December 25, 2019

Acting Inspector General Joanne Chiedi  
Office of Inspector General  
Department of Health and Human Services  
Attention: OIG-0936-AA10-P, Room 5521  
Cohen Building  
330 Independence Avenue, SW  
Washington, DC 20201

Submitted electronically via: http://www.regulations.gov

RE: 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 Acting Inspector General Chiedi,

OCHIN applauds OIG for their extensive work to update the 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 and seek input from health care and health IT leaders to improve care delivery. We are grateful for the opportunity to respond thoughtfully to your request for information.

OCHIN is a 501(c)(3) not-for-profit community-based health information technology (HIT) collaborative, and a national leader in promoting high-quality health care in historically underserved areas across the country. Our extensive experience supporting safety net providers has given us great insight into substance use disorder and its treatment, as well as how to meet the needs of this population. We support over 500 health centers including public health, corrections, mental health, and youth authority. We continue to innovate and advance virtual care and telehealth within the safety net through our collaborative and the California Telehealth Network (CTN). The patients OCHIN members care for face significant challenges to acquiring high quality and easily accessible care. We utilize innovative strategies to expand capacity to ensure underserved and geographically isolated patients can remain in their communities while gaining access to the care they need.

**OCHIN General Summary**

As expressed within the preamble of the proposal, the Anti-Kickback Statute was made for a health care system which is unlike the system we are rapidly moving towards today. The
law was not created with a focus on the safety net and those who serve them, including community health centers (CHCs), Federally Qualified Health Centers (FQHCs), or small or rural providers. Created under the fee-for-service model, it is not fit as written for the value-based model of care. In some situations, current law hinders integrated delivery models and alternative payment models, which are critical for caring for the many complex patients our members serve.

OCHIN is advocating for the existing constructs of the system to remain unchanged until the overall system can be evaluated. We genuinely appreciate OIG’s RFI on these questions, and the thoughtfulness around them. We believe that the current rule does not accommodate a value-based system, but reform must be done thoughtfully to avoid potential harm to small and rural providers, FQHCs, and other community health centers who will be impacted by these proposed changes. Those who care for the most complex patients in these small settings cannot afford to take on the risk being proposed, and the new value-based system should be constructed with the most complex patients in mind.

As explicitly expressed by OIG, there is the concern of “reduced patient freedom of choice among providers, potential decreases in competition among health providers, and potential financial benefits to healthcare professionals or providers that may vary inappropriately based on their ordering positions.” We caution that these exact concerns are highly likely consequences of these exceptions. Although on the surface it may appear updating the remuneration provision maybe a cost-effective way to expand interoperability and further EHR adoption, these changes will cause market consolidation resulting in lack of competition driving up prices, community health centers and small and rural providers losing their autonomy, and underserved communities losing even more resources creating more significant health disparities than exist today.

**OCHIN General Comments:**

**Donation Impacts on Rural & Safety Net Providers**

OIG and CMS have proposed in both Anti-Kickback and Stark to allow for donation of both cybersecurity technology and electronic health record (EHR) systems to small and rural providers who operate on tight margins. Currently, the EHR exception and safe harbor requires the donation recipient to pay 15% of the donor’s cost of the EHR items and services (in advance of receipt of the items and services). Although we strongly support and advocate for affordability and increased access of high quality EHR systems and cybersecurity for our members, we believe the current constructs should remain, and an alternative method should be employed to improve interoperability.
We have seen what happens time and time again when large health care entities extend their health information technology systems down into these clinics. First, these entities lose their autonomy as independent community providers. Second, the lack of competition in the area results in inflated pricing.\(^1\)\(^2\) Third, these community health centers and small clinics often don’t deliver the profits needed by the large health care system, resulting in the closure of the few health care clinics serving underserved communities.

CMS and OIG propose the donation exemption or safe harbor as one with no associated requirements. However, a reasonable mind can predict that these donations are delivered with unspoken strings attached. We believe these donations are figuratively a wolf in sheep’s clothing. These smaller entities will become beholden to the system which extends their EHR. What were once external referrals become internal and reporting requirements become far more challenging to execute. Data is the new currency of health care, and where all the small or rural provider’s data become part of the larger system, it not only becomes difficult to access, but its value then belongs to the larger health system. Additionally, where a small or rural provider wants to regain their autonomy, this will be opposed by the donor system, burdensome to execute, and costly for the provider.

As an alternative to the donation exclusions proposed, OCHIN suggests creating and funding a program to assist these providers with gaining access to cybersecurity technology and EHRs independently, and of their own choice. This could be done in partnership with organizations that can deliver these services to scale and are proficient in supporting small and rural providers. Some organizations also offer skilled 24/7 cybersecurity monitoring. This method to improve interoperability would alleviate any concerns of unintended consequences as well as increase competition and drive down prices. To help small and rural providers remain autonomous and continuing to best serve their community, they should be assisted in supporting the current market structure and choose the EHR provider of their choice to best meet their needs.

**Anti-Competitive Consequences**

The current administration commonly urges to increase competition as a way of improving market pricing and ultimately, consumer benefit. Allowing for an exemption for the donation of EHR systems and associated cybersecurity is consequently anti-competitive. The entities positioned to donate their instance of an EHR to a small or rural provider are large systems using a select few EHR systems. We support the ability for all providers to be able to choose the system of their choice, one which best meets their needs.

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\(^1\) [https://www.americanprogress.org/issues/healthcare/reports/2018/12/05/461780/provider-consolidation-drives-health-care-costs/](https://www.americanprogress.org/issues/healthcare/reports/2018/12/05/461780/provider-consolidation-drives-health-care-costs/)

By permitting large, donor entities to extend their EHR instances down to these small providers, market choices become slim, and historically more expensive when a select number of donors’ preferred systems take over the market. Smaller providers who do not want to give up their autonomy to more extensive system will have difficulty finding a reliable, cost-effective system to host them. It is critical to ensure variety in pricing and product options which become scarce as monopolization occurs.

**Value-Based Arrangements**

The Anti-Kickback proposed safe harbors pose challenges for safety net providers to participate in value-based alternative payment methodologies (APMs). Entities caring for the nation’s most complex patients would undertake an unreasonable and dangerous amount of risk to participate meaningfully in APMs. As stated in the preamble of the Anti-Kickback proposal, there is a great risk of patients experiencing comorbidities and other complex conditions being underserved by this system. In turn, providers who primarily see complex patients face significant challenges in meeting requirements to increase quality of care and create financial savings when their patients historically require more considerable amounts of services and have negative outcomes.

How is this system going to serve physicians facing extreme downside risk when their patient population predicts an inability to meet these standards? Clinics serving low-risk communities will see benefits from increased coordination and preventative care, and those serving high-risk patients will face severe consequences as a result of the risk they would undertake. Providers would be incentivized to report outcomes inaccurately or drop high cost patients so as not to have to pay out of pocket for missing a benchmark. As preventative and coordinated value-based care would provide the greatest benefit to complex safety-net patients, the primary focus should be on improving the value of care for this population specifically. To encourage participation and realize these benefits, it must be designed to incentivize high-quality care for these patients without putting small and rural providers in financial jeopardy.

Improving care for the most complex patient population requires a system that explicitly supports quality care for high-cost patients by removing downside risk, includes patient satisfaction in quality of care calculations, and increases care coordination for this population to improve accountability further. This will allow smaller providers to continue caring for the safety net population but in a value-based arrangement despite their deficiency of a robust and easily accessible referral system and administrative and financial resources.

This system must also support value-based arrangements for these small and rural providers by simplifying the process to enter these arrangements. Where legal consultation is
required to enter into these arrangements, small and rural providers are at a disadvantage with their inability to easily afford this kind of assistance or have such assistance in-house. Similarly, the reporting requirements associated with these arrangements must be relatively light or automated where possible to not disincentivize participation in these arrangements.

**Definitions**

- **Rural**: It is critical to standardize the definition of “rural” under the Stark and Anti-Kickback Laws. We suggest using the Census definition of population, housing, and territory not included in an urban area, defined as 50,000 or more people.
- **Commercially Reasonable**: We suggest the latter of the alternate definitions which states “The arrangement makes commercial sense and is entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty.”
- **Electronic Health Record (EHR) and Interoperable**: We agree with the proposal to align the definition of EHR and interoperable with those found in the 21st Century Cures Act.

We appreciate your consideration of our comments. Please contact Jennifer Stoll at stollj@ochin.org should you have any questions.

Sincerely,

Jennifer Stoll  
EVP, Government Relations and Public Affairs