

June 10, 2013

Submitted Electronically

James A. Cannatti II
Office of Counsel to the Inspector General
Department of Health and Human Services
Attention OIG-404-P, Room 5541C
Cohen Building
330 Independence Avenue, SW
Washington, DC 20201

Michael Zleit
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Ave, SW
Washington, DC 20201

Re: Medicare and State Health Care Programs; Fraud and Abuse; Electronic Health Records Safe Harbor under the Anti-Kickback Statute; Proposed Rule (Federal Register, Vol. 78, No. 69, April 10, 2013); and Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships: Exception for Certain Electronic Health Records Arrangements; Proposed Rule (Federal Register, Vol. 78, No. 69, April 10, 2013)

Dear Mr. Cannatti and Mr. Zleit:

The [American Health Care Association](http://www.ahca.org) (AHCA) appreciates the opportunity to comment on the above referenced rules addressing the important regulatory protection under the Federal anti-kickback law and the physician self-referral (Stark) law. The protection of permissible donations of software and technical assistance related to the use of Electronic Health Records (EHRs) is critically important to the long-term and post-acute care (LTPAC) provider community as an important means of acquiring and implementing EHR systems and exchange health information to enhance care coordination with acute care hospitals and other providers.

AHCA's mission is to improve lives by delivering solution for quality care. As the nation's leading long term care organization, AHCA and our membership of more than 11,000 non-profit and for-profit facilities are dedicated to continuous improvement in the delivery of professional and compassionate care provided daily by millions of caring employees to more than 1.5 million of our nation's frail and elderly as well as people with disabilities who live in nursing facilities, assisted living residences, sub-acute centers, and homes for persons with developmental disabilities.

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Our comments on the proposed rules fall into the following categories which will be described in further detail below:

- 1) **Support for extension of both the Safe Harbor and Exception**
- 2) **Support for removal of the electronic prescribing capability requirement**
- 3) **Support for inclusion of a broader array of covered technology**
- 4) **Support for maintaining the current set of protected donors**
- 5) **Support for current conditions to prevent donors from locking-in data and referrals**

Support for extension of both the Safe Harbor and the Exception

We strongly support the extension of both the Safe Harbor to the Federal anti-kickback law as well as the exception to the physician self-referral law. In addition, we encourage OIG and CMS to consider making these regulatory protections permanent. However, if permanent extension is not possible, we encourage OIG and CMS to extend the regulatory protection through the end of the Medicaid EHR Incentive Program for Meaningful Use – December 31, 2021. These regulatory protections are particularly important for the LTPAC provider community as these providers, such as nursing homes, are ineligible to participate in the Medicare and Medicaid EHR incentive programs. The regulatory protections provide a meaningful and financially viable mechanism for LTPAC providers to adopt and implement EHRs and exchange health information with other providers which is crucial to improved care coordination and quality of care delivery as well as potential cost-savings. Furthermore, while the benefits of the incentive programs are time-limited, the need to adopt and implement EHRs is not. As new providers enter the market, these regulatory protections may provide the only viable financial model for LTPAC providers to adopt and implement EHRs.

Support for removal of the electronic prescribing capability requirement

We support OIG and CMS' proposal to remove the electronic prescribing capability requirement. Subsequent legislative developments and the evolving environment of health information technology (HIT) no longer indicate a need for or benefit from this requirement.

Support for inclusion of a broader array of covered technology

We appreciate the array of covered technologies included in the current Safe Harbor and Exception. The protected software, information technology, and training services are all relevant and necessary to maximize the interoperable exchange of health information. We also encourage OIG and CMS to consider a broader array of covered technologies, including information technologies that support broader triple-aim policy goals such as reducing re-hospitalizations as a means to better care and better value. Furthermore, telemonitoring and telemedicine are increasingly being used to provide more patient-centered, coordinated care across a medical team and with the patient outside of traditional office settings. Broader use of EHRs supports these activities and fosters greater real-time communication with providers and patients across settings of care and the home or other care setting. In addition to covered technologies, third-party fees related to health information exchange such as health information exchange service charges for interconnectivity are critical to the use of EHRs to support coordinated care. We would appreciate clarification from CMS and OIG that provision of support for these types of fees are protected as part of service agreements related to the use of covered technologies.

Support for maintaining the current set of protected donors

We support maintaining the current set of protected donors for covered technologies. We do not believe OIG and CMS should limit the types of donors that may donate covered technologies. In particular, we do not support the suggestion to remove durable medical equipment (DME) suppliers and independent home health agencies from the list of protected donors.

Support for current conditions to prevent donors from locking-in data and referrals

Given existing complexity of the regulatory requirements governing the LTPAC provider community as well as the complexity of the existing Safe Harbor and Exception for donation of covered technologies, we encourage OIG and CMS not to include any additional conditions to prevent donors of covered technologies from locking-in (or hoarding) data and/or referrals. We believe the current conditions and safeguards as well as market pressures adequately protect against data and referral lock-in. Furthermore, imposing additional conditions may undermine the utility of the current Safe Harbor and Exception and actually limit its use.

Conclusion

Thank you for the opportunity to comment on the extension and modification of the Stark exemption. The protection of permissible donations of software and technical assistance related to the acquisition and utilization of EHRs is critically important to LTPAC providers to enhance care coordination with acute care hospitals and other providers, particularly as LTPAC was excluded from having access to Meaningful Use funding. Please do not hesitate to contact us should you have questions or would like additional information.

For ourselves, AHCA will continue to reach out to the Congress to encourage expansion of the eligible providers for Meaningful Use funding to include LTPAC and in other ways to support the adoption and utilization of HIT in LTPAC. Should the extension be granted, we also plan on reaching out to the LTPAC and broader health care community to make them aware of this unique opportunity to further encourage HIT adoption in LTPAC and achieve the broader goals of improving health, care and value. We welcome your support and assistance.

We know the challenges before us are great. We want to be part of the solution. Please do not hesitate to contact us if you have questions or would like additional information.

Sincerely,



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