



December 31, 2019

Seema Verma, Administrator  
Centers for Medicare & Medicaid Services,  
Department of Health and Human Services,  
Attention: CMS-1720-P,  
P.O. Box 8016,  
Baltimore, MD 21244-8016

RE: CMS-1720-P- Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations

Submitted via [www.regulations.gov](http://www.regulations.gov)

Dear Administrator Verma,

Trinity Health appreciates the opportunity to respond to the Centers for Medicare & Medicaid Services' (CMS) proposed rule *Modernizing and Clarifying the Physician Self-Referral Regulations*. We appreciate CMS working to appropriately balance ensuring program integrity and compliance with the physician self-referral law, while providing the flexibility required for successful participation in value-based care arrangements. Our comments 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. Our People-Centered Health System puts 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 16 Clinically Integrated Networks (CINs) that are accountable for approximately 1.5 million lives across the country through alternative payment models (APMs) across all populations and product lines: Medicaid, Commercial, Medicare Advantage and Medicare ACOs. Trinity Health participates in the Medicare Shared Savings Program (MSSP)—Basic and

Enhanced Tracks, Next Generation ACO, Comprehensive Primary Care Plus (CPC+), and the Bundle Payment for Care Improvement Advanced programs.

The comments below are informed by the significant experience our system has in establishing and supporting CINs and APMs. Trinity Health is currently accountable for nearly \$10 billion in total cost of care for 1.5 million people—given our investment in programs and models that promotes people-centered care, we are clearly committed to transformation and are pleased HHS is making regulatory changes that may make APMs and other population health activities more successful. Trinity Health strongly supports and applauds the direction CMS is heading with the proposed rule—the agency listened to many recommendations we submitted on the August 2018 Physician Self-Referral Law Request for Information and we appreciate CMS' attempts to reduce burden and provide additional protections for value-based care arrangements. We appreciate CMS' attempts to reduce burden and provide additional protections for value-based care arrangements and recommend CMS and the OIG work to more closely align Anti-Kickback and Stark requirements where possible to reduce complexity and confusion for providers.

### **New exceptions for value-based arrangements**

CMS proposed to establish new exceptions for value-based arrangements that are not tied to any specific payor or payment model. Of the proposed exceptions, two are defined broadly but require participants to take certain degrees of financial risk: 1) the first is satisfied if the value-based enterprise (VBE), as a whole, undertakes “full financial risk” for items and services covered by the applicable payor and 2) the second is satisfied if a physician accepts at least 25% of risk or is accountable for all of a defined set of patient care items or services for a target population. The third proposed exception does not have a financial risk requirement and instead evaluates whether the value-based activities are expected to advance “value-based purposes”.

### Comment

The “full financial risk” exception unreasonably limits the range of “at risk” arrangements that it protects and will not be widely used. In the Medicare context, for example, the exception would not protect a hospital that provides care management analytics or pay-for-performance bonuses if they relate solely to reducing the costs of inpatient care. Instead of requiring that an arrangement be at risk for every and all services that a payer's enrollee may need to qualify for the exception, the focus should be on whether the arrangement has full financial risk for the items and services to which the protected remuneration relates.

For the physician “meaningful risk” exception, the requirement that the physician—rather than the VBE—must accept at least 25% of risk is a significant deterrent and could slow the momentum and growth of alternative payment models. Further, it does not reflect common real-world risk arrangements. A VBE goal is to improve the health of the community and, therefore, would include competing physicians. With a goal of improving health in a community, VBEs may include competing physicians--it is our experience that independent physician groups are reluctant to bear risk for a competitor's performance. Requirements that push physicians—rather than a VBEs—to take on risk may push them away from alternative payment arrangements.

CMS should make this exception more flexible or require the *VBE* to take on at least 25% of risk, rather than the physician. In addition, CMS should make the full-risk exception more flexible by allowing for *VBEs* to carve out or cover a subset of services. The important factor in value-based care arrangements is the *VBE's* investment in patient care, quality, and reducing costs—the physician's investment is to reduce costs by using the right level and setting of care. CMS could reconsider how they are defining "risk" for a physician, such as a reduction in reimbursement for certain services. We are pleased CMS agrees on the important role strong partnerships between physicians and entities play in providing value-based care, regardless of the degrees of risk parameters and supports the proposed exception for compensation arrangements that qualify as value-based arrangements regardless of their risk parameters.

In addition, we support CMS' decision to omit "fair market value" and "volume or value of referrals" requirements for the new value-based care exceptions, which CMS recognized as potential deterrents to innovation under existing law—existing elements create confusion and present barriers to creating innovative payment arrangements. Further, we agree with the proposed rule that these exceptions apply to both payments and in-kind remuneration.

### **Monitoring of Value-Based Arrangement**

CMS seeks comments on whether monitoring should occur at specific intervals and whether value-based purposes should be deemed as "unachieved" under the value-based activities requirement under the arrangement.

#### Comment

Given the potential loss of Stark protections for failing to meet measures if the value-based activity doesn't work as intended, CMS should be incredibly clear on the monitoring and outcome requirements—and resulting consequences—in the final rule. Any compliance monitoring obligations should be included in the regulations. In the commentary, CMS's mention of "implicit" compliance monitoring obligations is confusing and potentially concerning. It should be clear whether an enforceable duty is being created. If that is the intent, it should be explicitly stated and incorporated into the regulation text itself. In the context of a strict liability statute, ambiguity places a hospital at unacceptable risk.

We recommend CMS provide flexibility around monitoring and outcomes, as it takes time to see results in new arrangements and metrics may be met in some years and not others. We strongly recommend CMS keep the methodology simple and consistent: *VBEs* should reduce cost as compared to their historical or market benchmark and achieve quality goals. We also support maintenance of any gains as achieving the metric. Further, value-based arrangements that are unsuccessful in achieving measures should be allowed to modify their measures or implement additional tools or processes to course correct, rather than lose Stark protections or terminating their arrangements.

Any required monitoring related to performance of the value-based arrangement should recognize that the goals are prospective. The proposed rule recognizes that in a value-based activity, participants will come together to engage in an action or refrain from an action in a manner reasonably designed to achieve a value-based purpose. The activity will be evaluated prospectively at the outset of the arrangement and when it is up for renewal. During the course

of the arrangement, however, there will be an opportunity to observe, learn, adjust and improve. CMS should be clear that an arrangement is not subject to termination during the course of the activity simply because a goal or purpose proves difficult to achieve or needs adjusting.

### **Cybersecurity Technology and Related Services**

CMS proposes a new Stark exception that would protect the donation of certain cybersecurity technology and related services (not including hardware). The technology and services must be necessary and used predominantly to implement and maintain effective cybersecurity, and eligibility could not be conditioned on future referrals or business.

#### Comment

Trinity Health support this new exception, however, CMS should provide more clarity around replacement technology given the rapid rate at which technology changes. Further, we recommend CMS provide more certainty around how cybersecurity technology and services are defined.

### **Clarification of Value/Volume Requirement**

CMS proposed new rules establishing an objective standard on when compensation is “determined in a manner that varies with or takes into account the value or volume of referrals or other business.” These rules focus on the actual methodology used to determine the compensation. For variable compensation, the compensation would take into account the value or volume of referrals or other business only if the actual methodology uses a formula that includes a physician’s referrals as a variable. With respect to a fixed compensation amount, compensation would only take into account the volume or value of referrals where the parties utilize a predetermined tiered approach to compensation under which the volume or value of a physician’s prior referrals is the basis for determining the compensation from an entity to a physician.

#### Comment

The current volume or value standard does not provide an objective standard against which to judge whether a proposed compensation arrangement takes into account the volume or value of referrals or the volume or value of other business generated by a physician. Trinity Health strongly supports the proposed revisions and clarity describing what actions are prohibited and recommends CMS require a direct relationship between compensation and value or volume in order to trigger this prohibition.

### **Fair Market Value Definition**

The proposed rule would amend the definition of “fair market value” to conform to the generally accepted meaning of a transaction between two parties at arm’s length and delete the current language that excludes consideration of similar transactions between parties in a position to generate business for the other party in determining market value.

#### Comment

Trinity Health appreciates CMS is proposing to move closer to the statutory definition of fair market value and align it with more general market value in the rule and supports this change. We support the impact of this revision on de-coupling the required evidence of fair market value

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. Further, the modification will increase the number of benchmarks available and provide more support for providers seeking to comply with requirements.

### **Commercial Reasonableness Definition**

CMS is proposing to define an arrangement as commercially reasonable where the particular arrangement furthers a legitimate business purpose of the parties and is on terms and conditions that are similar to like arrangements. The definition also provides that an arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties

#### Comment

We fully support clarifying guidance that providers are able to establish compliance by reference to benchmarks. We also applaud CMS' recognition that delivering value to patients and the community is commercially reasonable and that profit is not required. CMS should finalize the proposed definition of "commercially reasonable" with one important modification. Much of the litigation related to this concept has mistakenly focused on whether the arrangement generated a "profit." We urge that the second sentence, which attempts to address that problem, be revised by making absolutely clear that profit is irrelevant to commercial reasonableness by inserting "Commercial reasonableness is unrelated to the profitability of the arrangement to one or more of the parties."

### **Compliance with Anti-Kickback Statute (AKS)**

The proposed rule would eliminate the requirement in many of the Stark compensation exceptions that an arrangement not violate the AKS or any federal or state billing rules. While CMS noted the parties to an arrangement still have an independent duty to comply with appropriate laws, requiring compliance in order to qualify for a Stark exception was an unnecessary burden.

#### Comment

Trinity Health supports de-coupling intent-based requirements from Stark, especially in light of the difficulty in proving no intent.

### **Designated Health Services Definition**

The proposed Stark regulation would modify the definition of designated health services to exclude services furnished to hospital inpatients if the service does not affect the hospital's Medicare inpatient prospective payment system (IPPS).

#### Comment

Trinity Health cautiously supports this revision—care coordination requires some degree of care management and providers need the ability to work together across our organization to ensure patients receive the right care at the right time. The proposed definition removes some of the existing perceived barriers under the Stark law for innovating care delivery. Further, we recommend CMS expand the definition to also include the Medicare outpatient prospective

payment system (OPPS) as they are paid under similar rate systems as IPPS and be clear the definition is applicable solely for IPPS and OPPS revenue in risk-bearing arrangements.

### **New Special rule for Distribution of Revenue Related to Participation in a Value-Based Enterprise**

CMS proposes to add a new special rule to address downstream compensation deriving from payments made to a group practice (rather than directly to a physician in the group) that relate to the physician's participation in a value-based arrangement.

#### Comment

Under the proposed rule, distribution of profits from DHS that are directly attributable to a physician's participation in a value-based enterprise would be deemed to not directly take into account the volume or value of the physician's referrals. Thus, a group practice could distribute directly to the physician who participated in the value-based enterprise the profits from DHS furnished by the group that derive from the physician's participation; this would include profits from DHS referred by the physician. Trinity Health supports this proposed revision; however, we strongly recommend the following revisions to reduce barriers to qualifying as a group practice:

- 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. **We recommend CMS expand the group practice exception to include hospital/health system affiliated groups, including foundations, limited liability, and professional corporations.**
- The existing exception at 42 CFR 411.357 (g) 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 be 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. We recommend CMS remove subsection (g)(2).

### **Liability for Writing Mistakes**

Trinity Health supports reducing Stark liability for writing mistakes as proposed. Specifically:

- The "limited remuneration to a physician" exception for annual payments under \$3,500 will be extremely helpful to avoid liability for non-abusive conduct. It also will save hospital and

CMS resources in resolving self-disclosures related to arrangements that do not pose risks to federal health care programs.

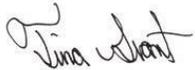
- Similarly, the special rule permitting writings to be completed within 90 days of when an arrangement begins will save hospitals and CMS resources that would otherwise be spent resolving self-disclosures for lapses that do not pose risks to Medicare program. To further address lapses that do not pose a risk to the Medicare program, we urge CMS to deem that a writing requirement is satisfied if the arrangement constitutes an enforceable contract under applicable state law.

### **Conclusion**

Trinity Health shares HHS' 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 and there are additional changes to HHS programs, policies and regulations that are essential to transforming the nation's health care system. Trinity Health is committed to working with HHS to achieve these goals and appreciates the Department's commitment to helping accelerate this transformation and removing barriers.

Thank you for the opportunity to respond to this proposed rule. If you have questions on our comments, please feel free to contact me at [granttw@trinity-health.org](mailto:granttw@trinity-health.org) or 734-343-1375.

Sincerely,



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