



August 24, 2018

Seema Verma
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1720-NC
P.O. Box 8013
Baltimore, MD 21244-8013

RE: CMS-1720-NC; Medicare Program; Request for Information Regarding the Physician Self-Referral Law as published in Vol. 83, No. 122 Federal Register 29524-29527 (Monday, June 25, 2018)

Submitted electronically via <http://www.regulations.gov>

Dear Ms. Verma:

UnityPoint Health (“UPH”) appreciates the opportunity to provide comments on CMS’s Request for Information related to the Physician Self-Referral Law. UPH is an integrated, nonprofit health system that provides care throughout Iowa, Illinois and Wisconsin. On an annual basis, UPH hospitals, clinics and home health agencies provide a full range of coordinated care to patients and families through more than 6.2 million patient visits. In addition, UPH is actively engaged in numerous initiatives which support population health and value-based care.

UPH is an early adopter of innovative value-based models and has partnered in CMS Innovation Center demonstrations for seven years. **UPH participates in Innovation Center contracts under the Bundled Payment for Care Improvement Model 2, the Home Health Value-Based Purchasing Model, and the Medicare Care Choices Model. In addition, UnityPoint Accountable Care (UAC) is the Accountable Care Organization (ACO) affiliated with UPH and has value-based contracts with multiple payers, including Medicare. UAC is one of the largest ACOs participating in the Next Generation ACO Model with more than 80,000 beneficiaries attributed to this program and has received first-year savings.** Historically, UAC has providers that have participated in the Medicare Shared Savings Program as well as providers from the Trinity Pioneer ACO, which was a rural ACO. Participation in both ACOs resulted in overall savings to the Medicare program.

Since the initial enactment of the Stark Law in 1989, the delivery of health care services and the methods of payment for those services – among all payers, both government and private – has changed dramatically. The Stark Law has not kept pace with the Congressional and regulatory imperative to transition healthcare payment from a fee-for-service system to one of risk-based provider payment. For your consideration, *Appendix A – Value-Based Arrangements* is a proposed Stark Law exception from Health Systems for Stark Reform (HSSR), of which UPH is a member and has actively contributed input. The exception addresses innovative value-based payment models that establish networks involving designated health services entities and referring physicians to assume financial risk and provide high-value services. *Appendix B – Other Modification to Existing Exceptions*, also developed by HSSR, includes harmonizing language to provide clarity within existing Stark Law exceptions for value-based arrangements.

In addition, we respectfully offer the following feedback to CMS’s specific areas of inquiry:

1. Arrangements that involve designated health services (DHS) entities and referring physicians within alternative payment models (APM) or other financial arrangements

APM or other financial arrangements take many forms and regulatory guardrails should be set broadly to facilitate high-value care and innovation. Pursuant to Patient Portability and Affordable Care Act (ACA) requirements, any ACO that has contracted with CMS must post all arrangements approved for Waiver treatment. Each of these arrangements would be examples of novel financial arrangements approved under the CMS regulations. For UAC, these arrangements can be found at: <https://www.unitypoint.org/compliance-1.aspx>.¹ Some examples are: Waiver of the 3-day hospitalization requirement (now a Next Generation ACO Model beneficiary enhancement); incentives to physicians to report data to their ACO in compatible format; providing the availability of mental health services in primary care clinics; providing greater observation of chronic condition patients to reduce Emergency Department visits; providing transportation support to enable patients to get to healthcare services; and/or providing home services to non-homebound patients. These arrangements assist UAC in advancing population health objectives and providing patients with appropriate care at the appropriate time in the appropriate setting. They also represent circumstances where the financial arrangement may trigger current Stark Law concerns related to fair market value and commercial reasonableness standards.

¹ For the Next Generation ACO Model, Waiver guidance is "Medicare Program; Final Waivers in Connection with the Shared Savings Program" published on November 2, 2011 and the extension of such rules and regulations to the Next Generation ACO Model is in the "Notice of Amended Waivers of Certain Fraud and Abuse Law in Connection with the Next Generation ACO Model" issued December 29, 2016.

As financial arrangements are developed, the Stark Law is always a consideration and, in many cases when a potential Stark Law risk is identified, it has been a barrier. In our view, the Stark Law is focused solely on fee-for-service payment methodology. As healthcare providers continue to assume more risk and transition toward value-based payments, regulations should emphasize care delivery innovation and afford Stark Law flexibility for the parties to risk-bearing arrangements. Currently, the Stark Law contains numerous ambiguities in its substantive terms that unfairly create hurdles and barriers for health care providers, impeding physician alignment, network growth and integrated care delivery. The physician and provider community has developed a logical reluctance to enter into alternative arrangements that have Stark Law risk due to the lack of clarity about what is permitted and the huge financial risk (as well as possible False Claims Act liability) that result from Stark Law investigations and/or violations. Even when a Medicare Shared Savings Program or Next Generation ACO Model Waiver applies to proposed arrangements aligning financial incentives, the reluctance to enter into alternative financial arrangements by the physicians and the provider community persists.

In the context of our ACO, being able to align the financial interests of UAC providers is key to UAC being able to achieve the performance that Congress and CMS encourage in terms of improving the patient experience, improving the health of populations and reducing the per-capita costs of healthcare. Laws, such as the Stark Law, that have worthy application to fee-for-service arrangements, should not be a barrier to the shift of financial risk of healthcare delivery to providers. The risks of overutilization, which the Stark Law is intended to prevent, do not apply to payment arrangements that pay for patient outcomes. The economic incentive to overutilize healthcare services does not exist in these arrangements, and the continued presence of the uncertain risks the Stark Law provides, makes it a substantial barrier to ACA intended reformation of the financial risk of healthcare delivery. This shift must occur in order to reduce the rise in healthcare costs and to help to provide more certainty to state and federal government budgets.

Although arrangements differ, we believe that value-based care substantially mitigates or eliminates incentives for inappropriate self-referrals and overutilization of items and services. In our arrangements, we monitor ownership interests and require disclosure pursuant to American Medical Association guidance. Also, CMS quality measures as well as our clinical oversight function track efficiency measures and identify duplicative services and overutilization. In general terms, the greater the economic risk that the providers assume, the greater the economic disincentive to overutilize services. In addition, we monitor our network's economic performance on risk-based arrangements through the UAC network physician governance process. Overutilization hurts performance, is identified and provider behavior conforms while quality indices continue. Stark Law application to these

arrangements is not necessary. Stark Law “presence” and risk uncertainty preventing arrangements that promote, enhance and further the ACA’s purposes is backwards.

2. Additional Stark Law exceptions between DHS entities and referring physicians

We recommend a new exception to Stark Law and clarifying language in associated laws for value-based arrangements. Suggested language is provided in *Appendix A – Value-Based Arrangements* and *Appendix B – Other Modification to Existing Exceptions*. In addition, we believe that an exception that protects ACO governance approved arrangements (per the current regulations) is appropriate. We believe the current Waiver approval process properly assures the appropriate review and approval of arrangements that promote what CMS wishes to accomplish in terms of payment reform, while establishing legal accountability for the approved arrangements.

3. Additional Stark Law exceptions for care integration and coordination outside the APM

These protections are contained within the *Appendix A* exception. As a past and current ACO Participant, we believe that the current CMS regulations for Medicare Shared Savings Program or Next Generation ACO Model are appropriate constructs for additional exceptions in this area. The current regulations encompass what should be protected and permit local decision-making and flexibility while retaining responsibility (fiduciary obligation of ACO governance) for integrity of program/model funds.

4. Current risk-sharing arrangement exception (42 CFR 411.357(n))

This exception for risk-sharing arrangements applies to physicians and Managed Care Organizations (MCOs) or Independent Physician Associations (IPAs) for services provided to enrollees of a health plan. While the mere presence of this exception is helpful, in that it denotes a situation warranting excepted Stark Law treatment, its broad language is ambiguous. It should also be noted that this exception does not apply to provider-sponsored organizations (PSOs), which are frequent participants in ACO and other APM arrangements.

6. Single exception versus a multifaceted exception approach

We believe that a single exception, like that proposed in *Appendix A*, would suffice and be the preferred approach. We would also suggest that CMS consider language contained in *Appendix B* to clarify ambiguities in current law.

7/8/9/10. Definitions

In general, UPH supports further clarity, including new and revised definitions. Among the new and/or revised definitions included in *Appendix B* are:

- Commercial reasonableness
- Fair market value

- Referral
- Signed by the parties
- Compensation arrangement

As for the proposed Value-Based Arrangements exception in *Appendix A*, definitions are proposed for the terms:

- Value based arrangement
- Value based transaction
- Value based network
- Value based goals
- Value based risk-sharing arrangement
- Financial incentives

As government enforcement agencies will likely shift their resource allocation to different areas of regulatory enforcement, we expect the current regulatory risk (primarily Stark Law) of financial arrangements between hospitals and physicians will not increase as payment methodologies shift towards payment for outcomes methodologies. That said, we urge the adoption of these definitional clarifications because the current law and interpretation is unclear enough that many beneficial arrangements are not adopted and providers do not spend the intellectual capital to explore new arrangements as they are concerned the proposals will not be implemented.

11. Consideration of volume or value within the definition of compensation

This provision is particularly problematic and creates a standard that is not practical; it is difficult to compensate physicians without reference to activities that impact the volume or value of referrals or other business generated between the parties. Fair market value for physicians is a function of the income they can produce. Providing professional medical services is their primary income producing activity. Medical services are primarily paid for by the volume and value of what is provided; so fair market value compensation is based on the physician's provision of medical services and the value or volume of what is provided. Compensation based on 'relative value units' (RVUs) or 'work RVUs' (wRVUs) are accepted methods of valuing the services of physicians and are used to help to establish fair market value for Stark Law purposes. The very definitions used to establish fair market value (to comply with Stark Law) use value and volume of their professional services (which is prohibited by Stark Law.) Item 11 in Appendix B (*Definition of Compensation Arrangement Not Varying With or Otherwise Taking Into Account Volume or Value*) is our proposal to address this issue.

In the context of alternative arrangements, compensation methodology to pay physicians fair market value does not have to be based on value or volume. Instead, compensation

methodology could be tied to other population health objectives – quality outcomes, patient satisfaction, use of clinical protocols, etc. These legitimate population rationales should be facilitated and not discouraged by ambiguities within the Stark Law. For instance, if wRVUs is used as a reference for establishing compensation in payment for outcomes or other compensation arrangements, does the arrangement vary by value or volume, thus involving Stark Law risk?

14. Remuneration unrelated to DHS (42 CFR 411.357(g))

This exception is ambiguous and serves as a barrier to alternative arrangements. In order to cover a broader array of arrangements, prior interpretations that signal a very broad interpretation would need to be rescinded or replaced. 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’² has resulted in UPH’s non-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 Waiver arrangements.

15. Additional clarifications

We again encourage CMS to consider adopting the proposals within *Appendix A* and *Appendix B*. In particular, we urge your careful review of the proposal related to the definitions of fair market value and commercial reasonableness as well as the clarification as to volume and value within compensation arrangements.

16. Role of transparency

The Stark Law was intended to reduce overutilization and thereby reduce costs to the Medicare program and reduce beneficiary exposure to unnecessary services and costs. Will this intent be furthered through transparency efforts aimed at physician financial relationships, pricing, or quality data? Generally, UPH is supportive of healthcare and provider transparency and accountability, but we encourage CMS to be thoughtful about what information will be meaningful to consumers and impact cost balanced against physician reporting burdens. For instance, although transparency on price and quality holds more savings potential if it impacts consumer cost-sharing, this entails more operational complexity related to definition of price/quality and how to collect and report. On the other hand, transparency as to ownership interests may be easier to report, but the impact of cost may be negligible as patients usually follow physician care recommendations.

² 69 (59) Fed Reg 16093 (March 26, 2004) - *D. Remuneration Unrelated to the Provision of Designated Health Services (DHS) (Section 1877(e)(4) of the Act; Phase II; § 411.357(g))*

We believe that Medicare will receive greater cost savings and beneficiaries will receive better care coordination by revising the Stark Law to permit and protect alignment of economic incentives among healthcare providers to provide better care and better results. The current requirement of website presence and description of Waiver arrangements is a good practice. Consideration could be given to providing transparency information to patients involved in arrangements approved by the ACO.

18. Compliance costs

We appreciate CMS requesting further information on costs, as time and effort on Stark Law compliance is significant and diverts resources from other needs. The annual cost of Stark Law compliance for UnityPoint Health is approximately \$4 million—by far more than the compliance costs of any other single law. In comparison, this cost for Stark Law compliance approximately equals the total expense for the salaries and benefits of our 17 employed attorneys.

20. Measurement and evaluation of impact and/or effectiveness

When Congress passed the Stark Law in 1989, it was premised on evidence of overutilization. Because of the exceptions and language ambiguity, we believe that any analysis would be difficult and the results subject to scrutiny. We would also question whether this analysis could even be applied to alternative payment methodologies since Stark Law targets Medicare fee-for-service payment.

We appreciate the opportunity to provide comments on the Stark Law Request for Information. To discuss our comments or for additional information on any of the addressed topics, please contact Sabra Rosener, Vice President, Government and External Affairs at Sabra.Rosener@unitypoint.org or 515-205-1206.

Sincerely,



Denny Drake
SVP, Corporate Integrity and General Counsel



Sabra Rosener
VP, Government and External Affairs

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(1)).~~ “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.