



December 12, 2005

Daniel R. Levinson, Esq.
Inspector General
Office of Inspector General
Department of Health and Human Services
Attention: OIG-405-P
Rome 5246, Cohen Building
330 Independence Avenue, SW
Washington, DC 20201

Re: OIG-405-P; Medicare and State Health Care Programs; Fraud and Abuse; Safe Harbor for Certain Electronic Prescribing Arrangements Under the Anti-Kickback Statute; Proposed Rule

Dear Inspector General Levinson:

The Catholic Health Association (CHA) is pleased to submit comments on the above proposed rule, which seeks to establish a new safe harbor under the Federal anti-kickback statute to allow hospitals and other providers to donate computer hardware, software, and related training "solely to receive and transmit electronic prescription drug information." While CHA understands that the Medicare Modernization Act mandated the creation of an electronic prescribing (e-prescribing) safe harbor, we believe the lack of a formal, more encompassing and less onerous safe harbor for the much larger universe of health information technology (HIT), including electronic health records (EHRs), is a major oversight (especially since the Centers for Medicare and Medicaid Services (CMS), in its parallel proposed rule, specifies requirements for EHR exceptions under the Stark Self-Referral Law).

OIG's proposed rule does acknowledge that the adding of EHR safe harbors would be beneficial, providing descriptions of what these might look like, but without the final detailed regulatory language necessary for a well considered response. Thus, while CMS and OIG both state their proposed rules are "consistent with the President's goal of achieving widespread adoption of interoperable electronic health records for the purpose of improving the quality and efficiency of health care," there is no formal EHR safe harbors offered by OIG to parallel the Stark EHR exceptions proposed by CMS. This lack of synchrony within HHS on such an important topic creates a high level of uncertainty for potential HIT donors that, along with the specific concerns contained in our attached CMS comment letter, are likely to chill rather than speed widespread EHR adoption.

The optimal impact of a national interoperable EHR infrastructure cannot be achieved with sets of CMS and OIG rules that are so narrowly defined and technically onerous that they completely undermine the goal of rapid HIT expansion. The first step would be to encourage harmony in the development and donation of HIT by creating a single, holistic safe harbor, rather than fragmenting HIT into separate stand alone systems (such as e-prescribing). Such fragmentation is not only costly, it moves counter to the growing movement and support for integrating all HIT system components.

With nationwide interoperability the goal, sufficient time should be allowed to develop and meet prospective national interoperability standards, allowing current donations of HIT to proceed without fear of future non-compliance issues. Also, ideally, all providers of health care must be connected electronically, so it is vital that OIG expand the list of covered recipients under its safe harbor to include non-staff physicians, physician assistants, nurse practitioners, as well as other institutions, such as skilled nursing facilities and federally qualified health centers.

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CHA hopes the above comments, along with those in the attached letter to CMS, are helpful in helping OIG and HHS arrive at a final set of rules that support, rather than retard, achievement of its challenging and worthwhile national EHR goal.

Sincerely,

A handwritten signature in cursive script that reads "Sister Carol Keehan".

Sister Carol Keehan, DC
President and CEO