



October 26, 2018

Daniel R. Levinson
Inspector General
Department of Health and Human Services
330 Independence Avenue, SW, Room 5250
Washington, DC 20201

RE: Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducement CMP;
Submitted electronically via <http://www.regulations.gov>

Dear Inspector General Levinson,

Trinity Health appreciates the opportunity to respond to the Office of Inspector General's (OIG) Request for Information (RFI) on ways to modify or add regulatory safe harbors and exceptions for the Anti-Kickback Statute (AKS) and beneficiary inducement Civil Monetary Penalty (CMP) to foster arrangements that would promote care coordination and advance the delivery of value-based care, while also protecting against harms caused by fraud and abuse. 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 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 1.5 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 Next Generation ACO, Medicare Shared Savings Program (MSSP) Tracks 1, 1+ and 3, the Comprehensive Primary Care Plus (CPC+) program, and the Bundle Payment for Care Improvement (BPCI) and BPCI Advanced programs.

Our comments and recommendations on the AKS 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 and we recently were approved to participate in the Bundled Payments for Care Improvement Advanced 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 1.5 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.

Trinity Health is very interested in further pursuing care delivery and payment enhancements, such as care coordination, value-based arrangements, alternative payment models, arrangements involving innovative technology, and other novel financial arrangements, such as outcomes based incentives that may implicate the anti-kickback statute or beneficiary inducements CMP. Current laws, regulations and safe harbors impair providers' ability to measure and incent reductions in length of stay, coordination of care involving continuity of care within networks and care delivery in the appropriate setting. Currently rewards to providers for value-based care carry the imputation that the rewards are payments for referrals. Current CMP and beneficiary inducement limitations also impair providers' ability to incent beneficiaries to choose and actively participate in coordinated care and care delivery innovations including telehealth services.

We agree with the observations of the American Hospital Association (AHA) noting that the Department of Health and Human Services (HHS), the Centers for Medicare & Medicaid Services (CMS), the Office of the Inspector General (OIG), hospitals, and health systems all agree that fraud and abuse laws can be an impediment to the development and implementation of value-based payment models that reward providers for delivering higher-quality, cost-effective care with better outcomes. These barriers impair beneficiaries' access to high quality, coordinated and cost effective care.

We concur with the AHA's recommendation that to reach the full potential of a value-based system, OIG should create two new AKS safe harbors: one for value-based payment arrangements, and the other for assistance to patients for better health.

The value-based payment arrangement safe harbor should remove from the definition of remuneration payments between participants in programs designed to assure coordinated care and improved outcomes for patients. Programs that include monitoring and measurements of impacts on readmissions and costs of care should be permitted for patients previously cared for by the provider and patients who are included in the provider's attributable lives. Investments in development of new models of care delivery and funding for collaborative efforts including conferences, analytics and technology should be included in a value-based safe harbor. The CMPs should be expanded to protect programs where the documented and measured goals are high quality and lower cost. Direct and indirect value to referring providers should be permitted in these programs.

The assistance to patients' safe harbor should remove from the definition of remuneration items of value provided to patients to ensure coordinated care, access to social services, health care and improved health status of patients. For example, providers should be able to provide patients with supplies, non-covered items, coaching and counseling, shelter, food and transportation (social determinants of health) to facilitate recuperation and/or health living. Patients should be permitted the choice to obtain services from providers who provide patient-centered care designed to meet the patients' health and well-being.

We support the continued use of waivers for new and innovative programs, but believe waivers alone are insufficient due to duration and program limitations. We encourage the OIG and CMS to extend the waivers to all patients, including patients covered by commercial insurance and self-pay.

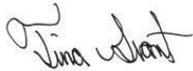
To facilitate implementation of these important enhancements in the delivery of care we also urge OIG and CMS to ensure that the exceptions to the physician self-referral law and safe harbors to the anti-kickback statute align and support the goals of a value-based payment and delivery system.

Mitigating the risks to the Medicare program and beneficiaries are transparency and financial accountability to payers. Payment models that do not increase costs to Medicare should not be required also to establish the fair market value of each payment in the model.

We agree with AHA that existing quality of care measures and safeguards are sufficient and that new safe harbors can be established without risk of negatively impacting quality. Finally, we, like AHA, urge OIG to make clear that satisfaction of a safe harbor will protect providers from prosecution regardless of the existence of alleged wrongful intent.

Trinity Health believes strongly that CMS payment policies and rules should not interfere with making sure the right thing is done at the right time for all beneficiaries. Thank you for the opportunity to respond to this RFI. If you have questions on our comments that follow, please feel free to contact me at granttw@trinity-health.org or 734-343-1375.

Sincerely,

A handwritten signature in cursive script that reads "Tina Weatherwax Grant".

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