



AMERICA'S ESSENTIAL HOSPITALS

December 20, 2019

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue SW
Washington, DC 20201

Ref: CMS-1720-P: Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations

Dear Administrator Verma:

Thank you for the opportunity to submit comments on the Centers for Medicare & Medicaid Services' (CMS') above-referenced proposed rule regarding the physician self-referral law, or "Stark 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 often impede the ability of essential hospitals to fully engage in value-based care and alternative payment models (APMs). With that in mind, America's Essential Hospitals asks CMS to consider the challenges inherent in caring for our members' complex patient populations when developing modifications to the Stark law and other federal laws.

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 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. § 1395nn.

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.

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 actively engage in accountable care organizations (ACOs), patient-centered medical homes, chronic-care management systems, bundled payment models, and other new modes of care delivery.

However, essential hospitals have found themselves in an untenable position due to regulatory uncertainty. The very activities they undertake to support new delivery system and payment models—activities Congress and CMS have encouraged—increase their exposure under the Stark law. It is absolutely critical that complex patient populations and the essential hospitals that care for them are not left out of the movement to value-based payment and APMs. The national goal of improving outcomes and reducing costs will not be fully realized if essential hospitals treating vulnerable populations are unable to coordinate care and promote and reward quality, efficiency, value, and access.

We appreciate that CMS recognizes the barriers that the Stark law poses to delivery system and payment transformation. The proposals and clarification of fundamental terminology set forth by CMS are welcomed steps toward aligning fraud and abuse laws with the value-driven health care system of today—and, just as important, of tomorrow. We urge CMS to promote value-based care by encouraging coordinated revisions to all fraud and abuse laws, including the Stark law, anti-kickback statute (AKS), and civil monetary penalties (CMP) law. Thus, our comments here align with our response to the Office of the Inspector General's (OIG's) proposed rule regarding the AKS and CMP law (OIG-0936-AA10-P). Our specific comments on Stark law proposals are below.

1. CMS should finalize proposals for exceptions to the Stark law that support value-based arrangements and include social determinants of health as a value-based purpose under the final exceptions.

The administration has asked hospitals and providers to participate in integrated delivery models, APMs, and other arrangements to foster improvements in outcomes and reductions in costs. Historically, however, they have faced barriers imposed by outdated fraud and abuse laws and regulations that are far too narrow to provide meaningful assurance.

At the outset, we support CMS' proposal to adopt three new, broad exceptions to cover value-based arrangements and activities necessary to build infrastructure to coordinate care and accept (or prepare to accept) increased levels of financial risk. We also support the proposal that value-based enterprises (VBEs) do not need to be a

distinct legal entity, but rather could comprise a network of participants that have agreed to collaborate. We believe modest modifications to CMS' proposals—to enable the promotion and rewarding of quality, efficiency, and access—would further strengthen the Stark law to promote value-based care.

- a. CMS should refine the proposed definitions in the new value-based arrangement exceptions to account for complex patients served by essential hospitals.

CMS proposes terminology as part of the new exceptions and related regulations targeted at VBEs engaging in better care coordination—specifically for what constitutes a VBE, value-based arrangement, value-based purpose, and target patient population. CMS proposes to define a VBE as two or more 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. “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. **Overall, CMS has sought to be as neutral as possible with respect to the types of VBEs and value-based arrangements covered by the proposed exceptions. We support CMS in its flexibility to enable innovation and experimentation in the health care marketplace.**

CMS proposes to define a target patient population as “an identified patient population selected by a VBE or its VBE participants based on legitimate and verifiable criteria that are set out in writing in advance of the commencement of the value-based arrangement.” **We support this definition and encourage CMS not to limit the scope of protection to a particular patient population, and to permit providers to adopt value-based payment or APMs for all patient populations.**

We urge CMS to also expand the definition of “value-based purpose” in its final exceptions to explicitly include promoting access for a target patient population. In Medicaid, CMS has approved numerous APMs and delivery system reform initiatives that are designed to promote access. 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 merit protection under the fraud and abuse laws.

Further, CMS should explicitly include efforts to mitigate social determinants of health for a target patient population in its final definition of “value-based purpose.” Essential hospitals treat a high proportion of patients with social risk factors—factors outside the control of the hospital, such as lack of transportation. Physicians at essential hospitals do not seek profit through self-dealing; they struggle to find or provide accessible sources of care for their patients in need. Our member hospitals stretch scarce dollars to meet sometimes overwhelming demand by individuals who have nowhere else to turn. Essential hospitals build strong networks with community-based providers to ensure they can appropriately coordinate care to avoid deterioration of these patients' conditions to the point in which they need expensive inpatient services. **CMS should ensure that the definition of “value-based purpose” protects hospitals' efforts to**

connect patients to nonmedical care or to foster innovative collaboration outside the hospital walls to mitigate social determinants of health.

Additionally, a barrier associated with most existing Stark law exceptions is that payment arrangements must not take into account the “volume or value of referrals” and must ensure the payment reflects the “fair market value” of the items or services in question.³ We appreciate CMS’ recognition that these requirements conflict with the goal of reducing regulatory barriers to value-based care transformation. We encourage CMS to finalize its proposal, which does not require remuneration be consistent with fair market value and allows remuneration to be determined in a manner that takes into account the volume or value of a physician’s referrals, in the new exceptions for value-based arrangements. We agree with CMS’ belief that its proposed value-based definitions will “operate in tandem with the requirements included in the proposed exceptions and be sufficient to protect against program and patient abuse.”

- b. CMS should finalize its new exception for value-based arrangements regardless of financial risk, including protection for in-kind and monetary remuneration, and exempt essential hospital providers from any contribution requirement.

CMS proposes a new exception for compensation arrangements that qualify as value-based arrangements, regardless of the level of financial risk undertaken by the VBE or its VBE participants. As proposed, the exception for value-based arrangements with no financial risk would permit both monetary and nonmonetary remuneration between the parties. Patients treated at essential hospitals are among the most vulnerable and require extensive time and resources, including the development of innovative partnerships with entities beyond the hospital walls to coordinate care. Fraud and abuse laws should support arrangements between hospitals and post-acute providers, rather than hinder effective collaborations. As such, **we strongly support CMS’ broad application of the value-based arrangement exception to protect both monetary and nonmonetary remuneration.** In separate comments to OIG, we urge adoption of the same allowance—for both monetary and nonmonetary remuneration—in its proposed care coordination safe harbor under the AKS.⁴

For the proposed value-based arrangements exception, CMS also is considering whether to require the recipient of any nonmonetary remuneration to contribute at least 15 percent of the donor’s cost for the in-kind remuneration. In proposing this contribution requirement, CMS seeks feedback on the proposed contribution amount and whether such a requirement could inhibit the adoption of value-based arrangements. Further, CMS is considering whether certain recipients the agency feels would not be able to afford the contribution amount, such as small or rural providers, should be exempt from this requirement. **We urge CMS to consider the role of essential hospitals in supporting patients’ broader health and social needs to improve outcomes and efficiency, and exempt providers at these hospitals from the contribution requirement.** The contribution requirement will only stifle the adoption of value-based arrangements, without adding any meaningful protection. **Without such exemption,**

³ 42 U.S.C. § 1395nn.

⁴ 84 Fed. Reg. 55694 (October 17, 2019).

providers at essential hospitals will be severely hampered in their ability to engage in value-based care.

- c. CMS should finalize its proposed full financial risk and meaningful financial risk exceptions with modifications to ensure broader participation by hospitals, including essential hospitals.

CMS also proposed exceptions to the Stark law for VBEs that have taken on financial risk. Specifically, CMS proposes an exception that would apply to value-based arrangements between participants in a VBE that has assumed full financial risk, defined as having responsibility for the cost of all items and services covered by the applicable payor for each patient in the target population (e.g., capitated payment or global payment).

We urge CMS to consider expanding the scope of this exception to protect items and services that are at full financial risk, regardless of whether all payer-covered items and services are included in the risk-based payment arrangement. In many instances, state Medicaid programs and providers first test the waters of full financial risk with a subset of services or carve out certain services. For example, behavioral health services, long-term supports and services, and high-cost services like hepatitis C treatment often are carved out or phased in over time. When providers are at full-risk, there is clear protection against overuse of the services covered by the risk arrangement. To encourage essential hospitals to take the substantial step of moving to full-risk, the exception should provide clear protection to any items and services covered under a full-risk arrangement.

A second exception would apply to value-based arrangements with meaningful downside financial risk to physicians. Notably, the exception as proposed would not cover arrangements where there is meaningful downside financial risk to hospitals if that risk is not passed down directly to physicians. We encourage CMS to revise the exception in the final rule to cover arrangements involving meaningful downside financial risk to hospitals. In many cases, hospitals—not physicians—are in the best position to accept risk, with their more comprehensive services and providers, and more advanced and coordinated data collection capabilities and technologies. The exception, as proposed, is likely to discourage the shift to meaningful financial risk. We believe there would be adequate safeguards against abuse if the exception is expanded. When hospitals assume meaningful downside risk, it is imperative that they engage with their physicians and align physician incentives to achieve efficiency and cost savings. The hospital's finances are directly impacted by the clinical practices and referral patterns of physicians, creating strong protections and incentives to monitor this activity.

2. CMS should not include price transparency requirements as part of the value-based arrangements exceptions proposed under the Stark law.

CMS seeks comment on ways to pursue its price transparency objectives—to facilitate consumers' ability to participate actively and meaningfully in decisions relating to their care—in the context of the Stark law. Specifically, CMS is considering the inclusion of a price transparency requirement in every proposed exception for value-based

arrangements. For example, CMS could require physicians alert patients that their out-of-pocket costs for referred items and services might vary based on the site of service and type of insurance. **We do not support the inclusion of price transparency requirements as part of the value-based arrangements exceptions proposed under the Stark law. Such requirements would not serve the purposes of the Stark law, which is to promote untainted medical decision making by providers, not value-based decision making by consumers.** A strict liability statute that prohibits all referrals of designated health services and related billing in noncompliance with technical requirements is not an appropriate mechanism for promoting CMS' separate price transparency objectives, important as those objectives may be.

3. CMS should finalize proposals that protect against cyberattacks; confirm protection under new exceptions for the broad use of technologies to improve access to and coordination of care; and eliminate the electronic health records (EHR) contribution requirement for physicians at essential hospitals.

As America's Essential Hospitals described in our response to CMS' earlier request for information, we believe there is a need to revise the Stark regulations to promote the adoption of technologies that improve quality, access, and coordination of care.⁵

- a. CMS should finalize its proposal related to the donation of cybersecurity, make permanent the EHR exception, and confirm in its final rule that the donation of telemedicine or other technologies is protected under the proposed value-based exceptions to the extent that it promotes a value-based purpose.

CMS proposes to adopt a new exception that would protect the donation of cybersecurity software and related services. We agree with the agency that this type of donation is low risk because a primary reason for the donation typically is to allow the donor to protect themselves from cyberattacks. We support the adoption of a new cybersecurity exception for the Stark law to protect against cyberattacks.

Further, CMS proposes to remove the sunset date of the current EHR exception, scheduled for December 31, 2021. We agree with CMS that the EHR exception plays a part in achieving the goal of promoting EHR adoption and that advancements in EHR technology "are continuous and rapid" and so must continue indefinitely. As such, **we support the elimination of the sunset provision, making the exception permanent, to provide certainty through ongoing protection of donations of EHR items and services.**

While cybersecurity is important, it does not necessarily promote coordination or value-based purposes. There are, however, technologies that promote care coordination and access to care that could squarely fall within CMS' definition of value-based purpose. Telemedicine expands the geographic reach of specialists and other providers, efficiently leveraging workforce capacities to connect patients to high-quality care, expand access, and improve population health. One essential hospital in West Virginia

⁵ America's Essential Hospitals. Comments on CMS-1720-NC. August 24, 2018. https://essentialhospitals.org/wp-content/uploads/2018/08/AEH-STARK-RFI_8.24.18.pdf. Accessed December 5, 2019.

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 has the ability to not only improve access to care, but also to facilitate provider-to-provider education. For example, 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 successfully implemented, the program spread to include many sites within New Mexico and across the United States.

However, like EHRs, telemedicine technologies can be costly and 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 CMS to confirm in its final rule that the value-based exceptions would include the donation of telemedicine or other technologies, to the extent that it promotes a value-based purpose.**

- b. CMS should eliminate the EHR contribution requirement for physicians at essential hospitals.

To succeed in value-based models, providers across sites of care must have real-time access to data to inform, coordinate, and manage patient care. However, there are few protections in the Stark and AKS laws that promote the widespread adoption of technologies, which require a significant investment of time and financial resources and can be cost prohibitive for many providers. The primary exception, for EHRs, is specific to that particular technology. It is narrowly tailored, with numerous detailed conditions that must be satisfied, 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 proven burdensome and a barrier to adoption of EHR technology. CMS 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 that technology is critical to the success of value-based payment and APMs. Yet, the adoption of new technology requires a significant investment of time and financial resources and can be cost prohibitive for many providers, like essential hospitals. **We encourage CMS to eliminate or reduce the contribution percentage in the EHR safe harbor for all recipients or, at a minimum, to exempt certain recipients, including small, rural, and essential hospitals.**

4. **CMS should finalize its clarified definition of “commercially reasonable” and further clarify that uncompensated care provided by essential hospitals is an appropriate consideration under the definition of “fair market value” and “commercially reasonable.” The agency also should finalize its proposed modification of the “designated health services” definition.**

America’s Essential Hospitals strongly supports CMS’ proposal to clarify in regulation text that an arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties. This clarification is absolutely critical for essential

hospitals, which often operate at a loss or must subsidize physician groups that operate at a loss to maintain access for Medicaid and uninsured patients and to reduce costly and medically unnecessary hospital readmissions. We appreciate CMS' acknowledgement that arrangements of this type present a low risk of fraud and abuse and are not a means to secure inappropriate referrals. Further, we encourage the agency to clarify that it is appropriate to consider hospitals' and physicians' uncompensated care burden in assessing the fair market value and general market value of an arrangement.

Additionally, we urge CMS to finalize its proposed modification to the definition of "designated health services," which clarifies that a service provided by a hospital to an inpatient does not constitute a designated health service payable, in whole or in part, by Medicare if it does not affect the amount of Medicare's payment to the hospital under the Inpatient Prospective Payment System (IPPS). CMS has rightfully recognized that the IPPS payment methodology, coupled with attributes of care in the inpatient setting, adequately protect against fraud and abuse. This modification will greatly reduce provider burden and the scope of potential liability under the Stark law.

5. CMS should finalize its proposal to decouple the Stark law from the AKS and further narrow the scope of the Stark law.

Under current law, exceptions under the Stark law require that an arrangement not violate the AKS. We agree with CMS that there is no longer a need to include compliance with the AKS as a requirement for Stark law exceptions. **As such, America's Essential Hospitals supports CMS' proposal to decouple the Stark law from the AKS.**

Even with the proposed change, however, the Stark law and AKS will continue to overlap significantly, with both applying to the same set of physician compensation arrangements. America's Essential Hospitals supports efforts to further narrow the scope of the strict liability Stark law to reflect the evolution of the health care industry that has occurred since the law was enacted.

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,

Bruce Siegel, MD, MPH
President and CEO