asserted that the inclusion of ''non-market factors'' (that is, the influence of donors, rather than end users) in the decision to adopt electronic health records technology may result in lower quality products or services and/or higher costs, often with an adverse impact on technology adoption and innovation. Still others asserted that, given the financial incentives that the government itself has provided, it is no longer necessary to spur the adoption of electronic health records technology through the underwriting of the cost of electronic health records technology by outside entities.

Response: Although we appreciate the commenters' concerns, we continue to believe that the exception serves to advance the adoption and use of interoperable electronic health records. However, we caution that a compensation arrangement involving the donation of electronic health records technology runs afoul of the physician self-referral law unless it satisfies each requirement of the exception at § 411.357(w). Arrangements that disguise the ''purchase'' or lock-in of referrals and donations that are solicited by the physician recipient in exchange for referrals would fail to satisfy the requirements of the exception. We disagree with the commenters that asserted that encouragement for the ''underwriting'' of electronic health records technology by organizations other than the government is no longer necessary, particularly in light of the developments in integrated patient care delivery and payment models.

Comment: Numerous commenters suggested that the exception at § 411.357(w) should 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 (authorizing an exception 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 in section III.D.1. of this final rule.

D. Additional Proposals and Considerations

1. Protected Donors

As we discussed in the proposed rule, despite our goal of expediting the adoption of electronic health records technology, we have concerns about the potential for abuse of the exception by certain types of providers and suppliers (including suppliers of ancillary services that do not have a direct and primary patient care relationship and a central role in the health care delivery infrastructure). The OIG indicated that it has concerns related to the potential for laboratories and other ancillary service providers to abuse its safe harbor, as it has received comments suggesting that abusive donations are being made under the electronic health records safe harbor. In order to address these concerns, we proposed to limit the scope of protected donors under the electronic health records exception.

In the proposed rule, we stated that we were considering revising the exception to cover only the MMA-mandated donors we originally proposed when the exception was first established: hospitals, group practices, prescription drug plan 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—suppliers of ancillary services associated with a high risk of fraud and abuse—because donations by such 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 permissible donors, as their donations have been the subject of complaints. We also discussed excluding other high-risk categories of potential donors, 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 permitted to utilize the exception given its goals.

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 protection for such donations, either by excluding laboratory companies from the scope of protected donors (if we extend the availability of the exception), or by letting the exception sunset altogether. (For more detailed discussion of comments concerning the sunset provision, see section III.C. of this final rule.) Other commenters raised similar concerns, but did not suggest a particular approach to address them.

We 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 exclude laboratory companies from the types of entities that may donate electronic health records items and services under the exception. We believe this decision is consistent with and furthers our continued goal of promoting the adoption of interoperable electronic health records technology that benefits patient care while reducing the likelihood that the exception will be misused by donors to secure referrals. We also believe that our decision will address situations identified by some of the commenters involving physician recipients conditioning referrals for laboratory services on the receipt of, or redirecting referrals for laboratory services following, donations from laboratory companies.

Comment: Many commenters raised concerns that, notwithstanding a clear prohibition in the exception, laboratory companies are, explicitly or implicitly, conditioning donations of electronic health records items and services on the receipt of referrals from the physician recipients of those donations or establishing referral quotas and threatening to require the physician 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 are targeting potential physician recipients based on the volume or value of their anticipated referrals.

Response: The current requirement at § 411.357(w)(6) prohibits determining the eligibility of a physician recipient or the amount or nature of the items or