making it necessary to retain the electronic prescribing capability requirement in the electronic health records exception.

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $7.0 million to $34.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. The Secretary has determined that this proposed rule would not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. The Secretary has determined, that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2013, that threshold is approximately $141 million. This proposed rule would have no consequential effect on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this regulation does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this rule was reviewed by the Office of Management and Budget.

List of Subjects for 42 CFR Part 411

Kidney diseases, Medicare, Physician Referral, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR part 411 as set forth below:

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 1. The authority citation for part 411 continues to read as follows:

Authority: Secs. 1102, 1860D–1 through 1860D–42, 1871, and 1877 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh, and 1395nn).

■ 2. Section 411.357 is amended by:

■ A. Revising paragraph (w)(2).

■ B. Removing and reserving paragraph (w)(11).

■ C. In paragraph (w)(13), removing the date ''December 31, 2013'' and adding the date ''December 31, 2016'' in its place.

The revision reads as follows:

§ 411.357 Exceptions to the referral prohibition related to compensation arrangements.

* * * * *

(w) * * *

(2) The software is interoperable (as defined in § 411.351) at the time it is provided to the physician. For purposes of this paragraph (w), software is deemed to be interoperable if a certifying body authorized by the National Coordinator for Health Information Technology has certified the software to any edition of electronic health record certification criteria identified in the then-applicable definition of Certified EHR Technology in 45 CFR part 170, on the date it is provided to the physician.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: January 24, 2013.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: March 7, 2013

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2013–08312 Filed 4–8–13; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Part 1001

RIN 0936–AA03

Medicare and State Health Care Programs: Fraud and Abuse; Electronic Health Records Safe Harbor Under the Anti-Kickback Statute

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Proposed rule.

SUMMARY: In this proposed rule, the Office of Inspector General (OIG) proposes to amend the safe harbor regulation concerning electronic health records items and services, which defines certain conduct that is protected from liability under the Federal anti-kickback statute in the Social Security Act (the Act). The proposed amendments include an update to the provision under which electronic health records software is deemed interoperable; removal of the electronic prescribing capability requirement; and extension of the sunset provision. In addition, OIG is requesting public comment on other changes it is considering.

DATES: To assure consideration, comments must be delivered to the address provided below by no later than 5 p.m. Eastern Standard Time on June 10, 2013.

ADDRESSES: In commenting, please reference file code OIG–404–P. Because of staff and resource limitations, we cannot accept comments by facsimile (fax) transmission. However, you may submit comments using one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronically through the Federal eRulemaking Portal at *http://www.regulations.gov.* (Attachments should be in Microsoft Word, if possible.)

2. *By regular, express, or overnight mail.* You may mail your printed or written submissions to the following address: Patrice Drew, Office of Inspector General, Department of Health and Human Services, Attention: OIG–404–P, Room 5541C, Cohen Building, 330 Independence Avenue SW., Washington, DC 20201.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier.* You may deliver, by hand or courier, before the close of the comment period, your

printed or written comments to: Patrice Drew, Office of Inspector General, Department of Health and Human Services, Cohen Building, Room 5541C, 330 Independence Avenue SW., Washington, DC 20201.
Because access to the interior of the Cohen Building is not readily available to persons without Federal Government identification, commenters are encouraged to schedule their delivery with one of our staff members at (202) 619–1368.

Inspection of Public Comments: All comments received before the end of the comment period will be posted on *http://www.regulations.gov* for public viewing. Hard copies will also be available for public inspection at the Office of Inspector General, Department of Health and Human Services, Cohen Building, 330 Independence Avenue SW., Washington, DC 20201, Monday through Friday from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (202) 619–1368. Comments received by OIG will be shared with the Centers for Medicare & Medicaid Services (CMS).

FOR FURTHER INFORMATION CONTACT: James A. Cannatti III or Heather L. Westphal, Office of Counsel to the Inspector General, (202) 619–0335.

SUPPLEMENTARY INFORMATION:

Social Security Act Citation	United States Code Citation
1128B	42 U.S.C. 1320a–7b

Executive Summary

A. Purpose of the Regulatory Action

Pursuant to section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987 and its legislative history, Congress required the Secretary of Health and Human Services (the Secretary) to promulgate regulations setting forth various ''safe harbors'' to the anti-kickback statute, which would be evolving rules that would be periodically updated to reflect changing business practices and technologies in the health care industry. In accordance with this authority, OIG published a safe harbor to protect certain arrangements involving the provision of interoperable electronic health records software or information technology and training services. The final rule for this safe harbor was published on August 8, 2006 (71 FR 45110) and is scheduled to sunset on December 31, 2013 (42 CFR 1001.952(y)(13)). The purpose of this proposed rule is to update certain aspects of the electronic health records safe harbor and to extend the sunset date.

B. Summary of the Major Provisions

This proposed rule would amend the current safe harbor in at least three ways. First, the proposed rule would update the provision under which electronic health records software is deemed interoperable. Second, we propose to remove the requirement related to electronic prescribing capability from the safe harbor. Third, we propose to extend the sunset date of the safe harbor. In addition to these proposals, we are soliciting public comment on other possible amendments to the safe harbor, including limiting the scope of protected donors and adding or modifying conditions to limit the risk of data and referral lock-in.

C. Costs and Benefits

The proposed rule would modify an already-existing safe harbor to the anti-kickback statute. This safe harbor permits certain entities to provide technology-related items and services to certain parties to be used to create, maintain, transmit, or receive electronic health records. Parties may voluntarily seek to comply with safe harbors so that they have assurance that their conduct will not subject them to any enforcement actions under the anti-kickback statute, but safe harbors do not impose new requirements on any party.

This is not a major rule, as defined at 5 U.S.C. 804(2). It is also not economically significant, because it will not have a significant effect on program expenditures, and there are no additional substantive costs to implement the resulting provisions. The proposed rule would update the provision under which electronic health records software is deemed interoperable, remove the requirement related to electronic prescribing capability, and extend the safe harbor's sunset date (currently set at December 31, 2013). We expect these proposed changes to continue to facilitate the adoption of electronic health records technology.

I. Background

A. Anti-Kickback Statute and Safe Harbors

Section 1128B(b) of the Social Security Act (the Act) (42 U.S.C. 1320a–7b(b), the anti-kickback statute) provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit, or receive remuneration in order to induce or reward the referral of business reimbursable under any of the Federal health care programs, as defined in section 1128B(f) of the Act. The offense is classified as a felony and is punishable by fines of up to $25,000 and imprisonment for up to 5 years. Violations of the anti-kickback statute may also result in the imposition of civil monetary penalties (CMP) under section 1128A(a)(7) of the Act (42 U.S.C. 1320a–7a(a)(7)), program exclusion under section 1128(b)(7) of the Act (42 U.S.C. 1320a–7(b)(7)), and liability under the False Claims Act (31 U.S.C. 3729–33).

The types of remuneration covered specifically include, without limitation, kickbacks, bribes, and rebates, whether made directly or indirectly, overtly or covertly, in cash or in kind. In addition, prohibited conduct includes not only the payment of remuneration intended to induce or reward referrals of patients, but also the payment of remuneration intended to induce or reward the purchasing, leasing, or ordering of, or arranging for or recommending the purchasing, leasing, or ordering of, any good, facility, service, or item reimbursable by any Federal health care program.

Because of the broad reach of the statute, concern was expressed that some relatively innocuous commercial arrangements were covered by the statute and, therefore, potentially subject to criminal prosecution. In response, Congress enacted section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987, Public Law 100–93 (section 1128B(b)(3)(E) of the Act; 42 U.S.C. 1320a–7b(B)(3)(E)), which specifically required the development and promulgation of regulations, the so-called ''safe harbor'' provisions, that would specify various payment and business practices that would not be subject to sanctions under the anti-kickback statute, even though they may potentially be capable of inducing referrals of business under the Federal health care programs. Since July 29, 1991, we have published in the **Federal Register** a series of final regulations establishing ''safe harbors'' in various areas.[1] These OIG safe harbor provisions have been developed ''to limit the reach of the statute somewhat by permitting certain non-abusive arrangements, while encouraging beneficial or innocuous arrangements.'' 56 FR 35952, 35958 (July 29, 1991).

Health care providers and others may voluntarily seek to comply with safe harbors so that they have the assurance that their business practices will not be subject to any enforcement action under the anti-kickback statute, the CMP provision for anti-kickback violations,

[1] 56 FR 35952 (July 29, 1991); 61 FR 2122 (Jan. 25, 1996); 64 FR 63518 (Nov. 19, 1999); 64 FR 63504 (Nov. 19, 1999); 66 FR 62979 (Dec. 4, 2001); 71 FR 45109 (Aug. 8, 2006); and 72 FR 56632 (Oct. 4, 2007).

or the program exclusion authority related to kickbacks. In giving the Department of Health and Human Services (Department or HHS) the authority to protect certain arrangements and payment practices under the anti-kickback statute, Congress intended the safe harbor regulations to be updated periodically to reflect changing business practices and technologies in the health care industry.

B. The Electronic Health Records Safe Harbor

In the October 11, 2005 **Federal Register** (70 FR 59015), we published a notice of proposed rulemaking (the 2005 Proposed Rule) that would promulgate two safe harbors to address donations of certain electronic health records software and directly related training services, using our authority at section 1128B(b)(3)(E) of the Act. *See* 70 FR 59015, 59021 (Oct. 11, 2005). One proposed safe harbor would have protected certain arrangements involving donations of electronic health records technology made before the adoption of certification criteria. The other proposed safe harbor would have protected certain arrangements involving nonmonetary remuneration in the form of interoperable electronic health records software certified in accordance with criteria adopted by the Secretary of HHS (Secretary) and directly related training services. In the same issue of the **Federal Register** (70 FR 59182 (Oct. 11, 2005)), CMS simultaneously proposed similar exceptions to the physician self-referral law.

On August 8, 2006 (71 FR 45110), we published a final rule (the 2006 Final Rule) that, among other things, finalized a safe harbor [2] at 42 CFR 1001.952(y) (the electronic health records safe harbor) for protecting certain arrangements involving interoperable electronic health records software or information technology and training services. In the same issue of the **Federal Register** (71 FR 45140 (Aug. 8, 2006)), CMS simultaneously published similar final regulations at 42 CFR 411.357(w). The electronic health records safe harbor is scheduled to sunset on December 31, 2013. 42 CFR 1001.952(y)(13).

The present proposed rule sets forth certain proposed changes to the electronic health records safe harbor. CMS is proposing almost identical changes to the physician self-referral law electronic health records exception [3] elsewhere in this issue of the **Federal Register**. We attempted to ensure as much consistency as possible between our proposed safe harbor changes and CMS's proposed exception changes, despite the differences in the respective underlying statutes. We intend the final rules to be similarly consistent. Because of the close nexus between this proposed rule and CMS's proposed rule, we may consider comments submitted in response to CMS's proposed rule when crafting our final rule. Similarly, CMS may consider comments submitted in response to this proposed rule in crafting its final rule.

II. Provisions of the Proposed Rule

A. The Deeming Provision

Our current electronic health records safe harbor specifies at 42 CFR 1001.952(y)(2) that the donated software must be ''interoperable at the time it is provided to the recipient.'' As discussed in a recently issued Request for Information (RFI) from the Department, ''HHS envisions an information rich, person-centered, high performance health care system where every health care provider has access to longitudinal data on patients they treat to make evidence-based decisions, coordinate care and improve health outcomes.'' 78 FR 14793, 14795 (Mar. 7, 2013). Additionally, as emphasized in the RFI, interoperability will play a critical role in supporting this vision. Interoperability is also an important concept in the context of the electronic health records safe harbor. Although we have long been concerned that parties could use the offer or donation of technology to capture referrals, we have viewed interoperability as a potential mitigating factor, or safeguard, to justify other safe harbor conditions that are less stringent than might otherwise be appropriate in the absence of interoperability. This is because if the donated technology is interoperable, the recipient will be able to use it to transmit electronic health records not only to the donor, but to others, including competitors of the donor, and will not be ''locked in'' to communications with the donor only. *See* 70 FR 59015, 59023 (Oct. 11, 2005); 71 FR 45110, 45126 (Aug. 8, 2006). For purposes of this safe harbor, ''interoperable'' means ''able to communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks, in various settings, and exchange data such that the clinical or operational purpose and meaning of the data are preserved and unaltered.'' Note to paragraph (y) of 42 CFR 1001.952. The current provisions of the electronic health records safe harbor state that for purposes of meeting the condition set forth in subparagraph (y)(2), ''software is deemed to be interoperable if a certifying body recognized by the Secretary has certified the software within no more than 12 months prior to the date it is provided to the recipient.'' 42 CFR 1001.952(y)(2). We propose to update two aspects of this deeming provision to reflect the current Office of the National Coordinator for Health Information Technology (ONC) certification program for electronic health record technology.

First, we propose to modify the provision to reflect that ONC is responsible for ''recognizing'' certifying bodies, as referenced in this provision. *See* 42 U.S.C. 300jj–11(c)(5). To become a certifying body ''recognized'' by the Secretary, an entity must successfully complete an authorization process established by ONC. This authorization process constitutes the Secretary's recognition of a certifying body. Accordingly, we propose to revise the phrase ''recognized by the Secretary'' in the second sentence of subparagraph (y)(2) to read ''authorized by the National Coordinator for Health Information Technology.''

Second, we propose to modify the portion of this provision concerning the time period within which the software must have been certified. Currently, the electronic health records safe harbor deeming provision requires that software must have been certified within no more than 12 months prior to the date of donation in order to ensure that products have an up-to-date certification. Subsequent to issuing the final electronic health records safe harbor, ONC developed a regulatory process for adopting certification criteria and standards. That process is anticipated to occur on a 2-year regulatory interval. (For more information, *see* ONC's September 4, 2012 Final Rule titled ''Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology'' (77 FR 54163).) Further, some certification criteria could remain unchanged from one edition of the electronic health record certification criteria to the next. Thus, the current 12-month timeframe is

[2] For the reasons discussed in more detail in the preamble to the 2006 Final Rule, we abandoned the proposal to have separate pre- and post-interoperability safe harbors for electronic health records arrangements. *See* 71 FR 45110, 45121 (Aug. 8, 2006).

[3] 42 CFR 411.357(w).

not in line with the anticipated 2-year regulatory interval and does not account for the fact that some certification criteria may not change from one edition to the next. Therefore, we propose to modify this portion of the safe harbor by removing the 12-month timeframe and substituting a provision that more closely tracks the current ONC certification program. Accordingly, we propose that software would be eligible for deeming if, on the date it is provided to the recipient, it has been certified to any edition of the electronic health record certification criteria that is identified in the then-applicable definition of Certified EHR Technology in 45 CFR part 170. For example, for 2013, the applicable definition of Certified EHR Technology identifies both the 2011 and the 2014 editions of the electronic health record certification criteria. Therefore, in 2013, software certified to meet either the 2011 edition or the 2014 edition could satisfy the safe harbor provision as we proposed to modify it. The current definition of Certified EHR Technology applicable for 2014, however, identifies only the 2014 edition. Thus, based on that definition, in 2014, only software certified to the 2014 edition could satisfy our proposed, modified provision. Future modifications to the definition of Certified EHR Technology could result in the identification of other editions to which software could be certified and satisfy our proposed, modified provision. As we stated in the 2006 Final Rule, we understand ''that the ability of software to be interoperable is evolving as technology develops. In assessing whether software is interoperable, we believe the appropriate inquiry is whether the software is as interoperable as feasible given the prevailing state of technology at the time [it] is provided to the recipient.'' 71 FR 45110, 45126 (Aug. 8, 2006). We believe our proposed change is consistent with that understanding and our objective of ensuring that products are certified to the current standard of interoperability when they are donated. We seek comment on our proposal, including if removing the 12-month period will impact donations and whether we should consider retaining it as an additional means of determining eligibility under the deeming provision.

B. The Electronic Prescribing Provision

Our current electronic health records safe harbor specifies at 42 CFR 1001.952(y)(10) that the donated software must ''contain [ ] electronic prescribing capability, either through an electronic prescribing component or the ability to interface with the recipient's existing electronic prescribing system, that meets the applicable standards under Medicare Part D at the time the items and services are provided.'' In the preamble to the 2006 Final Rule, we stated that we included ''this requirement, in part, because of the critical importance of electronic prescribing in producing the overall benefits of health information technology, as evidenced by section 101 of the [Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. L. 108–173].'' 71 FR 45110, 45125 (Aug. 8, 2006). As we noted, it was ''our understanding that most electronic health records systems already include an electronic prescribing component.'' *Id.*

We continue to believe in the critical importance of electronic prescribing. However, in light of developments since the 2006 Final Rule, we do not believe that it is necessary to retain a requirement related to electronic prescribing capability in the electronic health records safe harbor. First, Congress subsequently enacted legislation addressing electronic prescribing. In 2008, Congress passed the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), Pub. L. 110–275. Section 132 of MIPPA authorized an electronic prescribing incentive program (starting in 2009) for certain types of eligible professionals. Further, in 2009, Congress passed the Health Information Technology for Economic and Clinical Health (HITECH) Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (ARRA), Pub. L. 111–5. The HITECH Act authorizes CMS to establish Medicare and Medicaid electronic health record incentive programs for certain eligible professionals, eligible hospitals, and critical access hospitals. 42 U.S.C. 1395w–4(o), 1395ww(n), 1395f(l)(3), and 1396b(t). The HITECH Act requires that eligible professionals under the Medicare and Medicaid electronic health record incentive programs demonstrate meaningful use of certified electronic health record technology, including the use of electronic prescribing. 42 U.S.C. 1395w–4(o)(2)(A)(i). Second, the industry has made great progress related to electronic prescribing. Recent analysis by ONC notes an increase in the percentage of physicians electronically prescribing via electronic health record technology from 7 percent in 2008 to 48 percent in 2012, reflecting rapid increases over the past few years in the rate of electronic health record-based electronic prescribing capabilities.[4] Furthermore, the regulations recently published to implement Stage 2 of the EHR Incentive Programs continue to encourage physicians' use of electronic prescribing technology. *See* 77 FR 53968, 53989 (Sept. 4, 2012); 77 FR 54163, 54198 (Sept. 4, 2012).

In light of these developments, we propose to delete the electronic prescribing condition at 42 CFR 1001.952(y)(10). We believe that there are sufficient alternative policy drivers supporting the adoption of electronic prescribing capabilities. We also note that electronic prescribing technology would remain eligible for donation under the electronic health records safe harbor or under the electronic prescribing safe harbor at 42 CFR 1001.952(x). Additionally, we considered whether removing this condition would increase the risk of fraud or abuse posed by donations made under the safe harbor; we do not believe that it would.

C. The Sunset Provision

The electronic health records safe harbor is scheduled to sunset on December 31, 2013. In adopting this condition of the electronic health records safe harbor, we acknowledged ''that the need for a safe harbor for donations of electronic health records technology should diminish substantially over time as the use of such technology becomes a standard and expected part of medical practice.'' 71 FR 45110, 45133 (Aug. 8, 2006). Some have suggested that we extend the sunset date or even remove the sunset provision entirely.

In recent years, electronic health record technology adoption has risen dramatically, largely as a result of the HITECH Act in 2009. For example, see Farzad Mostashari, M.D., ScM., National Coordinator, ONC, U.S. Department of Health and Human Services, Testimony before the Subcommittee on Technology and Innovation Committee on Science and Technology, available at *http://science.house.gov/sites/republicans.science.house.gov/files/documents/HHRG-112-SY19-WState-FMostashari-20121114.pdf* and HHS News Release, ''More than 100,000 health care providers paid for using electronic health records,'' June 19, 2012, available at *http://www.hhs.gov/news/press/2012pres/06/20120619a.html*; see also OIG, OEI Report OEI–04–10–00184,

[4] State Variation in E-Prescribing Trends in the United States—available at: *http://www.healthit.gov/sites/default/files/us_e-prescribingtrends_onc_brief_4_nov2012.pdf.*

''Memorandum Report: Use of Electronic Health Record Systems in 2011 Among Medicare Physicians Providing Evaluation and Management Services,'' June 2012, available at *https://oig.hhs.gov/oei/reports/oei-04-10-00184.pdf.* However, while the industry has made great progress, use of such technology has not yet been universally adopted nationwide, and continued electronic health record technology adoption remains an important Departmental goal. We continue to believe that as this goal is achieved, the need for a safe harbor for donations of such technology should continue to diminish over time. Accordingly, we propose to extend the sunset date to December 31, 2016. We selected this date because it corresponds to the last year in which one may receive a Medicare electronic health record incentive payment and the last year in which one may initiate participation in the Medicaid electronic health record incentive program. For more information, see ''CMS Medicare and Medicaid EHR Incentive Payment Milestone Timeline,'' available at *http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/downloads/EHRIncentProgtimeline508V1.pdf.* As an alternative to this proposed extended sunset date of December 31, 2016, we are also considering establishing a later sunset date. For example, we are considering extending the sunset date to December 31, 2021, which corresponds to the end of the electronic health record Medicaid incentives. *See id.* While these sunset dates are associated with specific Medicare and Medicaid electronic health record incentive programs, we recognize that not all health care providers to whom donations can be made are eligible for such incentives. These health care providers include, for example, many in the mental health and behavioral health communities as well as long-term and post-acute care facilities. We specifically solicit comment on our proposed extension of the sunset date to December 31, 2016. We also seek comment on whether we should, as an alternative, select a later sunset date and what that date should be.

D. Additional Proposals and Considerations

1. Protected Donors

As we stated in the preamble to the 2006 Final Rule for the electronic health records safe harbor, ''[w]e [originally] proposed to limit the scope of protected donors under § 1001.952(y) to hospitals, group practices, [prescription drug plan (PDP)] sponsors, and [Medicare Advantage (MA)] organizations, consistent with the MMA-mandated donors for the electronic prescribing safe harbor.'' 71 FR 45110, 45127 (Aug. 8, 2006); *see also* 70 FR 59015, 59023 (Oct. 11, 2005). However, ''[m]indful that broad safe harbor protection may significantly further the important public policy goal of promoting electronic health records, and after carefully considering the recommendations of the commenters, we [ ] concluded that the safe harbor should protect any donor that is an individual or entity that provides patients with health care items or services covered by a 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).'' 71 FR 45110, 45127 (Aug. 8, 2006). Notwithstanding this conclusion, we indicated that ''[w]e remain concerned about the potential for abuse by laboratories, durable medical equipment suppliers, and others, but believe that the safe harbor conditions in the [2006 Final Rule] and the fact that the safe harbor is temporary should adequately address our concerns.'' 71 FR 45110, 45128 (Aug. 8, 2006). We went on to state that ''[w]e intend to monitor the situation. If abuses occur, we may revisit our determination.'' *Id.*

We have received comments suggesting that abusive donations are being made under the electronic health records safe harbor. For example, some responses to our annual solicitation of safe harbors and special fraud alerts allege that donors are using the safe harbor to provide referral sources with items and services that appear to support the interoperable exchange of information on their face, but, in practice, lead to data and referral lock-in. *See, e.g., https://oig.hhs.gov/publications/docs/semiannual/2009/semiannual_fall2009.pdf.*

In light of (1) these comments, (2) our continued concern about the potential for fraud and abuse by certain donors that we articulated in the 2006 Final Rule,[5] and (3) the proposed changes to the electronic health records safe harbor conditions discussed in this proposed rule, we propose to limit the scope of protected donors under the electronic health records safe harbor, with the continued goal of promoting adoption of interoperable electronic health record technology that benefits patient care while reducing the likelihood that donors will misuse electronic health record technology donations to secure referrals. In this regard, we are considering revising the safe harbor to cover only the original MMA-mandated donors: hospitals, group practices, PDP sponsors, and MA organizations. We are considering, and seek comments regarding, 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 are considering retaining the current definition of protected donors, but excluding specific types of donors. Specifically, we are considering excluding 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 are considering excluding laboratory companies from the scope of permissible donors as their donations have been the subject of complaints. We are also considering excluding other high-risk categories, such as durable medical equipment suppliers and independent home health agencies. We seek comment on the alternatives under consideration, including comments, with supporting reasons, regarding particular types of providers and suppliers that should or should not be protected donors given the goals of the safe harbor.

2. Data Lock-In and Exchange

In the preceding section, we propose to limit the scope of permissible donors as a means to prevent donations that subvert the intent of the safe harbor—because they are used to lock in referrals—from receiving safe harbor protection. We are also considering inclusion of new or modified conditions in the safe harbor as an alternative or additional means of achieving that result. We are particularly interested in new or modified conditions that will help achieve two related goals. The first goal is to prevent the misuse of the safe harbor in a way that results in data and referral lock-in. The second, related goal is to encourage the free exchange of data (in accordance with protections for privacy). These goals reflect our interest, which we discussed above, in promoting the adoption of interoperable electronic health record technology that benefits patient care while reducing the likelihood that donors will misuse electronic health record technology

[5] *See* 71 FR 45110, 45128 (Aug. 8, 2006).

donations to secure referrals. The 2006 Final Rule requires donated software to be interoperable at the time it is donated to the recipient. The software is deemed interoperable if it is certified as described above. However, it has been suggested that even when donated software meets the interoperability requirements of the rule, policies and practices sometimes affect the true ability of electronic health record technology items and services to be used to exchange information across organizational and vendor boundaries.[6] We seek comments on what new or modified conditions could be added to the electronic health records safe harbor to achieve our two goals and whether those conditions, if any, should be in addition to, or in lieu of, our proposal to limit the scope of permissible donors. For example, 42 CFR 1001.952(y)(3)requires, as a condition of the safe harbor, that ''[t]he donor (or any person on the donor's behalf) [ ] not take any action to limit or restrict the use, compatibility, or interoperability of the items or services with other electronic prescribing or electronic health records systems.'' We solicit comments with regard to whether this condition could be modified to reduce the possibility of lock-in.

3. Covered Technology

We received questions concerning whether certain items or services, for example services that enable the interoperable exchange of electronic health records data, fall within the scope of covered technology under the electronic health records safe harbor. The answer to such questions depends on the exact items or services that are being donated. In the 2006 Final Rule, we explained that we interpreted the term '' 'software, information technology and training services necessary and used predominantly' for electronic health records purposes to include the following, by way of example: [i]nterface and translation software; rights, licenses, and intellectual property related to electronic health records software; connectivity services, including broadband and wireless Internet services; clinical support and information services related to patient care (but not separate research or marketing support services); maintenance services; secure messaging (*e.g.,* permitting physicians to communicate with patients through electronic messaging); and training and support services (such as access to help desk services).'' 71 FR 45110, 45125 (Aug. 8, 2006). It also has been suggested that we modify the regulatory text of the electronic health records safe harbor to explicitly reflect this interpretation. We believe that the current regulatory text, when read in light of the preamble discussion, is sufficiently clear concerning the scope of covered technology, but we seek input from the public regarding this issue.

[6] For more information on interoperability in health IT, *see* ''EHR Interoperability'' on the HealthIT.gov Web site at *http://www.healthit.gov/providers-professionals/ehr-interoperability.* For further discussion of interoperability and other health IT issues, *see* Arthur L. Kellermann and Spencer S. Jones, *ANALYSIS & COMMENTARY: What It Will Take to Achieve The As-Yet-Unfulfilled Promises Of Health Information Technology,* Health Aff. January 2013 32:163–68.

III. Regulatory Impact Statement

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (Sept. 30, 1993); Executive Order 13563 on Improving Regulation and Regulatory Review (Jan. 18, 2011); the Regulatory Flexibility Act (RFA) (Sept. 19, 1980, Pub. L. 96–354, codified at 5 U.S.C. 601 et seq.); section 1102(b) of the Act; section 202 of the Unfunded Mandates Reform Act of 1995 (Mar. 22, 1995; Pub. L. 104–4); Executive Order 13132 on Federalism (August 4, 1999); and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We believe this proposed rule does not reach the economic threshold for being considered economically significant and thus is not considered a major rule. We solicit comment on the assumptions and findings presented in this initial regulatory impact analysis.

The proposed rule would update the provision under which electronic health records software is deemed interoperable, remove the requirement related to electronic prescribing capability, and extend the safe harbor's sunset date (currently set at December 31, 2013). Neither this proposed rule nor the regulation it amends requires any entity to donate electronic health record technology, but we expect these proposed changes to continue to facilitate the adoption of electronic health record technology by filling a gap rather than creating the primary means by which this technology will be adopted.

The summation of the economic impact analysis regarding the effects of electronic health records in the ambulatory setting that is presented in the 2006 Final Rule still pertains to this proposed regulation. 71 FR 45110 (Aug. 8, 2006). However, since the 2006 Final Rule, several developments have occurred to make us conclude that it is no longer necessary to retain a requirement related to electronic prescribing capability in the electronic health records safe harbor. These developments include: (1) In 2008, Congress passed the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), Pub. L. 110–275; (2) in 2009, Congress passed the Health Information Technology for Economic and Clinical Health (HITECH) Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (ARRA), Pub. L. 111–5; and (3) an increase over the past few years in the rate of electronic health record-based electronic prescribing capabilities.

As discussed in more detail earlier in the preamble, section 132 of MIPPA authorized an electronic prescribing incentive program (starting in 2009) for certain types of eligible professionals. The HITECH Act authorizes CMS to establish Medicare and Medicaid electronic health record incentive programs for certain eligible professionals, eligible hospitals, and critical access hospitals. Also, the HITECH Act requires that eligible professionals under the Medicare and Medicaid electronic health record incentive programs demonstrate meaningful use of certified electronic health record technology, including the use of electronic prescribing. Specifically, the final regulation of the Stage 2 meaningful use (77 FR 53968 (Sept. 4, 2012)) includes more demanding requirements for electronic prescribing and identifies electronic prescribing as a required core measure. As a result, beginning in CY 2015 an eligible professional risks a reduction in the Medicare Physician Fee Schedule amount that will otherwise apply for covered professional services if they are not a meaningful EHR user for an EHR reporting period during that year. Our intent remains to allow potential recipients not to receive products or services they already own, but rather to receive electronic health record technology that advances its adoption and use. Lastly, according to ONC, electronic prescribing by physicians using electronic health record technology has increased from 7 percent

in December 2008 to approximately 48 percent in June 2012.[7] Furthermore, the regulations recently published to implement Stage 2 of the EHR Incentive Programs continue to encourage physicians' use of electronic prescribing technology. 77 FR 53968, 53989 (Sept. 4, 2012); 77 FR 54163, 54198 (Sept. 4, 2012). Due to data limitations, however, we are unable to accurately estimate the level of impact the electronic health records safe harbor has contributed to the increase in electronic prescribing. Therefore, we believe as a result of these legislative and regulatory developments advancing in parallel, the increase in the adoption of electronic prescribing using electronic health record technology will continue without making it necessary to retain the electronic prescribing capability requirement in the electronic health records safe harbor.

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $7.0 million to $34.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. The Secretary has determined that this proposed rule would not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. The Secretary has determined that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2013, that threshold is approximately $141 million. This rule will have no consequential effect on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this regulation does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

In accordance with Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

IV. Paperwork Reduction Act

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

List of Subjects in 42 CFR Part 1001

Administrative practice and procedure, Fraud, Grant programs—Health, Health facilities, Health professions, Maternal and child health, Medicaid, Medicare, Social Security.

Accordingly, 42 CFR part 1001 is proposed to be amended as set forth below:

PART 1001—[AMENDED]

■ 1. The authority citation for part 1001 continues to read as follows:

Authority: 42 U.S.C. 1302, 1320a–7, 1320a–7b, 1395u(j), 1395u(k), 1395w–104(e)(6), 1395y(d), 1395y(e), 1395cc(b)(2)(D), (E) and (F), and 1395hh; and sec. 2455, Pub. L. 103–355, 108 Stat. 3327 (31 U.S.C. 6101 note).

■ 2. Section 1001.952 is amended by revising the introductory text, paragraph (y) introductory text, and paragraphs (y)(2) and (y)(13), and by removing and reserving paragraph (y)(10).

The revisions read as follows:

§ 1001.952 Exceptions.

The following payment practices shall not be treated as a criminal offense under section 1128B of the Act and shall not serve as the basis for an exclusion:

* * * * *

(y) *Electronic health records items and services.* As used in section 1128B of the Act, ''remuneration'' does not include nonmonetary remuneration (consisting of items and services in the form of software or information technology and training services) necessary and used predominantly to create, maintain, transmit, or receive electronic health records, if all of the following conditions are met:

* * * * *

(2) The software is interoperable at the time it is provided to the recipient. For purposes of this subparagraph, software is deemed to be interoperable if a certifying body authorized by the National Coordinator for Health Information Technology has certified the software to any edition of the electronic health record certification criteria identified in the then-applicable definition of Certified EHR Technology in 45 CFR part 170, on the date it is provided to the recipient.

* * * * *

(13) The transfer of the items and services occurs, and all conditions in this paragraph (y) have been satisfied, on or before December 31, 2016.

* * * * *

Dated: January 22, 2013.

Daniel R. Levinson,

Inspector General.

Approved: March 7, 2013.

Kathleen Sebelius,

Secretary.

[FR Doc. 2013–08314 Filed 4–8–13; 4:15 pm]

BILLING CODE 4152–01–P

[7] State Variation in E-Prescribing Trends in the United States—available at: *http://www.healthit.gov/sites/default/files/us_e-prescribingtrends_onc_brief_4_nov2012.pdf.*

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 15

[ET Docket No. 13–49; FCC 13–22]

Unlicensed National Information Infrastructure (U–NII) Devices in the 5 GHz Band

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document proposes to amend the Commission's rules governing the operation of Unlicensed National Information Infrastructure (U–NII) devices in the 5 GHz band. The Commission has gained much experience with U–NII devices since it first made spectrum available in the 5 GHz band for U–NII in 1997. The Commission believes that the time is now right to revisit the rules. The initiation of this proceeding satisfies the requirements of the ''Middle Class Tax Relief and Job Creation Act of 2012'' which requires the Commission to begin a proceeding to modify the rules to