



December 31, 2019

VIA ELECTRONIC MAIL

Joanne M. Chiedi
Acting Inspector General
Office of Inspector General
U.S. Department of Health & Human Services
220 Independence Ave SW, Room 5521
Washington, DC 20201

Re: Medicare and State Healthcare Programs; Fraud and Abuse: Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements (OIG-0936-AA10-P) (84 Fed.Reg. 55,694 (Oct. 17, 2019))

Dear Ms. Chiedi:

The Health Care Transformation Task Force (HCTTF or Task Force) appreciates the opportunity to comment on the referenced Office of Inspector General, Department of Health & Human Services (OIG) proposed rule addressing the anti-kickback and civil monetary penalty laws ("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 the OIG'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 Center for Medicare & Medicaid Services (CMS) has issued a separate proposed rule that seeks to promote greater protection of value-based arrangements under the physician self-referral law. We urge OIG and CMS to finalize compliance policies with as much consistency as possible, which would impose a reasonable implementation burden 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 safe harbors.

I. General Comments

HCTTF supports the consumer-focused goals of the anti-kickback (AKS) and civil monetary penalty (CMP) laws to shield the delivery of health care items and services from improper financial incentives. The underlying framework of both laws should be preserved, while being modernized to address the continuing advancement of value-based payment and care delivery models designed with modern financial arrangements that promote high quality care at lower cost driving desirable outcomes and improved population health.

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

We commend the OIG for proposing new regulatory safe harbors for value-based payment arrangements. By adopting an approach specifically focused on value-based payment arrangements, the OIG emphasizes the importance of value-based payment and care delivery concepts that are worthy of protection and recognizes the consumer-favorable nature of these programs. If finalized with the modifications outlined below, the safe harbors 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. OIG's Value-Based Safe Harbors Should Protect Existing and New VBP Arrangements Alike

Below, we address the specifics of the new value-based safe harbors in more detail. Here, we raise a broader concern that the newly proposed safe harbors, 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 safe harbors 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 Proposed Rule's preamble to support highly integrated systems with mature value-based care portfolios.

II. Proposed Safe Harbors for Value-based Payment Arrangements

A. General Framework for Safe Harbors

HCTTF supports foundation of and premises behind the proposed value-based payment safe harbors. However, we are concerned that the safe harbors do not offer protection to meaningful value-based arrangements that are not tied to a physician's shared risk of losses. The Proposed Rule sensibly provides great flexibility to stakeholders in designing these arrangements, while calibrating the requirements necessary to support the arrangements based on the level of shared accountability (or downside risk) for which participating physicians are responsible. However, many entry-level value-based payment models do not put physicians at downside risk, yet shared many of the same purposes that are otherwise worthy of safe harbor

protection. **We urge the OIG to provide safe harbor protection for upside risk only models so that uptake of value-based models is not curtailed over concerns about potential AKS exposure.**

We are also concerned that unlike the proposed physician self-referral exceptions, the OIG's proposed safe harbors would impose traditional requirements related to commercial reasonableness, fair market value, and taking into account volume or value of referrals that are the primary obstacles today to operating value-based payment models. We urge the OIG to rethink this approach and finalize safe harbors that better recognize value-based arrangements that provide remuneration related to achieving certain clinical or cost improvements that are tied to changes in referral patterns.

We support the decision not to tie the safe harbor protections to a specific type of legal structure or a limited set of desirable payment models. The OIG's flexible approach is most likely to lend itself to a system of meaningful safe harbors that can evolve over time in combination with advancements in value-based payment and care delivery.

B. Full Financial Risk Safe Harbor

The proposed "full financial risk" safe harbor establishes a desirable "north star" model for value-based payment stakeholders for fully pursuing a move to shared accountability value-based models. However, some question remains as to whether the proposed exception would adequately capture and protect all 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 55,699*), we seek to clarify that the safe harbor 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 safe harbor 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 safe harbor could be used by an integrated delivery system. (A similar concern relates to the care management safe harbor, which uses the same language regarding remuneration and value-based activities.)

C. Substantial Downside Risk Safe Harbor

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 an AKS safe harbor. However, our members believe the substantial downside risk parameters sets the bar too high based on the current state of value transformation progress. More modest parameters would establish a more realistic standard based upon current marketplace activity without heightening concerns about creating inappropriate payment incentives that the AKS is designed to address.

D. Care Coordination Arrangements Safe Harbor

HCTTF general supports the proposed Care Coordination Arrangements Safe Harbor. However, we urge the OIG to expand the permissible remuneration beyond just in-kind and provide greater flexibility and acceptance in recognizing other types of remuneration that may incentivize the desired behavior.

We support the proposed termination policy. It's important to establish expectations for what should occur when an arrangement is determined to not be successful in coordinating and managing care for the target population. The proposed termination policy is triggered by regular monitoring and assessment of an arrangement for which the proposed safe harbor sets a reasonable timeframe.

This safe harbor should protect remuneration that benefits patients outside of the target patient population, and the OIG should not pursue its alternate proposal to only protect remuneration that is tied to the target patient population. The broader benefit to patient populations as a whole is a logical outcome of effective value-based payment models, such that tying protection to a targeted patient population will often be too narrow and limiting.

E. CMS-Sponsored Models and Patient Incentives Safe Harbor

HCTTF fully supports the OIG's proposed safe harbor for CMS-sponsored models and patient incentive programs. While the other proposed safe harbors have a broader impact and apply potentially across multiple lines of business, a safe harbor that protects Centers for Medicare & Medicaid Innovation Center models will provide clarity and consistency for participants in those models and obviate the need for the development of specific AKS-related waivers, which are often finalized late in a model development process and therefore impactful on the decisions to participate by health care organizations.

F. Patient Engagement and Support Safe Harbor

The HCTTF generally supports the inclusion of the proposed safe harbor for arrangements for patient engagement and support to improve quality, health outcomes, and efficiency. With an ever-increasing focus on the social needs of enrollees or target populations, it is critical that such innovative initiatives receive support and protection. We urge the OIG to leave sufficient flexibility in the safe harbor by not being overly restrictive with a specified list of tools and supports to protect at the exclusion of others. The safe harbor should be styled in a way that allows for the advances likely to come forward in the next few years to receive similar protections.

G. Proposed Safe Harbor for Integrated Delivery Systems

As indicated above, our members question whether the proposed safe harbors 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 the OIG's proposed framework, adding another additional safe harbor may be an easier and cleaner way to achieve this goal.

Our members believe the OIG should consider promulgating another new safe harbor for integrated delivery systems. This safe harbor 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.

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 safe harbors. 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 the OIG 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 the OIG to revisit the definition of value-based enterprise (VBE), as we are concerned that the proposal does not adequately cover existing arrangements and structures of integrated delivery systems. Specifically, the OIG should consider refining this definition consistently with the comments offered above related to the full financial risk safe harbor.

The Proposed Rule indicates that VBEs are prohibited from marketing to patients. While generally supportive of the policy, we are concerned that the prohibition may go too far and bar the VBE from publishing quality improvement or cost reduction results. In the shared interest of transparency, VBEs should be permitted to share performance data regarding VBE participants to help inform patient choice of high performing providers.

B. Value-Based Purpose

HCTTF generally supports the 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 supported 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 safe harbors should be designed both 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 the OIG 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, the OIG 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 safe harbors because a specified target population is not be identified for an organization's value-based programs.

IV. Local Transportation

The HCTTF supports the proposed changes which expand the scope of protected local transportation services. The removal of the mileage limits on hospital discharge transports to a patient's residence is sensible, and the definition of residence should include a custodial care facility, which may be needed on a temporary or permanent basis. We believe the OIG should adopt a similar policy for transports to a sub-acute care facility too.

Given the rising importance of addressing social needs, we believe the OIG should add protection of transportation to non-medical facilities that are part of a care coordination plan and/or that address social determinants of health (e.g., access to food, social services, exercise facilities).

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HCTTF appreciates HHS and the OIG's leadership on the Regulatory Sprint to Value-Based Care and in particular the proposal to modernize the anti-kickback and civil monetary penalty-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.

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