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June 7, 2013

Ms. Marilyn B. Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1454-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

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

Dear Ms. Tavenner:

On behalf of the over 79,000 members of the American College of Surgeons (ACS), we appreciate the opportunity to submit comments to the proposed rule: Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships: Exception for Certain Electronic Health Records Arrangements that was published in the Federal Register on April 10, 2013.

The Federal physician self-referral statute (Stark law) prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which he or she (or an immediate family member) has a financial ownership interest or compensation arrangement, unless an exception applies. The Stark law also prohibits the entity from submitting claims to Medicare for those referred services, unless an exception applies. CMS published an exception to the Stark law to protect certain arrangements involving the donation of interoperable electronic health records (EHRs) software or information technology and training services from protected donors (for example, a hospital) to physicians. This exception is scheduled to sunset on December 31, 2013.

In this rule, CMS proposes to amend the current exception by: (1) updating the provision under which EHRs are deemed interoperable; (2) removing the requirement related to electronic prescribing (eRx) capability; and (3) extending the sunset date. We discuss each of these proposals below.



1. Deeming Provision

The current EHR exception to the Stark law specifies that the donated software must be interoperable at the time it is provided to the physician and must be certified by the appropriate body (the Office of the National Coordinator for Health Information Technology (ONC)) no more than 12 months prior to the date it is provided to the physician. CMS proposes to modify the 12-month requirement to conform to the ONC's two-year regulatory process for adopting certification criteria because the 12-month requirement is not in line with the ONC's two-year regulatory interval. As such, CMS proposes that software will be eligible for deeming if, on the date it is provided to the physician, it has been certified to any applicable edition of the EHR certification criteria in the ONC definition of Certified EHR Technology. For example, for 2013, the applicable definition of Certified EHR Technology identifies both the 2011 and 2014 editions of EHR certification criteria, so in 2013, software certified to meet either the 2011 or 2013 editions could satisfy the Stark law exception as CMS proposes to modify it. However, the definition of Certified EHR Technology applicable for 2014 only identifies the 2014 edition of EHR certification criteria. So in 2014, only software certified to the 2014 edition could satisfy the new CMS proposal.

We appreciate CMS' flexibility and recognition that the 12-month requirement might be unnecessary in cases where the definition of Certified EHR Technology includes editions from more than one year (e.g. 2011 and 2014 editions of EHR certification criteria are identified for the 2013 definition of Certified EHR Technology). **We support this proposal, but we urge CMS to allow software to be eligible for deeming under this exception if it has been certified to any edition of the EHR criteria that is in the applicable definition of Certified EHR Technology at the time of donation (CMS' proposal) OR certified within the past 12 months (CMS' current policy).**

2. eRx Provision

The EHR Stark exception specifies that donated software must contain eRx capability, either through an eRx component or the ability to interface with the physician's existing eRx system. The eRx capability must meet applicable standards at the time the EHR software is donated. CMS proposes to no longer retain an eRx requirement for the purposes of the EHR Stark exception. CMS believes that because Congress has enacted the eRx Incentive Program, because there is an eRx provision included in the EHR Incentive Program (also referred to as "Meaningful Use"), and because the industry has made great progress toward eRx, it is no longer necessary to include the eRx requirement

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as part of the EHR Stark exception as well. **We agree with CMS that there are sufficient alternative policy drivers supporting the adoption of eRx capabilities, and we support the removal of the eRx requirement from the EHR Stark exception.**

3. Sunset Provision

The EHR Stark exception is scheduled to sunset on December 31, 2013. CMS acknowledged that the need for donations of EHR technology should diminish substantially over time, and that while there has been progress, the use of such technology has not yet been universally adopted nationwide. Because continued EHR technology adoption remains an important goal of the Department of Health and Human Services (HHS), CMS proposes to extend the sunset date of the EHR Stark exception to December 31, 2016 (the last date that an Eligible Professional may receive a Medicare EHR incentive payment and the last date an Eligible Professional may initiate participation in the Medicaid EHR incentive program). Alternatively, CMS proposes extending the sunset date to December 31, 2021, which corresponds to the end of the Medicaid EHR incentive program.

We appreciate CMS' recognition that this sunset should be extended; however we urge CMS to not include a sunset date at all. If HHS intends to keep EHR technology a high priority for the future, one way HHS can continue to encourage EHR adoption is by not including a sunset for this exception. In addition, whereas the EHR Incentive Program bonus payments will end on December 31, 2021, there is no definitive end date for the penalties. The EHR Stark exception should not only be tied to the incentives, rather, the exception should also be tied to the penalties. **For this reason also, we recommend that no sunset apply to this exception. If CMS were to extend the sunset for this exception, we ask that it be extended to December 31, 2021.** We agree that although there has been significant advancement in the adoption and meaningful use of EHRs, there are still many physicians and physician practices who have not adopted this technology and the EHR Stark exception is an important component of the implementation of these policies.

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Ms. Tavenner

June 7, 2013

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We appreciate the opportunity to comment on this proposed rule. The ACS looks forward to continuing dialogue with CMS on these important issues. If you have any questions about our comments, please contact Bob Jasak, Deputy Director for Regulatory and Quality Affairs, in our Division of Advocacy and Health Policy. He may be reached at bjasak@facs.org or at (202) 672-1508

Sincerely,

David B. Hoyt, MD, FACS
Executive Director

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