AMERICA'S ESSENTIAL HOSPITALS

October 26, 2018

Daniel Levinson
Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5513
330 Independence Avenue SW
Washington, DC 20201

Ref: OIG-0803-N: Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP

Dear Mr. Levinson:

Thank you for the opportunity to submit comments on the Office of Inspector General's (OIG's) request for information regarding the anti-kickback statute (AKS) and the definition of "remuneration" under the beneficiary inducements civil monetary penalty (CMP) law.[1] America's Essential Hospitals appreciates and supports the agency's work to prioritize care coordination, improve the delivery of high-quality health care across the health care continuum, and reduce regulatory burdens that impede essential hospitals' ability to fully engage in value-based care and alternative payment models (APMs). With that in mind, America's Essential Hospitals asks OIG to consider the challenges inherent in caring for our members' complex patient populations when developing modifications to the AKS and CMP statute.

America's Essential Hospitals is the leading champion for hospitals and health systems dedicated to providing high-quality care to all. While our members represent just 6 percent of hospitals nationally, they provide 20 percent of all charity care nationwide, or about $3.5 billion, and 14.4 percent of all uncompensated care, or about $5.5 billion.[2] The high cost of providing care to low-income and uninsured patients leaves essential hospitals with limited financial resources. Even with their limited means, our member hospitals demonstrate an ongoing commitment to serving vulnerable patients. Essential hospitals provide specialized services that their communities otherwise would lack (e.g., trauma centers, emergency psychiatric facilities, burn care); expand access with extensive networks of on-campus and community-based clinics; furnish culturally and

[1] 42 U.S.C. § 1320a-7b.
[2] Clark D, Roberson B, Ramiah K. Essential Data: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2016 Annual Member Characteristics Survey. America's Essential Hospitals. June 2018. www.essentialdata.info/. Accessed October 8, 2018.

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linguistically appropriate care; train health care professionals; supplement social support services; and offer public health programs.

Essential hospitals use their limited resources to drive increasingly efficient strategies for providing high-quality care to their patients. Our member hospitals develop innovative new care delivery models, especially for low-income Medicaid and uninsured populations, and participate in a variety of initiatives at the federal, state, and local levels. They are well-situated to do so because of the comprehensive, integrated nature of their delivery systems, their strong primary care base, their staffing models, and their historic need to provide high-quality care on a shoestring budget. Like the rest of the hospital industry, they are actively engaging in accountable care organizations (ACOs), patient-centered medical homes, chronic-care management systems, bundled payment models, and other new modes of care delivery.

For example, an essential hospital in Missouri developed a patient care transition program involving licensed clinical social workers, client-community liaisons, advanced-practice registered nurses, and other staff to ensure the hospital could focus on social, as well as clinical, issues affecting its patients. This program led to fewer hospital admissions, fewer emergency department (ED) visits, and cost savings. Other essential hospitals, often are at the forefront of caring for those affected by the opioid crisis, adopt new care models to respond to this public health emergency. For instance, an essential hospital in Oregon worked with several partners—including community organizations and a Medicaid ACO—to conduct a needs assessment and subsequent response to substance use disorder in its area. The hospital and its partners then created a care model for medically complex patients experiencing substance use disorder; the model employs a consultation service, direct access to post-hospital treatment, and a medically supported residential care program.[3]

Policymakers and regulators should want to replicate and expand on these activities and results. Yet, to date, regulatory uncertainty has put essential hospitals in an untenable position. The very activities our members undertake to support new delivery system and payment models—activities Congress and the Centers for Medicare & Medicaid Services (CMS) have encouraged—increase their exposure under the AKS and CMP law. As a result, essential hospitals expend enormous time, effort, and financial resources to ensure each step they take to engage beneficiaries, coordinate care, align incentives, promote value, and transform care delivery does not unwittingly violate the AKS (or other fraud and abuse laws).

We appreciate that OIG recognizes the barriers that the AKS and CMP law pose to delivery system and payment transformation. We urge the agency to exercise its authority to the broadest extent possible to align fraud and abuse laws with the value-driven health care system of today—and, just as important, of tomorrow. We also urge OIG to promote value-based care by making coordinated revisions to all fraud and abuse laws, including the AKS, CMP, and Stark law. Thus, our proposals here align with

[3] Susman K. The Opioid Crisis: Hospital Prevention and Response. America's Essential Hospitals. June 2017. https://essentialhospitals.org/wp-content/uploads/2017/06/Opioid-Brief-1.pdf. Accessed July 2018.

our response to CMS' request for information regarding the Stark law (CMS-1720-NC). Our specific recommendations regarding the AKS and CMP law are below.

1. OIG should significantly narrow the application of the AKS and CMP law.

Congress adopted the AKS in a volume-driven, fee-for-service environment to protect against overutilization. The purpose and structure of the AKS is inherently at odds with the shift to value-based payment and APMs. The AKS is designed to keep hospitals and physicians separate, but the national movement, led by CMS, toward coordinated and efficient care, value-based payment, and improved outcomes requires closer alignment of and coordination among hospitals, physicians, and other providers beyond the hospital's walls. For instance, the AKS treats financial incentives offered to physicians as suspect, even if the primary purpose is to ensure compliance with a hospital's appropriate quality metrics or evidence-based protocols. Today, the success of many APMs is dependent on patients receiving care from a network of providers who are aligned, integrated, and applying the same evidence-based practices. Under current law, efforts to encourage care within a specific network are viewed with suspicion because referrals are necessarily influenced.

Further, the AKS is extremely broad and can reach any "remuneration" that has the potential to influence referrals, even if the arrangement ultimately benefits patients or results in more efficient care. Given the breadth of the AKS and the severe civil and criminal penalties that apply—particularly when the AKS is coupled with the False Claims Act—providers need certainty that the arrangements they undertake to support value-based care and improved outcomes are compliant. To date, safe harbors under the AKS are narrow and prescriptive, leaving providers limited options for structuring value-based initiatives unless they are willing to undergo the expensive and time-consuming advisory opinion process. But advisory opinions provide protection only to the requesting provider and to the specific facts of the arrangement, stifling widespread innovation.

Likewise, the beneficiary inducements CMP is at odds with value-based care. With limited exceptions, the CMP law bars providers from offering any remuneration to Medicare or Medicaid beneficiaries if doing so might influence a patient's choice of provider. Yet now, more than ever, patients have become a key part of the care team. Under many APMs, it is critical that patients obtain timely and cost-effective treatment and comply with providers' treatment plans. CMS has granted states more flexibility to encourage patients to engage in healthy behaviors and consider cost in their health care choices, but the CMP law prohibits providers from undertaking similar initiatives.

While America's Essential Hospitals understands and supports the goals that initially drove the adoption of the AKS and CMP law more than 30 years ago, the abuses they seek to prohibit now seem far removed from the world that essential hospitals inhabit. Our member hospitals stretch scarce dollars to meet overwhelming demand by individuals who have nowhere else to turn. Patients served by essential hospitals are among the most complicated, with chronic diseases, comorbidities, and social risk factors that are nothing short of daunting. Essential hospitals build strong networks with community providers, not to profit from lucrative referrals but to ensure they can

appropriately coordinate care to avoid the need for expensive inpatient services. Under value-based payment models, essential hospitals no longer are expected simply to treat a diagnosis and episode, but to take responsibility for the overall health and outcomes of their patients. As a result, essential hospitals seek to support patients' broader health and social needs to improve outcomes and efficiency, not to inappropriately influence patients' choice of provider for financial gain.

We urge OIG to substantially narrow the application of the AKS and CMP law and provide greater certainty to providers by broadening and expanding the availability of fraud and abuse waivers; adopting new or expanded AKS safe harbors and CMP exceptions; or clarifying the application of key regulatory requirements.

2. OIG should adopt more flexible approaches to accommodate value-based care and APMs that target the Medicaid and uninsured populations.

In recent years, OIG and CMS have adopted program-specific waivers from the AKS and other fraud and abuse laws to accommodate new payment and care models, including the Medicare Shared Savings Program (MSSP).[4] In addition, OIG has issued a limited number of narrowly tailored AKS safe harbors (e.g., health centers, electronic health records [EHRs], local transportation) and CMP exceptions (e.g., access to care). The prescriptive nature of these new protections has limited the way providers can organize and collaborate with other providers and patients to promote quality, efficiency, value, and access.

Today, there are no fraud and abuse waivers available for uninsured populations or those covered by Medicaid, both of which present unique challenges for essential hospitals. Providers in the MSSP are eligible for waivers allowing subsidized start-up costs, shared infrastructure, distribution of shared savings, and certain patient incentives, but there are no similar waivers for Medicaid ACOs. A one-size-fits-all model is inadequate for Medicaid. Unlike Medicare (for which the MSSP and similar programs are national models with uniform requirements), reform efforts in Medicaid and for the uninsured vary from state to state, and even from locality to locality. Medicaid was designed to allow states to act as laboratories for innovation, testing different models and approaches to payment and delivery system reform for low-income populations. A fraud and abuse waiver or exception that is crafted to protect Medicaid APMs or related activities in one state might not work for another; thus, broader protections and greater flexibility are needed to support providers' efforts to transform care for Medicaid and uninsured patients.

We must not exclude these patient populations and the essential hospitals that care for them from the movement to value-based payment and APMs. Essential hospitals treat many of the costliest and most complex patients. In communities served by our members, more than 25.3 million individuals live below the poverty line and 19.4

[4] 42 CFR Chapter IV, Office of Inspector General, 42 CFR Chapter V, Medicare Program; Final Waivers in Connection With the Shared Savings Program; Final Rule. Department of Health and Human Services. October 29, 2015. https://www.gpo.gov/fdsys/pkg/FR-2015-10-29/pdf/2015-27599.pdf. Accessed October 10, 2018.

million are without health insurance.[5] The nation cannot realize its goal of improving outcomes and reducing costs if essential hospitals treating these disadvantaged populations cannot coordinate care and promote and reward quality, efficiency, value, and access. **We urge OIG to think outside the box and consider broader fraud and abuse waivers and exceptions to ensure payment and delivery system reform efforts reach the Medicaid and uninsured populations. OIG should develop AKS safe harbors, CMP exceptions, and/or fraud and abuse waivers that protect financial arrangements needed to support CMS-approved Medicaid APMs and delivery system initiatives.** CMS' approval—whether through a Section 1115 waiver or the managed care directed payment preprint—reflects that these programs promote the underlying goals of value-based care and deserve flexibility under the fraud and abuse laws. America's Essential Hospitals and our members stand ready to help craft meaningful protections for providers while limiting the risk of abuse.

3. OIG should modify the AKS and CMP law to promote value for all patient populations and to enhance patient access to medical and health-related nonmedical services.

CMS encourages hospitals and providers to participate in integrated delivery models, APMs, and other arrangements to foster outcome improvements and reduced costs. However, outdated laws and regulations are far too narrow to provide meaningful assurance. Fraud and abuse laws must strike the right balance between preventing harmful and fraudulent conduct and promoting a higher-quality, more efficient modern health care system—one that does not limit a hospital's ability to provide the full scale of assistance patients might need to maintain optimal health. There is a need for clear and comprehensive protection under the AKS and CMP law for financial relationships designed to:

- foster collaboration and coordination in health care delivery;
- link payment to quality or outcomes;
- promote accountability for the overall care of patients;
- reward efficiencies;
- enhance access; and/or
- address social determinants of health.

a. <u>OIG should develop a broad AKS safe harbor to protect financial arrangements that support value-based payment or APMs and a corresponding CMP exception to protect related patient incentives.</u>

We recommend that OIG create a safe harbor under the AKS for financial arrangements that support the implementation of value-based payment methodologies or APMs. OIG should define value-based payment and APMs to include integrated delivery systems; accountable care; team-based care; coordinated care, including for individuals dually eligible for Medicare and Medicaid; bundled payments; payments linked to quality or outcomes; Medicaid waiver–based delivery system reform

[5] Clark D, Roberson B, Ramiah K. Essential Data: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2016 Annual Member Characteristics Survey. America's Essential Hospitals. June 2018. www.essentialdata.info/. Accessed October 10, 2018.

programs; and Medicaid managed care value-based or delivery system reform directed payments. The definition should include flexibility to accommodate new payment models as they develop. **We urge OIG to create a safe harbor that does not limit the scope of protection to a specific patient population, but rather permits providers to adopt value-based payment or APMs for all patient populations.**

Current exceptions restrict hospitals' ability to share or subsidize infrastructure (space, equipment, personnel, etc.) and provide in-kind assistance to community-based providers. Developing the infrastructure required to participate in innovative payment and delivery models involves substantial upfront costs, including technology upgrades, process redesign, personnel changes, care coordination, expanded quality measurement, risk management, compliance, network development, governance, and legal restructuring. Many community providers do not have the resources to make these investments, and thus might be precluded from participating in value-based payment models and APMs.

To encourage participation by and alignment with community providers, OIG should ensure that a new safe harbor for value-based payment models accommodates shared infrastructure, in-kind assistance, and flexibility in the design of shared-savings arrangements. Community-based behavioral health providers historically have experienced fragmented funding sources and disinvestments in the treatment of patients with complex behavioral health needs; it is important to protect arrangements that support care coordination in this population.

In addition, OIG should adopt a corresponding CMP exception allowing providers to offer patient incentives that support value-based care or APMs. Within the exception, OIG should consider protecting incentives that promote:

- patient adherence to treatment plans and healthy behaviors;
- management of chronic diseases;
- patient safety;
- appropriate use of health care (e.g., avoiding unnecessary ED visits);
- care within the provider network participating in a value-based payment arrangement or APM; and
- access to nonmedical services that promote health.

b. <u>OIG should create a broad AKS exception for arrangements that promote access to care.</u>

While there is an exception under the CMP law for patient incentives that promote access to care, there is not a corresponding AKS safe harbor for provider incentives. We urge OIG to adopt a broad AKS exception that protects provider incentives that promote access to care. As described further below, such an exception could protect a wide variety of beneficial arrangements.

i. Technology

Value-based care aims to provide access to high-quality, efficient, coordinated care across the health care continuum. Technology is critical to the success of value-based payment and APMs. To succeed in these models, providers across sites of care must have real-time access to data to inform, coordinate, and manage patient care. Yet the adoption of new technology requires a significant investment of time and financial resources and can be cost prohibitive for many providers.

There are few protections in the AKS that promote the widespread adoption of technologies. The primary safe harbor, specific to EHRs, is narrowly tailored with numerous detailed conditions, including a requirement that physicians pay a significant portion of the costs of EHR systems. Often, physicians cannot bear these costs.

Existing fraud and abuse laws offer no protection for other critical technologies that support efforts to improve access. A shared mission to provide access to care for all drives essential hospitals to invest in technology to improve access. However, significant obstacles remain for patients receiving specialty care, whether due to geographic location, limited transportation, or language barriers. Medicaid recipients have consistently reported less timely access to specialists compared with patients who have other types of coverage. Further, while states must adopt time and distance standards for access to specialty care, one recent study concluded that these standards alone are unlikely to result in meaningful improvements in access to such care. For Medicaid recipients, additional policy interventions might be necessary.[6]

Technology can play a key role in assuring patient access to quality care. Telemedicine expands the geographic reach of specialists and other providers, efficiently leveraging workforce capacities to expand access, connect patients to high-quality care, and improve population health. One essential hospital in West Virginia provides outpatient services to rural residents through its telehealth program. Since it began in 1993, this program has provided more than 20,000 telemedicine consultations, including for pediatrics, telestroke, and nephrology. Telemedicine can improve access to care and facilitate provider-to-provider education. An essential hospital in New Mexico developed a groundbreaking telehealth initiative that trains rural primary care providers to treat a variety of conditions typically outside their scope. After it was implemented successfully, the program spread to include many sites within New Mexico and across the United States. However, like EHRs, implementing telemedicine technology can be cost prohibitive for community providers. In the absence of legal fraud and abuse protections, essential hospitals are discouraged from further engaging with other providers and leveraging the benefits of telemedicine.

To promote initiatives to improve access to care, **OIG should adopt a straightforward, broad-scale safe harbor protecting financial arrangements that support the adoption and use of technologies that promote care coordination, value-based payment, and access to care.** Unlike the EHR safe harbor, a broad technology safe

[6] Ndumele CD, Cohen MS, Cleary PD. Association of State Access Standards With Accessibility to Specialists for Medicaid Managed Care Enrollees. *JAMA Internal Medicine.* 2017;177(10):1445–1451.

harbor would keep pace with advancements in care delivery and foster innovation and efficiency, while improving access to services.

ii. Post-Discharge Support

The successful transfer of patients from one level of care or one setting to another requires careful attention to patient care goals and treatment preferences, as well as availability of post-hospital services. Patients at essential hospitals are among the most vulnerable and require extensive time and resources to ensure their discharge planning process is tailored to their clinical needs. This process also must account for social factors outside the control of the hospital, such as homelessness, cultural and linguistic barriers, and low literacy. Essential hospitals across the country develop innovative partnerships with entities beyond the hospital walls to coordinate care and ensure post-discharge access for complex patient populations. For example, one essential hospital in California recognized the importance of linking homeless patient to primary care services and developed a homeless health care program. The program offers not only a main, physical clinic site, but also a smaller medical respite program at a local homeless shelter. Homeless patients who receive care at medical respites have fewer admissions, total hospital days, and 90-day readmissions, as well as shorter admission length of stay.[7] Examples like this show why fraud and abuse laws should support of arrangements between hospitals and post-acute providers, rather than hinder effective collaborations.

In many instances, essential hospitals cannot identify post-acute providers willing to accept their patients. In some cases, post-acute providers are unwilling to accept uninsured patients or those with Medicaid coverage, which often reimburses below costs. In other cases, post-acute providers do not offer the resources or staffing to handle patients with complex behavioral or other health care needs. Essential hospitals invest their limited resources into efforts to discharge patients who no longer require intensive inpatient services to the most appropriate care setting. Current fraud and abuse laws limit hospitals' ability to collaborate with post-acute providers to overcome financial disincentives that hinder the discharge process and, ultimately, patient outcomes. As part of an access-to-care safe harbor, **OIG should adopt protections that allow financial arrangements among essential hospitals and post-acute providers to encourage cost-effective care in the most appropriate setting.**

iii. Social Determinants of Health and Health-Related Nonmedical Services

Members of America's Essential Hospitals are called to fulfill the complex clinical and social needs of all patients that come through their doors. Our members treat a high proportion of patients with social risk factors—factors outside the control of the hospital, such as lack of transportation for follow-up care or limited access to nutritious food—that can affect health outcomes. Our members understand that non–health care social services (e.g., food banks, counseling, housing assistance) are critical to achieving effective care transitions and improved outcomes, including reduced readmissions.

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[7] Doran KM, Ragins KT, Gross CP, Zerger S. Medical Respite Programs for Homeless Patients: A Systematic Review. *Journal of Health Care for the Poor and Underserved.* 2013;24(2):499–524.

As noted by the National Academies of Sciences, Engineering, and Medicine (The Academies), in its series of reports on accounting for social risk factors in Medicare programs, "achieving good outcomes (or improving outcomes over time) may be more difficult for providers caring for patients with social risk factors precisely because the influence of some social risk factors on health care outcomes is beyond provider control."[8] The challenges essential hospitals face in mitigating social risk factors create unique opportunities and responsibilities, often better positioning them to help improve patient and population health. For example, food insecurity is a serious health problem with profound clinical consequences and a deep connection to sociodemographic factors that affect health. Essential hospitals use screening, on-campus resources, community partnerships and engagement, and referrals to nutrition assistance programs to reduce food insecurity—and they use the same strategies to meet other medical and nonmedical needs of their patient population.

Taking a population health approach involves many components, such as cultural shifts, community partnerships, new health information technologies, and sustainable funding. Essential hospitals recognize the effect of upstream factors outside of their control and constantly work to mitigate social determinants of poor health on two levels: screening and new program implementation. Many essential hospitals are screening patients for food insecurity, housing instability, and other social determinants of health and referring these patients to community resources to help meet their social needs.

Essential hospitals lead the field in partnering with local organizations, starting intervention programs, and cultivating a health-focused environment for their patients and the community. Our members have a long history of working with disadvantaged populations and are uniquely positioned to expand their role to include upstream factors affecting health. They often serve as anchors within their communities, with deep economic and social ties to the residents; this leads to a clear understanding of the nonclinical influences on patients and population health. However, significant challenges exist in developing partnerships, building needed infrastructure, engaging patients, measuring progress, and creating sustainable funding models. **OIG should ensure that fraud and abuse laws, originally intended to protect patients from the misuse or use of unnecessary services, do not thwart hospitals' efforts to connect patients to nonmedical care or foster innovative collaboration outside the hospital walls.** For example, OIG's recently adopted safe harbor for transportation assistance fails to protect patients accessing nonmedical services that support health. In adopting a new access-to-care AKS safe harbor, we encourage OIG to protect arrangements that promote access to health-related nonmedical services.

4. OIG should clarify the definition of "fair market value" by incorporating the amount of uncompensated care provided by essential hospitals.

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[8] National Academies of Sciences, Engineering, and Medicine. *Accounting for Social Risk Factors in Medicare Payment.* Washington, D.C.: The National Academies Press; January 2017. http://nationalacademies.org/hmd/Reports/2017/accounting-for-social-risk-factors-in-medicare-payment-5.aspx. Accessed October 10, 2018.

Under current laws, the boundaries of what constitutes "fair market value"—a condition of most AKS safe harbors—are unclear. Concerningly, there appears to be a presumption that an arrangement cannot be at fair market value or commercially reasonable if a physician group generates a loss for an affiliated hospital because the group's professional revenues do not cover expenses. Essential hospitals and their affiliated physicians treat a disproportionate share of Medicaid and uninsured patients; thus, many services are reimbursed below cost, if at all. It is not unusual for physician groups serving these vulnerable populations to operate at a loss. Essential hospitals often need to provide financial support to sustain these practices, not to secure referrals but to preserve and ensure access to necessary services for Medicaid and low-income populations in the community and reduce costly and medically unnecessary readmissions. **We urge OIG to clarify that hospitals' and physicians' uncompensated care burden should be considered in assessment of fair market value.**

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America's Essential Hospitals appreciates the opportunity to submit these comments. If you have questions, please contact Senior Director of Policy Erin O'Malley at 202-585-0127 or eomalley@essentialhospitals.org.

Sincerely,

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