technology adoption and innovation. Still others asserted that, given the financial incentives that the Federal government itself has provided, it is no longer necessary to spur the adoption of electronic health record technology through the underwriting of the cost of electronic health record technology by outside entities.

Response: Although we appreciate the commenters' concerns, on balance we continue to believe that the safe harbor serves to advance the adoption and use of interoperable electronic health records. However, we caution that a donation arrangement is not protected under the anti-kickback statute unless it satisfies each condition of the safe harbor at 42 CFR 1001.952(y). Arrangements that disguise the ''purchase'' or lock-in of referrals and donations that are solicited by the recipient in exchange for referrals would fail to satisfy the conditions of the safe harbor.

Comment: Numerous commenters suggested that the safe harbor sunset as scheduled on December 31, 2013, but only with respect to laboratories and pathology practices, ''ancillary service providers,'' entities not listed in section 101 of the MMA (directing the creation of a safe harbor for certain donations of electronic prescribing items and services), or entities that are not part of an accountable care organization or not integrated in a meaningful manner.

Response: We consider these comments to be related to ''protected donors'' and address them later in section II.D.1.

D. Additional Proposals and Considerations

1. Protected Donors

As we discussed in the 2013 Proposed Rule, while broad safe harbor protection may significantly further the important public policy goal of promoting electronic health records, we continue to have concerns, which we originally articulated in the 2006 Final Rule, about the potential for fraud and abuse by certain donors. 78 FR 21314, 21318 (Apr. 10, 2013). We also noted that we had received comments suggesting that abusive donations are being made under the electronic health records safe harbor. *Id.*

In order to address these concerns, we proposed to limit the scope of protected donors under the electronic health records safe harbor. In the 2013 Proposed Rule, we stated that we were considering revising the safe harbor to cover only the MMA-mandated donors we originally proposed when the safe harbor was first established: hospitals, group practices, prescription drug plan (PDP) sponsors, and Medicare Advantage (MA) organizations. We stated that we were also considering whether other individuals or entities with front-line patient care responsibilities across health care settings, such as safety net providers, should be included, and, if so, which ones. Alternatively, we stated that we were considering retaining the current broad scope of protected donors, but excluding specific types of donors—providers and suppliers of ancillary services associated with a high risk of fraud and abuse—because donations by such providers and suppliers may be more likely to be motivated by a purpose of securing future business than by a purpose of better coordinating care for beneficiaries across health care settings. In particular, we discussed excluding laboratory companies from the scope of protected donors as their donations have been the subject of complaints of abuse. We also discussed excluding other high-risk categories, such as durable medical equipment (DME) suppliers and independent home health agencies. We sought comment on the alternatives under consideration, including comments (with supporting reasons) regarding particular types of providers or suppliers that should or should not be protected donors, given the goals of the safe harbor.

Many commenters raised concerns about donations of electronic health records items and services by laboratory companies and strongly urged us to adopt our proposal to eliminate from the safe harbor protection for such donations, either by excluding laboratory companies from the scope of protected donors (if we extend the availability of the safe harbor), or by letting the safe harbor sunset altogether (for more detailed discussion of comments concerning the sunset provision, please see section II.C. of this final rule). Other commenters raised similar concerns, but did not suggest a particular approach to address them. We summarize the relevant comments and provide our responses below. We have carefully considered the comments that we received on this proposal and, based on the concerns articulated by commenters and the wide-ranging support from the entire spectrum of the laboratory industry (from small, pathologist-owned laboratory companies to a national laboratory trade association that represents the industry's largest laboratory companies), we are finalizing our proposal to remove laboratory companies from the scope of protected donors under the safe harbor. We believe this decision is consistent with and furthers the goal of promoting the adoption of interoperable electronic health record technology that benefits patient care while reducing the likelihood that the safe harbor will be misused by donors to secure referrals. We also believe that our decision will address potential abuse identified by some of the commenters involving potential recipients conditioning referrals for laboratory services on the receipt of, or redirecting referrals for laboratory services following, donations from laboratory companies.

Protected Donors: Comments and Suggestions Regarding Laboratory Companies

Comment: Many commenters raised concerns that, notwithstanding a clear prohibition in the safe harbor, laboratory companies are, explicitly or implicitly, conditioning donations of electronic health records items and services on the receipt of referrals from the recipients of those donations or establishing referral quotas and threatening to require the recipient to repay the cost of the donated items or services if the quotas are not reached. Some commenters suggested that such *quid pro quo* donations, and donations by laboratory companies generally, are having a negative effect on competition within the laboratory services industry (including increased prices for laboratory services) and impacting patient care as referral decisions are being made based on whether a laboratory company donated electronic health records items or services, not whether that company offers the best quality services or turnaround time. A few commenters also raised concerns that laboratory companies were targeting possible recipients based on the volume or value of their potential referrals.

Response: The current safe harbor provision at 42 CFR 1001.952(y)(5) prohibits determining the eligibility of a recipient or the amount or nature of the items or services to be donated in a manner that directly takes into account the volume or value of referrals or other business generated between the parties. Accordingly, the *quid pro quo* arrangements and targeted donations described by the commenters would not qualify for safe harbor protection. Such arrangements are not consistent with the purpose of the safe harbor and can result in the precise types of harm the anti-kickback statute is designed to prevent, such as corruption of medical decision making. We urge those with information about such arrangements to contact our fraud hotline at 1–800–