October 26, 2018

VIA ELECTRONIC MAIL

Daniel Levinson
Inspector General
Office of the Inspector General
330 Independence Avenue SW
Washington, DC 20201

Re: Request for Information regarding the Anti-Kickback Statute and Beneficiary Inducements CMP

Dear Inspector Levinson:

The Health Care Transformation Task Force (HCTTF or Task Force) thanks the Office of the Inspector General (OIG) for seeking information from the public on how to address regulatory provisions of the anti-kickback statute (AKS) and beneficiary inducements civil monetary penalty (CMP) that may act as barriers to coordinated care and value-based care.

The Task Force is a consortium of over 40 private sector stakeholders that support accelerating the pace of transforming the delivery system into one that better pays for value. Representing a diverse set of organizations from various segments of the industry – including providers, health plans, employers, and consumers – we share a common commitment to transform our respective businesses and clinical models to deliver better health and better care at reduced costs. Our member organizations aspire to have 75 percent of their business in value-based arrangements by 2020. We strive to provide a critical mass of policy, operational, and technical support from the private sector that, when combined with the work being done by HHS and other public and private stakeholders, can increase the momentum of delivery system transformation.

When physicians are financially incentivized not by the volume of services but by the efficiency of services and treatment outcomes, their economic self-interest aligns with the interest to eliminate unnecessary services. Increasingly, the laws intended to protect from overutilization and decisions based on financial interest – including the Anti-Kickback Statute – have become a significant impediment to implementing value-based care and alternative payment model (APM) arrangements in both the Medicare fee-for-service and Medicare Advantage programs.

In this letter, the Task Force identifies areas where OIG can mitigate the impact of the AKS regulations on providers and health plans participating in alternative payment models to encourage

better care coordination. Our comments herein reiterate many of our recommendations to CMS in response to a parallel request for information regarding Stark law regulations.[1] While there are desired changes that will take Congressional action to better align the relevant statutes, OIG and CMS can and should take action now to achieve greater consistency in definitions and safe harbors/exceptions to support the transition to value.

I. Promoting care coordination and value-based care

With the risk-sharing provisions of advanced APMs, providers are taking on a given percentage of risk related to overall revenue. OIG should modernize its fraud and abuse policies to support value-based care and allow for greater care coordination within the construct of APMs.

A. Create new safe harbors and exceptions for risk-taking alternative payment model participants

i. Alternative Payment Model exception

Additional AKS safe harbors/CMP exceptions are warranted for alternative payment model participants that involve at least nominal risk-taking and encourage integration of care, items, services, and payment. This type of risk arrangement between providers and payers for services provided to APM aligned beneficiaries is analogous to the risk arrangements defined in existing risk-sharing exceptions. OIG should expand existing the exception to apply to arrangements as a part of alternative payment models, and this may easily be accomplished by expanding related definitions. In particular, we recommend that a safe harbor be created to protect all Accountable Care Organizations (ACOs) and other organizations implementing Alternative Payment Models (APMs), including all provider types within those organizations, that meet certain conditions – regardless of whether or not they participate in a Medicare-sponsored project (e.g., ACO, APM, bundled payment initiative) and whether the ACO participates in a value-based (cost and quality built into the model) alternative payment arrangement with a Medicare Advantage plan or a managed Medicaid plan (or similar health plans which contract with the government on a capitated or other financial risk basis).

ii. Disease Management and Prevention exception

We propose a consistent AKS safe harbor and CMP exception that provides protection for items and services provided in evidence-based disease management and prevention programs. We recognize and appreciate the availability of the preventive care exception to the CMP statute but note that the same exception does not exist under the Anti-Kickback or the Physician Self-Referral (i.e., Stark) laws. While the OIG has acknowledged the value of preventive services with this CMP exception, a complicated and burdensome analysis is still required to ensure compliance with AKS and Stark. We urge the OIG to consider alignment and simplification when it comes to an exception for preventive care. A single, broader disease management and prevention exception would reflect the greater emphasis, in health care, on preventive care and managing chronic diseases and better empirical data on wellness and management techniques. Such programs improve communication between providers and patients, care coordination and patient engagement. They can also reduce the cost of health care over time by reducing hospitalizations and other expensive treatments.

[1] http://hcttf.org/cms-stark-law-rfi-response/

B. Define terminology regarding health care delivery and payment reform

OIG and CMS should together strive to establish clear definitions and bright line standards for payment arrangements that take into account the volume or value of services, in line with definitions established under the Quality Payment Program (MACRA).

i. Fair Market Value

HCTTF recommends that OIG and CMS clarify, in regulation or guidance, the definition of fair market value (FMV), and establish simpler and standard processes for establishing FMV. We recommend redefining FMV to account for value-based payment models and provide flexibility to allow collaboration among various stakeholders. Additionally, HCTTF recommends that OIG issue regulations or guidance on establishing and documenting FMV in value-based payment settings. A new definition of FMV and standards for documenting FMV should include safeguards relating to quality, payment caps, and similar criteria to ensure accurate assessment in a value-based environment without compromising program integrity or patient access.

ii. Volume or Value

HCTTF proposes that OIG issue regulatory guidance on how to apply the "volume or value of referrals" standard within the changing healthcare payment environment. For example, this guidance could clarify whether incentive payments to improve quality, even if they partially reflect the volume or value of a provider's referrals, are permissible. To protect against fraud or abuse, the definition could include quality of care requirements to ensure that variable payment rates based on volume or value vary solely or primarily on outcomes. CMS should solicit stakeholder input on the quality of care requirements to apply in this definition.

II. Current fraud and abuse waivers

With the implementation of Alternate Payment Models (APMs), HHS has recognized the need to waive certain compliance requirements for APM participants.[2] Through existing waivers, APM participants have been able to better meet the needs of individual patients in a variety of innovative ways. The current waiver process could be improved in the following ways.

A. Expand sub-regulatory guidance regarding the applicability of AKS

Our members have been early adopters of Medicare's APMs and utilize the fraud and abuse waivers to support improved patient care. However, given the novelty of APMs, providers are understandably cautious to utilize waivers when applicability is unclear. Our members report uncertainty around the availability of particular waivers due to limited commentary about OIG's and CMS's intended scope or applicability for particular APM participants. Given that waivers are currently available on an opt-in basis, this uncertainty has led some stakeholders to decline the opportunity out of fear of noncompliance if they implement a waiver incorrectly.

Despite CMS defining the methodology and program rules for APMs as well as administering program integrity oversight for APM participants, the Agency is currently not authorized to comment, informally or formally, on the application of the fraud and abuse waivers issued for the Model to each

[2] https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html

potential participant's unique circumstances. While this limitation is understandable, **we urge OIG to expedite and regularly update Frequently Asked Questions guidance documents and/or commentaries in response to recurrent questions regarding common provider circumstances**.[3] HCTTF would be pleased to collaborate with OIG in developing common provider situations on which guidance would be helpful. OIG and CMS should also explore mechanisms for providers to ask questions for guidance about the waivers short of a traditional Advisory Opinion.

When regulated entities have abundant sub-regulatory guidance on their legal compliance requirements under Stark, entities will have a better understanding of what activities are and are not permitted. If OIG and CMS were to provide more frequent and timely sub-regulatory guidance on AKS Stark, this in itself could reduce some of the regulatory burden of compliance and may encourage more providers to participate in APMs.

B. Simplify and streamline available waivers in the context of APM arrangements

HHS should streamline available waivers and safe harbors in the context of alternative payment model arrangements. We recommend the Department specify a core set of waivers for all APMs which would serve as a minimum approach to regulatory relief, without the need for an opt-in approach, and add additional waivers on a model-by-model basis. With the plethora of APMs now being tested by CMMI, a hodgepodge of regulatory waivers exists. With different waivers applying to different models, there is confusion about the applicability of these waivers. For instance, there is extreme confusion in the market place about how the BPCI program gainsharing waivers and Medicare Shared Savings Program (MSSP) waivers interact when an entity is participating in both programs.

HCTTF believes that a core set of waivers for all APMs would go a long way in alleviating the current confusion. Additionally, members report that the process for implementing the waivers can be burdensome and confusing as it differs among models, and requires additional data collection and reporting to comply. HCTTF recommends that CMS and OIG establish one uniform process for waiver implementation, to assist in compliance, and publish any exceptions on the OIG and CMS web sites in a central location so that stakeholders are aware of allowable practices and of the applicability of waivers to certain programs. The Department should align waiver language and applicability around the APM entity definitions defined by the Quality Payment Program to further gain efficiencies across multiple CMS programs.

III. Intersection of physician self-referral law and anti-kickback statute

Any changes made to the Stark Law regulations or AKS implementing regulations should be accompanied by corresponding changes to the other to ensure consistency of approach and enforcement across CMS and OIG. A consistent approach by the two agencies will serve to reduce regulatory burdens for providers. As mentioned above, Stark and AKS regulatory definitions should also be aligned with the Quality Payment Program to promote consistency and reduction in regulatory burden on stakeholders.

[3] We note that CMS has issued numerous FAQs under other statutes, as have other agencies, to provide regulated entities guidance on frequently-occurring fact patterns to assist in compliance.

IV. Legislative action needed to further modernize fraud and abuse laws

There are clear actions that OIG can take now to improve the impact of the AKS law on innovative new payment models that hold providers accountable for cost and quality outcomes, but further action is needed from Congress to create a policy framework conducive to shifting care to value-based models. HHS and Congress should work to align the Stark Law with the Anti-Kickback Statute, to ensure consistency across governing agency interpretations. This may include making conforming changes to the Anti-Kickback Statute and/or its implementing regulations, ensuring that modified Stark language aligns with existing Anti-Kickback provisions, and/or issuing joint agency guidance discussing how to approach and manage changes to either or both laws.

The Task Force appreciates the opportunity to advise OIG regarding the impact of the Anti-Kickback Statute regulations. Please contact HCTTF Executive Director Jeff Micklos (jeff.micklos@hcttf.org or 202.774.1415) with questions related to this statement.

Francis Soistman
Executive Vice President and President of Government Services
Aetna

Stuart Levine, MD
Chief Medical and Innovation Officer
agilon health

Farzad Mostashari, MD
Founder & Chief Executive Officer
Aledade, Inc.

Shawn Martin
Senior Vice President, Advocacy, Practice Advancement and Policy
American Academy of Family Physicians

Hoangmai Pham, MD
Vice President, Provider Alignment Solutions
Anthem, Inc.

Peter Leibold
Chief Advocacy Officer
Ascension

Warren Hosseinion, MD
Chief Executive Officer
ApolloMed

David Terry
Founder & Chief Executive Officer
Archway Health

Marci Sindell
Chief Strategy Officer and Senior Vice President of External Affairs
Atrius Health

Dana Gelb Safran, Sc.D.
Chief Performance Measurement & Improvement Officer and
Senior Vice President, Enterprise Analytics Performance Measurement & Improvement
Blue Cross Blue Shield of Massachusetts

Kevin Klobucar
Executive Vice President, Health Care Value
Blue Cross Blue Shield of Michigan

Rahul Rajkumar, MD
Chief Medical Officer
Blue Cross Blue Shield of North Carolina

Ann T. Burnett
Vice President
Provider Network Innovations & Partnerships
Blue Cross Blue Shield of South Carolina

John Driscoll
Chief Executive Officer
CareCentrix

Gaurov Dayal, MD
Executive Vice President, Chief of Strategy & Growth
ChenMed

Jean Drouin, MD
Founder and Chief Executive Officer
Clarify Health

Monica Deadwiler
Senior Director, Health Care Payment Innovation
Cleveland Clinic

Susan Sherry
Deputy Director
Community Catalyst

Colin LeClair
Chief Development Officer
ConcertoHealth

Shelly Schlenker
Vice President, Public Policy, Advocacy & Government Affairs
Dignity Health

Mark McClellan, MD, PhD
Director
Duke Margolis Center for Health Policy

Chris Dawe
Senior Vice President
Evolent Health

Karen Murphy, **PhD**
Executive Vice President, Chief Innovation Officer
Geisinger

Angelo Sinopoli, MD
Vice President, Clinical Integration & Chief Medical Officer
Greenville Health System

David Klementz
Chief Strategy and Development Officer
Encompass Health

Anne Nolon
President and Chief Executive Officer
HRH Care Community Health

Anthony Barrueta
Senior Vice President, Government Relations
Kaiser Permanente

Leonardo Cuello
Director
National Health Law Program

Debra Ness
President
National Partnership for Women & Families

Robert Sehring
Chief Exective Officer
OSF HealthCare System

David Lansky
President and Chief Executive Officer
Pacific Business Group on Health

Sree Chaguturu, MD
Chief Population Health Officer
Partners HealthCare

Jay Desai
Founder and Chief Executive Officer
PatientPing

Blair Childs
Senior Vice President, Public Affairs
Premier

Christopher Garcia
Chief Executive Officer
Remedy Partners

Jessie Israel
Senior Director of Accountable Health
SCL Health

Richard J. Gilfillan, MD
Chief Executive Officer
Trinity Health

Martin Hickey, MD
Chief Executive Officer
True Health New Mexico

Judy Rich
President and Chief Executive Officer
Tucson Medical Center Healthcare

Mary Beth Kuderik
Chief Strategy & Financial Officer
UAW Retiree Medical Benefits Trust

J.D Fischer
Program Specialist
Washington State Heath Care Authority