



AMERICA'S ESSENTIAL HOSPITALS

August 24, 2018

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-NC: Medicare Program: Request for Information Regarding the Physician Self-Referral Law

Dear Ms. Verma:

Thank you for the opportunity to submit comments on the Centers for Medicare & Medicaid Services' (CMS') request for information 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 high-quality health 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 association and champion for hospitals and health systems dedicated to providing high-quality care to all. While our membership represents 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, including by providing specialized services that their communities otherwise would lack (e.g., trauma centers, emergency psychiatric facilities, burn care); expanding access with extensive networks of on-campus and community-based clinics;

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 2016 Annual Member Characteristics Survey. America's Essential Hospitals. June 2018. www.essentialdata.info/. Accessed August 13, 2018.

furnishing culturally and linguistically appropriate care; training health care professionals; supplementing social support services; and offering 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 are innovators in developing new care delivery models, especially for low-income Medicaid and uninsured populations, participating 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, one essential hospital in Missouri developed a patient care transitions program that involved licensed clinical social workers, client-community liaisons, and advanced practice registered nurses, among other staff, to ensure the hospital could focus on the social issues affecting its patients, as well as the clinical issues. This program led to fewer hospital admissions, fewer emergency department visits, and cost savings. Other member hospitals, who often are at the forefront of caring for communities and patients affected by the opioid crisis, are adopting new care models to respond to this public health emergency. One 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 worked to create 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

These are activities and results that policymakers and regulators should want to replicate and expand on. Yet, to date, 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. As a result, essential hospitals expend enormous time, effort, and financial resources to ensure that each step they take to coordinate care, align incentives, promote value, and transform care delivery does not unwittingly violate the Stark law (or other fraud and abuse laws). The stakes could not be higher—the strict liability nature of the Stark law coupled with the increasing use of the False Claims Act, with its treble damages, to enforce Stark law means an unintentional misstep can easily lead to devastating financial penalties.

We appreciate that CMS recognizes the barriers that the Stark law poses 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

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.

system of today, and, just as importantly, of tomorrow. Our specific recommendations are below.

1. CMS should significantly narrow the application of the Stark law.

The Stark law has outlived its usefulness. The law was adopted in a volume-driven, fee-for-service environment to protect against overutilization. The purpose and structure of the Stark law is inherently at odds with the shift to value-based payment and APMs. It is designed to keep hospitals and physicians separate, when 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. Moreover, with its extremely broad prohibition and limited and prescriptive exceptions, the Stark law necessarily trails behind innovation and limits providers' flexibility to adapt to new payment and care delivery models. As currently structured, CMS must issue regulations specifically identifying acceptable payment arrangements under Stark law otherwise the arrangements are legally prohibited.

While America's Essential Hospitals understands and supports the goals that initially drove the adoption of Stark law and related legislation, the abuses they seek to prohibit now seem far removed from the world that essential hospitals inhabit. 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 are not looking to make money by skimping on medically necessary care. They are trying to stretch scarce dollars to meet sometimes 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 deterioration of these patients' conditions to the point in which they need expensive inpatient services.

At the outset, America's Essential Hospitals would like to convey our support for substantially limiting the application of the Stark law by removing its compensation provisions, thereby leaving the more flexible, intent-based Anti-Kickback Statute (AKS) as the mechanism to oversee compensation arrangements. We recognize, however, that congressional action would be needed to accomplish this. Thus, **we encourage CMS to exercise its existing regulatory authority to the fullest extent possible to narrow the application of the Stark law to promote value-based care and APMs.** The agency could accomplish this by broadening and expanding the availability of Stark law waivers; adopting new or expanded exceptions; carving out certain arrangements from key definitions like "remuneration" or "referral"; or clarifying the application of key regulatory requirements, such as "fair market value." **We also encourage CMS to urge the adoption of corresponding changes to other fraud and abuse laws, including the AKS.**

2. **CMS should consider adopting more flexible approaches to accommodate value-based care and APMs that target the Medicaid and uninsured populations.**

In recent years, the Department of Health and Human Services (HHS) and CMS have adopted program-specific waivers from the Stark law and other fraud and abuse laws to accommodate new payment and care models, including the Medicare Shared Savings Program (MSSP).⁴ In addition, HHS and CMS have issued a limited number of narrowly tailored new Stark law exceptions (e.g., electronic health records, assistance for nonphysician practitioners, timeshare arrangements) and AKS safe harbors (e.g., health centers, electronic health records, local transportation). The prescriptive nature of these new protections has limited the way providers can organize and collaborate to promote quality, efficiency, value, and access.

Today, there are no fraud and abuse waivers available for the Medicaid program or uninsured populations, which present unique challenges for essential hospitals. Unlike Medicare, for which the MSSP and similar programs are national models with uniform requirements across the country, reform efforts in Medicaid and for the uninsured vary from state to state, and even from locality to locality. The Medicaid program is meant 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 is needed to support providers' efforts to transform care for Medicaid and uninsured patients.

It is absolutely critical that these patient populations and the essential hospitals that care for them are not left out of 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 25.2 million individuals live below the poverty line, and 19.4 million are without health insurance.⁵ The national goal of improving outcomes and reducing costs will not be fully realized if essential hospitals treating these vulnerable populations are unable to coordinate care and promote and reward quality, efficiency, value, and access. **We urge CMS to think outside the box and consider broader fraud and abuse waivers and exceptions than it has adopted in the past to ensure payment and delivery system reform efforts reach the Medicaid and uninsured populations. CMS should develop 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

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 August 13, 2018.

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 August 13, 2018.

deserve flexibility under the fraud and abuse laws. America's Essential Hospitals and our members stand ready to work with CMS to craft meaningful protections for providers while limiting the risk of abuse.

3. CMS should consider amending fraud and abuse laws to promote value for all patient populations; support the use of technologies to improve access to and coordination of care; support collaboration with post-acute care providers; and address social risk factors.

Hospitals and providers are asked to participate in integrated delivery models, APMs, and arrangements to foster improvements in outcomes and reductions in costs. However, they face barriers imposed by outdated laws and regulations that 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 Stark law and other fraud and abuse laws for financial relationships designed to:

- foster collaboration and coordination in the delivery of health care;
 - 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. CMS should create a broad exception for financial arrangements that support value-based payment or APMs.

We recommend that CMS create a broad exception that enables providers to adopt financial arrangements that support the implementation of value-based payment methodologies or APMs. Value-based payment and APMs should include integrated delivery systems; accountable care; team-based care; coordinated care, including for dual-eligibles; 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, with flexibility to accommodate new payment models as they develop. **We urge CMS to create a new exception that does not limit the scope of protection to a particular patient population, but rather permits providers to adopt value-based payment or APMs for all patient populations.**

Current exceptions restrict hospitals' ability to share infrastructure (space, equipment, personnel, etc.) and provide in-kind assistance to community-based providers; this is a major flaw considering that shared infrastructure and other assistance might be critical to community providers' ability to participate in value-based payment and APMs. 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. **CMS should ensure that a new exception for value-based payment models accommodates shared infrastructure, in-kind assistance, and flexibility in the design of shared savings arrangements to encourage participation by and alignment with community providers.** Additionally, 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.

- b. CMS should develop a broad exception to protect financial arrangements that support the use of technologies that coordinate and improve access to care.

The goal of value-based care is to provide access to high-quality, efficient, coordinated care across the larger 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 Stark and AKS laws that promote the widespread adoption of technologies. The primary exception, for electronic health records (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 significant portion of the costs of EHR systems. Often, physicians are not able to bear these costs.

Existing fraud and abuse laws offer no protection for other critical technologies that support efforts to improve access. Essential hospitals are driven by a mission to provide access to care for all and have invested in technologies to improve access. However, there still are patients for whom significant obstacles remain to receiving specialty care, whether due to geographic location, limited transportation, or language barriers. Medicaid recipients have consistently reported less timely access to specialists when 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 linking patients to quality care. For example, 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 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

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.

only improve access to care, but also 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 implemented successfully, the program spread to include many sites within New Mexico and across the United States. However, like EHRs, the implementation of 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.

Rather than adopting prescriptive, technology-specific exceptions, **we urge CMS to develop a straightforward, broad-scale exception to protect financial arrangements that support the adoption and use of technologies that promote care coordination, value-based payment, and access to care.** Unlike the current EHR exception, a broad-based technology exception would keep pace with advancements in care delivery and would foster innovation and efficiency, while improving access to services.

- c. CMS should create exceptions that protect compensation arrangements or incentives that support collaboration between hospitals and post-acute providers.

The successful transfer of patients from one level of care to another, or from one setting to another, requires careful attention to patient care goals and treatment preferences, as well as availability of post-hospital services. Patients treated at essential hospitals are among the most vulnerable and require extensive time and resources to ensure the discharge planning process is tailored to their clinical needs. Providers also must consider social factors outside the control of the hospital, such as homelessness, cultural and linguistic barriers, and low literacy. Many essential hospitals across the country develop innovative partnerships with entities beyond the hospital walls to coordinate care for complex patient populations. For example, one essential hospital in California, recognizing the importance of linking homeless patients to primary care services, developed a homeless health care program that offers a main, physical clinic site, as well as a smaller-scale medical respite program at a local homeless shelter. Homeless patients who receive care at medical respites show a reduction in admissions and total hospital days, 90-day readmissions, and admission length of stay.⁷ Fraud and abuse laws should support these types of arrangements between hospitals and post-acute providers, rather than hinder effective collaborations.

In many instances, essential hospitals are unable to identify post-acute providers willing to accept their patients post-discharge. In some cases, post-acute providers are unwilling to accept uninsured patients, or even those with Medicaid coverage, which often reimburses below costs. In other cases, patients have complex behavioral or other health care needs that require greater resources or staffing than post-acute providers have available. Driven by their mission, essential hospitals continue to serve these

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.

patients and invest already scarce resources in their 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, affect patient outcomes. **We urge CMS to adopt protections for financial arrangements between hospitals and post-acute providers to encourage better, more cost-effective care in a more appropriate setting.**

- d. When crafting fraud and abuse exceptions, CMS should consider the unique challenges of hospitals that treat a disproportionate share of patients with social risk factors.

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 the critical contribution non-health care social services (e.g., food banks, counseling) make to achieving effective care transitions and improved outcomes, including reduced readmissions. For example, food insecurity is a serious health problem with profound clinical consequences and a deep connection to sociodemographic factors that affect health. Through screening, on-campus resources, community partnerships and engagement, and referral to nutrition assistance programs, essential hospitals are addressing the medical and nonmedical needs of their patient population, including food insecurity. The challenges that essential hospitals face in mitigating these social risk factors create unique opportunities and responsibilities, better positioning them to help improve patient and population health. **CMS should ensure that the fraud and abuse laws, which originally were intended to protect patients from the misuse or use of unnecessary services, do not thwart hospitals' efforts to connect patients to nonmedical care or to foster innovative collaboration outside the hospital walls.**

- e. CMS should consider broader fraud and abuse exemptions for activities that promote value-based payment and APMs.

While we believe the exceptions identified above are necessary, we note that the process of adding exceptions to the Stark law on a case-by-case basis as new models and circumstances arise will trail behind innovation. Therefore, **we urge CMS to consider broader carve-outs for activities that promote value-based payment and APMs.** For example, certain payment arrangements that support value-based payment or APMs could be exempt from the definition of "remuneration" or "referral." This would allow more flexible innovation and eliminate the need to structure programs that promote value to narrowly-tailored and specific regulatory conditions. There is precedent for this approach under both the AKS and the civil monetary penalties law.

4. CMS should clarify key definitions in the Stark law.

Current fraud and abuse laws are complex, and because their requirements are uncertain, hospitals are discouraged from investing in integrated care and innovative

payment arrangements. As such, CMS should provide clear, unambiguous definitions for key components of the Stark law.

- a. CMS should clarify the definition of “fair market value” by taking into account the amount of uncompensated care provided by essential hospitals.

Current laws are unclear on the boundaries of what constitutes “fair market value”—a condition of most regulatory exceptions. Concerningly, there appears to be a presumption that an arrangement cannot be 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 as a means to secure referrals but to preserve and ensure access to necessary services for Medicaid and low-income populations in the community and to reduce costly and medically unnecessary hospital readmissions. **We urge CMS to clarify that hospitals’ and physicians’ uncompensated care burden should be taken into account in assessing fair market value.**

- b. CMS should clarify how the definition of “fair market value” and the prohibition on accounting for the “volume or value of referrals” can accommodate value-based payment.

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 of services in question.⁸ The application of these standards to value-based payment is unclear. Incentive payments tied to quality might partially reflect the volume or value of referrals, yet these types of payments will help drive the transition to a value-based health care payment system. Likewise, CMS historically has viewed fair market value narrowly, tying value to personal productivity, when new payment models seek to connect value to outcomes. **We urge CMS to clarify how the “volume or value of referrals” and “fair market value” requirements in existing exceptions can accommodate value-based payment models, or to adopt a new value-based payment and APM exception without these requirements.**

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.

⁸ 42 U.S.C. § 1395nn.

Sincerely,

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