American
Clinical Laboratory
Association

COMMENTS OF THE
AMERICAN CLINICAL LABORATORY ASSOCIATION
ON THE MEDICARE PROGRAM; WAIVER DESIGNS IN CONNECTION WITH THE MEDICARE SHARED SAVINGS PROGRAM AND THE INNOVATION CENTER; NOTICE WITH COMMENT PERIOD (CMS-1345-NC2)

The American Clinical Laboratory Association (ACLA) is pleased to have this opportunity to submit our comments on the *Medicare Program: Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation Center; Notice with Comment Period* (the "Draft Notice").[1] ACLA is an association representing clinical laboratories throughout the country, including local, regional, and national laboratories. As providers of clinical diagnostic laboratory services to Medicare beneficiaries, ACLA member companies will be directly impacted by the Medicare Shared Savings Program and any waivers of health care fraud and abuse laws that are finalized by the Centers for Medicare & Medicaid Services (CMS) and the Office of the Inspector General (OIG).

ACLA believes it is important for OIG to be extremely careful in granting waivers to entities engaged in ACOs. ACLA urges CMS and OIG not to expand the scope of the waivers of the Physician Self-Referral Law, the Anti-Kickback Statute and the Civil Monetary Penalty law beyond those proposed in the Draft Notice. ACLA understands that a partial waiver of the fraud and abuse laws may be needed in order to ensure participation by prospective accountable care organizations (ACOs) in the Medicare Shared Savings Program. However, these laws are in place to protect beneficiaries of Medicare, Medicaid and other federal health programs and to ensure fairness, transparency and high quality in the delivery of care. Expanding the scope of these waivers could open the door to abusive arrangements that only seek to take advantage of the Medicare Shared Savings Program and fail to deliver on the promise of ACOs. For this reason, CMS and OIG should ensure that the final waivers are limited to what has been proposed and are narrowly tailored in their application. Specifically, the agencies should ensure that only distributions of shared savings and financial relationships directly related to participation in the Medicare Shared Savings Program are covered under the waiver and that these limitations do not become broader, either in the final notice or over time.

We are particularly concerned about a potential expansion of the existing Stark exception and Anti-Kickback safe harbor for donations of electronic health records (EHRs). As we wrote in 2009 in response to the OIG's Notice of Intent to Develop Regulations (OIG-113-N), we

[1] 76 *Fed. Reg*. 19655 (Apr. 7, 2011).

believe that the exception and safe harbor are no longer necessary—EHR incentive payments under the American Recovery and Reinvestment Act are more than sufficient to achieve the original purpose of the exception and safe harbor which was to promote the adoption of EHR technology—and should therefore be rescinded. If they are not rescinded, however, ACLA urges CMS and OIG to maintain strict enforcement of the restrictions on permissible EHR donations. More importantly, ACLA urges CMS (a) not to expand the scope of the exception and safe harbor for purposes of the Medicare Shared Savings Program, and (b) not to waive the Stark and Anti-Kickback laws for ACO arrangements that satisfy the existing exception and safe harbor but are expected to occur after they sunset in 2013. It is conceivable, in the spirit of the proposed waivers, that donation of an EHR system could be "directly related" to operations of the ACO within the Medicare Shared Savings Program. However, the same adverse incentives that exist today will remain present in the ACO context, and so CMS and OIG should monitor these arrangements closely to ensure that they comply with both the letter and the spirit of the regulations. Finally, in no case should CMS and OIG extend the safe harbor and Stark exception past the current sunset date.

For the above reasons, ACLA urges CMS and OIG to finalize the waivers proposed in the Draft Notice without broadening them further.

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ACLA appreciates the opportunity to comment on the Draft Notice. If you have any questions or need any further information, please do not hesitate to contact JoAnne Glisson at (202) 637-9466 or glisson@clinical-labs.org.