December 31, 2019

Joanne Chiedi
Acting Inspector General
Department of Health and Human Services
330 Independence Avenue, SW, Room 5250
Washington, DC 20201

RE: OIG-0936-AA10-P: 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

Submitted via www.regulations.gov

Dear Inspector Chiedi,

Trinity Health appreciates the opportunity to respond to the Office of Inspector General's (OIG) proposed rule *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.* 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 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 the direction HHS is headed with the proposed rule and applauds the OIG for creating new safe harbors for value-based arrangements and patient engagement—the agency listened to many recommendations we submitted on the October 2018 Anti-Kickback Statute (AKS) and Beneficiary Inducement Civil Monetary Penalty (CMP) Request for Information. We appreciate OIG's attempts to reduce burden and provide additional protections for value-based care arrangements and recommend the OIG and CMS work to more closely align Anti-Kickback and Stark requirements where possible to reduce complexity and confusion for providers.

Proposed Anti-Kickback Safe Harbors

The proposed AKS regulation would create three new safe harbors for value-based arrangements:1) participants take on "full financial risk" for all covered items and services, with prospective payment by the payor, 2) option in which participants take on substantial downside financial risk—at least 40% of shared losses; at least 20% of total losses for episodic or bundled payments; prospective population-based payment; or 3) a partial capitated payment reflecting a discount of at least 60% from expected fee-for-service payments. The third safe harbor does not require taking on risk and would permit certain in-kind benefits under a value-based arrangement that promotes care coordination and management for a target patient population.

Comment

Trinity Health appreciates the OIG needs to balance facilitating innovation with fraud and abuse concerns; however, there is room for the AKS safe harbors to more closely mirror the exceptions being proposed in the CMS Stark rule—such as removing the monetary restriction and the 15% contribution requirements. As proposed, it will be challenging to foster innovation under the new safe harbors—entities involved in value-based arrangements will need to continue to rely on lawyers to provide opinions on the degree of risk; maintaining existing burdens HHS is seeking to lessen. We suggest OIG consider adding that compliance with stark rebuts any implication of intent under AKS and for this reason suggest that the Stark and AKS safe harbors should be mirrors.

OIG could provide additional flexibility to the no risk safe harbor by requiring provider participants to pay expenses for operating the value-based arrangements prior to sharing generated savings. In other words, participants would be entitled to monetary compensation provided that the enterprise first satisfies its expenses and only allow for remuneration if actual value is created—avoiding having value-based enterprises running at a loss perpetually. For example, Trinity Health participates in the Next Generation ACO Model run through the Centers for Medicare and Medicaid Innovation (CMMI). Once we receive payment from CMMI, we first pay off costs associated with running the model—i.e. care management, data analytics, etc.—

prior to passing on savings to participants. Therefore, we ensure doctors are driving down costs through the model prior to providing payment from model savings.

The AKS safe harbors require evidence-based outcome measures with the consequence of terminating an arrangement within 60 days if outcomes are not met. We recommend OIG provide flexibility around monitoring and outcomes of these arrangements as it takes time to see results in new arrangements and metrics may be met in some years and not others. In addition, long-standing arrangements may see a plateau in achieving outcomes after they've been in place for a while. We recommend OIG revise the rule to allow participants to prospectively modify their measures, rather than be required to end the value-based arrangement. We suggest that maintenance of gains should be a permitted outcome and also suggest remedies could include new tools or processes. We also support continued attention to measures to ensure they are meaningful and contribute to quality and cost reduction

Patient Engagement tools (new safe harbor)
The OIG proposes a new AKS safe harbor allowing a participant in a value-based arrangement to offer in-kind "patient engagement tools or support" directly to patients in a target population, up to an aggregate retail value of $500 per year. The protected tools or support must be related to care coordination and management for the target population and must be recommended by the patient's licensed health care provider. These could include preventive items or services, health care technology, patient monitoring tools and services, and support or services designed to address social determinants of health, but not gift cards, cash or cash equivalents.

Comment
Trinity Health is committed to advancing the health of individuals and populations and strongly believe HHS can do more to support addressing social influencers of health, which research has shown to be related to health outcomes. Trinity Health fully supports the new safe harbor that allows participants in a value-based care arrangement provide patient engagement tools and supports. However, we urge the OIG to allow for more than $500 per year, as this allotment is too low for patients with complex medical conditions, such as dual eligibles or patients with end-stage renal disease, and annual caps may be difficult to track due to ambiguity in defining support. We recommend OIG work with CMS to develop an appropriate methodology, feasible alternatives may be: 1) determine allotments for patient engagement by patient eligibility category (i.e., aged, disabled, dual-eligible) or disease, 2) propose a limit based on historical cost, or 3) identify an appropriate cap per patient engagement tool. Further, certain types of support should not be counted – such as transportation and home monitoring – many of which are reimbursed by government payers. Trinity Health recommends OIG work with CMS to determine supports that should be excluded from the financial limits.

Other Modifications
Local transportation
OIG proposes modifications to the existing safe harbor for local transportation that expand mileage limits for rural areas and for transportation for patients discharged from inpatient facilities.

Transportation to and from medical appointments is vital for our patients and we support all new flexibilities. However, we recommend OIG review the reporting and record keeping requirements associated with transportation authority through the lens of HHS' Patients Over Paperwork Initiative and identify ways to streamline requirements and reduce burden.

ACO beneficiary incentive programs

Trinity Health appreciates OIG's codification of ACO beneficiary incentive programs. However, similar to the transportation flexibility, we recommend OIG review the administrative burden associated this flexibility---which we find is the key deterrent to providing these services. Requirements for beneficiary incentive programs must be broadly applied, and can therefore lack impact, and the record keeping is burdensome.

Telehealth technology

The proposed rule would amend the existing definition of remuneration that incorporates the new statutory exception to the prohibition on beneficiary inducements for telehealth technologies furnished to certain in-home dialysis patients.

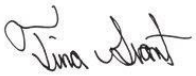
Trinity Health strongly supports any flexibility that helps to encourage in-home dialysis.

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 or 734-343-1375.

Sincerely,



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