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August 24, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1720-NC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Request for Information Regarding the Physician Self-Referral Law
File Code CMS-1720-NC

Dear Administrator Verma:

We are health care attorneys at Epstein Becker Green writing on behalf of a number of clients of the firm and based on our own experience to respond to CMS's Request For Information (RFI) regarding the physician self-referral law (commonly referred to as the "Stark Law.") 83 Fed. Reg. 29524 (June 25, 2018). Among us, we have decades of experience assisting clients throughout all segments of the health care industry in navigating the complexities of the fraud and abuse laws, including the Stark Law. We also are authors of the American Health Lawyers Association book ***Legal Issues in Health Care Fraud and Abuse: Navigating the Uncertainties (4th Edition)***.[1]

We laud CMS's willingness to provide the health care community the opportunity to address the impediments to innovation that have been the unintended consequence of the Stark Law. This is important because the Stark Law affects a far wider range of activity than just the Medicare or other federal health care programs. Because the Stark Law is triggered with respect to "any financial relationship" between a physician and a designated health service ("DHS") entity, whether or not that financial relationship involves Medicare or another government payor, the Stark Law has created a chilling effect on innovation throughout the U.S. health care industry. This means that the Stark Law's proscriptions constrain not only innovation under the Medicare and other government payment programs, but it also affects innovation in the private payor context.

[1] In addition to the signatories of this letter, other contributors to this letter include Leonard Lipsky, Bonnie Scott, and Victoria Sheridan.

Moreover, the Stark Law's exceptions and interpretations have been so complex and fraught with "gotchas" and complicated expensive compliance obligations that they frequently create a chilling effect even on activities that would be lawful. Thus, an overriding theme of our comments is to make certain exceptions crystal clear, even if potentially duplicative, so that people can plainly understand that certain activities are permitted under the Stark Law, and so that they are encouraged to collaborate and innovate instead of being dissuaded from collaborating and innovating.

In addition to providing CMS with these written comments, we would like to offer/suggest that we arrange a time to meet in person to discuss these issues after you have had an opportunity to review not only our comments but also comments from other interested parties.

Request for Information #1 – Existing or Potential Arrangements that involve DHS entities and referring physicians that participate in alternative payment models or other novel financial arrangements.

It is important for the success of all integration and coordination efforts that physician incentives are aligned with these goals. To the extent physicians have no "skin in the game" with respect to the services they order or refer for their patients or, worse, have only financial incentives to do more physician work, whether it be office visits or procedures, the less likely it is that we will reach our goals for quality, cost-efficient, coordinated health care services.

The current Stark Law exceptions are not broad enough to protect the cost reduction measures that providers need to engage in to bring down costs both in the Medicare program and in the private pay arena as well or to align incentives among all players. Here are a few examples.

Example 1: A hospital wants to start a back pain program where orthopedists will be incentivized not to order high cost MRIs and similar expensive imaging, but instead order a course of physical therapy, and a portion of the savings achieved by the avoidance of high cost imaging (and perhaps surgery as well) will be paid to the physicians. The Stark Law's personal services exception requires that compensation be set in advance and not vary based on the volume or value of referrals for Medicare covered designated health services or other business between the parties. While there is an "exception within an exception" for certain physician incentive plans, they are defined as those which could "reduce or limit care." ***We believe that it is at best unclear whether financial incentives for referrals for physical therapy (another designated health service) instead of imaging could be factored into a physician incentive plan in a Stark-compliant manner, absent MCO inovlement under a risk sharing arrangement.***

Example 2: An integrated delivery system wants to align incentives among all components of the system by making its employed physicians or one or more affiliated groups of physicians part of the overall executive compensation formula that takes into account overall system financial results, which is at least in part a function of the volume or value of referrals within the system. ***While this makes sense from an organizational standpoint, it does not appear to be expressly protected under the Stark Law absent a risk assumption/MCO context.***

Example 3: A hospital wants to ensure that its patients are compliant with certain medication treatments to improve outcomes and reduce readmissions. The hospital seeks to incentivize physicians in an affiliated group, as well as oncologists on the medical staff, in order to satisfy certain metrics regarding patient completion of certain infusion treatments. ***Since the financial incentive involves a DHS (outpatient prescription drugs) ordered by the physician, it may not be protected under the Stark Law absent a payor-sponsored risk arrangement for its enrollees.***

Example 4: A hospital wishes to incentivize certain physicians to meet certain quality and cost-effectiveness measures and then sell its services (and those of its physicians) to an employer who self-funds its employee health benefits. There may be a TPA administering the network and benefits but the TPA would not be acting as an MCO in the traditional sense. ***It is not clear whether this type of arrangement, to the extent it involves incentive payments from the hospital to the physicians, would be protected by the risk-sharing exception.***

Request for Information #2 – Additional Exceptions Protecting Financial Arrangements between DHS entities and referring physicians who participate in the same alternative payment model.

Care coordination could be improved if the Stark Law was modified to reduce, or eliminate entirely, its applicability to arrangements that involve payment for health care services pursuant to models designed to improve the quality and/or efficiency of health care services (e.g., value based payment models, ACOs, clinically integrated networks, integrated health care delivery systems). As such, the Stark Law should only be implicated in situations in which health care services are reimbursed by Medicare (or, at most, government programs) on a straight fee-for-service basis. Clinically integrated networks, ACOs, and especially fully integrated health care delivery systems are deserving of Stark Law protection, yet the patchwork of Stark Law exceptions currently in existence is not sufficient to protect the broad range of value-based activities these organizations engage in. Each of these is addressed separately below. We would suggest that it is appropriate for CMS to adopt broad-based exceptions for the types of collaborative organizations enumerated below (i.e., an exception that would be included in 42 C.F.R. § 411.355 and not an exception applicable to simply an ownership interest at 42 C.F.R. § 411.356 or a compensation arrangement at 42 C.F.R. § 411.357.)

PROPOSAL: CMS Should Create a New General Exception for "Arrangements that are Unrelated to Federal Health Care Program Business."

First and foremost, we suggest that CMS adopt a new exception for "arrangements that are unrelated to federal health care program business." This would encompass arrangements such as private pay ACOs, gainsharing, etc. where there may be no MCO or enrollees involved. This is the type of exception that was envisioned by the Stark statute in the exception for "Remuneration unrelated to the provision of Designated Health Services." However, that exception only applies to payments by hospitals to physicians, and CMS's overly narrow regulatory interpretation of that statutory exception excludes any expense that could go on a Medicare cost report or is selective

among physicians. As a result, virtually nothing can qualify as being "unrelated." See further discussion below.

PROPOSAL: CMS Should Create a New Stand-Alone General Exception for "Services Furnished by a Clinically Integrated Network or ACO"

We also propose that CMS create an exception for services provided by a clinically integrated network. This would be similar to the manner in which the FTC recognizes protection from the antitrust laws for clinically integrated networks that engage in joint financial activities. The FTC defines clinical integration as "an active and ongoing program to evaluate and modify practice patterns and create a high degree of interdependence and cooperation to control costs and ensure quality." *See* Federal Trade Commission, Markus H. Meier, *"Clinical Integration: "A Patient History.*[2] In the FTC context, clinical integration generally involves 1) goals for cost saving and quality improvement; 2) comprehensive, evidence-based clinical guidelines designed to modify practice patterns and achieve goals, including development, implementation, and performance measurement and monitoring; 3) electronic medical records to facilitate care coordination and other substantial investment of capital in infrastructure; 4) recruiting and retaining the network providers likely to further the network's goals; and 5) in-network referrals to in-network specialists who have committed to following the network's clinical guidelines.

Significantly, to the extent the ACO or CIN does not have a more comprehensive HMO or similar managed care license, there are states that license/regulate ACOs and CINs and private accreditation organizations that will accredit clinically integrated networks as well as ACOs. Accreditation criteria are stringent, setting standards for structure and operations, health information technology, clinical and population health management, and quality. Much as CMS uses "deeming authority" to allow CMS providers to meet certain Conditions of Participation through accreditation, CMS could consider licensure and/or accreditation as one of the ways in which an organization could qualify as an ACO or clinically integrated network for purposes of qualifying for Stark Law protection.

The FTC's construct would be useful for consideration by CMS for Stark Law exception purposes. A clinical integration exception would allow the transfer of funds to accomplish network objectives and coordination of care through in-network referrals among members of a clinically integrated network without triggering the Stark Law referral ban. The essence of this exception is that where there is a sufficient degree of clinical integration, it is as if the parties are one and the same with respect to network operations for certain regulatory enforcement purposes. As such, the movement of funds from one entity to another should not, in and of itself, trigger the Stark Law's referral prohibition, and referrals between and among the components of the clinically integrated system or network similarly should not be stymied due to the Stark Law.

A clinical integration exception would protect those arrangements that do not necessarily involve an affiliated payor (although the exception would protect payor involvement as well), and so

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[2] Available at https://www.ftc.gov/sites/default/files/documents/public_events/clinical-integration-health-care-check/meier-presentation-clinical-integration-workshop.pdf (last accessed August 22, 2018).

would be broader than the exception proposed elsewhere in this comment for integrated delivery systems that include payors. Its adoption would allow transformative activities to be undertaken by providers themselves through the establishment of clinically integrated networks or ACOs without necessarily relying on payors. Unlike the risk-sharing exception, a clinical integration exception would not require that there be "enrollees" of a health plan (ACOs typically do not have enrollees.)

Request for Information #3 – Additional Exceptions Protecting Financial Arrangements that Involve Integrating and Coordinating Care Outside of an Alternative Payment Model

While encouraging the development of new alternative payment models through enhanced protection is important, it is also important to remember that there already are existing, integrated models of care for which protection from the physician self-referral law remains warranted and should be strengthened.

PROPOSAL: CMS Should Expand the Prepaid Plan Exception to Include Licensed HMOs, PPOs and Insurers that Manage Care.

We propose that CMS take a fresh look at expanding the prepaid plan exception. This is an important exception that applies categorically to certain types of organizations – that is, if the organization fits within the eligible category, it has blanket protection from the Stark Law without having to micromanage its delivery of services or physician incentives. Currently, the Prepaid Plan Exception applies only to certain enumerated categories of health plans that have contractual relationships with federal health care programs or are recognized as federally qualified (a designation that once qualified an HMO for federal seed money for the development of HMOs.)

Since the Stark Law is intended to address costs in a fee-for-service environment, risk bearing entities such as state licensed HMOs and insurers, which are subject to extensive state regulation and oversight, should be considered to be sufficiently regulated under state law to be worthy of Stark Law protection for all furnished services. Therefore, we would recommend that the list of organizations eligible for the prepaid plan exception should be expanded to include organizations with state HMO or insurance licenses, especially to the extent that insurers are engaged in managed care activities that mitigate fee for service incentives. Consideration should be given as well to including PPOs as well as ASO operations within the prepaid plan exception to the extent they are managing care in a manner that mitigates fee for service incentives.

Additionally, the prepaid plan exception should apply more broadly than it currently does to all lines of business of a health plan if a health plan is recognized as a prepaid plan. Under current CMS interpretation, even if a substantial portion of a health plan's business falls within one or more of the health plan categories protected under the prepaid plan exception (i.e., Medicare Advantage, Medicaid, federally qualified HMO, etc.) the health plan needs to find another exception for any of its activities that are outside these specified areas. This is a matter of CMS interpretation in 42 C.F.R. § 411.355(c) and can be corrected by eliminating the language "(not including services provided to enrollees in any other plan or line of business offered or administered by the same organization.)" There is statutory authority for expanding the exception in this way since the statute itself grants the

exception to "services furnished by an organization" that is one of the enumerated categories without the "line of business" limitation.

PROPOSAL: CMS Should Create a Stand-Alone New General Exception for Services Furnished by an Integrated Delivery System

We propose that there be a broad based exception for fully integrated health care delivery systems that include a payor (that is, those including one or more hospitals, an affiliated physician group and a payor), regardless of whether the payor is a prepaid health plan with a formal relationship with CMS. Generally speaking, these are closed systems, in which the affiliated physicians are medical staff members of the affiliated or contracted hospitals and other facilities, and are participating providers with the health plan. As such, they have the incentive to reduce health care costs and improve coordination and quality. Because the care provided is pursuant to the system's clinical protocols that are in place for all patients, there is little risk of program or patient abuse. And because these are closed systems, referrals will be generated almost exclusively within the system, making the Stark Law largely irrelevant. Since, by definition, patients of a fully integrated health care delivery system will almost always obtain care from a component of the integrated system, it should not matter where the services are located within the integrated system (physician group practice, hospital, free-standing, etc.) as to what level of Stark Law protection is warranted. Since the components of these integrated delivery systems essentially operate as one organization with respect to patient care, broader Stark Law exemption is warranted, irrespective of funding flows and location of designated health services.

Although these systems are largely risk-based, they occasionally address the health care needs of patients who are not members of the integrated health plan. For example, Medicare fee-for-service patients might be treated due to the integrated hospital's EMTALA obligations, or because the IDS's charitable status requires it to treat all on a non-discriminatory basis. This turns into a "tail wagging the dog" exercise when the system seeks to incentivize physicians to provide cost efficient, coordinated, high quality care or work together among its components to recruit new physicians.

We suggest that a new, stand-alone exception for integrated delivery systems that includes a payor component be created as a general exception, meaning that it would apply to both ownership and compensation arrangements. It could be modeled after the Academic Medical Center (AMC) exception, which is also a general exception. The AMC exception protects in the collective a hospital, affiliated physician, and an affiliated medical school. The exception would replace the affiliated medical school of the AMC exception with an affiliated payor. That is, the essential components for qualification for this exception would include a health plan, one or more hospitals, and one or more affiliated physician groups. Like the AMC exception, the affiliation could be through an agreement that provides for financial integration or could be through a corporate relationship that accomplishes such an integration. Additionally, like the AMC exception, a substantial portion of the affiliated physicians would need to be on the hospital medical staff as well as participating physicians in the affiliated health plan organization. The affiliated or contracted hospital also would need to be a participating provider in the affiliated health plan.

The goal of the exception would be to provide an explicit Stark Law exception for all services furnished or arranged by an integrated delivery system that includes a payor, irrespective of where the service is furnished or arranged. The exception would expressly recognize that the clinical and/or financial integration and care coordination that exists in established integrated delivery systems is sufficient to warrant Stark Law protection without having to undertake a protracted, resource intensive and expensive analysis with respect to system-wide efforts to incentivize care coordination where there may be certain patients who are non-members but who are treated by the integrated delivery system. This could be because of EMTALA requirements or because of the system's charitable obligations or for continuity of care purposes. So long as these systems furnish care to all patients under the system's established clinical integration and care coordination protocols, there would be no need to differentiate the extent of Stark Law protection among patients or product lines.

Similar to the way AMCs are protected with respect to transfers of funds among AMC components, the exception would allow all components of an integrated delivery system that includes a payor to contribute to physician compensation (base and bonus or other incentive compensation). Such an exception would broadly cover all services furnished or arranged by the system, irrespective of which component is furnishing the services or paying the compensation. As the system includes a payor, we would suggest that, like the various other managed care related exceptions (prepaid plan, risk sharing, etc.), the exception not include a requirement for fair market value. This is important because accomplishing managed care goals often requires physicians to refrain from providing certain services, or to provide lower intensity care when clinically appropriate, which may impact the ability to determine fair market value on an RVU basis, but is important to the appropriate cost-saving, care coordination plan objectives.

CMS Should Create a Stand-Alone Compensation Exception for Incentive Payments, Shared Savings Programs and Other "Gainsharing" Type Arrangements

CMS recognized in 2008 that the existing Stark Law exceptions were not flexible enough to allow for appropriate incentive payment and shared savings programs, such as gainsharing programs, that promote quality of care with cost savings. 73 Fed. Reg. 38502 (July 7, 2008). At that time, CMS proposed an incentive payment and shared savings programs exception to the Stark Law for arrangements between hospitals and physicians. However, CMS never finalized the proposed exception. 73 Fed. Reg. 69726 (Nov. 19, 2008).

As CMS has itself recognized, because physicians are paid separately under Medicare Part B (and generally by managed care and other payers), they do not necessarily share the hospital's motivation to control patient care costs. CMS recognizes that physicians are not financially at risk for the items and services that they use and prescribe, and therefore, do not have a financial stake in controlling the hospital's patient care costs. 73 Fed. Reg. at 38548. Yet, incentivizing physicians to control costs is not expressly protected under the Stark Law. As such, at a minimum, CMS should now finalize an exception to protect gainsharing-type arrangements.

Now that Congress has amended the CMP to eliminate the restrictions on hospital payments to physicians that reduce or limit care in favor of a limitation on reductions in medically necessary care, CMS has greater flexibility to adopt a broad based gainsharing exception that has the potential to truly control costs and affect outcomes, as well as consider an even broader exception for other types of incentive payments and shared savings programs, including pay-for-performance, value-based purchasing, and quality incentives and the like.

In light of the significant public policy need to support carefully structured, clinically supported quality and cost-efficiency programs in hospitals, we submit that the time has come for careful consideration of Stark exceptions for appropriately structured programs that include appropriate payments to physicians for their participation in gainsharing arrangements, without which such programs will not succeed. The success of governmental quality initiatives and industry pay-for-performance programs involving hospitals depends on physicians' willingness to participate in such programs, and hospitals and physicians being protected from risk of violating the various fraud and abuse laws and their onerous penalty provisions.

Currently, the gainsharing construct is generally based on an interpretation of the personal services exception that requiring otherwise independent physicians to practice in a particular manner and to engage in the development and following of certain protocols, is itself a "service" worthy of protection. However, we believe the time has come for CMS to expressly recognize gainsharing and other incentive arrangements as worthy of regulatory protection in and of itself and on the face of the regulation. These arrangements are necessary to achieve overarching goals of the Medicare program to enhance quality and reduce costs through collaboration and innovation.

We propose criteria for a new exception protecting gainsharing and other quality initiative and incentive programs. Our proposal is based on standards adopted by the OIG in individual advisory opinions on gainsharing, as well as previous CMS proposals and commentary. Our proposal also borrows from Stark regulations governing referrals and distribution of referred ancillary service revenues by group practice physicians.

In the original proposal for an exception for incentive payments and shared savings programs, CMS asked whether parties should be permitted to establish their own quality measures for inclusion in a protected incentive payment or shared savings program. 73 Fed. Reg. at 69795. CMS's approach here should be similar to its approach to fair market value which permits documentation of fair market value by various means. Thus, parties should be able to use a variety of support for establishing quality measures, which may include engagement of independent expertise, reliance on CMS measures, or reliance on other sources of objective quality protocols and metrics, so long as the quality or cost saving measures are supported by credible documentary evidence that they enhance quality, control costs and will not adversely affect patient care.

We note that when CMS originally proposed its gainsharing exception, the gainsharing demonstration project was already underway but there were not yet results. Since that time, the demonstration concluded and a final report was submitted to Congress recognizing that gainsharing is a promising model for healthcare reform. CMS Report to Congress, *Medicare Gainsharing: Final*

Report to Congress (June 3, 2014).[3] A number of the quality-of-care metrics used in the gainsharing demonstration project were beyond those that have been approved in OIG advisory opinions and include metrics such as 30-day mortality and readmission rates as well as reduced lengths of stay. CMS should consider including these types of measures as protected under the Stark Law, since these types of measures can be enormously impactful on the provision of quality, cost-effective care.

There also was considerable discussion in the CMS Report about the difficulty of educating physicians regarding the gainsharing reporting metrics, underlying data and overall purpose of the initiative. This suggests that simply announcing a program does not make it effective and that takes a while to achieve and sustain a measure. Rebasing on an annual basis inhibits the ability of the hospital to make sure that the changes in behavior are sustainable for an extended period of time. A three to five year limitation on the particular arrangement should be sufficient for this purpose without requiring annual rebasing. Because the arrangement will be limited in duration to three to five years, this should alleviate concerns regarding paying physicians for previous achieved cost-savings or measures that have become standard practice. We reiterate that it takes a considerable amount of time for changes in behavior to "stick" and so repetitive payments for purposes of sustaining adherence to measures should not be viewed as inappropriate.

Moreover, paying a physician more or less according to whether he or she has contributed more or less to the achievement of the performance measures should not result in program or patient abuse to the extent that the physician's base year practice patterns are factored into the calculation. Consideration also should be given to allowing adjustments in the base year to the extent that there are market changes or physician practice growth unrelated to changes in referral patterns. To the extent CMS permits this, we are relatively certain that providers will develop methodologies and tracking mechanisms for this purpose.

CMS originally proposed a flat fifty percent on the amount of cost savings eligible for sharing with participating physicians. 73 Fed. Reg. at 69797. We believe that no such limit is necessary because there are inherent business controls in hospitals wanting to retain savings and the application of the Anti-Kickback Statute should create inherent constraints to the size of sharing. However, we can envision certain circumstances where hospitals will want to retain the flexibility to share greater savings either at the outset or through the duration of the program. For example, hospitals may want to accelerate the engagement of physicians in the program by committing a greater proportion of savings in the first year. This may be particularly appropriate where the hospital and its medical staff have little previous experience in joint programs. We can also envision a hospital that may be seriously lagging behind in certain measures to want to maximize the potential for adherence to the measures by sharing a greater proportion of the savings with the physician.

While assessment of the impact on patient care is a necessary element, how this is measured should be left up to hospital discretion based on the types of quality metrics selected. Similar to the selection of the metrics, parties should be able to use a variety of assessment techniques including in house review, engagement of an independent medical review expert, or some combination thereof, to asses patient care impact.

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[3] Available at https://innovation.cms.gov/Files/reports/MedicareGainsharingRTC.pdf (last accessed August 23, 2018).

We do not believe that it is necessary to restrict physician participation to pools of more than 5 or more physicians or to distribute to members on a per capita basis or institute absolute caps on financial incentives. There are a number of other safeguards adopted in other Stark exceptions that could be useful here, as well as more flexible safeguards. For instance, CMS may want to borrow from the recruitment exception approach in which the time period initially chosen for the recruitment arrangement is honored and the subsidy program cannot be changed based on initial results. We agree with CMS that an incentive payment or shared savings program should not be used as a recruiting tool or as disguised payments for rewarding referrals and suggest that that CMS explicitly include this prohibition in its exception. 73 Fed. Reg. at 69796. This is a similar approach to what CMS takes in other exceptions where it explicitly states that the arrangement cannot violate the Anti-Kickback Statute. CMS also could consider adopting the "cannot violate the Anti-Kickback Statute" provision itself although this is a more vague approach. In addition, rather than a pool of five, which could limit these arrangements where physicians do not sign on or in hospitals with smaller medical staffs, CMS could adopt the provision currently in medical staff incidental benefits exception that, "the compensation is offered to all members of the medical staff practicing in the same specialty (but not necessarily accepted by every member to whom it is offered)." 42 C.F.R. §411.357(m). Finally, instead of adopting absolute caps, CMS could adopt more flexible guidelines requiring the use of objective historical and clinical measures to establish thresholds beyond which no savings will accrue to the participating physicians. We also think in certain circumstances that limiting distribution to a per capita approach may result in excessive payments to referring physicians who participate in the program but contribute little to no work or expertise to the program as CMS noted in its previous commentary. 73 Fed. Reg. at 69796.

In reviewing CMS commentary, and in particular concerns about incentive payment and shared savings programs and potential controls including audit requirements, we were struck by the evolution of sophisticated compliance programs that has occurred over the past 10 years since the original proposed exception was published. We would suggest that the need for additional standards included within the exception, including auditing, monitoring, etc., should no longer be necessary because these elements are inherent in a robust compliance program.

PROPOSAL: CMS Should Adopt A Gainsharing/Incentive Arrangements Exception As Follows:

The prohibition on referrals set forth above does not apply to incentive arrangements where:

(1) The arrangement is set out in writing and signed by the parties.
(2) The term of the arrangement is for not less than one (1) year nor more than three to five (3-5) years.
(3) The arrangement includes a compensation methodology that is set in advance as a specific formula in the agreement between the parties. The formula for determining the compensation must be set forth in sufficient detail so that it can be objectively verified, and the formula may not be changed or modified during the course of the agreement in any manner that directly takes into account the volume or value of referrals or other business generated by the referring physician.
(4) The arrangement incorporates quality performance and/or cost effectiveness measures that may include reductions in length of stay and readmissions so long as there is no reduction in medically

necessary care and which may direct the use of specific devices and supplies or establish protocols for cost-effective use or standardization of products. Neither the measures nor the performance indicators may be modified during the course of the arrangement; however, additional measures may be added.

(5) Each measure is clearly and separately identified in writing prior to implementation and any cost savings resulting from such measure is separately tracked and paid from any other measure. Measures may include global quality metrics as well as individually identified and tracked patient care quality measures.

(6) The measures shall not be disproportionately applied to Federal health care program beneficiaries.

(7) The individual physicians who participate in the arrangement, or their group practice or physician organization, receive an objectively determined share of the payment pool that may be based on one of the following:

(i) a per capita share of the aggregate payment pool made available for participation in the measure or the cost-savings generated by the results of the measure; or

(ii) the proportion of savings attributable to the particular physician (or group or physician organization) based on that physician's (or group's or physician organization's) hospital practice during the base year.

If payment is made to a group or physician organization, the group or physician organization has independent discretion to distribute the payment in accordance with any methodology permitted under the Group Practice definition.

(8) Payments made to individual physicians or a group practice or physician organization shall be adjusted to not take into account increases in value or volume of patients or services ordered or referred by each such referring physician. Adjustments may take into account volume changes due to market forces or physician practice growth rather than changes in physician referral patterns.

(9) The compensation is offered to all members of the medical staff practicing the same specialty (but not necessarily accepted by every member to whom it is offered).

(10) The compensation is not used as a recruiting tool or as disguised payments for rewarding referrals.

(11) Written disclosure of the measure(s) and the physician's financial relationship with the hospital pertaining to the measure(s) is made to each patient whose care may be affected by the measure(s) prior to the furnishing of services. Any request by a patient that one or more measures not be applied to them shall be granted.

(12) In connection with measures that encourage product standardization, a protocol will be put in place that allows participating physicians to access the same selection of products as existed prior to the measure being implemented upon request.

(13) Each quality or cost-saving measure is supported by credible medical evidence that implementation of the measure enhances quality and will not adversely affect patient care. Adoption by CMS of a measure shall constitute credible medial evidence for purposes of this criterion.

(14) Protections shall be implemented against inappropriate reductions in service by utilizing objective historical and clinical measures to establish baseline thresholds beyond which no savings will accrue to the participating physicians.

(15) Payment for any individual measure shall be reasonably limited in duration and amount so as to produce sustainable results yet reduce the likelihood of duplicate payment, including but not limited to step-down compensation methodology.
(16) The hospital monitors physician compliance with these requirements and documents its audits and oversight activities and results, and takes prompt action to remove from participation any physician who fails to comply.

Request for Information #4 – Thoughts on the Current Exception for Risk Sharing Arrangements

The "risk sharing" exception was designed to remedy the unintended consequence of the Stark Law impacting private pay relationships, but in its focus on "enrollees", MCOs and risk-sharing, it is not sufficiently broad to free up innovation in the private pay context. Innovative alternative payment arrangements such as ACOs and bundled arrangements do not necessarily have enrollees, do not necessarily involve MCOs and may not involve "risk sharing" in the traditional sense of the term. We remain concerned that despite helpfully broad preamble language, many in the health care community tell us that they look at the plain words of the exception and assume that they cannot meet it because they are not capitated. We are also concerned that the exception does not protect incentives for care coordination and integration outside of these formalized arrangements. ***Thus, we believe that the risk sharing exception should be modified to eliminate the word "enrollee" as well as the reference to MCOs.***

We also believe that the risk sharing exception should be moved to the General Exceptions which apply to both ownership and compensation arrangements. It has often been said that risk sharing arrangements largely eliminate the need for physician self-referral restrictions because they act inherently to control overutilization. ***As such, we think that the Stark Law protections available for risk sharing should apply to ownership interests as well as compensation arrangements, and thus the exception should be moved from the exceptions related to compensation arrangements to the General exceptions portion of the regulation that applies to both ownership and compensation exceptions.***

PROPOSAL: Expand the Current Risk Sharing Exception to All Risk Sharing Arrangements Irrespective of MCO Involvement and Move It to the General Exception.

The language "Compensation pursuant to a risk sharing arrangement" should be eliminated and replaced by "Services to the extent they are subject to a risk sharing arrangement." We also think that the advent of ACOs suggests that the application only to "enrollees of a health plan" is antiquated and the language should be eliminated and replaced by the word "patients". To the extent CMS believes this would result in too broad an exception, the protection could be limited only to DHS subject to the risk arrangement.

Request for Information #5 – Thoughts on the Special Rule for Compensation under the Physician Incentive Plan Exception

CMS has requested information on the utility of the special rule for compensation under a physician incentive plan, which is included within the exception for personal services arrangements. As one of us (Carrie Valiant) was part of the original conversations on Capitol Hill in 1993 that resulted in this "exception within an exception" becoming part of the statute, we can provide the historical context for this. It was originally designed to allow health plans to own and directly furnish designated health services while also having risk based compensation arrangements with physicians where the arrangements were not protected under the more limited prepaid plan exception that only applied to certain types of federal health care program contracted health plans. We are of the view that this "exception within an exception" has been very helpful with respect to certain managed care arrangements and that a similar "exception within an exception" also needs to be part of the "indirect" exception as well. This is because, originally, the personal services exception was assumed to apply to both direct and indirect compensation arrangements. Once CMS adopted the definition of "indirect" and the exception for indirect compensation arrangements, and then determined that the personal services exception no longer could be used for indirect relationships, much of the value of this "exception within an exception" was lost. This means, for example, that if an MCO directly furnishes DHS it can have incentive arrangements with physicians that take into account those DHS referrals, but not if the MCO owns DHS in a separate entity. This limitation makes no sense in that it unnecessarily restricts legitimate business structures and extols form over substance.

We, therefore, suggest that the Special Rule for Compensation under a Physician Incentive Plan within the Personal Services Exception be expanded to all relevant compensation exceptions, including the indirect exception, the fair market value exception, and the employment exception. We also propose since health care collaborative relationships have broadened considerably in the 25 years since Congress adopted the "exception within an exception" that it, too, be broadened beyond "enrollees" and "health plans".

Request for Information #6 – Possible Approaches to Addressing Alternative Payment Models and other Novel Financial Arrangements

We believe a flexible approach is best for addressing alternative payment models and other novel financial arrangements under the physician self-referral law. While some may prefer a one-size fits all single exception, such as we proposed above, we believe that one exception alone, without amending the restrictive nature of other existing exceptions, will not be sufficient to provide flexibility to protect future innovative arrangements. Thus we would suggest amending current exceptions as provided herein, plus adopting several of the other exceptions described herein such as a clinical integration exception and an integrated delivery system exception.

Request for Information #7 – Thoughts on Definitions for Critical Terminology

CMS should use caution in defining critical terminology to avoid restricting the ability to develop innovative alternative payment models by locking things up in strict definitions. Innovation

requires flexibility to address alternative payment models and other novel financial relationships. We cannot define today what tomorrow's alternative payment models. As such, we have specifically refrained from proposing specific definitional terms related to these concepts. Nevertheless, conceptual definitions are addressed herein in our proposals for additional exceptions. In this regard, we applaud CMS's decision to refrain from defining "MCO" or "risk sharing" the risk sharing exception (42 C.F.R. §411.357(n)) as it was a step in the right direction. We believe that the definitions of "enrollee" and "health plan" similarly need a more flexible definition to enable use of the currently existing incentive exceptions (*i.e.*, physician incentive plan, risk sharing) to be used in a meaningful way with respect to innovative approaches to health care collaboration and coordination.

Specifically, we already have suggested in this comment that the risk sharing exception's focus on "enrollees" as that term as traditionally understood makes the exception far too narrow to work for the broad range of alternative payment models that do not have traditional enrollees in the managed care sense. Nevertheless, we believe there is statutory authority for CMS to adopt a broader definition of the term "enrollee" that takes into account that patients may be "enrolled" for purposes of the various exceptions to the extent that the services are in connection with one of the recognized alternative payment models, including bundled payments, ACOs, integrated delivery systems with payor components, clinically integrated networks, etc. Similarly, the terms "health plan" and "MCO" could be interpreted in their broadest possible sense to include all of the recognized alternative payment models.

Request for Information #8 – Other Relevant Terminology

Designated Health Services

There has been a push on the part of CMS in recent years to expand the reach of the physician self-referral law through the expansion of the definition of what constitutes a DHS. This has had the result of expanding the reach of the Stark Law and its care coordination impediments to a far wider range of activities than was originally intended by Congress. The list of eleven DHS was very particularly delineated by Congress and we question CMS's authority to unilaterally expand the list through its rulemaking authority.

We would propose scaling back the expansive interpretations of the Stark Law that occurred in 2009 that transformed services that were not previously on the list of DHS, into DHS (i.e., inpatient and outpatient hospital services) when they were provided pursuant to a contractual relationship with a hospital and billed by a hospital. This was a drastic change in CMS's longstanding interpretation of the Stark Law. Until this time, CMS had always concluded that providing a non-DHS service, such as cardiac catheterization, under a contractual arrangement with a hospital that met a compensation exception was not a DHS (i.e., an under arrangement).

The fact that the "under arrangements" provision for the furnishing of DHS through a group was placed in the compensation exception portion of the statute demonstrates Congress's clear belief and intent that a compensation exception was sufficient to protect these types of "under

arrangements" agreements without the need for an ownership exception. Yet, CMS now says that physicians who own non-DHS need an ownership exception to protect what is essentially physician ownership of a non-designated health service.

We also would recommend eliminating from the definition of DHS the professional component of certain imaging services. This has turned into a "gotcha" with respect to compliance and has the unintended effect of reducing the ability of employed physicians in a hospital department to interpret each other's tests and receive bonuses based on these collaborative efforts to the extent a referring physician receives a bonus based on another's interpretation. The referring physician must perform the interpretation (personally performed DHS is exempt) in order for the service to be included in the bonus pool. This is the result of the definition of DHS applying to these physician services as well as CMS's interpretation that hospital employed physicians cannot qualify as a group practice which limits the flexibility of being able to incentivize collaborative work among physicians in the department.

Request for Information #9 – Approaches to Defining "Commercial Reasonableness"

We think CMS should weigh in more clearly and flexibly on the issue of commercial reasonableness. We have found that any variation by the parties to an arrangement where Stark can be implicated draws a challenge of lack of commercial reasonableness, when, in fact, parties in commercial relationships outside the health care industry frequently vary the conduct of their relationships to meet business objectives. By way of example, we have assisted clients experiencing a "commercial reasonableness" challenge where a hospital "held space" by allowing a group to occupy space sequentially as recruited physicians began work even though the space occupied was paid fair market value. Yet, commercial landlords routinely engage in various "sweeteners" including options for additional space, renovation allowances and the like. Without CMS commentary in this regard, prosecutors will continue to second guess reasonable business decisions under the guise of lack of "commercial reasonableness." If CMS would like additional examples, please let us know.

Request for Information #10 – Approaches to Modifying the Definition of Fair Market Value Consistent with the Statute and In the Context of the Exceptions

We have observed in recent years, since the proliferation of Stark-related false claims act litigation, that firms that provide physician compensation valuations have become increasingly conservative with respect to the determination of fair market value. For example, certain valuation firms will not approve compensation in excess of the 75th percentile even with significant business justifications. This will result in an inevitable spiral downward of physician compensation, with the 75th percentile becoming the 100th percentile and so on. We think this is an unfortunate turn of events at a time when health care organizations will want to pay physicians more to align their interests in cost savings and collaboration, and therefore believe that CMS attention in the area of fair market value is warranted.

We believe that CMS should make clear in its definition of fair market value that fair market value is a flexible term. For example, paying a physician more than a government health care program can be fair market value. Subsidizing low paying government programs in order to incentivize physicians to care for those patients can be fair market value and paying physicians a differential amount based on differing payor rates also can be fair market value (see below discussion on this under "volume or value of referrals", RFI #11.)

This type of flexibility is necessary because, in some communities, Medicare patients moving into a community cannot find physicians to care for them because federal health care program rates are too low and there is an enormous "hassle factor" of dealing with federal health care programs. We can envision hospital systems that may want to pay physicians a premium to ensure that the community need for health care services is addressed. We believe that the commercial definition of fair market value may allow this, and CMS's definition of fair market value should follow suit.

Additionally, achieving collaboration and efficiencies in health care delivery requires transforming the financial incentives inherent in fee for service medicine for physicians to produce more RVUs to justify the fair market value of their compensation to a system that rewards quality and the efficient use of health care resources. While the fee for service reimbursement system itself, with its reliance on RVU-based reimbursement, provides a substantial impediment to achieving this, the Stark Law and its over reliance on the fair market value of work personally performed by the physician provides a further impediment to achieving necessary and desirable cost efficiencies through innovation (e.g., use of other professionals.) Fair market value is not always (or only) a reflection of services personally performed but also of savings achieved.

Moreover, exceptions that contain a fair market value element tend to look at the overall income to the physician to determine if total compensation is within the range of fair market value. As CMS expands exceptions to address incentive payments and shared savings programs it will be important to clarify that those incentive based payments should not always be taken into account for determinations of fair market value. In other words, the fair market value of incentive compensation can be separate and apart from the determination of fair market value for compensation of physician services because it will frequently reward physicians for not doing certain things or for having others do certain things, which are factors that are generally not part of a fair market valuation of physician compensation.

Request for Information #11 – Thoughts on "Taking into Account the Volume or Value of Referrals" in the Context of the Physician Self-Referral Law

We suggest that the definition of "taking into account the volume or value of referrals" adopted by CMS with respect to certain compensation arrangements is far too broad and is contrary to Congressional intent. Congress in adopting Stark II was very clear in its Conference Report that taking into account the volume or value of referrals meant that payment could be on the basis of a fee schedule or other payment methodology that was set in advance so long as the payment rate did not fluctuate based on referrals during the contract term.

CMS, citing the court in *Council for Urological Interests v. Burwell*, 790 F.3d 212 (DC. Cir. 2015), quoted the court's finding that Congress could not have intended this result because Congress knew how to protect fee schedules and time-based payment when it wanted to, as evidenced by the "under arrangements with a group practice" exception some historical context should be relevant here. Actually, what occurred with respect to the Conference Report was that the personal services and lease exceptions were drafted first and made their way through the various layers of the Congressional approval process before the draft was shared for comment. We were assured that because the word "aggregate" had been removed from the text (it was drafted based on the OIG safe harbor but with the critical difference of eliminating the word "aggregate"), fee schedules would remain permissible. Congressional staff did not want to take new language back through the approval process and so instead drafted the Conference language to be sure that the regulations would reflect the Congressional intent to maintain the right to maintain payment based on a fee schedule. The reason the separate exception for group "under arrangements" situations looks different is because of timing. That provision was added later and went through the approval process after the discussions about the need for fee schedule compensation occurred, and so it was included in the statutory language, not just in the Conference Report. As such, CMS should affirmatively recognize that fee schedules and other payment methodologies are set in advance and are not based on volume or value of referrals so long as the payment rate does not fluctuate based on referrals during the contract term.

Request for Information #12 – Thoughts on "Taking into Account the Volume or Value of Referrals" in the Context of Alternative Payment Models and Other Novel Financial Arrangements

As stated in response to RFI #7, to the extent there is any separate Alternative Payment Model exception, it needs to include an allowance for incentive-based compensation similar to the incentive "exception within an exception" in the personal services exception, but without the limiting language requiring enrollees and health plans as these terms are now defined. Alternative payment models will need to involve physician incentives to collaborate, coordinate, and provide cost effective care whether or not a health plan or its enrollees are involved.

Request for Information #13 – Barriers to Qualifying as a Group Practice

The statutory exception for in office ancillary services has been important in protecting a broad range of designated health services furnished by group practices. Group practices have long been instrumental in providing the first level of integration and care coordination for patients, offering convenient, timely access, patient centered care and one-stop shopping for a wide array of services, with an opportunity for greater coordination and often at a lower cost than otherwise available in a hospital. Removing this exception wholesale, as some may be suggesting, would serve to further distance physicians from their patients, work against care coordination, delay testing and treatment and ultimately unfairly limit competition. As such, group practices are worthy of continued protection for the furnishing of in office ancillary services to the full extent intended by the Stark statute.

A group practice structure is largely dictated by state law physician licensure and corporate practice of medicine requirements. The Stark statutory definition of group practice was broad, expressly recognizing a variety of ways in which a group of "two or more physicians" may be legally organized, including a "partnership, professional corporation, foundation, not-for-profit corporation, faculty practice plan, or similar association…" There was no explicit rejection of multi-organizational or multi-state structures, nor was there any statutory use of the phrase "single legal entity" as it is used in the regulations. Nonetheless, the Stark regulations ended up far more restrictive than the statute required or contemplated.

For instance, the term "foundation" is explicitly used in the statute. This statutory terminology was designed to protect "foundation-model" group practices in which a nonprofit foundation holds all the assets of the group, including the designated health services, except for the physicians, which are housed in a separate professional corporation which contracts exclusively with the foundation. This structure was designed to meet the "corporate practice of medicine" prohibitions in a number of states and operated for many years before the adoption of the Stark Law. Yet, in the final regulations, foundation model group practices were not recognized (except for carrying over the word "foundation" stripped of its meaning).

Similarly, many nonprofit hospitals had created physician "groups" by creating a division that employed physicians. Before the final Stark regulations were issued, many were of the view that the use of the word "nonprofit" and "similar association" in the statutory definition included sufficient flexibility to allow hospitals to have a physician division that would be considered a "group" and could share responsibilities and coordinated care incentives in the same manner permitted to groups. However, the final Stark regulations took a contrary position, providing that the entity be "operating primarily for the purpose of being a physician group practice. We ask that CMS allow hospitals who directly employ physicians to qualify its physician operations division as a "group practice" such that the financial pooling that promotes coordination and collaboration among physicians and other professionals that is permitted for group practices will be able to be used in a similar manner for hospital employed physicians.

Restrictions also exist with respect to multi-state group practice structures. CMS has provided limited guidance on what is considered a single legal entity, nonetheless its regulations allow physician practices that operate in more than one State, and which are comprised of multiple legal entities, to be considered a "single legal entity" for purposes of meeting the federal physician self-referral law's "group practice" definition provided certain conditions are met. Unfortunately, for physician investors who wish to have more flexible or innovative structures, one of those conditions is that the legal entities forming the group practice must be "absolutely identical as to ownership, governance, and operation." 42 C.F.R. § 411.352(a)(2). The legal entities also must be in contiguous states and multiple entities must be required under state licensure law.

This "absolutely identical" language was added to the regulation by CMS in 2004, as part of CMS's Phase II rulemaking. CMS modified the regulatory language in response to comments requesting clarification on the application of the single entity rule to group practices with offices in more than one State and which operate "through 'mirror' entities with identical ownership and

governance." 69 Fed. Reg. 16053, 16076 (Mar. 26, 2004). Essentially reiterating the current regulatory language, CMS stated, "As long as both entities are absolutely identical as to ownership, governance, and operation, the States in which the group is operating are contiguous, and the group uses multiple legal entities solely to comply with jurisdictional licensing laws, we will consider the two entities to be a single legal entity." *Id.* CMS, has not, however, provided additional guidance with regard to its position on "identical" ownership. Given the strict liability nature of the physician self-referral law and its severe penalties, the lack of guidance attached to this narrow description has prevented physicians from creating more flexible multi-state structures. Given the focus on coordination of care, population management, and the efficiencies achieved by large group practices, we respectfully request that CMS reconsider its position requiring identical ownership. We ask that CMS modify its rule requiring "absolutely identical" ownership to a more flexible standard requiring a simple majority of common shareholders. Specifically, we request that CMS include in its definition of "single legal entity" multi-state physician practices that are owned by the majority of the same shareholders, and irrespective of whether they are in contiguous states or whether state licensure law requires multiple entities.

We think that care coordination and integration can be advanced if existing models of integration, such as group practices, are permitted to proliferate geographically to the full extent permitted under the physician self-referral statute. The current geographic and ownership limitations are not dictated by the statute, yet operate to maintain care in a geographically siloed way, not taking into account efficiencies that can be generated on a larger scale. More flexibility in this area will allow group practices to vary ownership in a manner that will give local physicians more "skin in the game" with respect to patient care and care coordination, yet still under a majority ownership umbrella promoting cohesiveness of overall management.

Alternatively, if CMS still requires identical ownership or contiguous states, we seek clarity that a group practice that has set up contiguous multi-state entities to comport with state practice requirements and who has the same shareholders, may in fact vary the percentage of ownership in the various state entities among its shareholders. Although CMS has not previously clarified its position in this regard, the requirement of identical ownership could be read to apply only to the identity of the shareholders, meaning that the individual shares owned by the same set of shareholders could vary across the different multi-state entities forming the group practice.

This distinction is very significant because certain practices may, logically, wish to vary ownership across the different mirror state entities that collectively form their group practice depending on where, for example, a given physician shareholder actually practices.

We also believe that the definition of "group member" poses a substantial impediment to group practices. In its "group practice" definition, CMS requires that the "members of the group" meet certain regulatory requirements; significantly, it requires that substantially all of the "patient care services" of those who are members of the group be furnished through the group, and that members of the group personally conduct no less than 75 percent of the physician-patient encounters of the group practice. *See* 42 C.F.R. § 411.352. However, a physician only qualifies as a "member

of the group" during the time he or she furnishes "patient care services"[4] to the group. 42 C.F.R. § 411.351.

Preamble language from CMS's Phase I rulemaking attempts to clarify the application of this point, stating, by way of example, that a "hospital-based physician [owner of a group practice], who does not practice medicine as part of the group, is not a member of the group practice for purposes of the definitional tests." 66 Fed. Reg. 856 903 (Jan. 4, 2011). However, CMS further noted that such a nonparticipating physician owner is also not a member of the group for any other purpose, and thus would not be eligible to share in the group practice's overall profits. *Id.* (emphasis added). We also note that CMS has previously voiced concern about the potential for "sham group practice arrangements or physicians forming groups substantially for the purpose of profiting from DHS referrals," and thus has concluded that "a group practice owned by other functioning medical groups cannot meet the single legal entity requirement." 69 Fed. Reg. 16053, 16077 (Mar. 26, 2004).

Based on the above, it seems clear that a passive physician owner of hypothetical Group A, who does not furnish "patient care services" to Group A, would not be considered a "member of the group" for federal physician self-referral law purposes. What is not clear, however, is whether this remains true if the passive physician owner actively provides patient care services through another group practice, Group B (even where no referrals are made to Group A from Group B physicians). Because no referrals would be made from Group B physicians to Group A, such an arrangement would not appear to trigger the concerns voiced by CMS about potential sham arrangements designed to profit from referrals. It is also not clear that such passive physician owner should be deemed ineligible to share in a pro-rata share of Group A's overall profits (though the preamble language above suggests that this should be the case). The portion of the regulation governing profit shares does not require a physician to be a "member of the group" in order to be eligible to share in overall profits on a pro-rata share basis. Thus, the fact that the passive physician owner is not considered a member of the group of Group A should not disqualify the physician from being able to receive a pro-rata share of Group A's profits.

Accordingly, we ask that CMS clarify: (i) that a passive physician owner of a group practice who does not provide patient care services through that group, nor refer designated health services to that group, is not considered a member of that group for federal physician self-referral law purposes notwithstanding the fact that the same physician actively practices and/or owns another group; and (ii) that this passive physician owner remains eligible to receive pro-rata profit sharing from the original group (i.e., the group through which he does not provide patient care services and to which he does not refer designated health services).

[4] "Patient care services" are defined as "any task performed by a physician in the group practice that address the medical needs of specific patients or patients in general, regardless of whether they involve direct patient encounters or generally benefit a particular practice…[and] can include, for example, the services of physicians who do not directly treat patients, such as time spent by a physician consulting with other physicians or reviewing laboratory tests, or time spent training staff members, arranging for equipment, or performing administrative or management tasks." 42 C.F.R. § 411.351.

Request for Information #14 – Thoughts on the Utility of the Current Exception for Remuneration Unrelated to DHS

When Congress enacted the Stark Law, a broad compensation exception was included for remuneration which is provided by a hospital to a physician if such remuneration does not relate to the provision of designated health services. 42 U.S.C. § 1395nn(e)(4). However, when CMS adopted the regulations related to this provision, CMS completely eviscerated the utility of this exception by expanding what constitutes "related to the furnishing of DHS" to the extent that it makes the exception meaningless and renders even arrangements that involve no federal health care programs or no health care services at all impermissible under the Stark Law absent another exception. It was the evisceration of this exception that has resulted in many of the consequences to private pay programs that were not intended by Congress. If any portion of what the hospital is paying the physician can be reported by the hospital on its cost report, or if the payments are only made to a subset of physicians, regardless of the composition or purpose of this subset of physicians, the exception is arguably not available under CMS's narrow interpretation. Since virtually everything a hospital spends goes on its cost report, and virtually everything a hospital would want to do with physicians regarding innovation would involve a subset of physicians, this exception is largely unavailable. CMS also prevented the use of this exception under a "hierarchy of exceptions" theory that a more specific exception must be used if relevant.

We believe that CMS lacks the statutory authority to further limit this exception. Indeed, this exception does not even include the language in other statutory exceptions giving the Secretary the authority to impose other requirements by regulation as needed to protect against program or patient abuse. Congress knew how to give the Secretary limiting authority in certain of the exceptions, yet chose not to do so with respect to this exception. CMS should honor this choice and retract its limited interpretation of this statutory exception.

Request for Information #15 – Additional Clarification for Other Exceptions

In 42 U.S.C. 1395nn(e)(8), Congress included broad protection for payments made by a physician to a (1) laboratory in exchange for the provision of clinical services, or (2) to an entity as compensation for other items or services if the items or services are furnished at a price that is consistent with fair market value. However, in Phase II, CMS modified this exception to apply only where no other compensation exception is available under the regulations, creating what is known as a "hierarchy of exceptions". This restriction leaves many legitimate purchases of items or services by a physician from a DHS entity without an available exception. 72 Fed. Reg. at 51,057.

We believe that CMS lacks the statutory authority for requiring that certain exceptions be used for certain things, and in particular in creating a hierarchy of exceptions. Indeed, this exception does not even include the language in other statutory exceptions giving the Secretary the authority to impose other requirements by regulation as needed to protect against program or patient abuse. Instead, it should be permissible for an arrangement to meet any exception without providers and their legal counsel having to "guess" what the most relevant exception may be.

In Phase III, CMS expanded the scope of the fair market value exception to cover payments to an entity from a physician, as well as payments from an entity to a physician. Thus, what looks like an expansion of the regulatory exception for fair market value was actually a further restriction on the once very broad "(e)(8)" statutory exception for payments by a physician to an entity, which only requires payment at fair market value. Congress plainly knew how to require standards beyond fair market value, as it did with other exceptions, when it chose to require only a fair market value standard in this exception. CMS should honor Congress's choice and return this exception to Congress's original intent.

Request for Information #16 – The Role of Transparency

We have always believed that transparency with respect to physician ownership and other financial arrangements goes a long way to protect against program or patient abuse. With health care increasingly recognizing the importance of patient responsibility, and patients increasingly wanting to be active participants in how and where they receive their health care, we think that transparency can assist patients in being informed decision-makers with respect to their health care, and play a greater role in protecting against program or patient abuse while allowing CMS to grant increasing flexibility under the Stark Law to health care organizations.

CMS already has recognized the role transparency plays in informed decision-making by incorporating disclosure requirements with respect to certain imaging services identified as "radiology and certain other imaging services" on the list of CPT/HCPCS Codes. 42 C.F.R. § 411.355(b)(7). We do not, however, believe that listing five other suppliers is necessary to accomplish the desired transparency. Therefore, we would request CMS to consider creating greater flexibility in designing transparency requirements going forward.

Request for Information #17 – Thoughts on Designing a Model to Test the Effect of Transparency

We question whether there is a need to test the effect of transparency. Our experience throughout the years of assisting clients with respect to disclosure of financial relationships to patients is that physicians take very seriously their responsibility that health care entities that they own provide quality care, and that patients who are given disclosures look back to the physician owner if they have any complaints about the facility to which they are referred. Disclosure puts a "face" on the often anonymous world of health care and a place for patients to turn if they are dissatisfied. Physicians with financial relationships also tend to pay more attention to providing seamless, coordinated care between their practices and health care entities with which they have a financial relationship. Although CMS may view that as just an increase in referrals, we believe there is a level of personalized care that becomes part of the patient experience when physicians have "skin in the game," and that transparency elevates the conversation between physician and patient in a manner that requires no testing.

Request for Information #18 – Compliance Costs for Regulated Entities

The cost of compliance to health care organizations implicated under the physician self-referral law is immense. We are perplexed every time CMS does its regulatory impact statement about physician self-referral law estimating the cost of compliance. It so underestimates the hours that will need to be spent, and the resources that will need to be committed to reviewing and understanding the regulations as well as the organization's physician financial relationships to be sure they remain in compliance.

Indeed, over the last 25 years, there have been multiple restructurings undertaken every time CMS comes out with a new interpretation of the law that expands the reach of designated health services, or limits the availability of an exception.

In addition, parties to a transaction, such as a hospital acquisition, spend a lot of time and money in performing diligence reviews of every arrangement for procedural Stark Law violations like unsigned agreements, late payments, etc. This often results in cumbersome reviews of multiple arrangements, including old relationships since some of the exceptions CMS crafted inexplicably can only be used once in a three year time period. In addition, as a way to minimize risk, often potential buyers are requiring self-disclosures be made to CMS for procedural violations, like late signatures or expired agreements. This often requires the seller to place into reserve large escrows based on the total dollar amount of physician referrals, despite that fact that CMS self-disclosures are routinely settled on fractions of the Medicare quantification. Because of the lag in response time by CMS, these large sums of money can sit in escrow for many years while the parties await the results of CMS's review and settlement of the disclosure. All of this comes at a time when providers should be spending more time and resources on providing quality, cost effective care. The millions of dollars held in escrow or spent to diligence procedural defects in contracts could be used to invest in health care infrastructure, such as enhanced electronic medical records or to increase staffing.

While CMS has reformed certain aspects of the Stark Law to reduce the burden and improve clarity regarding certain requirements within the exceptions, the analysis still requires a highly detailed review of the facts and circumstances of the arrangement and all available documentation. While this may have reduced the number of self-disclosures that are ultimately made, it does not alleviate the time and resource burden on providers to conduct an analysis of compliance with technical Stark requirements. Moreover, reducing the documentation burden associated with the Stark Law would be consistent with CMS's other initiatives to streamline patient service documentation requirements for physicians. 83 Fed. Reg. 35704, 35832-35848 (July 27, 2018).

We saw the burdensome cost of compliance have its first effect with group practices, many of which stopped providing one stop shopping for their patients because the regulatory requirements to do so were too onerous. Many have even thrown in the towel on private practice altogether. The power of the pen stroke over the years in eliminating certain forms of physician participation also has created a chilling effect on physician willingness to invest in health care. From a hospital perspective, there is a huge industry now in tracking compliance with the Stark requirements for physician contracts, since CMS in 2007 imposed stringent requirements on the personal services

exception regarding expired contracts and timely signature which are standards far beyond what one would see in the business world and what the Stark statute requires. None of these requirements were dictated by the statute, yet when CMS relaxed the requirements several years ago, it was only done prospectively, not retroactively, meaning that vestiges of these burdensome requirements still linger today.

Request for Information #19 – Recent studies

No comments at this time.

Request for Information #20 – Measuring the Effectiveness of the Physician Self-Referral Law

No comments at this time

Additional Comments

Medicaid

In 1998, as part of the "Stark II Proposed Regulations," CMS articulated its position that individuals and entities are not precluded from referring Medicaid patients or from billing for designated health services that otherwise would be prohibited under the Medicare Stark Law prohibition. Instead, CMS took the position that, in these circumstances, the state Medicaid programs may pay for these services even though the states will not be eligible to receive federal financial participation dollar for these services:

> … we do not believe these rules and sanctions apply to physicians and providers when the referral involves Medicaid services. The first part of section 1903(s) prohibits the Secretary from paying FFP to a State for designated health services furnished on the basis of a referral that would result in a denial of payment under Medicare if Medicare covered the services in the same way as the State plan. This part of the provision is strictly an FFP provision. It imposes a requirement on the Secretary to review a Medicaid claim, as if it were under Medicare, and deny FFP if a referral would result in the denial of payment under Medicare.

See 63 Fed Reg 1659, 1704 (January 9, 1998).

This position is supported by the statute itself. The referral and presentment prohibitions in SSA § 1877 apply by their terms only to those made "under this subchapter," which refers to the Medicare program. *See* 42 U.S.C. §1395nn(a)(1). Moreover, it is significant that when Congress amended the Stark Law in 1992 to include the cross reference to Stark in SSA §1903, Congress could have instead modified SSA §1877 to apply to Medicare "and Medicaid." However, Congress did **not** modify the statute in this way but simply addressed the application of Stark to whether states would be eligible for FFP payments.

In 2001, when CMS issued the Stark II Phase I Final Regulations (66 Fed. Reg. 856 (January 1, 2001)), CMS did not address the issue of the application of the Stark to the Medicaid program. Then in 2004, when CMS issued the Stark II Phase II Final Regulations, CMS stated that "in the interest of expediting publication of these rules, we are reserving the Medicaid issue for a future rulemaking …." See 69 Fed. Reg 16054, 16055 (March 26, 2004). However, over the course of the last 14 years, CMS has still not addressed the application of the Stark Law to the Medicaid program.

At the same time, there have been a number of courts that have taken it upon themselves to interpret the Stark Law as applying to Medicaid claims and as a result can serve as a basis for a false claims action. *See, e.g., United States ex rel. Schubert v. All Children's Health System* 2013 US Dist LEXIS 164075 (M.D. Fla. Nov. 15, 2013).[5]

Therefore, we believe that the time is ripe (if not "overripe") for CMS to address and finalize in regulations its position that the statute requires that states adopt a prohibition that reflects 42 U.S.C. § 1395nn and that 42 U.S.C. § 1395nn does not directly impacted on Medicaid because states have the ability to choose whether or not to seek federal financial participation dollars.

Stark/AKS Coordination

We have long been concerned about the discrepancies between the various exceptions in the Stark Law and the federal health care program Anti-kickback Statute. We also have positively acknowledged the times when CMS and OIG have issued rules that apply to both, such as the Electronic Medical Record safe harbor as well as the Shared Savings waivers. We request that CMS consider the ways in which it might provide Stark Law protection for various arrangements recognized under the Anti-Kickback Statute safe harbors. For instance, there is no small entity investment safe harbor under the Stark Law. The OIG's safe harbors are generally extremely difficult to fit into, and so CMS should consider it could grant a Stark Law exception for arrangements that fit within an OIG safe harbor.

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[5] For purposes of this RFI, we do not set out our position as to why we believe that violation of the Stark Law, even in the Medicare context, should not be viewed as basis for bringing a cause of action under the federal false claims act. If you would like, we are prepared to provide you with our legal analysis and position on this issue under separate cover.

We appreciate the opportunity to comment on this Request for Information. We again reiterate our offer/suggestions that we arrange a time to meet in person to discuss these issues. We look forward to hearing from you.

Sincerely,

Epstein Becker & Green, P.C.

Carrie Valiant

David Matyas

Jason Christ

Anjali Downs

cc: Lisa O. Wilson (CMS)
Leonard Lipsky (EBG)
Bonnie Scott (EBG)
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