June 10, 2013


The Honorable Daniel Levinson
Inspector General
Office of the Inspector General
U.S. Department of Health and Human Services

Re: Medicare and State Health Care Programs: Fraud and Abuse; Electronic Health Records Safe Harbor Under the Anti-Kickback Statute

Dear Inspector General Levinson:

The Home Care Technology Association of America (HCTAA) is an affiliate of the National Association for Home Care & Hospice (NAHC). HCTAA was established in 2005 to provide support for initiatives that encourage the use of technology that improve care coordination for patients in the home. We are pleased to have the opportunity to respond to the Medicare and State Health Care Programs: Fraud and Abuse; Electronic Health Records Safe Harbor Under the Anti-Kickback Statute proposed rule (the “Proposed Rule”) issued by the Office of the Inspector General (OIG).1 We have also taken the opportunity to comment on the complimentary proposed rule on the Medicare Program; Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships: Exception for Certain Electronic Health Records Arrangements issued by the Centers for Medicare & Medicaid Services (CMS).2

Home care and hospice providers are a critical component along the continuum of care for the most vulnerable Medicare beneficiaries who suffer from multiple medical conditions, including acute and terminal illnesses, long-term health conditions, and permanent disabilities. As we continue to move toward more integrated care delivery models, home-based and community care will play an increasingly significant role in coordinating the care of these high-risk and high-cost patients. The adoption of advanced technological solutions, including electronic health records (EHRs) and other health information technology will be key to this shift in care delivery. The interoperable health information technology that enable home care and hospice providers to connect to other providers ensures the free and open exchange of health

---

information in a timely and secure manner across all care settings – a prerequisite of providing more efficient and coordinated patient-centered care.

To this end, the home care and hospice industry is committed to the adoption and meaningful use of EHR technology to support new care delivery models that improve patient outcomes and reduce costs. Our comments below reflect this commitment by encouraging the OIG to – (1) extend the sunset date for the exception under the anti-kickback statute for certain EHR arrangements (the “EHR safe harbor”); (2) maintain the inclusion of home health providers as protected donors under the EHR safe harbor; and (3) apply the EHR safe harbor equally to all providers of home health services.

The Sunset Provision is Critical to Advancing the Adoption of EHR Technology

The federal anti-kickback statute prohibits individuals or entities from knowingly or willfully offering, paying, soliciting, or receiving remuneration to induce or reward referrals or generate business reimbursable under a federal health care program. Certain types of remuneration and business practices are permitted under regulatory safe harbors that would otherwise be prohibited under the statute. One such safe harbor applies to arrangements involving the donation of certain EHRs items and services. In proposing the EHR safe harbor, the OIG indicated that the purpose of the EHR safe harbor was to drive the adoption of interoperable health information technology. Referencing the corresponding CMS proposed rule establishing the physician self-referral exception for certain EHR arrangements, the OIG highlighted the potential of EHR technology to benefit both patient care and system efficiency.

Since the promulgation of the EHR safe harbor and other initiatives, such as the Medicare and Medicaid EHR Incentive Programs, the adoption of EHR technology has increased significantly. Most recently, Secretary Sebelius announced that more than 50 percent of all physicians and roughly 80 percent of all eligible hospitals and critical access hospitals have received Medicare or Medicaid incentive payments for adopting or meaningfully using EHRs. However, as observed by the OIG in this Proposed Rule, the Department of Health and Human Services has yet to reach its goal of universal and nationwide adoption of EHR technology.

HCTAA believes the EHR safe harbor is a tool that is necessary to further this goal. Extending the EHR safe harbor enables protected donors and recipient home care and hospice providers to continue to enter into arrangements involving the donation of interoperable EHRs items and services. Permitting these arrangements, as prescribed by the safe harbor, enables home care and hospice providers to more readily adopt EHR technology that may not otherwise be an affordable business expense.

Through the EHR safe harbor and other health information technology initiatives, the OIG must continue to support efforts that foster the adoption and meaningful use of health information technology. Importantly, the OIG must also strike a balance between achieving this goal and protecting against abusive practices that can lead to prohibited referrals and barriers to

---

4 Id. at 59021.
the open exchange of information between providers, as well as between providers and their patients. HCTAA believes that the current EHR safe harbor accomplishes this appropriate balance. Accordingly, HCTAA recommends that the OIG extend the sunset date for the EHR safe harbor indefinitely to ensure continued advancement of the Department’s goal of universal nationwide adoption of interoperable EHR technology. Alternatively, we recommend the sunset date be extended to December 31, 2021 to coincide with the conclusion of the Medicaid EHR Incentive Program.

**Home Health Agencies Should Remain as Protected Donors Under the EHR Safe Harbor**

In finalizing the EHR safe harbor in 2006, the OIG permitted any individual or entity that furnishes patients with health care items or services covered by a federal health care program and is reimbursed by a federal health care program for such items and services to donate certain EHR technology to protected recipients. As such, providers of home health and hospice services are protected donors. The OIG proposes to limit the scope of protected donors under the EHR safe harbor to hospitals, group practices, prescription drug plan sponsors, and Medicare Advantage organizations, as well as other entities that have “front-line patient care responsibilities across health care settings.” Alternatively, the OIG proposes to maintain the current definition of protected donors, but exclude specific types of donors, such as suppliers of ancillary services associated with a high risk of fraud and abuse.

HCTAA strongly encourages the OIG to maintain its current definition of protected donors. Specifically, OIG must ensure that home health providers continue to be recognized as protected donors for purposes of the EHR safe harbor. First, one of the most significant advances in quality and efficiency that can be made with respect to the provision of home health services is the adoption of interoperable EHRs for communications between home health and other providers. Interoperable EHRs enable quicker discharges from inpatient care settings to the home, more accurate transmission of care and pharmaceutical orders, and speedier transmission of the frequent care order changes that occur in the home care setting over a 60-day episode. In addition, EHR technology aids in the timely and compliant completion of the required physician certification and face-to-face encounter documentation.

Second, in many instances, home health agency staffs are in communication with caregivers from the patient’s bedside. Electronic communications are in the patient’s best interest as the documentation is more accurate and reliable than telephone communications. In addition, home health patients are often cared for by multiple personnel. The use of interoperable EHRs are, therefore, necessary to allow these varied caregivers to consistently meet patient needs.

Third, the proposal to consider excluding “independent home health agencies” from the protected donor classification is in conflict with the espoused standard that is advanced. The Proposed Rule indicates that the agency is considering limiting the protected donors to those parties that have a “direct and primary patient care relationship and a central role in the health care delivery infrastructure.” Currently, 3.5 million Medicare beneficiaries annually receive

---

Medicare-covered home health services. That is nearly 10 percent of the Medicare fee-for-service population. It also represents about 25 percent of all inpatient discharges.

Today’s home health care is highly integrated with inpatient care, other post-acute care providers and physicians both from institutional care settings and in the community. In rural areas, the health care infrastructure looks to home health agencies as one of the most important resources. In all geographic settings, home health is a primary provider of care to the chronically ill. As health delivery reforms continue to rebalance care to community-based settings, the importance and involvement of home health care in the Medicare and Medicaid populations will grow significantly. Leaving home health agencies out of the protected donor classification will only increase inefficiencies and inaccuracies in care, creating unnecessary burdens for all types of providers, particularly physicians, and risks for patients.

The depth, breadth, and frequency of communications between home health agencies and physicians, hospitals, SNFs and other direct care providers makes the use of interoperable EHRs essential if clinical outcomes and financial efficiencies are to be improved and achieved. The 3.5 million Medicare home health patients represent at least 10 times that many communications between a physician and the home health agency during the course of a 60-day episode of care. EHRs items and services are important tools to address such a communication demand.

While we recognize the agency’s concern regarding the potential for certain providers to abuse these protected arrangements, HCTAA does not agree with the OIG’s generalization that independent home health agencies present a higher risk for abuse as compared to other providers. The vast majority of home health agencies routinely comply with all federal fraud and abuse laws, including the anti-kickback statute. The home health providers that have been prosecuted or subjected to enforcement actions represent only a handful of the over 12,500 home health agencies participating in federal health care programs, making them the exception and not the norm. The OIG’s categorization of independent home health agencies as high risk ignores the primary motivation of the vast majority of home health providers to ensure their patients receive the coordinated care needed to transition from one care setting to another rather than to generate future business referrals.

Any concern that may exist about home health agencies using EHR support to “lock-in” patient referrals is negated by the OIG’s requirement that EHRs items and services be interoperable for purposes of the safe harbor. HCTAA believes that interoperability permits community-wide, home health agency-agnostic, clinical record communications enabling physicians and others to refer to any and all Medicare-qualified home health agencies. If physicians are relegated to securing home health care capable EHRs on their own, it is highly likely that full interoperability and complete integration of electronic communications will be compromised. Maintaining home health agencies as protected donors, furthers, rather than impedes, the goal of achieving the interoperable exchange of information.

Finally, to the extent there is risk, excluding independent home health agencies is not the appropriate solution. Indeed, the inclusion of home health agencies within the safe harbor would mitigate rather than further any risk of abuse because the lack of a safe harbor would not adequately deter an abusive provider that elects to inappropriately participate in prohibited EHRs
arrangements. Rather, maintaining all home health providers as protected donors levels the playing field and ensures that reputable home health providers are able to eliminate any advantage that abusive home health providers may have in improperly supporting other providers’ use or their own use of interoperable EHRs. In other words, abusive home health providers would lose the opportunity to incentivize prohibited referrals that might occur should reputable home health providers be unable to avail themselves of the EHR safe harbor.

Consequently, HCTAA strongly encourages the OIG to not exclude independent home health agencies from its definition of protected donors. As an alternative, we recommend the OIG continue to apply the EHR safe harbor to existing home health agencies and restrict its application to new home health agencies for a defined period of time.

All Home Health Agencies Should be Treated Equally Under the EHR Safe Harbor

HCTAA is also concerned with the agency’s attempt to distinguish between “independent home health agencies” and other home health agencies. While the OIG fails to define the term “independent home health agencies,” we interpret this term to include only freestanding home health agencies that are not related to or integrated into another provider, such as a hospital. This treatment of certain home health agencies would be counter to the goal of spurring the rapid adoption of EHR technology among providers, given the limited number of protected donors. In turn, patient care would also be compromised by the inability of home health providers to more effectively coordinate care and exchange health information with other providers. HCTAA believes this could not be the outcome the OIG intended.

As such, for purposes of the EHR exception, we recommend that the OIG continue to treat all providers of home health services equally. The OIG should not create a safe harbor under the anti-kickback statute that would unintentionally disadvantage certain home health providers and their patients.

* * *

In closing, we appreciate the opportunity to submit our comments on the Proposed Rule. If you have any questions or need any further information, please do not hesitate to contact us.

Sincerely,

Karen Utterback, McKesson Corporation
HCTAA Chair
Richard D. Brennan, Jr., MA
HCTAA Executive Director