician or a physician group as an inducement to reduce or limit medically necessary services furnished with respect to a specific individual ~~enrolled with~~ **served by** the entity.

(ii) Upon request of the Secretary, the entity provides the Secretary with access to information regarding the plan (including any downstream contractor plans), in order to permit the Secretary to determine whether the plan is in compliance with paragraph (d)(2) of this section.

(iii) In the case of a plan that places a physician or a physician group at substantial financial risk as defined at § 422.208, the entity or any downstream contractor (or both) complies with the requirements concerning physician incentive plans set forth in § 422.208 and § 422.210 of this chapter.

Modify 42 CFR § 411.351 (definition of physician incentive plan)

Physician incentive plan means any compensation arrangement between an entity (or downstream contractor) and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services furnished with respect to individuals ~~enrolled with~~ **served by** the entity.

### Conforming Changes to the Employment Exception

New Language [42 CFR § 411.357(c)]

(c)(2) The amount of the remuneration under the employment is—

(i) Consistent with the fair market value of the services; and

(ii) Except as provided in paragraphs (c)(4) **and (c)(5)** of this section, is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician.

...

Add new (c)(5)

***(5) Physician incentive plan exception. In the case of a physician incentive plan (as defined at § 411.351) between a physician and an entity (or downstream contractor), the compensation may be determined in a manner (through a withhold, capitation, bonus, or otherwise) that takes into account directly or indirectly the volume or value of any referrals or other business generated between the parties, if the plan meets the following requirements:***

***(i) No specific payment is made directly or indirectly under the plan to a physician or a physician group as an inducement to reduce or limit medically necessary services furnished with respect to a specific individual served by the entity.***

***(ii) Upon request of the Secretary, the entity provides the Secretary with access to information regarding the plan (including any downstream contractor plans), in order to permit the Secretary to determine whether the plan is in compliance with paragraph (5) of this section.***

***(iii) In the case of a plan that places a physician or a physician group at substantial financial risk as defined at § 422.208, the entity or any downstream contractor (or both) complies with the requirements concerning physician incentive plans set forth in § 422.208 and § 422.210 of this chapter as if it were an MA plan.***

### **Modification of Risk Sharing Exception**

New Language [42 CFR § 411.357(n)]

(n) Risk-sharing arrangements. Compensation pursuant to a risk-sharing arrangement (including, but not limited to, withholds, bonuses, and risk pools) between a MCO or an IPA and a physician (either directly or indirectly through a subcontractor) for services provided to enrollees of a health plan, ~~provided that the arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.~~ For purposes of this paragraph (n), “health plan” and “enrollees” have the meanings set forth in § 1001.952(l) of this title, ***except they shall also include Medicare and Medicaid and any enrollee or beneficiary in Medicare or Medicaid.***

### **Revision to Definition of Fair Market Value**

New language [42 CFR § 411.351]

Fair market value means the value in arm's-length transactions, consistent with the general market value. “General market value” means the price that an asset would bring as the result of bona fide bargaining between well-informed buyers and sellers ~~who are not otherwise in a position to generate business for the other party,~~ or the compensation that would be included in a service agreement as the result of bona fide bargaining between well-informed parties to the agreement, ~~who are not otherwise in a position to generate business for the other party,~~ on the date of acquisition of the asset or at the time of the service agreement. Usually, the fair market price is the price at which bona fide sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in bona fide service agreements with comparable terms at the time of the agreement, ~~where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals.~~ With respect to rentals and leases described in § 411.357(a), (b), and (l) (as to equipment leases only), “fair market value” means the value of rental property for general commercial purposes (not taking into account its intended use). In the case of a lease of space, this value may not be adjusted to reflect the additional value the prospective lessee

or lessor would attribute to the proximity or convenience to the lessor when the lessor is a potential source of patient referrals to the lessee. For purposes of this definition, a rental payment does not take into account intended use if it takes into account costs incurred by the lessor in developing or upgrading the property or maintaining the property or its improvements.

New Language [42 CFR § 411.354(d)(5)]

**Compensation will be presumed to be “fair market value” where the DHS entity has obtained a valuation of fair market value from a person or entity that has certified to the DHS entity their qualifications and training to provide such an opinion and their independence from the DHS entity. Where appropriate, the valuation may address and protect the methodology used to determine the compensation. The burden of proof in such circumstances will be on the person challenging such valuation.**

#### **Definition of When Compensation Does Not Vary With or Otherwise Take Into Account the Volume or Value of Referrals**

New Language [42 CFR § 411.354 (d)(5)]

**Except as provided in subparagraph (c)(2)(ii), compensation shall be deemed not to be “determined in a manner that takes into account the volume or value of referrals” if, by the plain terms of the arrangement, the amount of compensation does not increase or decrease according to increased or decreased value or volume of referrals, respectively during the term of the arrangement. Except as provided in subparagraph (c)(2)(ii), compensation based on personally performed relative value units shall be deemed not to take into account the volume or value of referrals solely because the physician’s professional service is related to or correlates with the physician’s DHS referrals, as in the case of surgeries performed in a hospital or evaluation and management services performed in a provider-based clinic.**

#### **Definition of Commercial Reasonableness**

New Language [42 CFR § 411.351]

**Commercial reasonableness shall mean that the services or items purchased or contracted for are of use in the business of the purchasing or contracting party and are of the amount, kind and type of items or services purchased or contracted for by similarly situated entities.**

## Revision to Definition of Referral

New Language [42 CFR § 411.351]

Referral—

(1) Means either of the following:

(i) Except as provided in paragraph (2) of this definition, the request by a physician for, or ordering of, or the certifying or recertifying of the need for, any designated health service for which payment may be made under Medicare Part B, including a request for a consultation with another physician and any test or procedure ordered by or to be performed by (or under the supervision of) that other physician, but not including any designated health service personally performed or provided by the referring physician **and only if such request results in an additional or increase in payment for the designated health service.** A designated health service is not personally performed or provided by the referring physician if it is performed or provided by any other person, including, but not limited to, the referring physician's employees, independent contractors, or group practice members.

(ii) Except as provided in paragraph (2) of this definition, a request by a physician that includes the provision of any designated health service for which payment may be made under Medicare, the establishment of a plan of care by a physician that includes the provision of such a designated health service, or the certifying or recertifying of the need for such a designated health service, but not including any designated health service personally performed or provided by the referring physician **and only if such request results in an additional or increase in payment for the designated health service.** A designated health service is not personally performed or provided by the referring physician if it is performed or provided by any other person including, but not limited to, the referring physician's employees, independent contractors, or group practice members.

## Revisions to Advisory Opinions Process

New Language [42 CFR § 411.370]

(b)(1) The request must involve **(i)** an existing arrangement or one into which the requestor, in good faith, specifically plans to enter; **or (ii) a general question of interpretation.** The planned arrangement may be contingent upon the party or parties receiving a favorable advisory opinion. CMS does not consider, for purposes of an advisory opinion, requests that that ~~present a general question of~~

~~interpretation, pose a hypothetical situation, or~~ involve the activities of third parties.

...

(e) Requests that will not be accepted. CMS does not accept an advisory opinion request or issue an advisory opinion if—

(1) The request is not related to a named individual or entity; **or**

~~(2) CMS is aware that the same, or substantially the same, course of action is under investigation, or is or has been the subject of a proceeding involving the Department of Health and Human Services or another governmental agency; or~~

~~(3)~~ CMS believes that it cannot make an informed opinion or could only make an informed opinion after extensive investigation, clinical study, testing, or collateral inquiry.

New Language [42 CFR § 411.380]

(c) CMS issues an advisory opinion, in accordance with the provisions of this part, within 90 days after it has formally accepted the request for an advisory opinion, or, for requests that CMS determines, in its discretion, involve complex legal issues or highly complicated fact patterns, within a reasonable time period. ***If CMS fails to issue an advisory opinion within 90 days after it has formally accepted the request for an advisory opinion (including any suspension for requests for additional information), a requestor may proceed with any proposed arrangement and will not be subject to disallowance or non-payment until 15 days after written notice from CMS on non-compliance.***

### **New Alternative Method for Satisfying Documentation Requirements**

New Language [42 CFR § 411.354 (d)(6)]

**A compensation arrangement shall be deemed to satisfy a requirement in any exception in § 411.357 that an arrangement or compensation be set out in writing and signed by the parties if the arrangement constitutes an enforceable contract under applicable state law.**

### **Clarification of When an Improper Compensation Arrangement Ends**

Amend 42 CFR § 411.353(c) by replacing everything after the second sentence

(c) Denial of payment for services furnished under a prohibited referral. (1) Except as provided in paragraph (e) of this section, no Medicare payment may be made for a designated health service that is furnished pursuant to a prohibited referral. The period during which referrals are prohibited is the period of disallowance. **For compensation arrangements, the period of disallowance associated with any financial arrangement ends no later than the earlier of (i) 30 days after the physician (or immediate family member) last receives remuneration from the entity or items or services are provided under an arrangement or (ii) the date on which an exception is satisfied. For ownership/investment interests, the period of disallowance ends no later than the earlier of the date on which the ownership/investment interest is terminated or an exception is satisfied. For purposes of this section, the period of disallowance begins at the time the financial relationship fails to satisfy the requirements of an applicable exception and ends no later than—**

**~~(i) Where the noncompliance is unrelated to compensation, the date that the financial relationship satisfies all of the requirements of an applicable exception;~~**

**~~(ii) Where the noncompliance is due to the payment of excess compensation, the date on which all excess compensation is returned by the party that received it to the party that paid it and the financial relationship satisfies all of the requirements of an applicable exception; or~~**

**~~(iii) Where the noncompliance is due to the payment of compensation that is of an amount insufficient to satisfy the requirements of an applicable exception, the date on which all additional required compensation is paid by the party that owes it to the party to which it is owed and the financial relationship satisfies all of the requirements of an applicable exception.~~**

### **Modifications to Payments by a Physician Exception**

New Language [42 CFR § 411.357(i)]

(i) Payments by a physician. Payments made by a physician (or his or her immediate family member)—

(1) To a laboratory in exchange for the provision of clinical laboratory services; or

(2) To an entity as compensation for any other items or services that are furnished at a price that is consistent with fair market value, ~~and that are not specifically excepted by another provision in §§ 411.355 through 411.357 (including, but not limited to, § 411.357(l)).~~ “Services” in this context means services of any kind, **including space**

**and equipment leases and** (not merely those defined as “services” for purposes of the Medicare program in § 400.202 of this chapter).

## **Elimination of Requirement of Compliance with Anti-Kickback Statute**

### Revised Language

The following sections are removed: 42 CFR § 411.353(f)(2)(iii); 42 CFR §§ 411.355(b)(4)(v), (e)(1)(iv), (f)(3), (f)(4), (g)(2), (g)(3), (h)(2), (h)(3), (i)(2), (i)(3), (j)(1)(iv); 42 CFR §§ 357(e)(4)(vii), (j)(3), (k)(iii), (l)(5), (m)(7), (p)(3), (r)(2)(x), (s)(5), (t)(3)(iv), (u)(3), (w)(12), (x)(1)(viii), and (y)(8). In addition, the following clause should be removed from both 42 CFR § 411.357(e)(6)(i) and (n): “, provided that the arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission”; and the definition of “Does not violate the anti-kickback statute” should be deleted from 42 CFR § 411.351. Further, these redesignations should be made: 42 CFR § 411.355(b)(4)(vi) as 42 CFR § 411.355(b)(4)(v); 42 CFR § 411.355(f)(5) as 42 CFR § 411.355(f)(3); 42 CFR § 411.355(g)(4) as 42 CFR § 411.355(g)(2); 42 CFR § 411.355(h)(4) as 42 CFR § 411.355(h)(2); 42 CFR § 411.357(m)(8) as 42 CFR § 411.357(m)(7); and 42 CFR § 411.357(y)(9) as 42 CFR § 411.357(y)(8).