AMERICA'S ESSENTIAL HOSPITALS

December 20, 2019

Joanne M. Chiedi
Acting Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5513
330 Independence Ave. SW
Washington, DC 20201

Ref: 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

Dear Ms. Chiedi:

Thank you for the opportunity to comment on the Office of Inspector General's (OIG's) proposed rule 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 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 finalizing proposed changes to the AKS and CMP rules.

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 23 percent of all charity care nationwide, or about $5.5 billion, and 17.4 percent of all uncompensated care, or about $6.7 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 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 2017 Annual Member Characteristics Survey.* America's Essential Hospitals. April 2019. www.essentialdata.info/. Accessed November 23, 2019.

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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. Essential 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, strong primary care base, staffing models, and historic need to provide high-quality care on a shoestring budget. Essential hospitals 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 its patients' social, as well as clinical, issues. This program led to fewer hospital admissions, fewer emergency department (ED) visits, and cost savings. Essential hospitals often are at the forefront of care for those affected by the opioid crisis, and they 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]

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).

At the outset, America's Essential Hospitals would like to commend OIG for proposing three new safe harbors to protect a variety of value-based arrangements. These proposals are a welcome step toward aligning fraud and abuse laws with the value-driven health care system of today—and, just as important, of tomorrow. We believe with relatively modest modifications, the new safe harbors can address barriers the AKS and CMP law pose to delivery system and payment transformation. We also urge OIG to promote value-based care by encouraging coordinated revisions to all fraud and abuse laws, including the AKS, CMP, and Stark law. Thus, our comments here align with our

[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.

response to CMS' proposed rule regarding the Stark law (CMS-1720-P). Our specific comments on proposals regarding the AKS and CMP law are below.

1. **OIG should further examine its proposed terminology—including value-based enterprise, value-based arrangement, value-based activity, value-based purpose, and target patient population—to account for essential hospitals and their complex patient populations before finalizing such terms for use in any AKS safe harbors.**

In proposing new safe harbors targeted at value-based enterprises (VBEs) engaging in better care coordination, OIG has first defined terms used in these safe harbors. Specifically, OIG has proposed definitions for what constitutes a VBE, value-based arrangement, a value-based purpose, as well as the target patient population. Below are comments in response to OIG's proposed terminology.

a. OIG should provide flexibility in its definitions for a VBE, value-based arrangement, and value-based purpose, to allow for innovation in care coordination, including incentives that promote access to care or address social determinants of health.

OIG proposes that the term VBE would be used to describe the "network of individuals and entities that collaborate together to achieve one or more value-based purposes." More specifically, a VBE would mean two or more VBE participants collaborating to achieve at least one value-based purpose, with an accountable body or person responsible for financial and operational oversight of the VBE. OIG proposes that value-based purpose would mean coordinating and managing the care of a target population, improving the care quality for that population, reducing costs to or growth in expenditures without reducing care quality, and transitioning from volume to value-based payment mechanisms. **We encourage OIG to expand the definition of value-based purpose to recognize incentives that promote access to care or address social determinants of health as promoting value.**

Further, OIG proposes to require that every value-based arrangement serve the value-based purpose of "coordination and management of care." OIG would define "coordination and management of care" to mean the deliberate organization of patient care activities and sharing of information between two or more VBE participants and VBE participants and patients, tailored to improving the health outcomes of the target patient population. We encourage the OIG to eliminate this requirement. Each of the identified value-based purposes is important and has independent value in improving patient care and the health care delivery system. The OIG asserts that the requirement is necessary to distinguish between legitimate care coordination arrangements and referral arrangements. But a separate definition already serves that purpose: the OIG defines "value-based activities" to exclude the making of a referral. Eliminating the requirement also would ensure that the AKS is aligned with CMS' proposed rule regarding the Stark law (CMS-1720-P).

The success of many value-based arrangements depends on patients receiving care from a network of providers who are aligned, integrated, and applying the same evidence-

based practices. As such, coordinated and efficient care, value-based payment, and improved outcomes require closer alignment of and coordination among hospitals, physicians, and other providers beyond the hospital's walls. **OIG should not preclude protection under the proposed safe harbors for arrangements between entities that have common ownership.** We urge OIG to define value-based care 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 programs; and Medicaid managed care value-based or delivery system reform directed payments. The value-based safe harbor definitions also should include flexibility to accommodate new payment models as they develop.

b. OIG should provide flexibility and not limit its definition of target patient population to patients with a chronic condition.

OIG proposes to define a target patient population as "an identified patient population selected by the VBE or its VBE participants using legitimate and verifiable criteria." The criteria would need to be set out in writing in advance and further the VBE's value-based purpose. Examples provided by OIG include the use of ZIP code or county of residence to define a patient population for the purpose of enhancing use of primary care services or for targeting patients with a particular disease (e.g., congestive heart failure) for intervention.

Essential hospitals' commitment to serving all people, regardless of income or insurance status, pose unique challenges. For example, patients treated at essential hospitals require extensive time and resources to ensure that their discharge planning process is tailored to their clinical needs and to social factors outside the control of the hospital, such as homelessness, cultural and linguistic barriers, low literacy, and others. OIG is considering for the final rule limiting the definition of a target patient population to patients with a chronic condition or shared disease set. Such a definition would be overly narrow and limit the ability of VBE participants to provide better care coordination for complex populations served by essential hospitals. Further, and as noted by OIG, there are other categories of patients who would benefit from value-based care activities and should be included in the definition of a target patient population, including patients who need preventive care and those with mental health conditions. For example, an essential hospital in Massachusetts has been a national leader in addressing the opioid crisis. The hospital runs the largest primary care office-based opioid treatment in New England. The program was the first of its kind in the nation and has been replicated in 35 states. It employs a collaborative care model, using nurse care managers to provide medication-assisted treatment to individuals with opioid use disorder. The program also has been tailored to meet the needs of specific patient populations, including adolescents and pregnant women.[4] **We urge OIG to adopt a more flexible definition, one that allows essential hospitals to further engage in innovative efforts tailored to their patient populations and community needs. At the very least, if OIG seeks to narrow the definition of target patient**

[4] Susman Katherine. The Opioid Crisis: Hospital Prevention and Response. June 2017. https://essentialhospitals.org/wp-content/uploads/2017/06/Opioid-Brief-1.pdf. Accessed November 24, 2019.

population, the final safe harbors should include in the target patient population underserved patients, such as uninsured and low-income patients; patients with social risk factors; and those with limited English proficiency.

2. **OIG should include types of risk other than downside financial risk in the development of safe harbors for VBEs.**

OIG states that its proposed safe harbors, in combination with existing safe harbors, would "provide pathways for protection for most beneficial care coordination and value-based care and payment arrangements." If finalized, these safe harbors would offer significant benefits to providers engaged in value-based arrangements, with a particular focus on VBEs that are taking on substantial downside risk. Specifically, OIG proposes a safe harbor for VBEs that have assumed full financial risk, defined as having responsibility for the cost of all items and services covered by the applicable payer for each patient in the target population (e.g., capitated payment). A second safe harbor would apply to VBEs that have assumed substantial downside risk, with suggested methodologies that would qualify—e.g., shared savings repayment obligation of at least 40 percent of any shared loss and repayment under a bundled payment arrangement of at least 20 percent of any total loss.

Essential hospitals require time and resources to engage in care redesign and targeted interventions that will have the best effect on the vulnerable populations they serve. Our members often face challenges finding the resources necessary to upgrade technology, redesign processes, and develop a network; these challenges can preclude them from participation as ACOs and other value-based care models. When they make the decision to participate, it often is with the recognition that costs incurred upfront will, over the course of the agreement period, lead to improved outcomes and shared savings.

For example, one essential hospital in New York participating in Track 1 (upside only track) of the Medicare Shared Savings Program (MSSP) has invested in creating an ACO population dashboard. The dashboard guides data-driven work, high-risk patient outreach, and performance feedback; integrates clinical, financial, and administrative data; and links to individual patient and individual physician data. The upfront investment in this type of proactive data management is critical to the success of the ACO to generate savings for Medicare and potential shared savings for itself. It is an investment that is not considered downside risk. OIG should recognize such upfront and ongoing investments incurred by essential hospitals in its development of safe harbors for VBEs.

OIG acknowledges in the rule that "value-based arrangements may assume certain types of risk other than downside financial risk … (e.g., upside risk, clinical risk, operational risk, contractual risk, or investment risk)." **We urge OIG to consider investments in infrastructure and care redesign, as well as clinical risk essential hospitals take on in the treatment of complex patient populations, as forms of downside risk.**

3. **OIG should include in the proposed care coordination arrangement safe harbor protection for in-kind and monetary remuneration, the use of valid outcome measures that account for differences among hospitals and patient**

populations, and exemption from the contribution requirement for essential hospitals.

Fraud and abuse laws must strike a balance between preventing harmful and fraudulent conduct and promoting a higher-quality, more efficient, and 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.

OIG proposes a safe harbor to protect in-kind remuneration associated with care coordination arrangements, exchanged between qualifying VBE participants. This safe harbor does not require parties to assume downside financial risk. In turn, OIG proposes certain required conditions and safeguards. **We support the adoption of a safe harbor for care coordination arrangements with no financial risk** and offer the following considerations as OIG looks to finalize this safe harbor.

a. OIG should align with other fraud and abuse law proposals to allow in-kind and monetary remuneration for the proposed care coordination arrangements safe harbor.

The proposed safe harbor for care coordination arrangements would protect only in-kind remuneration. For example, this safe harbor would allow a VBE participant to share a care coordinator with another VBE participant but would not protect cash provided by one VBE participant to another to hire a care coordinator. Monetary remuneration associated with care coordination would be protected under other proposed safe harbors, including the proposed full financial risk and substantial financial risk safe harbors.

OIG states that it coordinated closely with CMS to develop their respective proposed rulemakings in connection with HHS' Regulatory Sprint, such as proposing consistent terminology for value-based arrangements. As such, we would encourage OIG to align its proposals to CMS with regard to remuneration protected under care coordination arrangements. Namely, under CMS' proposed value-based arrangement exception to the physician self-referral law, the agency would permit both monetary and nonmonetary remuneration between the parties.[5] As with OIG's proposed safe harbor for care coordination arrangements, CMS' exception for compensation arrangements that qualify as value-based arrangements would apply regardless of the level of risk the VBE or its participants take. Given these similarities, **we urge OIG to allow for protection of monetary remuneration to ensure consistency in the application of fraud and abuse policies for both the Stark law and AKS.**

Further, to encourage participation by and alignment with community providers, **OIG should ensure that a new safe harbor for care coordination 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

[5] CMS–1720–P. Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations. Proposed rule. https://www.govinfo.gov/content/pkg/FR-2019-10-17/pdf/2019-22028.pdf.

patients with complex behavioral health needs; it is important to protect arrangements that support care coordination in this population.

Additionally, the benefits of value-based transformations, for example in an ACO context, extend beyond the ACO's defined patient population and have a broader effect on other Medicare beneficiaries. As an alternative to the requirement that remuneration primarily be used for its value-based purposes, OIG is considering excluding these "spillover" benefits from protection by the care coordination arrangements safe harbor. Given that in-kind remuneration might indirectly benefit patients beyond the target population, **we do not support this alternative approach.** In adopting value-based payment initiatives, CMS has consistently encouraged and promoted "spillover" benefits beyond the target population, which would be undermined by the alternative proposal. In finalizing fraud and abuse waivers for the MSSP, for example, CMS clarified that "arrangements involving care for ACO beneficiaries, but that also encompass care for non-ACO beneficiaries, may be eligible for waiver protection; such arrangements can further the purposes of the Shared Savings Program."[6] Parties require enough flexibility in the design of care coordination arrangements to allow meaningful improvement in the health of patients and efficiency in health care delivery beyond a targeted subset of patients.

b. OIG should engage a variety of stakeholders in developing outcome measures under the care coordination arrangements safe harbor to ensure validity and fairness in measurement.

OIG proposes to require that parties to a value-based arrangement establish one or more specific evidence-based, valid outcome measures against which the recipient of remuneration will be measured. These outcome measures would serve as benchmarks for assessing the recipient's performance under the value-based arrangement and advancement toward achieving the coordination and management of care for the target patient population.

Further, OIG defines "evidence-based" to mean the selected outcome measures are "grounded in legitimate, verifiable data or other information." This information can be internal to one or more of the VBE participants or from a credible external source, such as a medical journal, social sciences journal, scientific study, an established industry quality standards organization, or results of a payer- or CMS-sponsored model or quality program. While we encourage OIG to adopt a flexible approach for parties to choose the most appropriate outcome measure for their value-based arrangement, we also believe measures should be accurate and reliable. **We encourage OIG to seek input from stakeholders, including the National Quality Forum (NQF), with its measure endorsement and Measures Application Partnership (MAP) approval processes.** Through these processes, measures are fully vetted and approved through a consensus-building approach that involves the public and interested stakeholders.

America's Essential Hospitals supports patient empowerment to foster shared decision-making and engage beneficiaries in their health care choices. OIG does not consider

[6] 80 Fed. Reg. 66,726, 66,731 (October 29, 2015).

measures related to patient satisfaction to be valid outcome measures for purposes of this proposed safe harbor requirement. The expressed concern is that such measures might not reflect actual improvement in the quality of patient care, health outcomes, or efficiency in the delivery of care. However, in its justification for development of safe harbor proposals to promote value-based arrangements, OIG states that "care coordination arrangements, especially when linked to appropriate clinical or value-driven outcomes, can help improve health and the patient experience of care." Given OIG's recognition that patient experience is linked to value-based care, it is unclear why patient experience would be excluded as a valid outcome measure. **We urge OIG to allow for valid measures of patient experience and patient engagement in the care coordination safe harbor.**

OIG suggests incorporating CMS Quality Payment Program (QPP) measures into the requirement to establish outcome measures. America's Essential Hospitals has previously expressed concern that measures in CMS' quality programs—including the QPP and MSSP— unduly penalize hospitals that serve the nation's most vulnerable populations because of a failure to account for all external factors outside the control of the hospital and that impact outcomes. Race, homelessness, cultural and linguistic barriers, low literacy, and other socioeconomic factors can skew results on certain quality measures, such as those for readmissions. Given the strong link between improved care coordination and lowered readmission, it is foreseeable that a readmission measure could be used to satisfy the outcome measure requirement for this safe harbor. It also is well known that patients who lack reliable support systems after discharge are more likely to be readmitted to a hospital or other institutional setting. These readmissions result from factors beyond the control of providers and health systems and do not reflect the quality of care provided.[7] Failing to fully consider differences in patients' backgrounds that might affect readmission rates will skew readmission measure calculations against hospitals providing essential care to low-income individuals, including the uninsured. **America's Essential Hospitals urges OIG to recognize the differences among hospitals, and we encourage inclusion of outcome measures that adequately account for factors outside the control of the hospital, including sociodemographic status, language, and post-discharge support structure.**

Further, OIG expects the measures selected to serve as benchmarks used to determine whether the outcome measure was achieved and suggests rebasing of the outcome measures (i.e., reset the benchmark used) at least every year, for example, to avoid merely maintaining the status quo. **We agree that assessing the performance of the recipient of remuneration will serve to advance the coordination and management of care for the target patient population.** However, measure rebasing is a complex undertaking, particularly in this context, where the type of outcome measure might dictate the appropriate time frame for rebasing—e.g., it might take longer to see the impact of certain interventions. **We urge OIG to further examine, with stakeholder input, the development of a rebasing methodology to ensure this requirement is**

[7] See, e.g., National Quality Forum Technical Report. *Risk Adjustment for Socioeconomic Status or Other Sociodemographic Factors.* August 2014. https://www.qualityforum.org/Publications/2014/08/Risk_Adjustment_for_Socioeconomic_Status_or_Other_Sociodemographic_Factors.aspx. Accessed November 25, 2019.

not overly burdensome and a deterrent for VBEs seeking protection under the care coordination safe harbor.

How best to measure outcomes across patient populations, including Medicaid, also should receive consideration. For example, each year CMS publishes sets of core measures for adult Medicaid enrollees. The core set is for voluntary use by the Medicaid program. **We urge OIG to allow flexibility for providers to choose measures, including those in the Medicaid program, that are suited for their target patient population and value-based purpose.**

c. OIG should exempt essential hospitals from the contribution requirement for the care coordination safe harbor.

As proposed, OIG would condition the care coordination safe harbor protection on the recipient's payment of at least 15 percent of the offeror's cost for the in-kind remuneration. In proposing this contribution requirement, OIG seeks feedback on the proposed contribution amount and whether certain recipients, such as providers who serve underserved populations, should be exempted from the contribution requirement or pay a lower contribution percentage.

The vulnerable patients served by essential hospitals are among the most complex, with chronic diseases, comorbidities, and social risk factors that are nothing short of daunting. Our member hospitals stretch scarce dollars to meet overwhelming demand by individuals who have nowhere else to turn. At essential hospitals, persistently high levels of uncompensated and charity care pushed average margins down to one-fifth that of other hospitals in 2017 (1.6 percent versus 7.8 for hospitals nationwide), reflecting financial pressure that could deepen with federal funding cuts this year.[8] **We urge OIG to recognize the role of essential hospitals in supporting patients' broader health and social needs to improve outcomes and efficiency and to exempt these hospitals from the contribution requirement.** If not exempted, essential hospitals will be unduly and disproportionately burdened by the contribution requirement and unable to participate in value-based payment arrangements, restricting care coordination for many of the complex and underserved populations that would benefit the most from coordinated care.

4. OIG should finalize, with modification, its safe harbor to protect patient engagement and support, with explicit protection for tools and support that address social determinants of health; and adopt a corresponding CMP exception to protect related patient incentives.

Essential hospitals have a long history of working with underserved populations and are uniquely positioned to expand their role to confront upstream factors affecting health. They often serve as anchors in their communities, given their deep economic and social ties to residents. This leads to a clear understanding of the nonclinical influences on patients and population health. OIG proposes a safe harbor for arrangements for

[8] Clark D, Roberson B, Ramiah K. *Essential Data: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2017 Annual Member Characteristics Survey.* America's Essential Hospitals. April 2019. www.essentialdata.info/. Accessed November 25, 2019.

patient engagement and support to improve quality, health outcomes, and efficiency. **We strongly encourage adoption of protections for arrangements that promote patient engagement and support. We also urge OIG to extend such protection to arrangements in which the offeror is not part of a VBE**—e.g., a hospital provides patient engagement tools but is not part of the VBE.

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.

We offer the following comments as OIG looks to finalize this safe harbor.

a. OIG should include broad protection for patient engagement and support and explicit protection for tools and supports designed to identify and address social determinants of health.

Essential hospitals are called to meet the complex clinical and social needs of all patients who 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, and 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.

As noted by the National Academies of Sciences, Engineering, and Medicine 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."[9] Identifying which social risk factors might drive outcomes and determining how best to incorporate those factors into a safe harbor is a complex task, but doing so is necessary to ensure better outcomes, healthier populations, and lower costs. One essential hospital in Texas began a project to knock on every door in a pilot neighborhood to evaluate the health of its households and get help for people who need it. This household-level assessment is an example of a sweeping collaboration between several hospital departments and people in the community and tailored to the unique needs of a patient population. Providers

[9] 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.

need flexibility in designing tools and supports that will best serve their patient population. **OIG should provide broad protection for patient engagement and support to improve quality, health outcomes, and efficiency.**

OIG is considering whether explicitly to include protection for tools and supports that address certain social determinants of health. Specifically, OIG identifies factors that might be aligned better with preventive care and coordination and management of care—e.g., transportation to medical appointments, nutrition to address clinical conditions, and safe housing for patients discharged to their home.

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 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. 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.

We applaud OIG for recognizing the connection between social determinants of health and health care outcomes and costs, and we encourage **it to explicitly include protection for tools and supports that address factors such as food insecurity, housing instability, and transportation.** Such protection would support essential hospitals' work to meet the complex clinical and social needs of their patients.

b. <u>OIG should allow for an increase in the protected amount, above the proposed $500 per patient, based on financial need of the patient.</u>

Under the proposed safe harbor to protect certain arrangements for patient engagement tools and support, the aggregate retail value of tools and supports furnished by a VBE participant to a patient could not exceed $500 on an annual basis. We understand OIG's intent in setting a bright-line limit on the amount of protected remuneration: to mitigate against patients being improperly influenced by valuable gifts. But we question the appropriateness of a $500 monetary cap for all patients, particularly given the financial need of the patients essential hospitals serve.

Essential hospitals operate in a broad variety of communities—from expansive rural regions to the nation's largest cities, all facing significant social and economic needs. Nearly 24 million individuals live below the poverty line in communities essential hospitals serve.[10] OIG seeks comment on whether the proposed monetary cap should be increased for certain patients who lack financial resources. **We strongly support modification of the cap requirement, to allow for an increase in the protected amount based on an individualized determination of a patient's financial need.**

[10] Clark D, Roberson B, Ramiah K. *Essential Data: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2017 Annual Member Characteristics Survey.* America's Essential Hospitals. April 2019. www.essentialdata.info/. Accessed November 23, 2019.

OIG has explicitly recognized in an analogous context—the waiver of cost-sharing requirements—that greater levels of assistance are appropriate for patients for whom there is an individualized determination of financial need. In the case of cost-sharing waivers, there is no cap on the value of permissible cost-sharing waivers that needy patients may receive.[11]

5. **OIG should finalize the creation of a safe harbor for CMS-sponsored models and ensure this protection extends to 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 MSSP.[12] In addition, OIG has issued a limited number of narrowly tailored AKS safe harbors (e.g., health centers, electronic health records, 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.

OIG proposes a separate safe harbor for care delivery and payment arrangements, as well as beneficiary incentives pursuant to certain CMS-sponsored models, including Innovation Center models. This proposed safe harbor, which aims to simplify and standardize the OIG's approach to protecting CMS-sponsored model arrangements, would largely replace OIG's current model-by-model fraud and abuse waiver process for such models. **We support OIG's proposal to create a safe harbor for CMS-sponsored models.**

However, 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.

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.[13] 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. **OIG should broaden the scope of its proposed CMS-sponsored models safe harbor to 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,

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[11] See 42 C.F.R. 1003.110.

[12] 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 November 25, 2019.

[13] Clark D, Roberson B, Ramiah K. *Essential Data: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2017 Annual Member Characteristics Survey.* America's Essential Hospitals. April 2019. www.essentialdata.info/. Accessed November 23, 2019.

reflects that these programs promote the underlying goals of value-based care and deserve flexibility under the fraud and abuse laws. Through the approval process, CMS has the ability to oversee and embed program integrity protections into these Medicaid value-based initiatives, limiting the risk of abuse.

6. **We support the proposed safe harbor for donation of cybersecurity software and related services; the removal of the sunset provision of the electronic health record (EHR) safe harbor; the elimination (or, in the alternative, reduction) of the current contribution requirement for the EHR safe harbor; and clarification that the proposed safe harbor for care coordination includes protection for the broad use of technologies that promote care coordination, value-based payment, and access to care.**

OIG proposes a safe harbor to protect donations of certain cybersecurity technology and related services. This type of donation is lower risk because a primary reason for the donation is typically to allow donors to protect themselves from cyberattacks. **We support the finalizing of this safe harbor, as proposed.**

OIG also proposes to remove the sunset date of the current EHR safe harbor, scheduled for December 31, 2021. In adopting a sunset provision for this safe harbor, OIG believed the need for a safe harbor should diminish substantially over time, as the use of such technology becomes standard. We agree with OIG that the EHR safe harbor plays a critical part in achieving the goal of promoting EHR adoption. As such, **we support eliminating the sunset provision, making the safe harbor permanent, to provide certainty through ongoing protection of donations of EHR items and services.**

Further, the EHR safe harbor is narrowly tailored with numerous detailed conditions, including a requirement that physicians pay a portion of the costs of EHR systems (15 percent contribution). Often, physicians cannot bear these costs and, thus, the contribution requirement has proved burdensome and a barrier to adoption of EHR technology. OIG is considering eliminating or reducing the percentage contribution for certain providers (e.g., small or rural practices) or, alternatively, for all recipients. Essential hospitals understand 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 and to measure outcomes. Yet the adoption of new technology requires a significant investment of time and financial resources and can be cost prohibitive for many providers, including essential hospitals. **We encourage OIG to eliminate or reduce the contribution percentage in the EHR safe harbor for all recipients. Alternatively, we ask that CMS exempt essential hospitals from the contribution requirement or reduce the contribution percentage for such hospitals.**

Additionally, we seek clarification of protections related to the widespread adoption of technologies. 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. Technology can play a key role in ensuring patient access to quality care.

For example, 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 also 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. Without legal fraud and abuse protections, essential hospitals are further disincentivized to engage with other providers and leverage the benefits of telemedicine. We urge OIG to confirm in its final rule that the safe harbor for care coordination also would include the donation of telemedicine or other technologies, to the extent it promotes a value-based purpose.

7. OIG should finalize its modifications to the safe harbor for local transportation to eliminate the distance limit on transportation of discharged patients, including transport to any location of the patient's choice, and include transport for health-related, non-medical purposes in the final safe harbor.

Members of America's Essential Hospitals 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. Lack of access to affordable and reliable transportation affects access to health care and exacerbates other social determinants of health; for example, lack of transportation can trap low-income individuals within the food deserts where they live, perpetuating food insecurity. These transportation barriers are financial and logistical: for example, not having a car or the financial means to take a cab or rideshare, and/or living in an area without accessible, reliable, or efficient public transportation. These barriers prevent people from accessing the health care they need and result in high rates of missed appointments that strain health care operations.

OIG proposes to remove any mileage limit on transportation of a patient from a health care facility from which the patient has been discharged after an inpatient admission to the patient's residence. OIG also is considering protecting transportation to any location of the patient's choice, including to another health care facility. Communities served by essential hospitals include more than 360,000 homeless individuals.[14] Several essential hospitals have worked to address this social risk factor through various approaches, including temporary housing, long-term rental assistance, and development of new affordable housing capacity. For example, in Illinois and Vermont, essential hospitals provide temporary housing and case management to homeless patients as a way to address the needs of their patient population. **We encourage OIG to include**

[14] Clark D, Roberson B, Ramiah K. *Essential Data: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2017 Annual Member Characteristics Survey.* America's Essential Hospitals. April 2019. www.essentialdata.info/. Accessed November 23, 2019.

protection for transportation to a location of the patient's choice, including but not limited to temporary housing and shelters.

Additionally, 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. In Ohio, an essential hospital invested in the municipal transportation system to help add a bus line that serves the hospital's main campus, improving access not only to the hospital but also the surrounding neighborhood, including nonmedical locations. In these examples, the underlying goal is to support patients' needs, directly or indirectly. The current safe harbor for transportation assistance fails to protect patients accessing nonmedical services that support health. OIG must 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. As such, **we strongly support OIG's proposed inclusion of nonmedical purposes (e.g., transportation to food banks, exercise facilities, chronic disease support groups) in the final safe harbor,** to protect arrangements that promote access to health-related nonmedical services.

As with other social determinants of health, improving access to transportation can improve health outcomes, both related to and independent of health care itself. A few essential hospitals, including one in Illinois, have partnerships with a rideshare company to help patients without access to affordable transportation get to their medical appointments. **We thank OIG for its clarification that there is no difference between taxis (the language used in the safe harbor) and ride-sharing services, for purposes of protection under the safe harbor.**

8. **OIG should clarify the definition of "fair market value" to acknowledge uncompensated care provided by essential hospitals.**

Under current fraud and abuse laws, the boundaries of what constitutes "fair market value"—a condition of most AKS safe harbors—are unclear. It is concerning that 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. CMS has recognized that a compensation arrangement might be commercially reasonable even if it does not result in profit for one or more of the parties, and the agency has proposed regulatory text to clarify this policy. **We urge OIG to do the same and further clarify that hospitals' and physicians' uncompensated care burden should be considered in assessments 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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