



August 23, 2018

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Blvd
Baltimore, MD 21244

RE: Request for Information: Centers for Medicare & Medicaid Services, Physician Self-Referral Law;
Submitted electronically via <http://www.regulations.gov>

Dear Administrator Verma,

Trinity Health appreciates the opportunity to respond to the Centers for Medicare & Medicaid Services' (CMS) Request for Information (RFI) on the physician self-referral law ("Stark law"). Our comments and recommendations reflect a strong interest in public policies that support better health, better care and lower costs to ensure affordable, high quality, and people-centered care for all.

Trinity Health is one of the largest multi-institutional Catholic health care delivery systems in the nation, serving diverse communities that include more than 30 million people across 22 states. We are building a People-Centered Health System to put the people we serve at the center of every behavior, action and decision. This brings to life our commitment to be a compassionate, transforming and healing presence in our communities. Trinity Health includes 94 hospitals as well as 109 continuing care locations that include PACE, senior living facilities, and home care and hospice services. Our continuing care programs provide nearly 2.5 million visits annually. Committed to those who are poor and underserved, Trinity Health returns \$1.1 billion to our communities annually in the form of charity care and other community benefit programs. We have 35 teaching hospitals with graduate medical education (GME) programs providing training for more than 2,000 residents and fellows in 184 specialty and subspecialty programs. We employ approximately 133,000 colleagues, including more than 7,800 employed physicians and clinicians, and have more than 15,000 physicians and advanced practice professionals committed to 23 Clinically Integrated Networks (CINs) that are accountable for approximately 1.4 million lives across the country through alternative payment models (APMs).

Our comments and recommendations on the Stark Law are informed by the significant experience our system has in establishing and supporting CINs and APMs. As an organization, we are committed to rapid, measurable movement toward value in the delivery of and payment for health care. The Trinity Health Board of Directors have approved our system-wide strategy to "Build a People Centered Health System" that would be accountable for delivering better health, better care and lower costs for the communities we serve. Our People-Centered 2020 Plan includes initiatives to transform the way we deliver care and the ways we are reimbursed. One of our goals is to have 75 percent of our revenue flowing through APMs by 2020. To this end, Trinity Health is currently participating in 16 markets in Medicare Shared Savings Program (MSSP) ACOs and has five markets partnering as a Next Generation ACO. In addition, we have 33 hospitals participating in the Model 2 Bundled Payments for Care Improvement (BPCI) initiative, 11 Skilled Nursing Facilities (SNFs) in Model 3 BPCI, and two hospitals in the Comprehensive Care for Joint Replacement (CJR) program. Our experience in value-based contracting also extends beyond Medicare as illustrated by our participation in 133 non-CMS APM contracts. Trinity Health is currently accountable for \$8.6 billion in total cost of care for approximately 1.4 million people, and we have approximately \$2.5 billion dollars fully at risk for our clinical and cost performance. We have invested almost \$120 million to be successful in these population health efforts and we have generated significant shared savings. But, we are not yet at breakeven in our effort to be successful in APMs and related population health activities. With this

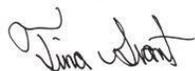
accountability and investment, we are clearly committed to transformation and we are pleased CMS is considering regulatory changes that may make APMs and other population health activities more successful.

We hope our experience demonstrates how deeply Trinity Health shares CMS' commitment to transforming the health care delivery system into one that pays for value. We agree wholeheartedly that care coordination is a key aspect of systems that deliver value but we also believe additional changes to CMS programs, policies and regulations are essential to transforming the nation's health care system. Trinity Health is committed to working with CMS to achieve these goals and appreciate the Department of Health and Human Services' (HHS) commitment to helping accelerate this transformation and removing barriers, including those related to the Stark law, as discussed in our comments and responses that follow.

In addition to our detailed responses below to questions 1-16, 18, and 20 of this RFI, Trinity Health also believes CMS should make existing payment policy waivers available to all beneficiaries. The 3-day payment window policy is one example. Currently, only beneficiaries attributed to a Next Generation ACO program or to a MSSP Track 3 program can receive the right care at the right location. Yet, our experience has demonstrated the 3-day payment window waiver available in limited CMS programs delivers value without any measurable risks to the beneficiary or to Medicare. **CMS payment policies and rules should not interfere with making sure the right thing is done at the right time for all beneficiaries. Therefore, Trinity Health encourages CMS to not only look at essential Stark law changes identified in this letter but to also consider removing other barriers that do not present high risks of program abuse and that enable providers to deliver the right care in the right location.**

Thank you for the opportunity to respond to this RFI. If you have questions on our comments, please feel free to contact me at granttw@trinity-health.org or 734-343-1375.

Sincerely,



Tina Weatherwax Grant, JD
Vice President, Public Policy and Advocacy
Trinity Health

- 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.*

Trinity Health participates in a variety of existing, value based arrangements that are not sponsored by CMS and is committed to growing these arrangements. For example, in Trinity Health Fiscal Year 2015, Trinity Health earned approximately \$16 million dollars in APM revenue. Revenue from 133 separate APMs grew to more than \$56 million dollars in our recently concluded Fiscal Year 2018.

One example of an increasingly common model among commercial products is happening in the state of Michigan. Trinity Health entered into an arrangement with a national commercial payer where the parties agreed on a total cost of care target and a medical cost trend target with the parties sharing equally in the shared savings based on the total cost of care. **Success in these arrangements is highly dependent on engaged physicians, care management programs targeted to assist those**

with chronic illness and excellent information technology that identifies and analyzes not only utilization but the care needs and trends of the patient population to ensure that those who have the greatest care needs receive the care in a timely and cost effective manner. Trinity Health believes this formula is a key driver of success for the patient and also results in services being provided at a lower cost. Yet this formula also poses several regulatory challenges such as:

- What Stark exception enables a health system to distribute shared savings to physicians that were instrumental in improving care and lowering costs in a APM program?
- How to quantify the appropriate allocation of shared savings in APM program among each physician to ensure consistency with Stark fair market value requirements?
- Can a health care system locate a care manager in an independent physician office to effectively manage the care of patients attributed to the health system in an APM?

CMS has addressed these matters in programs it administers by working with the OIG to issue certain waivers under the fraud and abuse statutes. However, such waivers do not extend to address similar needs in commercial insurance programs today. This results in uncertainty, which is a limiting factor in the growth of APMs in commercial arrangements.

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?

Trinity Health recommends that CMS develop a simple, verifiable and objective regulatory exception under the Stark Law that specifically addresses new population-based/APM arrangements. This exception would apply to the financial relationships between any provider and supplier who participates in the APM. The exception could require certain criteria such as being a Qualifying APM Participant provider, which is a provider that receives a percent of their payments or patients through an eligible alternative payment entity (a "QP"). If the provider is a QP, then any compensation arrangement between two or more QPs would satisfy the exception. The exception could apply to any financial arrangement that is reasonably related to the purposes of the APM, including without limitation payments related to achieving cost savings targets, quality measure achievement, care management resources and other population health management goals. **Having a clear exception that applies to all arrangements that are reasonably necessary to achieve the purposes of the APM would facilitate a team approach to patient care delivery among hospitals, physicians and post-acute providers.**

This new exception is needed because, under the current law, any compensation relationship between a DHS entity and a physician needs to meet an exception. When the APM payment bundles both the hospital's facility and the physicians' professional services reimbursement, it is unclear whether any of the current Stark Law exceptions apply to protect the financial arrangements between the hospital and physicians (as well as potentially other providers and suppliers) that are necessary to divide the APM payment.

Furthermore, under the potentially applicable exceptions, the Stark Law requires the compensation be fair market value and limited to the physician's personally performed services. The most common method for calculating physician compensation is using Work-RVU values for their personally performed services. As fee-for-service payment models change to APMs, however, physicians will likely see a decrease in their Work-RVU performance over time. As APMs become predominate, health systems and hospitals will face uncertainty as to how to continue to pay physicians when those services do not directly translate into a Work-RVU. It is unclear about how to measure the fair market value of services when those services involve meeting quality outcome goals that enable APM participants, both hospitals and physicians, to qualify for incentive payments. Even more unclear is how to calculate the value of services *not provided* by a specialty physician because of better population health management, such as greater preventative or primary care provided by the care team in which the specialty physician participates.

For example, one way for an integrated delivery system to manage population health and preventative care is through greater use of non-physician professionals, such as nurse practitioners and physician assistants. Historically physicians often resist greater use of non-physician professionals because it results in a decrease in the number of services that the physician performs, which in turn impacts Work-RVU based physician compensation. Yet, team-based care is becoming more common and more essential from a clinical integration/population health perspective. To ensure high-quality and coordinated care, it is desirable for a primary care physician to work closely with multiple non-physician professionals. Under the Stark Law's existing structure, the non-physician professional's productivity cannot be a factor in the compensation arrangement with the physician even though the physician is required to oversee the care delivered by the non-physician professional. Yet, encouraging this team approach would greatly expand access and lower the cost of delivering care without diminishing quality.

In order for this APM exception to work, it would need to 1) exclude any fair market value (FMV) requirement; and 2) permit payments that reflect or vary with the volume or value of DHS. For example, cost savings per admission would be a reasonable compensation metric to include in an arrangement implementing an APM involving hospitals and physicians, even though the payment amount would naturally vary depending on the physician's admission volume or value. The gainsharing civil monetary penalty law already prohibits payments to reduce medically necessary services, and provides sufficient incentives for the providers and suppliers to structure relationships in compliance with the law. The exception could require providers to maintain clear documentation of the standards used and their application in calculating payment amounts to ensure transparency in the event of government review. However, we caution CMS to avoid overly prescriptive standards that could result in an unworkable rule.

The new exception should also protect non-monetary compensation, such as investments in technology or other population health management tools that a health system makes available to physicians participating in an APM to deliver better and more cost effective care to the community.

Recommendation:

- Create a new exception that protects financial arrangements, including monetary and non-monetary compensation, between APM participants.
 - This new exception should not have FMV or volume/value requirements that would seriously limit the ability of the exception to promote APM development.
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?*

The Stark law should not preclude or restrict any arrangement that attempts to improve care coordination for beneficiaries or commercial patients. Improving care coordination activities should be encouraged by CMS. **A new exception should be created to protect coordinated care activities, which can include monetary or non-monetary compensation between health systems and physicians, outside of an APM context.**

Recommendation:

- Create a new exception that protects financial arrangements, including monetary and non-monetary compensation, related to providing coordinated care services to the community.
 - This new exception should not have FMV or volume/value requirements, as those requirements would seriously limit the ability of the exception to promote APM development
4. *Please share your thoughts on the utility of the current exception at 42 CFR 411.357(n) for risk-sharing arrangements.*

The current exception is ambiguous and unclear as to whether it provides sufficient protection. The risk-sharing exception is limited to compensation for services provided to *enrollees of a health*

plan. This could be read to mean that the risk-sharing exception only protects quality performance and shared savings incentives related to services for enrollees in a health plan that pays the hospital based on a risk-sharing model. However, it is not clear the risk-sharing exception will protect compensation by a hospital to physicians for services to patients who are not enrollees of the health plan to which the risk-sharing arrangement applies. **This limitation essentially renders the exception unworkable because hospitals are not able to create different physician compensation methodologies depending on the patient's health plan.**

Recommendation:

- Revise the risk-sharing exception by expanding its application to include federal health care program beneficiaries.

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.*

This exception also contains a limitation that impacts its ability to apply in care-coordinator or APM situations. Specifically, the physician incentive plan exception is limited to compensation arrangements between a DHS Entity (or downstream contractor) and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services furnished with respect to *individuals enrolled with the entity*.¹ This effectively restricts the exception to compensation arrangements with entities *that have enrollees*, so downstream arrangements between hospitals and physicians would not appear to qualify. In addition, CMS has stated that if a contract requires that a physician refer within a provider network, e.g., an HMO, the compensation to the physician takes into account the volume or value of the physician's referrals to the provider network, even if the compensation to the physician does not fluctuate or vary with the volume or value of referrals.² As a result, many payment arrangements in commercial or employer-provided health plans contain risk-sharing elements that would fail the physician incentive plan exception.³ Finally, the exception is only available to arrangements that otherwise meet the requirements of the personal services exception. In other words, the exception does not stand on its own two feet, but rather requires compliance with another exception.

Recommendation:

- Either create a stand-alone physician incentive plan exception that would apply to both employed and independent contractor physicians or add an incentive plan exception to the employment exception.
- Revise the incentive plan exception from "enrolled with" to "served by" the entity. We believe this expansion of the statutory exception language is permitted under CMS' regulatory authority to protect arrangements that do not pose risk to the programs.

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.*

In general, Trinity appreciates the efforts HHS has made to facilitate APMs through creating program-specific waivers. These waivers were an important catalyst to moving the entire healthcare industry away from a fee-for-service model and towards an APM model. However, the experience over this progression has shown that addressing the obstacles posed by the Stark Law (and other fraud and abuse laws) through piecemeal waivers issued for each APM does not holistically remove those obstacles. The waivers do not apply to commercial APM models, leaving those arrangements between

¹ 63 Fed. Reg. at 1712.

² *Id.*

³ 66 Fed. Reg. at 913.

DHS Entities and physicians in a place of uncertainty. In addition, managing compliance with separate waivers for each HHS model program is burdensome and creates the risk of potentially draconian penalties for technical non-compliance issues that do not impact the integrity of the Medicare program.

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, and Enrollee.*

Our prior answers address many of these terms.

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

Referral. Because care coordination requires some degree of care management, we need the ability to work together across our organization, and even outside of it, to ensure patients receive the right care at the right time. However, some of our physicians' efforts to do so are considered "referrals" under the current Stark law, even if the referral presents no risk for increased payment to our organization.

Recommendation:

- Revise the referral definition to clarify that a referral only implicates the Stark law when it results in an additional or increased payment from a federal healthcare program to the DHS entity.

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

In recent enforcement cases, the Department of Justice ("DOJ") appears to have taken the position that commercial reasonableness relates to the economic terms of an arrangement, such as whether there is a "practice loss" because the physician's professional collections do not cover the physician's compensation and other practice expenses. This position has created considerable concern among hospitals/health systems regarding their employment of physicians it seems inconsistent with the legislative intent and better reading of the employment and other exceptions that contain a commercial reasonableness requirement.

To illustrate this concern, a system may decide to acquire a physician practice for a variety of reasons, such as to ensure that the system has a physician network which satisfies the network adequacy requirements applicable to Medicare Advantage plans. In other words, if a hospital system desires to have a contract with a Medicare Advantage plan, it often needs to have a network of providers that is attractive to the plan and that meets applicable adequacy requirements. The Medicare Advantage plan then pays the hospital network a capitated payment. In this context, it is difficult to determine whether the hospital system is "subsidizing" any operating losses resulting from the acquired physician practice on a stand-alone basis. **As health care moves further toward capitated payment and bundled payment arrangements in both the commercial and federal context, distinguishing between professional and technical revenue loses relevance in the actual operation of a health system, especially when such new payment methodologies reduce the significance of these categories to a health system's operating strategies.**

"Losses" on physician practices are so commonplace in the health care industry that the leading survey company, Medical Group Management Association ("MGMA"), tracks and reports data on the

average practice loss from hospital-owned practices by specialty.⁴ Simply put, the position that any “loss” from a physician practice could potentially violate the Stark Law's commercial reasonableness requirement is not reasonable or realistic and exposes many hospitals/health systems to enormous financial penalties.

The better reading of the employment exception's language⁵ suggests that the purpose of the commercial reasonableness requirement relates to the non-economic or non-payment aspects of the arrangement – in other words that the "arrangement" be commercially reasonable, not the "remuneration." Examining an employment arrangement for commercial reasonableness involves ensuring the employment was *bona fide* and that the employer needed the services of the employee, separate from whether the employee made referrals to the employer or whether the employer made a profit from the employee's services. The appropriateness of the compensation amount is addressed in the separate fair market value and volume/value requirements of the Stark Law.

Clarifying the intent of the commercial reasonableness requirement in the Stark Law will enable us to clinically integrate with physicians for improved care coordination even when the purchase of a physician practice, when viewed on a stand-alone basis for example, appears to represent a net loss to our health system. **Trinity Health recommends an affirmative statement be made in the Stark Law regulations that states operating losses in a DHS-entity owned physician practice are not, in and of themselves, to be considered evidence of a lack of commercial reasonableness under the employment exception.**

Recommendation:

- Define “commercial reasonableness” as whether the items or services being purchased are useful to the purchaser’s business.
- Clarify that “practice losses” for DHS-Entity owned physician practices are not evidence that the arrangement is commercially unreasonable.

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.*

Trinity Health strongly recommends that CMS restore the definition of fair market value to the original language of the statute. Doing so would rightfully de-couple FMV from the volume/value element of the Stark law, giving our organization a chance to design incentives that may impact referrals but that do not drive overutilization nor undercut medically necessary utilization. **To that end, we recommend CMS define fair market value as the value in arms-length transactions consistent with general market value, and define general market value as the price of an asset or compensation for a service that would result from bona fide bargaining between well-informed parties to the agreement.** Whether or not the parties are in a position to generate business for each other is irrelevant (and the addition of that language to the regulation has created needless confusion).

⁴ MGMA survey data for 2014 reported a median loss of \$176,153 per physician for integrated delivery/health system owners of multispecialty practices (primary and specialty care).

⁵ The statute's phrasing is slightly different than the regulation, but also consistent with the above interpretation that the requirement speaks to the non-payment aspects of the relationship. Compare "the remuneration is provided *pursuant to an agreement which would be commercially reasonable* even if no referrals were made to the employer" (emphasis added) (42 U.S.C. § 1395(e)(2)) with "the remuneration provided *under an arrangement that would be commercially reasonable* even if no referrals were made to the employer" (emphasis added) (42 C.F.R. § 411.357(c)(3)).

Recommendation:

- Define “fair market value” as the value in an arms-length transaction consistent with general market value, and define general market value as the price of an asset or compensation for a service that would result from bona fide bargaining between well-informed parties to the agreement.
- Create a presumption that the compensation contained an arrangement is consistent with FMV absent clear and convincing evidence to the contrary. This appropriately shifts the burden to the government or a relator to prove the compensation is not FMV.
- We do not recommend CMS create a requirement for DHS Entities to obtain FMV valuations for every arrangement as a condition of meeting the exception. This new requirement has the potential to create significant new costs for DHS Entities and is not necessary for all arrangements.

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.*

The volume/value element of the Stark law has created immense confusion in our field, thereby chilling the drive of hospitals and health systems to create innovative payment arrangements. In response, **CMS should clarify that, for a fixed payment, the amount of compensation does not vary or take into account the volume or value of referrals if the amount is initially determined by a methodology that is not based upon referrals and is not subsequently adjusted during the term of the agreement based on referrals.** The parties’ state of mind in arriving at the amount of compensation is not relevant; rather, the central question is whether the methodology actually utilizes a physician’s referrals in determining the amount of compensation paid to a physician or an immediate family member. This clarification is essential to our ability to align the goals of our organization and of our physicians and to incentivize physicians to make value-based modifications on a patient-by-patient basis.

Recommendation:

- Clarify that, where the per-unit or other fixed payment is set in advance, the amount of compensation does not vary or take into account the volume or value of referrals if the amount is initially determined by a methodology that is not based upon referrals and is not subsequently adjusted during the term of the agreement based on referrals.
- Clarify that compensation based on personally performed wRVUs shall be deemed not to take into account the volume or value of referrals solely because the physician’s professional service is related to or correlates with the physician’s DHS referrals, as in the case of surgeries performed in a hospital or evaluation and management services performed in a provider-based clinic.

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.*

As discussed above, we believe that in order for this APM exception to work, it would need to permit payments that reflect or vary with the volume or value of DHS. For example, cost savings per admission would be a reasonable compensation metric to include in an arrangement implementing an APM with a physician, even though the payment amount would naturally vary depending on the physician's admission volume or value of payments in a historical fee for service payment arrangement. The gainsharing civil monetary penalty law already prohibits payments to reduce

medically necessary services, and should provide sufficient incentives for the providers and suppliers to structure the relationships in compliance with the law. The exception could also require providers maintain clear documentation of the standards used in determining the allocation of payment amounts among participating parties to ensure transparency in the event of government review. However, we caution CMS not to strictly prescribe the standards used which could result in a rule that is unworkable.

Recommendation:

- Permit compensation in any APM or coordinated care exception to vary with or take into account the volume or value of referrals.

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.*

The group practice model is challenging for hospitals that employ physicians. Due to many state corporate practice of medicine laws, the physician practice components of health systems cannot meet the group practice definition in several ways, including the single entity and unified business prongs. The group practice definition does helpfully permit compensating physicians for in-office ancillary services, which is something that puts health systems at an unfair disadvantage in comparison to independent physician practices. There is no discernable reason why an independent physician practice can include in-office ancillary services in physician compensation, but a health system affiliated physician practice cannot. **Expanding the group practice exception would be helpful, but it would not solve the problem of physician compensation in the APM and care coordination contexts because those payment methodologies go beyond in-office ancillary services.**

Recommendation:

- Expand the group practice exception to include hospital/health system affiliated professional corporations.

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 has limited utility largely because of subsection (g)(2) that prohibits remuneration that "is furnished, directly or indirectly, explicitly or implicitly, in a selective, targeted, preferential, or conditioned manner to medical staff or other persons in a position to make or influence referrals." There is little guidance from CMS on what arrangements would be considered to meet this exception. On its face, it would appear that the exception may only available to arrangements that are offered to every physician in the community, otherwise there could be risk that the government or a relator would view the arrangement as being offered in a prohibited manner.

Recommendation:

- Remove subsection (g)(2).

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.*

In addition to implementing changes to the Stark law that will enable and protect value-based payment arrangements and expand our ability to provide better and more cost-effective coordinated care, we request that CMS also provide relief from certain technicalities of the Stark law that inhibit our ability to focus on patient care. Specifically, we recommend that CMS address needlessly confusing and burdensome documentation requirements that expose us to potentially catastrophic payment denials without protecting against problematic arrangements. To do so, we urge CMS to provide an alternative method of compliance with documentation requirements that focuses on whether there is a legally binding agreement between the parties. **This method should provide that an agreement**

enforceable under applicable state law will be sufficient to satisfy the requirement in any Stark exception that an arrangement be set out in writing and signed by the parties.

In addition, the temporary non-compliance with the signature requirement is too restrictive to be truly useful for protecting DHS Entities from the enormous liability associated with Stark Law non-compliance for a documentation issue.⁶ Ninety (90) days is not enough time to remedy a signature issue in the life of a busy health care provider. Furthermore, the ability to invoke the exception only once every three years with the same referring physician is overly restrictive to be useful. We recommend eliminating the time limits on either obtaining the signature or the frequency of using the exception for the same referring physician.

These signature/writing issues pose real risk. In a case of first impression, a federal court found that the requirement that financial arrangements with physicians be memorialized in a signed written agreement could be material to the government's payment decision. *United States ex rel. Tullio Emanuele v. Medicor Associates*⁷ (*Emanuele*), in the US District Court for the Western District of Pennsylvania, involves Medicor Associates, Inc., a private medical group practice (Medicor), and Hamot Medical Center's (Hamot) exclusive provider of cardiology coverage. Tullio Emanuele, a *qui tam* relator and former physician member of Medicor, alleged that Hamot, Medicor, and four of Medicor's shareholder-employee cardiologists (the Physicians) violated the FCA and Stark Law because Hamot's multiple medical director compensation arrangements with Medicor failed to satisfy the signed writing requirement in the Stark Law's personal services or fair market value exceptions during various periods of time. The US Department of Justice declined to intervene in the case, but filed a statement of interest in the summary judgment stage supporting the relator's position.

In addition, we recommend that the personal services exception be revised to eliminate the second and third sentences in subsection (d)(1)(ii) requiring that the agreement either incorporate other agreements by reference or cross-reference a master list of contracts. While CMS has explained that the intent behind this requirement is to permit the government to track the relationships with the same physician, this requirement is overly burdensome in practice and unnecessary to achieve the government's objectives. The government has the ability to request all contracts with a particular physicians in an audit or investigation. It seems unlikely the government relies on this statement existing in the contract to identify all the agreements; the government more likely relies on a certification from the provider being audited or investigated that it has produced all the requested contracts. Instead, this requirement simply creates a compliance burden and a potential disclosure obligation to CMS or potential extreme financial exposure under the statute.

Recommendation:

- Expand the definition of a permissible writing to include agreements that would be enforceable under state law to significantly reduce unnecessary burden and risk to DHS Entities in light of the *Emanuele* decision.
- Remove the second and third sentences in subsection (d)(1)(ii) requiring that the agreement either incorporate others by reference or cross-reference a master list of contracts.

16. Please share your thoughts on the role of transparency in the context of the physician self-referral law.

Trinity Health is an organization deeply committed to transparency when that transparency is in the most appropriate form and will provide added benefit—not confusion—to consumers. We believe that promotion of the patient-provider relationship is most critical. As CMS knows, the financial arrangements within a health system or ACO are complex. It is not clear how additional disclosures about the financial relationships within a health system would enhance or improve that patient-provider

⁶ 42 C.F.R. § 411.353(g).

⁷ Doc. No. 345, No. 1:10-cv-00245, 32 (W.D. Pa. Mar. 15, 2017).

relationship without creating unnecessary confusion. We also believe that any transparency initiative needs to deeply consider the administrative burden on providers and balance that with the value it might provide. **We are concerned that creating additional disclosure obligations to patients or CMS would create, and not reduce, provider burden with little identifiable benefit targeted at the Stark Law's ostensible purpose.**

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

The compliance costs for DHS Entities are enormous when one factors in the costs of internal compliance and legal personnel, outside counsel, valuation consultants to manage compliance, and review and analyze potential instances of non-compliance as they inevitably occur given the complex and very technical requirements of many exceptions.

There are many examples of these “technical violations” that CMS likely has seen over the years in operating the Self-Referral Disclosure Program (SRDP). One such example is the following: a physician group leases space from a hospital to see patients on campus. The lease initially was intended to be temporary until the physicians moved into space in another building. The lease term was for one year and expired, but the group has been in the space for one and one half years because the construction delays on their new building. At the beginning of this year the new CFO raised the rent and the hospital began billing the group for 110% of the rent under the expired lease. The group has paid the higher rent, but a new lease has not been put in place.

This situation would require the involvement of in-house counsel, in-house operations personnel, and outside counsel to develop the facts, identify any relevant documentation, and analyze whether the space rental exception has been met, and if not, submit a disclosure to CMS in the SRDP to otherwise protect the hospital’s ability to keep the Medicare payments received for any DHS referred by the group. In this example, there are no facts to suggest that the arrangement is potentially abusive, e.g. operating as some reward or improper incentive for the physicians to refer to the hospital. It simply is a documentation and timing issue involving technical aspects of the exception.

And this is just one example. In the transactional setting when a health system looks to buy another hospital, the diligence process can involve the review of hundreds of contracts spanning years. Given the current regulatory structure, any diligence review virtually guaranteed to discover some technical non-compliance issues that need legal analysis and potentially an SRDP submission.

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.

The success of the Stark Law has not been in preventing unnecessary utilization, but in creating burdensome regulatory compliance landscape in which DHS Entities could be exposed to millions of dollars in exposure and vulnerability to relator actions. **The advancement of APMs intrinsically supports the prevention of unnecessary utilization. Therefore we believe the emphasis should be placed on APM advancement, not reliance on the Stark Law to prevent or reduce unnecessary utilization. We are concerned that any effort to measure effectiveness of the Stark Law will involve the creation of new, burdensome reporting requirements on DHS Entities.**

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Trinity Health applauds CMS for engaging in this critical examination of reducing regulatory burden of the Stark Law on DHS Entities. Simplifying the regulatory scheme will provide tremendous benefit to the health care system by reducing the expenditure of limited resources on technical compliance issues that do not actually impact the Medicare program or its beneficiaries. Furthermore, removing

obstacles the Stark Law creates on the development of APMs and coordinated care initiatives will go a long way in advancing the movement to value-based payment models.

While we believe many of the suggestions in this letter would help achieve these goals, we feel compelled to point out that the Stark statute itself creates its own obstacles that CMS is not able to address through regulation.

- **The statute creates the most significant obstacle – it prohibits payment for any DHS referred if the financial arrangement does not comply with an exception.** This strict liability payment prohibition structure results in the potential for draconian financial penalties and False Claims Act and Overpayment Statute exposure. The changes below would free CMS to enforce the statute by imposing civil monetary penalties on conduct it believed was problematic, but also in proportion to the conduct.
 - **Amend the Stark Law to require compliance as a condition of participation, not a condition of payment.**
 - **Expressly state in the statute that compliance is not material to payment.**
 - **Revise the civil monetary penalties provisions in section 1877(g)(3) and (4) to reframe the penalties as per non-compliant relationship and not per claim.**
 - **Eliminate the reference to section 1128A (which adds a multiplier of up to three times the amount of the claim and exclusion).**
- Provisions of statutory exceptions, such as commercial reasonableness and “takes into account,” are ambiguous and inherently create factual questions that can create risk. **The terms commercial reasonableness and “takes into account” should be eliminated from the statute.**
- Some of the “technical” compliance issues, such as writing and signature requirements, are also creations of the statute. **The writing and signature exception requirements should be eliminated from the statute.**

Trinity Health urges CMS to work with Congress to address these statutory issues.