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February 28, 2011

Daniel R. Levinson, JD
Inspector General
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Inspector General Levinson:

On behalf of the Board of Directors and members of HIMSS, we are pleased to submit written comments to the Department of Health and Human Services' Office of the Inspector General regarding the announcement in the Federal Register, entitled, "Solicitation of New Safe Harbors and Special Fraud Alerts" [OIG-118-N, December 28, 2010]. HIMSS appreciates the Office of the Inspector General's periodic review of existing Anti-Kick Back Safe Harbors. Our comments focus on the Electronic Health Record (EHR) Donation Rules, which are set to expire in December 2013. HIMSS Board of Directors and members strongly recommend removing the Sunset Provision and making the EHR Donation Rules a permanent Safe Harbor.

As you may know, HIMSS is a cause-based, not-for-profit organization exclusively focused on providing global leadership for the optimal use of information technology (IT) and management systems for the betterment of healthcare. Founded 50 years ago, HIMSS and its related organizations have offices in Chicago, Washington, DC, Brussels, Singapore, Leipzig, and other locations across the United States. HIMSS represents more than 35,000 individual members, of which two-thirds work in healthcare provider, governmental and not-for-profit organizations. HIMSS also includes over 500 corporate members and more than 120 not-for-profit organizations that share our mission of transforming healthcare through the effective use of information technology and management systems. HIMSS frames and leads healthcare practices and public policy through its content expertise, professional development, and research initiatives designed to promote information and management systems' contributions to improving the quality, safety, access, and cost-effectiveness of patient care.

Due to the desire for all Americans to have an EHR by 2014, in 2006 the Department of Health and Human Services (HHS), published final rules protecting eligible entities that provide EHR items and services to eligible recipients, which are referred to as the Stark exemptions and anti-kickback safe harbors for EHRs (EHR Donation Rules). The EHR Donation Rules allow nonmonetary remuneration (including items and services in the form of software or training services) necessary and used predominately to create, maintain, transmit or receive EHRs. To qualify for the safe-harbors and exemptions, the software must be "interoperable" at the time of donation. In addition, software must receive certification within 12 months of when they are provided to the recipient to be deemed interoperable.

While speaking at last week's [HIMSS11](#) Annual Conference & Exhibition in Orlando, Florida, Secretary of Health and Human Services, Kathleen Sebelius, outlined a three-part Call to Action for HIMSS and the health IT community to assist with the transformation of healthcare delivery in the U.S. Among the action steps, Secretary Sebelius implored the healthcare community to think creatively, and use all the available resources to assist providers to purchase and become Meaningful Users of Health IT.

"Another area where we need your help is reaching out to the 70 percent of America's doctors and nurses who belong to small practices. Switching from paper to electronic records is never easy. But it's a lot harder for the small practice with limited staff and resources than it is for the major hospital with a trained IT team and a big budget for capital improvements."

"We in the federal government are working hard to reach small practice providers, especially through the 62 Regional Extension Centers now operating around the country. But industry can play a key role too, whether it's offering financing options to reduce the up-front cost or providing better follow-up support after you make a sale. We already have a health IT gap in this country, with the average large, urban hospital way ahead of the average small, rural practice. If we want all Americans to enjoy the benefits of electronic health records, we need to close that gap."¹

As the healthcare community has prepared for the Medicare and Medicaid EHRs Incentive Programs authorized by the HITECH provisions of the American Recovery and Reinvestment Act of 2009, one tool that has become increasingly important over the past two years to closing the gap the Secretary references is the Safe Harbor associated with the EHR Donation Rules. To ensure the advancement of meaningful use of certified EHR technology and allow for better care coordination and information sharing among clinical providers, treatment facilities, and patients, HIMSS strongly recommends removing the Sunset Provision and making the EHR Donation Rules a permanent Safe Harbor. In carrying out this recommendation, the Secretary should implement necessary measures and requirements to protect against conflict of interest and improper relationships among providers and EHR vendors, and require that such exemptions and safe harbors only apply to software and related devices that comply with federally recognized standards and interoperability specifications, and are certified by federally recognized certification and testing bodies.

HIMSS appreciates the opportunity to comment on this important public policy topic for our members and health IT community colleagues. We look forward to continuing the dialogue between our members and the Department to ensure the development of an interoperable healthcare system. If you have any questions, please contact [Thomas M. Leary](#) via email or at 703.562.8814



H. Stephen Lieber, CAE
President/CEO

cc: David Blumenthal, M.D., M.P.P, National Coordinator for Health IT

¹ The Honorable Kathleen Sebelius keynote address to HIMSS11 participants, February 23, 2011