June 10, 2013


The Honorable Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services

Re: Medicare Program; Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships: Exception for Certain Electronic Health Records Arrangements

Dear Administrator Tavenner:

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 Program; Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships: Exception for Certain Electronic Health Records Arrangements (the “Proposed Rule”) issued by the Centers for Medicare & Medicaid Services (CMS).1 We have also taken the opportunity to comment on the complimentary proposed rule on the Medicare and State Health Care Programs: Fraud and Abuse; Electronic Health Records Safe Harbor Under the Anti-Kickback Statute issued by the Office of the Inspector General (OIG).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

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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 CMS to – (1) extend the sunset date for the exception under the physician self-referral statute for certain EHR arrangements (the “EHR exception”); (2) maintain the inclusion of home health providers as protected donors under the EHR exception; and (3) apply the EHR exception equally to all providers of home health services.

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

The physician self-referral statute prohibits physicians from referring certain designated health services (DHS) payable by Medicare to an entity with which he or she has a financial arrangement, unless an exception applies. One such exception is the donation of certain EHRs items and services, which would otherwise be impermissible nonmonetary remuneration under the statute. In proposing the EHR exception, CMS indicated that the purpose of the EHR exception was to drive the adoption of health information technology, particularly fully interoperable EHR systems. The implementation of EHR technology was described as a “national priority to improve [the health care] system” having the potential to increase health care quality, reduce medical errors, and improve efficiency, while ensuring that health information is protected and secure.

Since the promulgation of the EHR exception 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 CMS 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 exception is a critical tool that is necessary to further this goal. Extending the EHR exception enables protected donors, such as home health providers, and physicians to continue to enter into arrangements involving the donation of interoperable EHRs items and services. The exemption of these arrangements, as prescribed by the exception, enables physicians to more readily adopt EHR technology that may not otherwise be affordable to physicians and their practices.

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

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4 Id.
the open exchange of information between providers, as well as between providers and their patients. HCTAA believes that the current EHR exception accomplishes this appropriate balance. Accordingly, HCTAA recommends that CMS extend the sunset date for the EHR exception 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 Exception**

In finalizing the EHR exception in 2006, CMS permitted any Designated Health Services (DHS) entity to be a protected donor of EHR technology to physicians. As such, providers of home health services are protected donors. CMS proposes to limit the scope of protected donors under the EHR exception 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, CMS 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 CMS to maintain its current definition of protected donors. Specifically, CMS must ensure that home health providers continue to be recognized as protected donors for purposes of the EHR exception. 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 prescribing physicians and the providers of home health care. Interoperable EHRs enable quicker discharges from inpatient care settings to 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.

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7 Id.
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 CMS’ 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 physician self-referral 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 the Medicare program, making them the exception and not the norm. CMS’ categorization of 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 necessary 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 CMS’ requirement that EHRs items and services be interoperable for purposes of the exception. 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 home health agencies is not the appropriate solution. Indeed, the inclusion of home health agencies within the exception would mitigate rather than further any risk of abuse because the lack of an exception 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 a physician’s 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 exception.

Consequently, HCTAA strongly encourages CMS to not exclude independent home health agencies from its definition of protected donors. As an alternative, we recommend CMS continue to apply the EHR exception 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 Exception**

HCTAA is also concerned with the agency’s attempt to distinguish between “independent home health agencies” and other home health agencies. While CMS 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, as physicians and their practices would have less access to donated health information technology given the limited number of protected donors. In turn, patient care would also be compromised by the inability of home health providers and physicians to more effectively coordinate care and exchange health information across settings. HCTAA believes this could not be the outcome CMS intended.

As such, for purposes of the EHR exception, we recommend that CMS continue to treat all providers of home health services equally. CMS should not create an exception to the physician self-referral statute that would unintentionally disadvantage certain physicians and their patients.

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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