



AMERICAN ACADEMY OF
FAMILY PHYSICIANS
STRONG MEDICINE FOR AMERICA

June 5, 2013

Marilyn Tavenner, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1454-P
P.O. Box 8013
Baltimore, MD 21244-8013

Daniel R. Levinson, Inspector General
Office of Inspector General
Department of Health and Human Services
Attention: OIG-404-P
Room 5541C, Cohen Building
330 Independence Avenue SW.
Washington, DC 20201

Re: Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships:
Exception for Certain Electronic Health Records Arrangements and
Fraud and Abuse; Electronic Health Records Safe Harbor under the Anti-Kickback Statute

Dear Administrator Tavenner and Inspector General Levinson:

On behalf of the American Academy of Family Physicians (AAFP), which represents more than 110,600 family physicians and medical students nationwide, I write in response to the [proposed rule](#) titled "Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships: Exception for Certain Electronic Health Records Arrangements" and the separate [proposed rule](#) titled "Medicare and State Health Care Programs: Fraud and Abuse; Electronic Health Records Safe Harbor Under the Anti-Kickback Statute" that were published respectively by the Centers for Medicare & Medicaid Services (CMS) and the Office of Inspector General (OIG) in the April 10, 2013 *Federal Register*.

Under current law, the physician self-referral statute generally prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which the physician or an immediate family member has a financial relationship and generally prohibits the entity from submitting claims to Medicare for those referred services. The law includes several exceptions and authorizes CMS to create additional regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse. In a 2006 final rule, CMS published an exception to protect certain arrangements involving the provision of interoperable electronic health records software or information technology and training services. This exception is scheduled to sunset on December 31, 2013.

www.aafp.org

President

Jeffrey J. Cain, MD
Denver, CO

President-elect

Reid B. Blackwelder, MD
Kingsport, TN

Board Chair

Glen Stream, MD
Spokane, WA

Directors

Barbara Doty, MD, Wasilla, AK
Richard Madden, Jr., MD, Belen, NM
Robert Wergin, MD, Milford, NE
Wanda D. Filer, MD, York, PA
Rebecca Jaffee, MD, Wilmington, DE
Daniel R. Spogen, MD, Reno, NV

Carlos Gonzales, MD, Patagonia, AZ
H. Clifton Knight, MD, Indianapolis, IN
Lloyd Van Winkle, MD, Castroville, TX
Ravi Grivois-Shah, MD, (New Physician Member), Oak Park, IL
Sarah Tully Marks, MD, (Resident Member), Shorewood, WI
Aaron Meyer (Student Member), St. Louis, MO

Speaker

John S. Meigs, Jr., MD
Brent, AL

Vice Speaker

Javette C. Orgain, MD
Chicago, IL

Executive Vice President

Douglas E. Henley, MD
Leawood, KS

In the CMS proposed rule, the agency proposes to update the provision under which electronic health records software is deemed interoperable, to remove the requirement related to electronic prescribing capability from the exception, and to extend the sunset date of the exception.

Also under current law, Congress requires the Secretary of Health and Human Services (HHS) to promulgate regulations setting forth various "safe harbors" to the anti-kickback statute, which would be evolving rules that would be periodically updated to reflect changing business practices and technologies in the health care industry. As such in 2006 the OIG published a safe harbor to protect certain arrangements involving the provision of interoperable electronic health records software or information technology and training services and this safe harbor is scheduled to sunset on December 31, 2013.

The OIG proposed rule amends the current safe harbor by proposing to update the provision under which electronic health records software is deemed interoperable, to remove the requirement related to electronic prescribing capability from the safe harbor, and to extend the sunset date of the safe harbor.

Overall, the AAFP supports the policy changes that CMS and OIG propose. Family physicians continue to be strong supporters of electronic health records and the AAFP believes extending the two expiring sunset dates will further encourage medical practices to invest in the adoption of interoperable electronic health records.

The AAFP also agrees with the CMS and OIG proposals to revise the exception's and safe harbor's electronic prescribing requirements since CMS now separately conducts the Electronic Prescribing Incentive Program and the Medicare and Medicaid Electronic Health Record Incentive programs which all encourage the use of electronic prescribing. We appreciate that CMS clarifies policy that allows for and encourages the donation of electronic prescribing technologies.

The AAFP is concerned that many electronic health record systems lack capabilities to function within a patient-centered medical home (PCMH). The AAFP advocates for systems that are capable of integrating information from multiple, diverse sources into a single system to support the comprehensive information needs of primary care. Since these proposed regulations focus on electronic health records arrangements and donations between physicians and other providers, the AAFP urges CMS and the OIG to finalize policies that further strengthen the use of core electronic health records features. Family physicians practicing in PCMH need health information technologies that improve access, efficacy, efficiency, and service for patients.

The AAFP recognizes that CMS and the OIG need to create policies that prevent potential improper actions by certain categories of donors. One policy option that the AAFP would support is to exclude specific types of donors, such as laboratory companies, durable medical equipment suppliers and independent home health agencies.

We appreciate the opportunity to provide these comments and make ourselves available for any questions you might have or clarifications you might need. Please contact Robert Bennett, Federal Regulatory Manager, at 202-232-9033 or rbennett@aafp.org.

Sincerely,



Glen Stream, MD, MBI, FFAFP
Board Chair

CC: Ms. Patrice Drew