



**A Comparative Analysis of the final Stark Physician
Self-Referral Exceptions
and Anti-Kickback Safe Harbors for E-Prescribing and EHRs
to the 2005 HIMSS Comments to the Draft Final Regulations
August 2006**

Background:

In October 2005, the Department of Health and Human Services Centers for Medicare and Medicaid Services and the Office of the Inspector General published proposed rules to issue exceptions to the Stark Physician Self-Referral Regulation and safe harbors to the Anti-Kickback Act Regulation for electronic prescribing technologies and pre and post interoperability standard electronic health records. The proposed regulations were developed to address statutory requirements in the Medicare Modernization Act of 2003.

As part of the proposal review, industry was given 60 days to provide guidance to the Department on the impact and suggested changes to the proposed rules. HIMSS established a cross-organization work group to address the proposed regulations and develop a proposed response. On December 12, 2005, the HIMSS Board of Directors approved the submission of the HIMSS response, which applauded the OIG and CMS “for recognizing that regulatory changes are necessary to ensure the healthcare community can incorporate advances in health information technology (HIT) into healthcare quality and patient safety initiatives.”¹ The response recognized the important impact the proposed rules could have toward overcoming a leading barrier to HIT adoption in healthcare.

The HIMSS response provided recommendations on improving the rules to limit the negative impact on healthcare delivery and ensure widespread adoption of E-Prescribing and EHR solutions. The response highlighted the following:

- Replace the notional capitation ceilings with a graduated process that allows for higher volume donations early in the process and has set start dates for providers to enter into contractual agreements that moves the relationship from a donor-recipient to a financial exchange;
- Consider broadening the list of donors and recipients to allow for a greater number of scenarios for encouraging HIT adoption;
- Align interoperability and standards setting efforts with ongoing federal and private sector initiatives, including the Standards Harmonization and Certification Commission for Health IT contracts, and the Integrating the Healthcare Enterprise Initiative;
- Enable clinicians to use a common tool for tasks to streamline workflow, encourage IT usage, and thus improve patient safety and healthcare quality;
- Incorporate process with the national efforts to streamline biosurveillance and response and disaster management initiatives;

¹ Healthcare Information and Management Systems Society (HIMSS), “Response to HHS Proposed Rules Providing Stark Exceptions and Anti Kick Back Act Safe Harbors for Certain Electronic Prescribing Arrangements,” December 12, 2005

- Grant EHRs and E-Prescribing technologies equal exceptions and safe harbors to maintain a level competitive environment in the marketplace².

On August 8, 2006, the Department of Health and Human Services released the final regulations, which were consistent with the federal government's intention to address existing Stark and Anti-Kickback barriers on E-Prescribing and EHR donations to physician offices.

Given the HIMSS membership position on the proposed rules, the following analysis addresses the areas where the final rules agree and disagree with the HIMSS December 2005 comments.

Interoperability and the Distinction between Interoperable and pre-Interoperable Electronic Health Records

- CMS and OIG agreed with HIMSS and other commenting organizations that the distinction between Interoperable and pre-Interoperable EHRs was too cumbersome and has therefore created exceptions and safe harbors for interoperable EHRs.
- CMS and OIG agreed with HIMSS and other commenting organizations that meeting the interoperability definition needs to be expanded to include efforts by the Certification Commission for Health IT ([CCHIT](#)), the National Alliance for Health Information Technology ([the Alliance](#)) and other sources.
- The government's definition of interoperable under the safe harbor and exception is, "at the time of the donation, the software is able to (i) communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems; software applications, and networks, in various settings, and (ii) exchange data such that the clinical or operational purpose and meaning of the data are preserved and unaltered."³

Inclusion of Hardware, software, Operating System (OS) software, Training, Support Services, and Connectivity in the Stark Exception and AKA Safe Harbor:

- CMS and OIG agreed with HIMSS and other commenting organizations that software and connectivity should all be covered under the exceptions and safe harbors for reasons of promoting physician adoption of E-Prescribing technologies and EHRs.
- Under both regulations pertaining to electronic health records, hardware and OS software have been determined to be outside the scope of the respective exceptions and safe harbors because of limitations created by the Medicare Modernization Act. However, hardware may be donated under both regulations pertaining to e-prescribing. HIMSS comment on multi-functional devices being covered was also not accepted by the government for being outside the scope of the Medicare Modernization Act.
- The regulations exceed the HIMSS recommendations on connectivity, allowing donors to cover the costs of all levels of connectivity for a considerable length of time. HIMSS has suggested that connectivity fees should be an ongoing expense

² Ibid

³ Safe Harbor Final Regulation, page 80

recognized by the provider. Citing the need for the donor and the recipient to agree on the degree and complexity of connectivity, as well as concerns that the recipient would not fund connectivity after a donation period had expired, the government chose to support connectivity coverage as an ongoing donation by the donor.

Requiring written certification to distinguish between owned and donated equipment and services:

- CMS and OIG agreed with HIMSS and other commenting organizations' assertions that requiring written certification would be unnecessarily burdensome. The requirement was removed from the final rules.

Standards Development and Certification

- The federal government's comments that E-Prescribing standards will be required by DHHS is consistent with the observations made by HIMSS that incorporating standards identified in the final E-Prescribing rule in November 2005, as well as CHI standards and NCPDP V3.2., which is to provide a message based on real time adjudication for pharmacy claims.

Protected Donors

- OIG has kept the list of donors for the E-Prescribing safe harbor limited to the list of covered donors in Section 101 of the Medicare Modernization Act, to include hospitals to members of their medical staffs; group practices to their physician members; and Prescription Drug Plan sponsors and MA organizations to network pharmacists and pharmacies, and to prescribing healthcare officials.
- OIG has expanded the list of donors for the EHR safe harbor to include "any donor that is an individual or entity that provides patient with healthcare items or services covered by the Federal health care program and submits claims or requests for payment for those items or services (directly or pursuant to reassignment) to Medicare, Medicaid, or other Federal health care programs (and otherwise meets the safe harbor conditions)."⁴ The list of donors is expanded to include hospitals, group practices, physicians, nursing and other facilities, pharmacies, laboratories, oncology centers, community health centers, Federally Qualified Health Centers, dialysis centers, and health plans that are set forth as §1001.952(1)(2) of the Medicare Modernization Act.
- The government did not agree with the HIMSS request to the government to consider extending safe harbor to items and services provided to individuals or entities of a hospital, as well as other provider organizations, including connectivity services such as may be provided by Regional Health Information Organizations (RHIO) or through direct collaboration of provider organizations.

⁴ Ibid, page 85

- Of particular disappointment to many HIMSS members is the government's decision to exclude research and manufacturing entities (pharmaceutical manufacturers, biotechnology companies, etc.) to serve as potential donors of software and hardware services with appropriate provisions to safeguard against preferential product placement. The OIG made reference to the fact that these organizations do not provide healthcare items or services and the OIG's enforcement history suggests keeping these entities off the approved list. OIG also suggested that arrangements involving donations by these categories of organization should be reviewed on a case-by-case basis.
- With respect to the HIMSS suggestion to create blind trusts or foundations utilizing funds from several pharmaceutical companies to obviate this moral hazard, the government chose not to comment directly on the blind trust proposal. Instead, the OIG proposed that a case-by-case approach basing knowledge on the totality of the facts is more appropriate.

Multi-vendor RFP

- OIG and CMS did not agree with the HIMSS recommendation that the donating entity be required to offer hardware, software and connectivity solutions from a minimum of three vendors for the recipient to select, and require that these solutions be offered via an open, transparent RFP process typically used in government sponsored tenders. The OIG commented that the multi-vendor approach would be "unnecessarily burdensome and impractical and would potentially impose substantial transaction costs on donors."⁵ An open RFP process ensures that competitive market pricing is provided: it allows the recipient to participate in the selection process to ensure that services meet the needs of their clinical practice, and it provides a safeguard against lock-in by the donating entity.

Value of donated technologies and a cap.

- The value of donated technologies is a complex section of the final rules.
- OIG and CMS agreed with HIMSS and other organizations that determining the value of donated technologies or placing an artificial cap on donation levels would be cumbersome. OIG appreciated commenter observations that fair market value would drive donation and installation costs and that donors would not donate beyond a reasonable threshold because of decreasing return on investment.
- With respect to E-Prescribing, OIG and CMS eliminated a cap on donations and do not require the recipient to contribute to the cost of the technology.
- For EHRs, OIG and CMS do not force a cap on donations; however, they do require the recipient to contribute 15% of the cost of the technology. Their rationale is that the cost-sharing requirement will encourage active involvement

⁵ Ibid, page 91

by the recipient in selection of the technology that is appropriate for the practice, and will result in more active use of the technology.

EHR compliance with Public Health Information Network (PHIN) and BioSense preparedness standards:

- OIG and CMS decided not to include the requirement for EHRs to be compliant with the PHIN and BioSense in the final rule. Most organizations were opposed to creating a requirement because of the lack of preparedness standards and products. OIG recognized HIMSS and other organizations' caution that clinicians and patients may be concerned about being linked to government systems for Biosurveillance
- HIMSS is generally supportive of the idea of connecting EHR compliance to the PHIN, and robust collection strategies, and offered continued dialogue on these issues.

Sunset Timeline for Regulation:

- In both final rules, the government did not develop a sunset date for the respective exception and safe harbor for E-Prescribing.
- OIG and CMS did create a sunset date for the EHR rules at December 31, 2013. This date is consistent with the White House's call for most Americans having access to EHRs by 2014. It is, however, considerably longer than the timeline identified in the HIMSS response. The HIMSS response called for a considerable ramp up over the first two years, with decreased ability to donate the further down the road the timeline takes us. In the interest of promoting and accelerating adoption, the two rules are consistently looking for opportunities to limit barriers. The inclusion in the final rules supports to federal efforts in this area.

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