AHPA
ADVENTIST HEALTH
POLICY ASSOCIATION

September 8, 2015

Mr. Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS–1631–P
P.O. Box 8013
Baltimore, MD 21244–8013

BY ELECTRONIC SUBMISSION

Re: File Code CMS–1631–P — Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2016; Proposed Rule

Mr. Slavitt,

On behalf of the Adventist Health Policy Association, which is composed of five health systems comprising a total of 83 hospitals, nursing homes, home healthcare agencies and other health services in 20 states, I am pleased to submit the attached comments in response to the request by CMS in the proposed CY 2016 Physician Fee Schedule. Specifically, the Adventist Health Policy Association is providing recommendations on certain areas related to Stark law administration and application.

What you will find appended to this letter is the best thinking that we could bring to bear on this subject by legal counsel and our health policy staff. We address the general problems created by the application of the Stark law in the new era of healthcare reform and then some specific recommendations as to how the administration of the Stark law can be modified. In preparing this response, we consulted with outside legal counsel who have a long and extensive history of working with the Stark law and addressing the issues that it creates. This outside counsel included Mr. Kevin McAnaney, Esq., Mr. Troy Barsky, Esq., and Mr. Daniel Melvin, Esq. I should note that the positions taken in our comments do not necessarily reflect the opinion of any one of these attorneys or the firms that they represent.

As we went through the process of preparing these comments, it became apparent to us that at some point the Stark law itself will need to be modernized by Congress. Significant reforms to the healthcare industry are taking place, moving us away from the old fee-for-service environment in which the Stark law was originally conceived. It is our belief that the combination of the changes to Stark law administration and application that we are recommending and a future modernization of the Stark law by Congress will allow it to be able to achieve its intended purpose of protecting the Medicare program without creating an unnecessarily chilling effect upon much-needed reforms in health care.

The Adventist Health Policy Association appreciates your openness to considering changes to the regulatory interpretation and administration of the Stark law in light of the rapid and fundamental changes that are taking place in healthcare delivery. We hope our comments prove to be useful to you and your staff.

Sincerely,

Richard E Morrison

Richard E. Morrison
President, Adventist Health Policy Association

COMMENTS ON PROPOSED AMENDMENTS TO THE STARK REGULATIONS

A. General Comments

The Adventist Health Policy Association (AHPA) believes that the Stark Law should be reformed.[1] There are two principal reasons for this conviction. First, there is intensifying incompatibility between the "fraud and abuse" laws that originated in a fee-for-service environment and the value-based payment models that Congress and CMS have promoted in recent years and will be continuing to promote with even greater energy in the years ahead. This incompatibility is not of our own imagining. Rather, it is highlighted by the fact that Congress saw the need to give the Secretary authority to issue regulatory waivers for innovative payment and service delivery models, and the fact that the Secretary has, in fact, issued such waivers for the Medicare Shared Savings Program (MSSP), the Bundled Payments for Care Improvement Initiative (BPCI) and the Pioneer ACO Program. The risk for beneficiaries in a value-based payment environment is not overutilization of resources, which is the risk the Stark Law was designed to address. Instead, the fee-for-value payment models *themselves* dis-incentivize excessive utilization. When healthcare providers earn their margin not by the volume of services they provide, but by the efficiency of their services and, indeed, in many cases, by taking what is in effect some version of capitated risk, their economic self-interest aligns them with the interest of fraud enforcers seeking to recoup Medicare monies paid for unnecessary services. In an environment where health systems are earning an ever-increasing proportion of their income (Medicare and otherwise) outside fee-for-service, the Stark Law is superfluous in shaping desired behavior. Worse than that, however, as discussed below, the Stark Law impedes the shift from fee-for-service to value-based payments. Accordingly, Congress and CMS should reevaluate the Stark Law in light of the current aims of the Medicare program to avoid chilling innovative efforts by hospitals to achieve better coordination of physician and hospital services to beneficiaries. Such coordination of care can take various forms, some of which are still evolving as health care transitions to a value-based payment system. But one thing is clear: The Stark Law, created for a fee-for-service environment, is an impediment to such coordination.

Second, because the Stark Law is a strict-liability Medicare payment provision, affecting a provider's entitlement to payment for medically-necessary services provided, it is imperative that the Stark Law have "bright-line" rules and interpretations that enable providers to have a high degree of confidence that their claims are in compliance. This is all the more important in light of the FCA's applicability to these claims, and the burdens of proof in litigation on the elements

[1] The AHPA is the public policy arm of five healthcare systems in the United States that are affiliated in some fashion with the Seventh-Day Adventist Church. These are Loma Linda University Medical System, with facilities in southern California; Adventist Health, with facilities in Hawaii, California, Oregon, and Washington; Kettering Health Network, with facilities in Ohio; Adventist Healthcare, with facilities in the Washington, D.C. metro area and New Jersey; and Adventist Health System, with facilities in ten states primarily in the Southeast, Southwest and Midwest. In sum, these five companies have 83 hospitals, numerous other provider entities, such as urgent care centers, skilled nursing facilities and ambulatory surgery centers, and employ several thousand physicians. In the preparation of these comments, AHPA had the invaluable assistance of three leaders in the healthcare bar: Daniel Melvin, of McDermott Will & Emery; Kevin McAnaney, in solo practice in New York and Maryland; and Troy Barsky, of Crowell & Moring. These comments do not, however, necessarily in every respect reflect the opinions and views of our attorneys or their law firms.

of the exceptions. Notwithstanding CMS's historical efforts to provide "bright-line" rules and interpretations, the Stark Law's breadth, complexity and inscrutability has created a minefield for the healthcare industry; indeed, as Judge Wynn noted recently, "even for well-intentioned health care providers, the Stark Law has become a booby trap rigged with strict liability and potentially ruinous exposure—especially when coupled with the False Claims Act."[2] This is not the first time that serious concerns have been raised about the breadth, complexity and inscrutability of the Stark Law. In 1995, Congress voted to repeal the Stark Law as applied to compensation arrangements as part of the Balanced Budget Act (BBA) of 1995, but the BBA was vetoed by President Bill Clinton. More recently, the law's namesake, former Rep. Fortney "Pete" Stark, has urged its repeal.[3]

Whether the complete scope of needed reforms can be accomplished without legislative action is doubtful, but we think it clear that CMS has the authority to significantly improve the current situation. It can implement the Stark Law, through rulemaking and published interpretations, in a manner that is consistent with the goals of healthcare reform, and that does not unfairly set up well-intentioned and diligent healthcare providers for ruinous overpayment liability for services to beneficiaries that were medically necessary and valuable.

As we discuss in more detail in specific comments below, while the Stark Law's "volume or value," fair market value and commercial reasonableness standards were well-intentioned standards in a fee-for-service environment, they are an impediment to hospital-physician coordination in a value-based payment environment, including innovations such as gainsharing and pay-for-quality arrangements between hospitals and their medical staffs. Arguably, the amount and value of savings will reflect patient referral volume, the fair market value of savings and quality are uncertain and easily subject to dispute, and the sharing of cost savings or pay-for-quality incentives may only be commercially reasonable if there are referrals generating the savings and quality scores in the first place. *Accordingly, CMS should extend the regulatory waivers to commercial shared savings, bundled payment and other coordinated care arrangements, and create broad exceptions (or broaden current exceptions) that will accommodate these innovations in the delivery and payment for health care. As explained in more detail below, CMS has the ability to implement many of these changes now under existing authority.*

In addition, the fair market value, "volume or value" and commercial reasonableness standards have, through federal FCA litigation, come to take on meanings never contemplated by Congress or CMS when they fashioned the Stark Law as a strict-liability Medicare payment rule. If all it takes for a *qui tam* relator to survive a motion for summary judgment in Stark-related FCA

[2] United States *ex rel.* Drakeford v. Tuomey, No. 13-2219, 2015 U.S. App. LEXIS 11460 at *56, *69 (4th Cir. July 2, 2015) (Wynn, J., concurring). The Fourth Circuit previously described the Medicare statute generally as "among the most completely impenetrable texts within human experience." Rehab. Ass'n of Va. v. Kozlowski, 42 F.3d 1444, 1450 (4th Cir. 1994). This commentary was quoted approvingly by the U.S. District Court for the District of Columbia, adding: "Picture a law written by James Joyce [footnoting that the court refers to Joyce's later work, specifically *Finnegan's Wake*] and edited by E.E. Cummings." Catholic Health Initiatives–Iowa v. Sebelius, 841 F. Supp. 2d 270, 271 (D.D.C. 2012).

[3] *See* Joe Carlson, *Stark Law Complicated by "Smart Lawyers" Finding Loopholes*, MODERN HEALTHCARE (Nov. 30, 2013), http://www.modernhealthcare.com/article/20131130/MAGAZINE/311309955; David Whelan, *Stark Regrets: I Shouldn't Have Written That Law*, FORBES BLOG (Nov. 30, 2007, 1:52 PM), http://blogs.forbes.com/sciencebiz/2007/11/30/stark-regrets-i-shouldnt-have-written-that-law/.

litigation is to allege that a physician is paid more than what the employer collects from the physician's services, it is time for CMS to step in and assert its duly delegated authority from Congress to define "fair market value" and "commercial reasonableness" in a manner consistent with the Stark Law's status as a strict-liability Medicare payment rule, *not the federal anti-kickback statute*. Billions of dollars of payments for valuable and medically necessary health care to Medicare beneficiaries should not be jeopardized by violations of broad or vague standards for which it is impossible to establish indisputable compliance, *e.g.*, fair market value and commercial reasonableness.

Accordingly, we commend CMS for requesting comments on the fair market value, "volume or value" and commercial reasonableness standards, in particular, and wholeheartedly support CMS's proposal to consider addressing these standards through commentary and proposed rule changes. In this regard, we have two broad proposals, which are expanded upon in our specific comments below. *First, we propose that CMS interpret these three standards as narrowly as possible, leaving to the federal anti-kickback statute concerns about the rationale and purposes for compensation terms. Most notably, CMS should consider restricting the "volume or value" standard to actual referrals and actual compensation, and restricting the commercial reasonableness standard to non-financial terms (the fair market value and "volume or value" standards already addressing the financial terms). Second, we propose that CMS create "safe harbors" or "deeming provisions" for the fair market value standard, which would enable providers to lower the costs and administrative burdens of valuations, and, at the provider's option, avoid the uncertainty and litigation risk that comes with reliance on a valuation that can be disputed by another valuator.*

Finally, CMS's reports to Congress on the implications of the Stark Law for gainsharing and alternative payment models will have significant implications for the future of the Stark Law and, more importantly, the success of the Affordable Care Act, MACRA, and healthcare delivery reform. There is a much-needed dialogue on whether the Stark Law, as currently constituted, is a fair, effective and efficient means for addressing the corrupting influence of money on clinical decision-making and utilization of healthcare resources, especially in light of Medicare's transition to value-based payment. And as applied to compensation arrangements (versus ownership/investment interests), the Stark Law has become far too technical and arcane for effective application by healthcare operators, let alone juries. Thus, we hope this solicitation of comments by CMS is not only an opportunity to consider targeted regulatory and legislative reforms to accommodate gainsharing and alternative payment models, but also an opportunity for CMS and Congress to reconsider the wisdom of attempting to implement a physician self-referral law for compensation arrangements, when the federal anti-kickback statute can effectively regulate compensation arrangements.

B. Comments regarding the Stark Law and (1) Alternative Payment Models and (2) Clinical and Financial Integration Models

CMS: *Does the physician self-referral law generally and, in particular, the "volume or value" and "other business generated" standards set out in our regulations, pose barriers to or limitations on achieving clinical and financial integration? If so, are the barriers or limitations more pronounced for hospitals than for other providers or suppliers because all Medicare*

revenue is from DHS (and, thus, any compensation might be considered to take into account the volume or value of referrals or other business generated by the physician to whom it is paid)?

AHPA: Yes, the Stark Law poses barriers to and limitations on a hospital's ability to achieve clinical and financial integration with members of its medical staff, as discussed below. And the barriers and limitations are more pronounced and problematic for hospitals than certain other providers or suppliers because all of a hospital's Medicare revenue is from DHS.

The volume/value and "other business generated" standards ("volume/value standards") constrain any arrangements that seek to compensate physicians for cost-efficient care and use of resources in the inpatient and outpatient settings, including such simple actions as compliance with an evidence-based clinical protocol. By definition, a reduction in costs for patient care reimbursed on a prospective fixed basis (whether DRG or OPPS) results in increased profits (or reduced loss) for that episode of care. Thus, any sharing of those savings with physicians arguably results in compensation that varies with or takes into account the "value" of the referral. Since physicians control the great majority of patient care inputs, any meaningful attempt to constrain costs must incentivize them.

Importantly, the very vagueness and ambiguity in the critical terms "fair market value," "take into account volume or value," and "commercial reasonableness," combined with the enormous potential for disallowed claims and FCA damages and penalties, make prudent providers extremely wary of adopting innovative compensation methodologies. Given the strict-liability structure of Stark, providers cannot rely on expert counsels' advice and have no assurance that CMS, OIG, DOJ, or a relator will not challenge any innovative compensation methodology. Moreover, providers have the burden of proof that they comply with the conditions in the exceptions. Simply put, given the ambiguity of critical terms, the exceptions are not reliable protection, thereby chilling adoption of innovative arrangements.

CMS: *Which exceptions to the physician self-referral law apply to financial relationships created or necessitated by alternative payment models? Are they adequate to protect such financial relationships?*

AHPA: The risk-sharing, personal services, fair market value and indirect compensation exceptions are the principal exceptions potentially applicable to alternative payment and delivery models. <u>These exceptions are inadequate.</u> The personal services, fair market value and indirect compensation exceptions have strict volume/value standards and the risk-sharing exception is limited to compensation for services to <u>*plan enrollees*</u>, thereby excluding Medicare and Medicaid fee-for-service beneficiaries.

In addition, the risk-sharing exception does not address the most significant barrier that the Stark Law poses to the engagement of physicians in alternative payment models for which there are no waivers: there is no apparent exception for a hospital's or health system's subsidy of the costs of forming and operating a *commercial* accountable or coordinated care organization, or developing a commercial bundled payment program. If the hospital partner cannot insulate the physician participants from the financial risk of

development costs, for example, and the organization's earnings from cost savings or quality performance bonus payments are absorbed by the organization's indebtedness to the hospital partner, physicians are not motivated to participate.

CMS: *Is there a need for new exceptions to the physician self-referral law to support alternative payment models? If so, what types of financial relationships should be excepted? What conditions should we place on such financial relationships to protect against program or patient abuse? Should a new exception be structured to protect services, rather than a specific type of financial relationship, when established conditions are met (similar to the in-office ancillary services exception at § 411.355(b), which protects referrals for certain services performed by physician practices that meet the requirements of § 411.352)? Would legislative action be necessary to establish exceptions to support alternative payment models?*

AHPA: Yes, there is a need for action by CMS. As discussed above, the greatest impediment to developing alternative payment models is the lack of any apparent exception to protect a hospital or health system's donations to develop linkages and systems necessary for a coordinated care organization. Physicians simply lack the capital to pay a "fair market value" share of such development costs. Accordingly, our comments focus primarily on addressing that issue.

1. Extension of the Regulatory Waivers. CMS could incentivize greater physician participation in Medicare ACOs and other CMMI programs if it would simply extend the waivers for these coordinated care organizations and arrangements to commercial plans structured and implemented consistent with the principles applicable to these Medicare programs. CMS and OIG have already stated that financial relationships that are downstream from commercial contracts may qualify for the participation waiver.[4] At the time of the initial interim final rule regarding this waiver, CMS and OIG admitted that they did not yet have experience regarding the interplay between MSSP ACOs and commercial ACOs. But now that it is clear that ACOs engage in both Medicare and commercial markets, the government should state that the waivers can be applied to protect commercial relationships as well. CMS and OIG have the authority to expand MSSP and CMMI program waivers to corresponding coordinated care arrangements with commercial plans that are aligned with the aims of the MSSP and CMMI payment models, and should do so.

2. New Exception for Coordinated Care Organizations. If CMS does not believe it has the authority to extend the regulatory waivers to commercial ACOs, clinically-integrated networks or other commercial coordinated care organizations' (CCO) development and operations, CMS should create a new exception modeled after the waivers, or, if necessary to address risks of abuse, it could model the exception after the e-prescribing and electronic medical record donation exceptions, including the following elements:

[4] *See* 76 Fed. Reg. 67992, 68006 (Nov. 2, 2011).

- Caps on the percentage of the costs or funding for the development of the CCO that the DHS entity could donate, *e.g.*, 85%, without having to treat the capitalization as a loan or equity contribution.

- Restrictions on the duration, nature and type of no- or at-cost administrative support that could be provided.

- Prohibition on any of the funding compensating individual physicians or practices.

- Requiring public disclosure of the hospital's donations or contributions.

Alternatively, CMS should create a specific exception to the definition of remuneration that allows for the funding or capitalization of commercial CCOs by DHS entities where such funding is used for the benefit of the network or beneficiaries. The funding or capitalization of such CCOs does not create a risk of fraud or abuse to these programs or to beneficiaries.

* * *

As discussed in more detail in the comments addressing gainsharing, with respect to sharing the cost savings and making quality incentive payments, CMS should expand the risk-sharing exception to cover Medicare and Medicaid fee-for-service beneficiaries and confirm that the exception permits gainsharing and pay-for-quality arrangements. Alternatively, it should create a new gainsharing/incentive payments exception that, like the current risk-sharing exception, does not contain any fair market value, volume/value or commercial reasonableness standards.

DHS exceptions would not suffice because the exception must protect the compensation arrangement and not simply the "services" provided pursuant to the arrangement. The physicians would continue to make ***fee-for-service*** DHS referrals to the hospital for which a compensation exception is going to be needed. If the compensation arrangement nevertheless takes into account the volume or value of referrals or other business generated, any Medicare hospital services outside the arrangement would still potentially trigger the self-referral prohibition. This problem arising from the compensation arrangement is very similar to that which was the impetus for the current Stark risk-sharing exception.

CMS would not need to seek legislative action to create a new exception, or expand a current exception, that does not pose a risk of program or patient abuse, and we believe that new or expanded exceptions could include safeguards that would sufficiently address such risk.

CMS: *Which aspects of alternative payment models are particularly vulnerable to fraudulent activity?*

AHPA: Fraud mutates to suit its host, so it is hard in the abstract to determine the vulnerabilities of "alternative payment models." To the extent such payments are triggered by "savings" or quality measures, there will be an incentive to gild the lily and fabricate data to justify payments. CMS already has in place program integrity protections developed in the Medicare Advantage program to police against improper data reporting, and similar protections can be employed with alternative payment models. Further, if the alternative methodology results in Medicare or a commercial payor paying less than it otherwise would, it is unclear whether the payor should care how the savings are distributed. Again, in the Medicare Advantage context, CMS has left the distribution of incentive payments to health plans' discretion to distribute savings or allocate risk as they see fit, and there does not appear to be any justification to treat alternative payment models differently.

In this quickly changing environment, facilitating innovation should override attempts to anticipate and prospectively regulate possible or theoretical abuses. Neither the industry nor the government (including CMS, OIG, and DOJ) has the foresight to anticipate fraudulent schemes and regulate in advance to prevent them without seriously impeding the benefits of the alternative payment mechanisms. CMS, OIG, and DOJ have ample ability and tools to address fraud when and, more importantly, if it occurs.

CMS: *Is there need for new exceptions to the physician self-referral law to support shared savings or "gainsharing" arrangements? If so, what types of financial relationships should be excepted? What conditions should we place on such financial relationships to address accountability, transparency and quality, including how best to limit inducements to stint on care, discharge patients prematurely, or otherwise reduce or limit medically necessary care? Would legislative action be necessary to establish exceptions to support shared savings or "gainsharing" arrangements?*

AHPA: CMS does not need to create a new exception for gainsharing if it would clarify that the scope of the risk-sharing exception is broad enough to protect gainsharing and quality incentive payments associated with hospitals' commercial fee-for-service patients, and expand it to include Medicare and Medicaid fee-for-service. Alternatively, CMS could create a new gainsharing/incentive payments exception that, like the current risk-sharing exception, does not contain any fair market value, volume/value or commercial reasonableness standards. We note that the CMMI has not included a fair market value standard in the internal cost savings provisions of the BPCI or the proposed Comprehensive Care for Joint Replacement programs, using caps instead, *i.e.*, 50% of the Medicare physician fee schedule payment for the physicians' cases. For example, compensation for improving the hospital's quality and utilization performance scores could be capped at a percentage of the physician's prior year collections from professional services to patients in the applicable payor class, adjusted for any change in the physician's FTE status. This avoids the problems from trying to apply a fair market value standard to payments for which there is no or little comparability data.

Other safeguards against abuse could include the following items:

- Giving hospitals the option of excluding from participation physicians who individually accounted for 3% or less of the applicable case volume in the prior fiscal or calendar year, but otherwise prohibiting use of the volume or value of a physician's admissions or referrals as a criterion for eligibility.

- Clarifying that the exception in no way relieves the participants of liability under the CMP gainsharing provision.

- Requiring that the hospital continue to make available those supplies requested by a physician on grounds that it is in the best medical interest of the patient, and that there be no retaliation for such requests.

- Prohibit participation by physicians who have a financial relationship with any of the hospital's vendors providing supplies or services that are the subject of the gainsharing program.

- Requiring disclosure of the arrangement to patients.

CMS: *Should certain entities, such as those considered to provide high-value care to our beneficiaries, be permitted to compensate physicians in ways that other entities may not? For example, should we permit hospitals that meet established quality and value metrics under the Hospital VBP to pay bonus compensation from DHS revenues to physicians who help the hospital meet those metrics? If so, what conditions should we impose to protect against program and patient abuse? How should we define "high-value care" or "high-value entity"? Are there standards other than the value of the care provided to patients that would be appropriate as threshold standards for permitting a hospital or other entity furnishing DHS to compensate physicians in ways that other entities may not?*

AHPA: Payment to medical staff members for improvement in quality, efficiency and patient satisfaction should not be limited to the providers providing the highest value care; the providers with the lower scores are most in need of tools to incentivize physicians to change clinical and practice behaviors. A good way to create such incentives is to permit *any* hospitals to share the hospital's value-based incentive payments by Medicare and other payors with the medical staff. Permitting a hospital to allocate a portion of the hospital's valued-based incentive payments will assure that the payments are for value received. Other safeguards against abuse could include:

- Giving hospitals the option of excluding from participation physicians who individually accounted for 3% or less of the hospital's admissions in the prior fiscal or calendar year, but otherwise prohibiting use of the volume or value of a physician's admissions or referrals as a criterion for eligibility.

- Capping the aggregate pay-out to 50% of the hospital's value-based incentive payments or some percentage of a physician's reimbursement for his or her professional services to admitted patients.

- Prohibiting the payouts to individual participating physicians from *directly* taking into account the volume or value of the physician's hospital admissions.

- Clarifying that the permitted shared incentive payments in no way relieves the hospital of liability under the CMP gainsharing provision.

CMS: *Could existing exceptions, such as the exception at § 411.357(n) for risk-sharing arrangements, be expanded to protect certain physician compensation, for example, compensation paid to a physician who participates in an alternative care delivery and payment model sponsored by a non-federal payor? If so, what conditions should we impose to protect against program and patient abuse from the compensation arrangements resulting from participation in such models?*

AHPA: See response above to "*Which exceptions to the physician self-referral law apply to financial relationships created or necessitated by alternative payment models? Are they adequate to protect such financial relationships?"*

C. Comments regarding the Stark Law and (1) Physician Compensation Methodologies, (2) "Volume or Value" Standard Interpretation, and (3) Commercial Reasonableness Standard Interpretation

CMS: *Have litigation and judicial rulings on issues such as compensation methodologies, fair market value or commercial reasonableness generated a need for additional guidance from CMS on the interpretation of the physician self-referral law or the application of its exceptions? We are particularly interested in the need for guidance in the context of delivery system reform.*

CMS: *Is there a need for revision to or clarification of the rules regarding indirect compensation arrangements or the exception at § 411.357(p) for indirect compensation arrangements?*

AHPA: Yes. There is a need for additional guidance on each of the three substantive Stark exception standards: fair market value, the value or volume of referrals or other business generated and commercial reasonableness. Because the Stark Law is a strict-liability Medicare payment rule, CMS needs to provide clear, unambiguous safe harbors for each of these standards, so that the regulated community knows when it is protected and what is necessary to demonstrate compliance. Moreover, Stark Law policy and interpretation is too important to be left to litigation; CMS, not the courts, has the responsibility and expertise to interpret the substantive standards of the Stark Law. Recent civil litigation using the FCA to punish Stark violations shows that exceptions with "fair market value," volume/value and commercial reasonableness standards have become traps, not true "exceptions" because it is too easy for plaintiffs to challenge "fair

market value" with an expert or to claim that a hospital's hopes that a physician will refer patients show that its compensation "takes into account" referrals.

The fair market value standard lends itself to safe harbors, not unlike what CMS attempted with its now-repealed fair market value safe harbor. The following clarifying interpretations, however, would go a long way in improving the current situation for compliance with all three substantive Stark exception standards.

- Clarify that the "varies with" and "volume or value" standards only apply to anticipated referrals when the "varies with" and "volume or value" standard specifically references anticipated referrals. *Without this, there will never be any semblance of a bright-line application of the "volume or value" standard, because the purpose and intent of the compensation will be implicated.*

- Clarify that compensation takes into account the volume or value of actual referrals or other business generated only if the compensation varies or fluctuates with the volume or value of referrals; and that, to vary or fluctuate with the volume or value of referrals or other business generated, the physician's compensation must be more than it would have been had the physician made no referrals. *This, too, is a necessary clarification if there is ever going to be an objective, bright-line application of the "volume or value" standard.*

- Clarify that productivity compensation to a physician working in a hospital setting does not implicate the "varies with" or "volume or value" standards, *wherever* the standards may appear in the regulations, just because of the physician's corresponding referral for the hospital facility component of the physician's personally performed services, <u>*unless*</u>:

  (a) the productivity credit is explicitly or implicitly (such as through a referral requirement) conditioned on the physician performing the surgery or procedure *at a particular hospital facility*, and

  (b) this condition on the physician's compensation does not satisfy 42 C.F.R. § 411.354(d)(4), the special rule for conditioning compensation on referrals to a particular healthcare provider. *Without this clarification, hospitals and their affiliates paying fair market value productivity compensation to surgeons and proceduralists, for example, are at risk of a "varies with" or "volume or value" violation.*

- Add the productivity bonus exception to the "volume or value" standard found in the *bona fide* employment exception to the personal services, fair market value and indirect compensation exceptions. *There is no principled reason why productivity bonuses should be treated differently outside of the employment context.*

- Confirm that, because self-referred but self-performed DHS is not a "referral" for Stark Law purposes, the productivity bonus exception is not intended or needed to protect compensation that takes such referrals or other business into account. *If the*

judicial interpretation of the productivity bonus exception that limits the exception to personally performed, but self-referred, DHS is allowed to stand without CMS commentary, the productivity bonus exception will be mere surplusage, having no independent purpose or meaning. This is an unacceptable outcome.

- Change the "productivity bonus" exception to a "productivity compensation" exception.

- Clarify that percentage compensation can qualify for the special rule for "unit compensation," meaning that percentage of revenue or income compensation, *e.g.*, 50% of savings, would be deemed not to take into account the volume or value of referrals if: (a) the compensation is fair market value for services or items actually provided, and (b) the percentage rate does not vary over the course of the compensation arrangement in a manner that takes into account the volume or value of referrals. *This would eliminate the unprincipled distinction between "unit compensation" and "percentage compensation," both of which can be commercially reasonable compensation methodologies. There is no apparent reason why one is permissible and the other is cause for strict liability under the Stark Law. If CMS is comfortable that the safeguards applied to "unit compensation" address the risk of program and patient abuse, there is no principled reason why the same safeguards, applied to percentage compensation, would not also address the risk of abuse.*

- Confirm that where the "commercial reasonableness" standard is expressed as a requirement that the arrangement would be commercially reasonable even if the physician made no referrals to the DHS entity, "referrals" means referrals for DHS otherwise covered by Medicare, consistent with the regulatory definition of "referrals."

- Reaffirm that "commercial reasonableness" and "fair market value" are not determined by resorting to any particular method, principle, or assumption and, *therefore*, compensation to a physician that is in excess of what the employer or contracting entity collects from the services of the physician, or in excess of what the physician made previously in private practice, is not necessarily commercially unreasonable, commercially unreasonable in the absence of referrals, or above fair market value; such a determination would depend on the facts and circumstances of the arrangement.

- Clarify that "commercial reasonableness" is not intended to address the financial terms of the arrangement, which is the proper purpose and function of the "set in advance," "takes into account" and fair market value standards, but is intended to *add* to the exception an element that addresses the risk of a DHS entity purchasing services or leasing space or equipment, or a *quantity or type* of services, space or equipment for which it does not have a commercially reasonable need.

- Clarify that the Stark Law does not apply to the Medicaid program. In spite of recent Stark Law enforcement actions, the last time that CMS provided any regulatory

guidance on the application of the Stark Law to Medicaid, it clearly stated that it did not apply, but that it would revisit the issue in future rulemaking. To date, CMS has not done so. Without any further regulatory guidance, providers and suppliers are left in the untenable position of trying to apply the current Stark Law regulations, which only apply to the Medicare program, to the Medicaid program without any clear understanding of how to comply.

- Clarify that the "volume or value" standard is distinguishable from the "fair market value" standard. This clarification is necessary because the two standards are being conflated by the courts, and the "volume or value" standard is being read out of the statute and the regulations every time it appears with the "fair market value" standard. We elaborate below.

  The "fair market value" definition provides that, "[u]sually, the fair market price is 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. . . ." 42 C.F.R. § 411.351. To preserve the "volume or value" standard, and the objective nature of the standard, we request that CMS clarify that compensation determined in a manner that takes into account the volume or value of anticipated or actual referrals is not, *per se*, inconsistent with fair market value. While the DHS entity cannot establish fair market value by relying on market "comparables" where the compensation was determined in a manner that took into account the volume or value of anticipated or actual referrals, compensation determined in a manner that takes into account the volume or value of actual or anticipated referrals can still be fair market value. Any other result would, for example, mean that the employment exception's "volume or value" standard has no independent purpose to fill.

CMS: *Given the changing incentives for health care providers under delivery system reform, should we deem certain compensation not to take into account the volume or value of referrals or other business generated by a physician? If so, what criteria should we impose for this deemed status to ensure that compensation paid to a physician is sufficiently attenuated from the volume or value of his [or her] referrals to or other business generated for the entity paying the compensation? Should we apply such a deeming provision only to certain types of entities furnishing DHS, such as hospitals that provide high-value care to our beneficiaries?*

AHPA: Yes, as follows:

- Compensation that varies with, takes into account, or is determined in a manner that takes into account the volume or value of referrals or other business generated by the physician (hereinafter "takes into account the volume or value of referrals") because the physician's compensation is affected by fewer referrals for a good or service, *e.g.*, readmissions, should be deemed not to take into account the volume or value of referrals provided no patient is denied medically necessary services.

- While there is a special rule permitting a physician's compensation to be conditioned on referrals to a particular provider, supplier or practitioner (42 C.F.R. § 411.354(d)(4)), it would be helpful if CMS clarified that compensation that varies with, or takes into account, the volume or value of a physician's referrals or other business generated by the physician because the amount of the compensation is affected by where the patient is referred for DHS qualifies for the (d)(4) exception if all of the criteria therein are met.

- Clarify that 42 C.F.R. § 411.354(d)(4) is not offended by a restriction on where the physician can render clinical services, as an employee or independent contractor, to the DHS entity's patients. For example, while a physician-employee continues to be free to refer the employer's patients to any provider, supplier or practitioner that, in the physician's judgment, is in the best medical interest of the patient, the employer is still permitted to restrict where its employed physicians hold clinical privileges, and, thus, where they can treat the employer's patients.

- CMS should not try to identify "worthy" high-value providers and give them special benefits. The unintended consequences of such selection are more likely to impede beneficial arrangements than to promote them. Further, if CMS wishes to reward certain entities with special benefits, the focus should be placed on integrated delivery networks, either ACOs or similar entities. Rewarding clinically and financially integrated networks is consistent with the goals of the Affordable Care Act, MACRA and recent statements by CMS regarding the creation of alternative payment models and delivery systems.

D. CMS's Other Requests for Comments

1. We fully support CMS's proposal to establish a single 90-day grace period for signatures but request that CMS consider a longer period than 90 days. We further request that CMS remove the restriction on using the grace period more than once every three years for the same party. More frequent reliance on the grace period is not necessarily an indication that a party is indifferent or inattentive to compliance with the Stark Law.

2. We request that CMS establish a 60- or 90-day grace period for satisfying the *writing* requirement. For example, it is impossible to obtain a timely writing for a last-minute arrangement with a physician to provide ED call coverage when another physician is called away. A grace period for the writing is much needed, and the "set in advance," fair market value and volume/value standards would still apply from the commencement date, greatly minimizing any opportunity for abuse.

3. We request that CMS create a "safe harbor" term length for compensation arrangements that rely on the fair market value exception, *e.g.*, six months. Currently, the term length must be set forth in the writing. For example, if an arrangement lasts for at least six months, it would be deemed to have a term of six months for purposes of the fair market value exception, even if the six-month term is not set forth in the writing.

4. We fully support CMS's proposal to make the holdover provisions of the lease and personal services exceptions an indefinite period of time.

5. We request that CMS add an indefinite holdover provision to the fair market value exception. We can discern no principled reason why the fair market value exception should address expired arrangements any differently than the other compensation exceptions.

6. We fully support CMS's proposal to require that the held-over arrangement continue to satisfy the fair market value and other elements of the exception throughout the holdover, but request that CMS confirm that, other than holdover periods, fair market value is judged as of the commencement date, taking into account the term length.

7. We fully support CMS's clarification that when a DHS entity provides its resources to a patient and bills the patient and/or payor for the resources, and the physician separately bills the patient and/or payor for his or her services, there is no remuneration between the parties for purposes of the Stark Law. We commend CMS for not allowing an erroneous judicial holding on this issue to introduce confusion and uncertainty into the proper interpretation and application of the Stark Law.

8. We recommend not finalizing the proposed new exception for time share licenses. The proposed new exception is not necessary as time share leases or "licenses" have clearly fit within the existing exceptions. If some providers or suppliers have expressed concern regarding the application of the existing exceptions to time shares, we recommend providing clarification rather than the creation of a new exception. The creation of a new exception calls into question whether long-standing relationships have been in compliance with understood and accepted interpretations of existing exceptions. We do not believe that was CMS's intent in proposing this new exception, and to avoid any unnecessary confusion, we recommend not finalizing this proposal.

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