HEALTH SYSTEMS FOR STARK REFORM

August 24, 2018

VIA ELECTRONIC SUBMISSION (www.regulations.gov)

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

Re: CMS–1720–NC; Request for Information Regarding the Physician Self-Referral Law

Dear Ms. Verma:

On behalf of the coalition Health Systems for Stark Reform ("HSSR"), we submit the following comments in response to the above-referenced Request for Information (the "Stark RFI") from the Center for Medicare & Medicaid Services ("CMS"). The HSSR was convened by the Health Management Academy several years ago and its members have been constructively engaged in developing and advocating for Stark reform on Capitol Hill and with HHS since that time. HSSR's founding members include Adventist Health System, Advocate Aurora Health, Ascension, Intermountain Healthcare, and UnityPoint Health, representing more than 250 hospitals nationwide. Beyond these health systems, many others have supported the efforts of HSSR and have provided input supporting the information provided in these comments. The HSSR has benefitted in all its efforts, including the preparation of these comments, by the counsel of two Stark Law experts, Troy Barsky of Crowell & Moring, LLP, who is a former Director of the Division of Technical Payment Policy at CMS, and Kevin McAnaney, now in private practice after serving as Chief of the Industry Guidance Branch of the Office of Counsel to the Inspector General of the Department of Health and Human Services. We commend CMS for seeking to modernize its Stark Law regulations to move from a fee-for-service payment system to one that rewards and incentivizes value-based care. Our comments below address general problems created by the application of the Stark Law in the new era of health care reform, and then set forth specific answers to questions posed in the RFI. In addition, we provide regulatory modification proposals as Appendices A and B to this letter consistent with our comments and responses to the RFI's questions.

General Considerations

The Physician Self-Referral Law (commonly known as the "Stark Law")[1] was enacted to regulate financial arrangements among physicians (or their immediate family members) and certain health care providers in a reimbursement world that paid providers based on the volume of services provided. As Medicare and the health care economy are moving to payment arrangements that focus on value- and quality-based outcomes including clinically integrated networks, accountable care organizations ("ACOs"), or bundled payment arrangements involving DHS entities and physicians (collectively, "value-based arrangements"), and as CMS and Congress look to shift the financial risk of healthcare delivery into the provider community, the Stark Law has proved to be an impediment to them. Its breadth, complexity and inscrutability has created a minefield for the health care industry due to its huge financial penalty risks and its complicated, unclear provisions. These risks result in health care providers avoiding arrangements that could implicate the Stark Law even though the arrangements advance the purposes of the ACA and comply with applicable ACO regulations. Because the Stark Law is a strict liability statute, it does not matter whether the parties to an arrangement "intended" to comply with the law. This strict liability discourages participation in value-based arrangements, where care coordination among hospitals and physicians is necessary to advance preset quality and cost goals.

The Stark Law's origins in a volume-based reimbursement environment often conflict with the new value-based arrangements that are on the rise after the enactment of the Affordable Care Act in 2010 ("ACA") and the Medicare Access and CHIP Reauthorization Act in 2015 ("MACRA"). The Stark Law's existing exceptions often cannot adequately protect these arrangements from Stark Law risk, and given the risk profile of entering into arrangements that might implicate the Stark Law, many proposed arrangements are left on the drafting room floor. Even if providers attempt to fit value-based arrangements into the Stark Law's existing legal parameters, its definitions contain ambiguities that are too risky for providers to attempt to overcome in light of the Stark Law's punitive penalty structure. As we shift towards a value-based system, where we are incentivized for the outcomes and cost efficiency of the care provided, the Stark Law impedes the implementation of value-based care models by either prohibiting essential financial arrangements or continuing a risk environment in which providers are not interested in taking on Stark Law risk. This is evident by the fact that Congress saw the need to give the Secretary authority to issue regulatory waivers for innovative payment and service delivery models, specifically for CMS's Medicare Shared Savings Program ("MSSP"), Bundled Payments for Care Improvement ("BPCI") Model, and the Pioneer Accountable Care Organization ("ACO") Program. The need for and existence of these waivers demonstrate the

[1] 42 U.S.C. 1395nn.

inherent conflict between payment reform and the Stark Law and its implementing regulations. While these waivers provide necessary protection for participants in the aforementioned programs, because the waivers are merely temporary and are only granted on a piecemeal, program-by-program basis, they do not give the clarity or the permanence of the protections that the provider community needs in order to fully embrace value-based arrangements.

In addition, many arrangements that exist outside of the MSSP or other CMS demonstration programs seek to advance value-based goals but face several challenges due to the Stark Law's restrictions. This is especially true because value-based arrangements often rely upon coordinated, agreed-upon internal referral processes outside of the context of traditional managed care arrangements, such as with providers within a contractual network or with affiliated providers. Providers cannot provide different standards of care to patients based on the government or commercial sponsor of the health benefit plan of the patient. The proposals for Stark reform need to expressly apply to commercially-provided health care plans and self-insured health plans.

For these reasons, we propose a new exception to the Stark Law for "Value-Based Arrangements" that would protect a broad range of value-based payment models. This exception, as described in Appendix A, would provide certainty to providers seeking to enter into arrangements that promote "Value-Based Goals," which would include the same attributes as are currently included – accountability for care, coordination of care, and investment in infrastructure and redesigned care processes.

Further, while the Stark Law's "volume or value," "fair market value" and "commercial reasonableness" standards were well-intentioned standards in a FFS 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 staff. We recommend that CMS clarify these terms and adopt bright line rules surrounding the Stark Law, consistent with the original Congressional intent, as expressed by Congressman Pete Stark himself:

> "What is needed is what Lawyers call a bright line rule to give providers and physicians unequivocal guidance as to the arrangements that are prohibited. If the Law is clear and the penalties are substantial, we can rely on self-enforcement. Few physicians will knowingly break the Law. The Ethics in Patient Referrals Act provides this bright line rule."[2]

We include in Appendix B several additional proposals to clarify and expand the existing exceptions to the Stark Law and advisory opinion processes to allow for increased care coordination between hospitals and physicians in a value-based payment environment.

Comments in Response to Specific Questions

1. ***Please tell us about either existing or potential arrangements that involve DHS entities and referring physicians that participate in alternative payment models or other novel financial arrangements, whether or not such models and financial arrangements are sponsored by CMS. Please include a description of the alternative payment model(s) and novel financial arrangements if not sponsored by CMS. We recommend that you identify concerns regarding the applicability of existing exceptions to the physician self-referral law and/or the ability of the arrangements to satisfy the requirements of an existing exception, as well as the extent to which the physician self-referral law may be impacting commercial alternative payment models and novel financial arrangements. Please be specific regarding the terms of the arrangements with respect to the following:***

    - ***The categories/types of parties (for example, the parties are a hospital and physician group with downstream payments to individual physicians in the group).***
    - ***Which parties bear risk (and how and to what extent) under the arrangement (for example, per capita payments from a payor are paid to a hospital with downstream payments on a discounted fee schedule to individual physicians; a bundled payment from a payor for all hospital and physician services is split between a hospital and physicians based on a predetermined percentage; hospital-sponsored gainsharing program where participating physicians share in cost savings; physician incentive payments are available for achieving predetermined metrics; etc.).***
    - ***The scope of the arrangement (for example, non-Medicare beneficiaries only, Medicare beneficiaries only, or all patients regardless of payor).***
    - ***The timeframe of the arrangement (for example, ongoing or for a duration that aligns with a payor-specific initiative).***
    - ***Items and services provided under the arrangement and by whom (for example, infrastructure, such as electronic health records technology; physician services; care coordination services; etc.).***
    - ***How the arrangement furthers the purpose of the alternative payment model or novel financial arrangement.***
    - ***Whether and, if so, how the arrangement mitigates the financial incentives for inappropriate self-referrals, and/or overutilization of items and services, and patient choice.***

The provider community has developed a logical reluctance to enter into arrangements that could implicate the Stark Law due to the lack of clarity about what is permitted and the huge financial risk of Stark Law violation or

investigation, as well as possible False Claims Act ("FCA") liability. When arrangements aligning financial incentives are proposed, even if a waiver applies to the arrangement, providers are reluctant to participate because of the concern about Stark Law/FCA claims and the non-permanent nature of the waivers.

These arrangements or parties to the arrangements may not be participating in the MSSP or other CMS demonstration programs where fraud and abuse waivers are available. DHS entities and physician partners in these value-based arrangements are concerned that the provision of care-related improvements may be perceived as in-kind payments in exchange for referrals by physicians in violation of the Stark Law.

For instance, with respect to the "fair market value" requirements imposed in the personal service arrangements exception, a hospital seeking to finance the administrative operations and care-related improvements provided to the other parties to a value-based arrangement may find it prohibitive to adhere to the strict terms of a Stark Law exception. This is because, in many instances, care improvement items or services are provided below fair market value to participating providers that would otherwise not be able to afford them. Infrastructure investments are necessary for the success of these value-based arrangements. And even though one entity is providing an up-front benefit at below cost, it ultimately leads to better and higher quality care to all patients. Therefore, the "fair market value" requirements in many of the Stark exceptions may pose a barrier to care improvements necessary to maintain efficiency and coordination among providers in a value-based arrangement.

Further, because of the potential imbalance of contributions of all parties to a value-based arrangement, any potential indirect benefit to the value-based arrangement's participants and affiliates may also implicate the "commercial reasonableness" requirements under the Stark Law's exceptions. A party within a value-based arrangement may want to distribute brochures, emails, or other materials about fellow parties in that same arrangement to patients, e.g., where patients are transitioning from one treatment setting to another, without charging the other party for the costs of these marketing materials. The desire to promote and maintain defined referral patterns may be premised on the parties' decision that intra-arrangement referrals will result in better care and lower costs for patients. If the costs of the marketing materials are incurred without repayment, this could directly conflict with the requirement that arrangements must be commercially reasonable "even if no referrals are made" between the parties. Because the financial benefit is arguably created between a DHS entity and a referral source, where the referring physicians are not paying for the benefit, this arrangement could implicate both the fair market value and commercial reasonableness requirements under the Stark Law.

When the parties to the proposed arrangement understand the potential risk, the likelihood they will take the risk or rely on the protection of the 'temporary' waiver is reduced. Parties are hesitant to enter into high cost arrangements that involve the investment of significant resources, due to the greater problems that are created if the Stark Law risk becomes reality or if the regulations providing the waiver are eliminated. So many times, the best proposals for arrangements are the most likely to be missed. For instance, an electronic health records system consistent with an

ACO's electronic health records could be provided for care continuity, consistency of information, accuracy, and patient convenience. While an electronic health records system can be provided to employed physicians, the risk profile for providing one to independent physicians is such that, even if it is covered by an appropriate waiver, independent physicians are much less likely to be interested because of the risk of the waivers being discontinued. Physicians may be concerned about the ramifications to the group of switching electronic health records systems and then having to possibly switch back or buy the ACO's electronic health records system later when, but for the ACO's proposal, the group wouldn't have switched.

As we move towards a value-based reimbursement system in federal health care programs, value-based arrangements should encompass all physicians, both employed and independent. The Stark Law provides some protection for employed physicians, yet for affiliated or contracted physicians, the same protections largely do not exist. That means that health systems can more easily enter into value-based arrangements with employed physicians, but cannot enter into the same relationships with independent physicians. This result is contrary to the goal of value-based care to avoid market consolidation. This restriction likely prohibits compensation arrangements like the following:

- A recruitment agreement between a medical practice group and a hospital-led ACO with an income guarantee and additional practice management resources to support the recruitment of additional physicians into the ACO.
- Compensation arrangements that provide remuneration to physicians in part for cost-effective use of mid-level practitioners and junior medical staff.
- Incentives for physicians to report data to their Accountable Care Organization (ACO) in a compatible format.
- Provision of mental health services or other service providers within primary care clinics.

Another significant barrier to health providers' engagement in alternative payment models is that 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, for example, the hospital partner cannot insulate the physician participants from the financial risk of development costs, the physicians cannot realize any benefit from their efforts as the income earned by the organization from cost savings or quality performance bonus payments are absorbed by the organization's indebtedness to the hospital partner. As a result, physicians are not motivated to participate.

In summary, virtually any arrangement that is currently covered by ACO waivers could implicate the Stark Law; otherwise, there would be no need for the parties to create the waiver. That same risk prevents many arrangements

from being implemented due to Stark Law risk. By definition, aligning financial interests of physicians and hospitals is going to implicate the fair market value, commercial reasonableness, and volume or value provisions of the Stark Law. The Stark Law's current provisions do not provide sufficient protection for many value based arrangements and therefore, we encourage CMS to make the necessary changes needed to facilitate healthcare modernization.

2. ***What, if any, additional exceptions to the physician self-referral law are necessary to protect financial arrangements between DHS entities and referring physicians who participate in the same alternative payment model? Specifically—***

   - ***What additional exceptions are necessary to protect accountable care organization models?***
   - ***What additional exceptions are necessary to protect bundled payment models?***
   - ***What additional exceptions are necessary to protect two-sided risk models in a FFS environment?***
   - ***What additional exceptions are necessary to protect other payment models (please explain the nature and design of such models)?***
   - ***How (if at all) should a new exception (or exceptions) protect individual DHS referrals (see 42 CFR 411.355), ownership or investment interests (see 42 CFR 411.356), or compensation arrangements (see 42 CFR 411.357)?***

We recommend creating a "Value-Based Arrangements" exception as set forth in Appendix A to promote a wide-range of coordinated relationships and other related development and operations activities among providers, including APMs and risk-sharing arrangements, commercial ACOs, clinically-integrated networks, and bundled payments. The Value-Based Arrangements exception would provide certainty to parties entering into risk-sharing arrangements to promote Value-Based Goals. "Value-Based Goals" include:

- Promotion of accountability for quality, cost, coordination, and overall patient care;
- Management and coordination of patient care administered, furnished, or arranged by the parties to the arrangement; and
- Encouragement of investment in infrastructure and redesigned care processes for high quality and efficient service delivery for patients.

The exception would allow risk-sharing arrangements that capitate payments per patient, agree on a predetermined percentage of the payments under the arrangement, or use certain financial incentives. Where the parties share the

risk and are dedicated to Value-Based Goals, there is less risk of overutilization or inappropriate self-referrals because payment is no longer based on the volume of items or services rendered.

We believe that the Value-Based Arrangements exception is sufficiently flexible to protect a wide range of payment models. Undertaking a piecemeal approach for different value-based or risk-sharing models would ultimately limit flexibility and innovation.

Further, we believe that this broad exception that protects the financial arrangement based on the goals rather than on the mechanics of the arrangement is the better approach. Protection of individual referrals without protecting the underlying financial arrangement introduces uncertainty and limits the usefulness of the exception.

3. ***What, if any, additional exceptions to the physician self-referral law are necessary to protect financial arrangements that involve integrating and coordinating care outside of an alternative payment model? Specifically, what types of financial arrangements and/or remuneration related to care integration and coordination should be protected and why? How (if at all) should a new exception (or exceptions) protect individual DHS referrals (see 42 CFR 411.355), ownership or investment interests (see 42 CFR 411.356), or compensation arrangements (see 42 CFR 411.357)?***

As discussed above, we recommend that CMS protect any financial arrangements that meet the requirements of the Value-Based Arrangements exception, as proposed in Appendix A. This exception is sufficiently broad as to apply to financial arrangements that involve integrating and coordinating care outside of an alternative payment model, so long as it achieves one or more of the Value-Based Goals.

4. ***Please share your thoughts on the utility of the current exception at 42 CFR 411.357(n) for risk-sharing arrangements.***

The current risk-sharing exception is useful for certain carefully structured arrangements involving commercial and self-insured enrollees. Yet, only focusing on "enrollees" limits the utility of this exception. Expanding the definitions to include Medicare and Medicaid fee-for-service patients would expand its utility. Even so, the risk-sharing exception is only a supplement to, and not a substitute for, a broader value-based payment exception, like the one proposed in Appendix A.

5. ***Please share your thoughts on the utility of the special rule for compensation under a physician incentive plan within the exception at 42 CFR 411.357(d) for personal service arrangements.***

Like the risk-sharing exception, the proviso in the personal services exception for physician incentive plans, is useful in certain limited circumstances. It too is limited to enrollees of commercial & self-insured plans and should be expanded to include value-based arrangements involving Medicare and Medicaid fee-for-service reimbursement.

CMS should also make clear that physicians that are employed by a health system can also have a physician incentive plan in their compensation without triggering a "volume or value" issue.

6. ***Please share your thoughts on possible approaches to address the application of the physician self-referral law to financial arrangements among participants in alternative payment models and other novel financial arrangements. Consider the following:***

   - ***Would a single exception provide sufficient protection for all types of financial arrangements?***
   - ***Would a multifaceted approach that amends existing exceptions and/or establishes new exceptions be preferable?***
   - ***Would such a multifaceted approach sufficiently allow parties to identify and satisfy the requirements of one (or more) applicable exceptions in order to protect individual DHS referrals, ownership or investment interests, and/or compensation arrangements?***

We recommend adoption of a single Value-Based Arrangement as discussed above and provided for in Appendix A. A single and clear exception would reduce confusion among providers and minimize the administrative costs associated with proving compliance with different exceptions and greatly increase the likelihood that providers will feel confident enough that they will be willing to enter into appropriate arrangements that they have previously avoided due to Stark Law risk. Providing more exceptions and waivers to the existing Stark Law would only add additional layers of complexity into what is already a byzantine system of thousands of pages of regulations and guidance documents that continually exacerbate the unintended consequences the law is causing today.

For the Value-Based Arrangements exception to be truly valuable, we recommend that it not be limited to arrangements only involving health providers. Rather, the exception should recognize the new role of innovative technologies and other partnerships that are now driving the trend towards value-based care. Collaborations with manufacturers, startups, and developers should therefore be included in the development of new models.

Further, we recommend that CMS undertake the following additional changes to the Stark Law as provided for in Appendix B:

- Clarify the scope of the term "services" in the personal services arrangement and physician payments exceptions. (Items 1-2)
- Use the advisory opinion process to clarify and give certainty to providers regarding the proper interpretation of the regulations. (Item 3)

- Clarify the terms "volume or value," "fair market value," "commercial reasonableness," "signed by the parties," and "compensation arrangement." (Items 4-7 and 11)

- Clarify that consultations and resulting orders and plans of care in the hospital by non-admitting physicians that do not result in additional Medicare charges are not subject to disallowance under the Stark Law. (Item 6)

- Clarify that in the group practice context, the productivity bonus may be based on the services personally performed by another physician in the group practice. (Item 8)

- Provide more definite boundaries for the period of claims disallowance for Stark Law violations. (Item 9)

7. ***In the context of health care delivery, payment reform, and the physician self-referral law, please share your thoughts on definitions for critical terminology such as—***

- ***Alternative payment model***
- ***Care coordination***
- ***Clinical integration***
- ***Financial integration***
- ***Risk***
- ***Risk-sharing***
- ***Physician incentive program***
- ***Gainsharing***
- ***Health plan***
- ***Health system***
- ***Integrated delivery system***
- ***Enrollee***

Our proposed regulatory changes are attached as Appendices A and B and do not require redefining these terms. Therefore, we encourage CMS to focus on our regulatory proposals rather than defining these terms.

8. ***Please identify and suggest definitions for other terminology relevant to the comments requested in this RFI.***

We recommend adding a definition for "signed by the parties" to clarify the signature requirement under the Stark Law and provide guidance on when a "signed" agreement exists for purposes of determining compliance. We propose in Appendix B, item 7, that the "signed by the parties" requirement be met if there is any name, word,

mark, or symbol executed or adopted by a person with present intention to authenticate a writing or if there is any agreement between the parties to the terms of price and services reflected in a group of contemporaneous writings.

9. ***Please share your thoughts on possible approaches to defining "commercial reasonableness" in the context of the exceptions to the physician self-referral law.***

The Stark Law's requirement that physician compensation arrangements be "commercially reasonable" is extremely challenging for health care providers to meet. This requirement was initially intended to ensure that any compensation paid to physicians was for an arrangement that would be desirable even if no referrals were expected or anticipated between the physician and DHS entity. In other words, the "commercially reasonable" requirement confirmed that the arrangement was not a sham designed to cover payments for referrals. Yet, the government has asserted that where payments result in a loss in "profitability" to a party to the arrangement, the arrangement violates the "commercially reasonable" standard under the Stark Law. This legal interpretation flies in the face of health systems' reasonable business decisions to pay some practices at a loss to provide comprehensive higher quality care for patients. This interpretation prohibits arrangements like the following:

- Compensation offers to physicians in independent contractor arrangements with DHS entities even where the compensation being paid is fair market value and does not take into account referrals between the parties;

- A health system's compensation arrangement with physicians where physicians' professional fees did not cover salaries even where salaries paid were well within the range of fair market value; or

- Compensation payments by health system to some physician practices at a loss in order to provide a comprehensive network of providers to manage care for their patients.

We propose in Appendix B, item 4, that CMS interpret "commercial reasonableness" to mean that the services or items purchased or contracted for are useful in the purchasing or contracting party's business and purchased or contracted and are the kind and type of items or services in similar arrangements between similarly situated entities. This change will allow health providers to enter into clinical integration arrangements that benefit patient care, even if the arrangement viewed in isolation does not generate income. So long as the physician's compensation is fair market value and does not vary with volume or value of referrals, the risk of overutilization is minimized.

10. ***Please share your thoughts on possible approaches to modifying the definition of "fair market value" consistent with the statute and in the context of the exceptions to the physician self-referral law.***

As we proposed in Appendix B, item 5, we recommend that CMS redefine "fair market value" so that an annual or hourly payment for a physician's personal services are considered to be "fair market value" if the hourly payment is

established using an annual or hourly rate determined at or below the 75th percentile national compensation level for physicians with the same physician specialty (or, if the specialty is not identified in the survey, for general practice) in any national survey of physician compensation recognized by HHS. This should *not* lead to the presumption that hourly payment above the 75th percentile national compensation level for physicians with the same physician specialty (or, if the specialty is not identified in the survey, for general practice) in any national survey of physician compensation, recognized by the Secretary is above "fair market value."

CMS should also establish that a compensation arrangement for a physician's personal services is presumed to be "fair market value" absent clear and convincing evidence to the contrary. Currently, the Stark Law requires providers to demonstrate that all arrangements meet "fair market value," regardless of whether there is any evidence proving the contrary. The presumption that every arrangement among providers is inappropriate places significant burden on providers, who must procure extensive documentation to demonstrate compliance with such requirement, and even then are not protected from challenges.

Often, a hospital (one type of DHS entity) finances all, or nearly all of the administrative operations and care-related improvements provided to the other members of a value-based arrangement. As mentioned previously, these resources contributed by the DHS entity or any other participant in a value-based arrangement may be difficult to quantify in value and usage on an individual entity or provider basis. This makes it difficult to adhere to the strict terms of a Stark exception because it would require a party-by-party determination of the "fair market value" of the resource, as well as an evaluation of each party's reciprocal contribution. In other words, failure to identify a fair market value of a benefit is fatal under the Stark Law.

11. ***Please share your thoughts on when, in the context of the physician self-referral law, compensation should be considered to "take into account the volume or value of referrals" by a physician or "take into account other business generated" between parties to an arrangement. Please share with us, by way of example or otherwise, compensation formulas that do not take into account the volume or value of referrals by a physician or other business generated between parties.***

It is difficult to structure payment methodologies that reward physicians for engaging in referral behaviors in the short-term that would result in decreased costs, elimination of unnecessary care, and more cost-effective care in the long run, because of concerns that such payment structures would be deemed to take into account "the volume or value" of care in Stark Law. The "volume or value" parameters in the Stark Law appear to prohibit these actions even if they would result in better quality care or lower utilization of DHS overall. The types of arrangements prohibited would include:

- Rewards to physicians in a value-based arrangement for adherence to "best practices" protocols for inpatient care, as such payments may indirectly "take into account" both the volume and value of such

referrals if the protocol results in additional services delivered at hospital, even if the services improve quality of care;

- Agreements with preferred providers who would commit to certain metrics for clinical capabilities and medical coverage, communication and collaboration, access and transitional care management, and quality performance measures; or

- Payments to physicians of a portion of realized shared savings through a readmissions reductions program or other cost saving or gainsharing program (which could indirectly incentivize physicians to make referrals to the hospital).

As proposed in Appendix B, item 11, we recommend that CMS clarify that a compensation arrangement will be deemed not to take into account the "volume or value" of referrals if compensation is fair market value at the inception of the arrangement and does not increase or decrease with the volume or value of past or anticipated referrals during its term. We also propose that CMS clarify that a physician bonus is not considered to take into account the volume or value of referrals solely because the physicians' professional service is related to or correlates with the physician's DHS referrals, such as with surgeries performed in a hospital or evaluation and management services performed in a provider-based clinic. Finally, we request that CMS clarify that certain well-known compensation arrangements do not implicate the volume or value standard including salaries, relative value unit ("RVU") payments, and a percentage of net income based on personally performed services.

12. ***Please share your thoughts on when, in the context of alternative payment models and other novel financial arrangements, compensation should be considered to "take into account the volume or value of referrals" by a physician or "take into account other business generated" between parties to an arrangement. Please share with us, by way of example or otherwise, compensation formulas that do not take into account the volume or value of referrals by a physician or other business generated between parties.***

Rather than be duplicative, we have provided all of our comments regarding this issue in response to Question 11.

13. ***Please share your thoughts regarding whether and, if so, what barriers exist to qualifying as a "group practice" under the regulations at 42 CFR 411.352.***

We have not taken a position on the issues raised in Question 13.

14. ***Please share your thoughts on the application and utility of the current exception at 42 CFR 411.357(g) for remuneration unrelated to DHS. Specifically, how could CMS interpret this exception to cover a broader array of arrangements?***

This exception is ambiguous and serves as a barrier to alternative arrangements. In order to cover a broader array of arrangements, prior interpretations of this exception would need to be revised. For example, CMS application of the exception to remuneration 'wholly unrelated to the provision of DHS' and to 'any item, service, or cost that could be allocated in whole or in part to Medicare or Medicaid under applicable cost reporting principles'[3] has resulted in limited use of the exception because of the risk that an arrangement may be found to fail to meet the above quoted standards. One approach could be for CMS to revisit how it intends to interpret and apply the exception to recognize APMs and waivers. While we believe revising the exception could encourage some value-based arrangements, ultimately we believe the statute limits this exception's utility. We encourage CMS to instead focus on providing a broad value-based exception as proposed in Appendix A rather than attempting to broaden or revise this exception..

15. ***Please identify any provisions, definitions, and/or exceptions in the regulations at 42 CFR 411.351 through 411.357 for which additional clarification would be useful.***

As stated in our responses to Questions 1, 6, 8, 9, and Appendix B items 4, 5, 7, and 11, we recommend that CMS clarify the definitions regarding "fair market value," arrangements that vary by "volume or value," "signed by the parties," and "commercial reasonableness."

In addition, we also recommend that CMS clarify the definition of "referring physician" as we propose in Appendix B, item 6. Under current law, a physician "refers" a patient whenever he or she orders a service or develops a plan of care. With respect to many hospital services, consulting physicians and hospital-based physicians often order tests or services on patients that have been admitted or referred by other physicians. However, these tests or services do not have any impact on the prospectively fixed Medicare payment and are therefore not subject to overutilization as a result of financial incentives. Rather, these test and services derive from coordinating services with other providers and ensuring that patients receive the most timely and appropriate care. Since the Stark Law was intended to address arrangements where the physician compensation would incentivize ordering more DHS services, the definition of "referring physician" should be limited to only those referrals that result in an additional or increase in Medicare payments.

We also recommend that CMS clarify the definition of a "compensation arrangement." Under current law, a compensation arrangement is defined as any arrangement involving remuneration between a physician and an entity. As proposed in Appendix B, item 10, we recommend that CMS clarify that the remuneration must go from the entity to the physician, rather than in the other direction. In arrangements subject to the Stark Law, DHS entities seek referrals from physicians. In order to induce referrals, DHS entities provide remuneration to

[3] 69 Fed. Reg. 16093 (March 26, 2004).

physicians or immediate family members. But if a physician is making a payment to a DHS entity, both the referral and compensation are flowing towards the DHS entity. In other words, payments by physicians to DHS entities cannot induce referrals and therefore should not be subject to the Stark Law.

Additionally, we recommend that CMS specify that a compensation arrangement commences when the physician receives remuneration and ends within 90 days of when the physician last receives remuneration under the arrangement. The effect of the new "compensation arrangement" definition, combined with our proposed changes to 42 CFR § 411.353(c)(1) defining where denial of payment for service furnished under a prohibited referral must occur, will provide additional clarity regarding the determination of a period of disallowance where an arrangement violates the Stark Law. In sum, so long as the parties correct the noncompliant arrangement, the period of disallowance does not continue beyond 90 days after the last payment between the parties was made under the noncompliant arrangement's terms.

16. ***Please share your thoughts on the role of transparency in the context of the physician self-referral law. For example, if provided by the referring physician to a beneficiary, would transparency about physician's financial relationships, price transparency, or the availability of other data necessary for informed consumer purchasing (such as data about quality of services provided) reduce or eliminate the harms to the Medicare program and its beneficiaries that the physician self-referral law is intended to address?***

We are generally supportive of consumer transparency. Any transparency proposal should focus on which data actually would be meaningful to consumers and should be structured with that in mind. Burying consumers in data information could lead to confusion and poor choices, ultimately harming patients.

17. ***Please share your thoughts on whether and how CMS could design a model to test whether transparency safeguards other than those currently contained in the physician self-referral law could effectively address the impact of financial self-interest on physician medical decision-making.***

We have no views as to whether CMS could design a model to test this issue and we refer CMS to our response to Question 16.

18. ***Please share your thoughts on the compliance costs for regulated entities.***

The costs associated with the Stark Law are significant and increase dramatically depending on the complexity of the financial arrangements among the parties. As health providers increasingly seek to enter into value-based arrangements, the costs of the multiple legal analyses necessary to assess whether an arrangement could possibly implicate the Stark Law and determine how to engage physicians lawfully has increased dramatically. Health systems must obtain outside legal counsel on a wide range of issues, such as: how the infrastructure costs should be borne; how gainsharing and bonuses should be constructed; and, whether network physicians can be extended

discounted access to Electronic Health Records or other in-kind resources. The uncertainty inherent in engaging in these value-based arrangements and the tedious analysis that must examine each and every aspect of the arrangement greatly slow down the progress of providers in pursuing and achieving the quality and coordination-related improvements that underlie value-based arrangements. More importantly, these factors make the compliance costs associated with the Stark Law significantly high.

19. ***Please identify any recent studies assessing the positive or negative effects of the physician self-referral law on the healthcare industry. To the extent publicly available, please provide a copy of the study(ies).***

Please refer to the Senate Finance Report on Stark Law reform.[4] Our coalition provided comments to support the drafting of that report.

20. ***Please share your thoughts regarding whether CMS should measure the effectiveness of the physician self-referral law in preventing unnecessary utilization and other forms of program abuse relative to the cost burden on the regulated industry and, if so, how CMS could estimate this.***

We do not favor any such study if the effect would be to delay regulatory reform. We think the underlying principles of the Stark Law in a fee for service environment are helpful in combatting overutilization. We think this is a generally accepted position and therefore we question the utility of studies designed to provide a specific quantification of the benefit in this setting. Our proposals are not designed to alter the Stark Law in a fee for service setting, but instead to adapt it to work in a payment for outcome setting. To the extent a fee for service setting exists, our proposals intend to clarify certain definitions in a way that will not undermine its effectiveness in that setting, but will instead reduce the burden and costs of compliance.

Conclusion

We strongly believe that the recommendations provided above will bring much needed clarity and help accelerate providers' participation in APMs and value-based arrangements. We welcome the opportunity to discuss any of these recommendations and look forward to further discussions on how to modernize the Stark Law and its regulatory framework. If you have any questions or would like further information, please do not hesitate to contact us.

[4] Senate Finance Committee, Why Stark, Why Now? Suggestions to Improve the Stark Law to Encourage Innovative Payment Models (June 29, 2016).

APPENDIX A: NEW VALUE-BASED ARRANGEMENTS EXCEPTION

New Language: [42 CFR § 411.357]

(__) Value-Based Arrangements.

(1) In the case of any remuneration to a physician (or an immediate family member) arising under a Value-Based Arrangement.

(2) Definitions – For purposes of this exception, the following terms are defined as follows:

(i) A *Value-Based Arrangement* means any arrangement that meets the following requirements:

(A) The terms of such arrangement are in writing, including any items and services to be provided;

(B) Either the parties to the arrangement, or the governing board of the arrangement determines the compensation is reasonably related to Value-Based Goals; and

(C) The arrangement is either a Value-Based Transaction or any arrangement among participating entities in a Value-Based Network.

(ii) A *Value-Based Transaction* is defined as an arrangement among two or more parties that enter into a Value-Based Risk Sharing Arrangement in order to advance Value-Based Goals.

(iii) A *Value-Based Network* is defined as an entity that is (1) established or organized among, or operated by two or more participating entities, including providers, suppliers, or individuals to advance one or more Value-Based Goals and (2) that enters into a Value-Based Risk-Sharing Arrangement with one or more payors. Any arrangements among participating entities within a Value-Based Network that advance Value-Based Goals, shall qualify as Value-Based Arrangements even if such arrangements are not themselves Value-Based Risk-Sharing Arrangements.

(iv) *Value-Based Goals* refer to one or more of the following:

(A) Promoting accountability for quality, cost, coordination, and overall care of patient populations, including patient populations that receive services reimbursed by different payors;

(B) Managing and coordinating care for patients and administered, furnished, or arranged for by parties to the arrangement; or

(C) Encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery for patients, including but not limited to Medicare beneficiaries, where efficient service delivery includes, among other things, appropriate reduction of costs or growth in expenditures for health care items and services provided to patients, consistent with quality of care, physician medical judgment, and patient freedom of choice.

(v) *Value-Based Risk-Sharing Arrangement* shall refer to one or more of the following arrangements, which may be used alone or in combination to advance Value-Based Goals –

(A) An arrangement to accept capitation payment for each patient.

(B) An arrangement to accept a predetermined percentage of the payments under the Value-Based Risk-Sharing Arrangement.

(C) An arrangement to use financial incentives for entities in the arrangement, to advance Value-Based Goals.

(vi) *Financial incentives* include the following:

(A) Arrangements where parties to a Value-Based Risk-Sharing Arrangement agree to a withholding of a significant amount of the compensation due them, to be used for any of the following:

(*1*) To cover costs and losses of the arrangement.

(*2*) To cover costs or losses of other entities within the arrangement.

(*3*) To be returned to other entities within the arrangement if the parties to the arrangement meet its utilization management, cost containment, or quality goals for the specified time period.

(*4*) To be distributed among parties to the arrangement to meet its utilization management, cost-containment, or quality goals for the specified time period.

(B) Entities within the arrangement agree to preestablished cost, quality, or utilization targets and to subsequent financial rewards or penalties based on the entities within the arrangement's performance in meeting such targets. Such rewards or penalties may include, without limitation, shared savings, shared losses, payment of a percentage of premiums, medical loss ratio or similar targets, and bundled payment arrangements.

(C) Other mechanisms that demonstrate shared financial risk or that assist

in meeting risk sharing targets.

****

APPENDIX B: OTHER MODIFICATIONS TO EXISTING EXCEPTIONS

Additions are indicated using italicized/underlined text and deletions are indicated using strikethroughs.

1. Modification to the Personal Service Arrangements Exception

New language [42 CFR § 411.357(d)(1)(ii)]

> The arrangement(s) covers all of the services, *meaning any service that furthers the purposes of the entity, including any charitable purpose***,** to be furnished by the physician (or an immediate family member of the physician) to the entity. This requirement is met if all separate arrangements between the entity and the physician and the entity and any family members incorporate each other by reference or if they cross-reference a master list of contracts that is maintained and updated centrally and is available for review by the Secretary upon request. The master list must be maintained in a manner that preserves the historical record of contracts. A physician or family member can "furnish" services through employees whom they have hired for the purpose of performing the services; through a wholly-owned entity; or through locum tenens physicians (as defined at § 411.351, except that the regular physician need not be a member of a group practice).

2. Modification to the Payments by a Physician Exception

New language [42 CFR § 411.357(i)(2)]

> To an entity as compensation for any other items or services that are furnished at a price that is consistent with fair market value~~, and that are not specifically excepted by another provision in §§ 411.355 through 411.357 (including, but not limited to, § 411.357(l))~~. "Services" in this context means services of any kind**,** *including space and equipment leases* ~~(~~not ~~merely~~ *other than* those defined as "services" for purposes of the Medicare program in § 400.202 of this chapter~~)~~.

3. Modifications to Advisory Opinions Section

New language [42 CFR § 411.370(b)(1)]

> *Requests for advisory opinions may involve an existing, proposed, or hypothetical arrangement or a general question of interpretation***.** ~~The request must involve an existing arrangement or one into which the requestor, in good faith, specifically plans to enter.~~ The planned *or proposed* arrangement may be contingent upon the party or parties

receiving a favorable advisory opinion. ~~CMS does not consider, for purposes of an advisory opinion, requests that present a general question of interpretation, pose a hypothetical situation, or involve the activities of third parties.~~

New language [42 CFR § 411.370(e)]

Requests that will not be accepted. CMS does not accept an advisory opinion request or issue an advisory opinion if -

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

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

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

*The Secretary may not decline a request because a similar arrangement between other parties is under investigation or is the subject of a proceeding involving another government agency***.**

4. Definition of Commercial Reasonableness

New language [42 CFR § 411.351]

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

5. Revision to Definition of Fair Market Value

New language [42 CFR § 411.351]

Fair market value

(a) Definition – Fair market value means the value in arm's-length transactions, consistent with the general market value. “General market value” means the price that an asset would bring as the result of *bona fide* bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or the compensation that would be included in a service agreement as the result of *bona fide* bargaining between well-informed parties to the agreement who are not otherwise in a

position to generate business for the other party, on the date of acquisition of the asset or at the time of the service agreement. Usually, the fair market price is the price at which *bona fide* sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in *bona fide* service agreements with comparable terms at the time of the agreement, where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals. With respect to rentals and leases described in § 411.357(a), (b), and (l) (as to equipment leases only), "fair market value" means the value of rental property for general commercial purposes (not taking into account its intended use). In the case of a lease of space, this value may not be adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor when the lessor is a potential source of patient referrals to the lessee. For purposes of this definition, a rental payment does not take into account intended use if it takes into account costs incurred by the lessor in developing or upgrading the property or maintaining the property or its improvements.

(b) Safe Harbor – An annual or hourly payment for a physician's personal services (that is, services performed by the physician personally and not by employees, contractors, or others) shall be considered to be fair market value if the hourly payment is established using an annual or hourly rate determined at or below the 75th percentile national compensation level for physicians with the same physician specialty (or, if the specialty is not identified in the survey, for general practice) in any national survey of physician compensation, recognized by the Secretary. This provision shall not be construed as establishing a presumption that hourly payment above the 75th percentile national compensation level for physicians with the same physician specialty (or, if the specialty is not identified in the survey, for general practice) in any national survey of physician compensation recognized by the Secretary is above fair market value.

(c) Presumption – A compensation arrangement for a physician's personal services shall be presumed to be fair market value absent clear and convincing evidence to the contrary.

6. Revision to Definition of Referral

New language [42 CFR § 411.351]

Referral -

(1) Means either of the following:

(i) Except as provided in paragraph (2) of this definition, the request by a physician for, or ordering of, or the certifying or recertifying of the need for, any designated health service for which payment may be made under Medicare Part B, including a request for a consultation with another physician and any test or procedure ordered by or to be performed by (or under the supervision of) that

other physician, but not including any designated health service personally performed or provided by the referring physician *and only if such request results in an additional or increase in payment for designated health services*. A designated health service is not personally performed or provided by the referring physician if it is performed or provided by any other person, including, but not limited to, the referring physician's employees, independent contractors, or group practice members.

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

7. Revision to Definition of Signed By the Parties

New language [42 CFR § 411.351]

Signed by the parties means (i) a writing with signature(s) made manually or by means of a device or machine, and by the use of any name, including a trade or assumed name, or by a word, mark, or symbol executed or adopted by a person with present intention to authenticate a writing; or (ii) an agreement between the parties to the terms of price and services as reflected in a group of contemporaneous writings, including, but not limited to, the acceptance of payment in an amount that conforms with the payment terms specified in a contemporaneous writing(s).

8. Modification to Group Practice Language

New language [42 CFR § 411.352(i)(1)]

A physician in the group practice may be paid a share of overall profits of the group, provided that the share is not determined in any manner that is directly related to the volume or value of referrals of DHS by the physician. A physician in the group practice may be paid a productivity bonus based on services ~~that he or she has~~ personally performed *by the physician or another physician in the group practice*, or services "incident to" such personally performed services, or both, provided that the bonus is not determined in any manner that is directly related to the volume or value of referrals of DHS by the physician (except that the bonus may directly relate to the volume or value of

DHS referrals by the physician if the referrals are for services “incident to” the physician's personally performed services).

9. Modification to Prohibition on Referrals

Deleted language [42 CFR § 411.353(c)(1)]

Denial of payment for services furnished under a prohibited referral. (1) Except as provided in paragraph (e) of this section, no Medicare payment may be made for a designated health service that is furnished pursuant to a prohibited referral. The period during which referrals are prohibited is the period of disallowance. For purposes of this section, with respect to the following types of noncompliance, the period of disallowance begins at the time the financial relationship fails to satisfy the requirements of an applicable exception and ends no later than

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

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

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

10. Modification to the Definition of a Compensation Arrangement

New language [42 CFR § 411.354(c)]

Compensation arrangement. A compensation arrangement is any arrangement involving remuneration, direct or indirect, ~~between~~ *to* a physician (or a member of a physician's immediate family) and *from* an entity. *A compensation arrangement commences when the physician (or immediate family member) receives remuneration from the entity and ends no later than 90 days after the physician (or immediate family member) last receives remuneration from the entity under that arrangement.* An “under arrangements” contract between a hospital and an entity providing DHS “under arrangements” to the hospital creates a compensation arrangement for purposes of these regulations. A compensation arrangement does not include the portion of any business arrangement that consists solely of the remuneration described in section 1877(h)(1)(C) of the Act and in paragraphs (1)

through (3) of the definition of the term "remuneration" at § 411.351. (However, any other portion of the arrangement may still constitute a compensation arrangement.)

11. Definition of Compensation Arrangement Not Varying With or Otherwise Taking Into Account Volume or Value

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

*A compensation arrangement shall be deemed "not to vary with or otherwise take into account the volume or value of referrals" if the amount of compensation is fair market value at the inception of the arrangement and does not increase or decrease with the volume or value of past or anticipated referrals during its term. A compensation arrangement with a physician based on productivity shall be deemed not to vary with or otherwise take into account the volume or value of referrals solely because the physician's professional service is related to or correlates with the physician's designated health services referrals, as in the case of surgeries performed in a hospital or evaluation and management services performed in a provider-based clinic***.**