December 31, 2019

VIA ELECTRONIC MAIL

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd
Baltimore, MD 21244

Re: Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations (CMS-1720-P) (84 *Fed. Reg.* 55,766 [Oct. 17, 2019])

Dear Administrator Verma:

The Health Care Transformation Task Force (HCTTF or Task Force) appreciates the opportunity to comment on the referenced Centers for Medicare and Medicaid Services (CMS) proposed rule addressing the physician self-referral regulations ("Proposed Rule").

The Task Force is an industry consortium representing a diverse set of organizations from various segments of the industry – including providers, health plans, employers, and consumers – all committed to adopting payment reforms that promote a competitive marketplace for value-based health care. Based on their commitment to move from a system that incentivizes volume of services to one that rewards value of care, our member organizations aspire to have 75 percent of their business in value-based arrangements by the end of 2020. HCTTF strives to provide a critical mass of policy, operational, and technical support from the private sector that, when combined with the work being done by CMS and other public and private stakeholders, can increase the momentum of delivery system transformation.

HCTTF recognizes that CMS's Proposed Rule is one part of a multi-faceted "Regulatory Sprint" to value-based care that is a priority of the Secretary of Health & Human Services (HHS), and that HHS's Office of Inspector General (OIG) has issued a separate proposed rule that seeks to promote greater protection of value-based arrangements under the anti-kickback and civil monetary penalty laws. We urge CMS and OIG to create as much consistency across these important compliance policies as possible, which will help maintain a reasonable burden regarding implementation and reduce inconsistencies in application.

Below, HCTTF provides comments on the Proposed Rule's general approach as well as specific feedback to the newly proposed value-based payment and care delivery exceptions.

I. General Comments

HCTTF supports the consumer-focused goals of the physician self-referral law (Stark Law) to guard against physician referrals that result from inappropriate financial incentives instead of evidence-based clinical care decisions. We believe the underlying framework of the Stark Law should be preserved, while being modernized to address the continuing advancement of value-based payment and care delivery models that move away from the problematic incentives of the outdated fee-for-service system the Stark Law was designed to address.

As a strict liability statute, a party's intent in engaging in a financial arrangement is irrelevant to whether a violation of the Stark Law has occurred. Thus, clear and objective exceptions to the Stark Law are critically important to protect beneficial financial arrangements for which the risk of program or patient abuse is sufficiently low or reasonable and the value-based payment arena presents a ripe area for improvement under the Stark Law.

A. HCTTF Supports the New Approach for Protecting Value-Based Payment Arrangements

As the Proposed Rule notes, CMS's traditional approach to designing exceptions to the Stark Law does not lend itself well to the developing world of value-based payment (VBP), because financial incentives tied to driving desirable outcomes often falls outside traditional fee-for-service arrangements. Therefore, we commend CMS for proposing new regulatory exceptions for value-based payment arrangements that breaks the traditional mold in favor of a new paradigm. By adopting a different approach, CMS proposes to put aside an otherwise applicable set of standards and definitions that do not translate well to value-based payment and care delivery and would be cumbersome in application to those modernized payment concepts. If finalized, the new exceptions would be a major step in eliminating barriers currently faced in implementing value-based arrangements that reward care delivery that results in high quality, cost-efficient care that drives better outcomes for patients and communities.

B. CMS's Value-Based Exceptions Should Protect Existing and New VBP Arrangements Alike

Below, we address the specifics of the new value-based exceptions in more detail. Here, we raise a broader concern that the newly proposed exceptions, when taken as a whole, may not fully protect existing arrangements of health care organizations already providing value-based care through modernized payment arrangements with value principles at the core. Specifically, Task Force members are concerned the new exceptions may not adequately protect existing arrangements of integrated delivery systems. Our recommendations below are designed to address this concern and promote the objectives espoused in the preamble to support highly integrated systems with mature value-based care portfolios.

C. Any Final Monitoring Requirements Should Be Stated Expressly and Reflect the Prospective Nature of Value-based Payment Model Design

The preamble contains statements about troublesome implicit compliance monitoring obligations. Given the critical nature of compliance with exceptions to the Stark Law, **any final exceptions should expressly include specific monitoring requirements that CMS is likely to use to determine compliance**. Ongoing ambiguity around such requirements simply increases the compliance risk of participating parties and does not promote the transparency that parties to these arrangements desire.

Compliance monitoring policies should also reflect the reality that value-based payment and care delivery programs are designed to achieve prospective goals, and that arrangements that focus on engaging in an action or refrain from taking an action are "reasonably designed" to achieve a value-based purpose. However, despite good faith efforts, reasonable designs to achieve a value-based purpose may not to be successful and prospective goals may not be achieved. Under a reasonable regulatory framework, this situation should not immediately make an otherwise compliant arrangement non-compliant, especially retroactively.

Instead, parties should have a reasonable period time to drive and evaluate performance and, after ascertaining non-desirable performance outcomes. to modify the arrangement's design, refine the prospective goal or abandon the model altogether before a potential finding of non-compliance is made. As parties operate in good faith in designing a model, a similar good faith assumption should apply to reasonable performance periods and model evaluations as well as time to implement modifications to or even ending underperforming models. CMS should take steps to expressly recognize these considerations in a final rule.

II. Proposed Exceptions for Value-Based Payment Arrangements

A. General Framework for Exceptions

HCTTF supports the foundation of and premises behind the three proposed value-based payment exceptions. The Proposed Rule sensibly provides great flexibility to stakeholders in designing these arrangements, while calibrating the documentation requirements necessary to support the arrangements based on the level of shared accountability (or downside risk) for which participating physicians are responsible. We support the decision not to tie the protections to a specific type of legal structure or a limited set of desirable payment models. CMS's approach is most likely to lend itself to a system of meaningful exceptions that can evolve over time in combination with advancements in value-based payment and care delivery.

The newly proposed exceptions are also notable for what they do not contain. **We support CMS's decision to avoid inclusion of current Stark Law concepts of fair market value, commercial reasonableness, and "volume or value of referrals" conditions.** These concepts are integrally tied to a fee-for-service world but are materially less relevant in a value-based payment world.

HCTTF supports the decision not to limit the types of remuneration protected by the new exceptions. Flexibility is important across all aspects of these arrangements, and our members find the proposed approach of the HHS Office of Inspector General to limit the types of remuneration protected under proposed anti-kickback safe harbors to be too restrictive.

B. Full Financial Risk Exception

The proposed "full financial risk" exception establishes a desirable "north star" model for value-based payment stakeholders to fully pursue a move to shared accountability value-based models. However, some question remains as to whether the proposed exception would adequately capture and protect all of the various arrangements involving components of an integrated delivery system.

While the preamble states that both capitation and global budgets fall into the "full financial risk" category (*see* 84 *Fed.Reg* at 55,779), we seek to clarify that the exception would

cover all arrangements among integrated delivery components that operate under the capitation and global budget arrangements, including sub-capitation and more limited global budget arrangements. Clarification is needed because the proposed exception requires that remuneration is "for or results from" value-based activities undertaken by the recipient of the remuneration for the targeted population. It is not clear whether all activities of an integrated delivery system subject to global budget arrangements - either upstream or downstream – will relate to the value-based activities for a targeted population. Thus, there's a question as to whether this exclusion could be used by an integrated delivery system. (A similar concern relates to the value-based arrangements exception, which uses the same language regarding remuneration and value-based activities.)

C. Meaningful Financial Risk Exception

We understand and support the concept of a sliding scale related to the assumption of risk under value-based contracts and the level of protection afforded by a Stark exception. However, our members believe the meaningful financial risk exception parameter of at least 25 percent sets the bar too high based on the current state of value transformation progress. A more modest parameter would establish a more realistic standard based upon current marketplace activity without heightening concerns about creating inappropriate payment incentives that the Stark Law is designed to address. While physicians are moving in the direction of assuming greater risk, we urge CMS to significantly lower the qualifying threshold for this proposed exception to provide a meaningful financial risk parameter for this policy.

D. Value-Based Arrangements Exception

HCTTF supports the value-based arrangements exception as proposed, with minor modifications. While the Task Force firmly believes that value-based transformation should drive parties to shared accountability (or two-sided risk) arrangements, the reality is that is not where parties usually begin. Because the traditional Stark exceptions paradigm does not represent a good framework for value-based exceptions without regard to risk assumption, the value-based arrangement serves a useful purpose as a way to encourage adoption of value models. While HCTTF supports the move away from the cornerstone principle of fair market value in the more advanced value-based payment related exceptions, **we believe that a fair market value requirement would provide a reasonable guardrail in this more expansive exception and urge CMS to consider modifying the proposal accordingly.**

In line with other comments questioning whether the proposed exceptions adequately protect mature value-based models, we reiterate the comment made above in the context of the full financial risk exception.

E. Proposed Stark Exception for Integrated Delivery Systems

As indicated above, our members question whether the proposed exceptions protect all existing value-based arrangements that early adopters of value-based payment and care delivery models are operating**.** While other HCTTF recommendations address how this concern could be addressed through CMS's proposed framework, adding another additional exception may be an easier and cleaner way to achieve this goal.

Our members believe CMS should consider promulgating another new exception for integrated delivery systems. This exception could protect all remuneration paid among

components of a value-based integrated delivery system that includes a payer, hospitals, and dedicated physician/medical groups, including physician owners, employees and contractors, where all of the components of the integrated delivery system are substantially dedicated to value-based activities and the integrated system globally budgets for substantially all of the activities of its participants.

F. Proposed Stark Exception for CMS-Sponsored Models and Patient Incentives

HCTTF urges CMS to consider promulgating a Stark exception similar to the OIG's proposed safe harbor for CMS-sponsored models and patient incentive programs. (*See 42* C.F.R. Proposed §1001.952(ii).) While the other proposed exceptions have a broader impact and are potentially across multiple lines of business, an exception that protects Centers for Medicare & Medicaid Innovation Center models would provide clarity and consistency for participants in those models and obviate the need for the development of specific Stark-related waivers, which are often finalized late in a model development process and therefore impactful on the decisions to participate by multiple health care organizations.

III. Definitions

The Proposed Rule first sets forth a series of new definitions addressing a variety of value-based payment and care delivery concepts that are central to each of the three proposed new exceptions. HCTTF generally supports the new definitions; each effectively addresses important underpinnings of value-based payment and care delivery and provides a framework for the type of arrangements, purposes, actors and activities that should be protected.

A. Value-Based Enterprise

We understand that CMS intends for the definitions to be broad in scope to support protecting a wide range of value-based activities. With this goal in mind, we urge CMS to revisit the definition of value-based enterprise, as we are concerned that the proposal does not adequately cover existing arrangements and structures of integrated delivery systems. Specifically, CMS should consider refining this definition in a manner consistent with the comments made above for the proposed full financial risk exception.

B. Value-Based Purpose

HCTTF generally supports the four proposed categories of value-based purposes, and the flexibility for arrangements to pick or combine such purposes as desirable for particular arrangements. However, the desirable Triple Aim of higher quality care that costs less and results in better outcomes and population health remains a widely support framework, and the importance of pursuing models that both drive quality and reduce cost should be paramount. Therefore, HCTTF believes any protected payment arrangement under these new exceptions should be designed to reduce cost and improve quality at a minimum and may serve other value-based purposes, too.

C. Value-Based Activities

The range of covered activities should be sufficiently broad as to cover all ordinary operations of a value-based integrated delivery system. Where an integrated delivery system generally furnishes care under and through global budget or capitated arrangements, there are likely components of that continuum of care that fall outside those global budget or capitated

arrangements. Therefore, HCTTF urges CMS to consider adopting a "substantially all" test for the items and services for which the value-based enterprise assumes financial risk, such that the incidental services and associated remuneration for those services receive protection also.

D. Target Patient Population

Many existing value-based payments arrangements, including those operated by integrated delivery systems, focus on transforming the way care is delivered for all of their enrollees or patients, and not just a particular targeted population as the Proposed Rule contemplates. Thus, CMS should revisit its proposals addressing target patient populations to recognize this and finalize policy that does not result in a value-based arrangement running afoul of the new exceptions because a specific target population cannot be identified for an organization's value-based programs.

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HCTTF appreciated HHS and CMS leadership on the Regulatory Sprint to Value-Based Care and, in particular, the proposal to modernize Stark Law-related policies. Please contact HCTTF's Executive Director Jeff Micklos (jeff.micklos@hcttf.org or 202.774.1415) with any questions about or follow up to this letter.

Sincerely,

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