

B. What federal implementation plan provisions apply if a state fails to submit an approvable plan?

In addition to sanctions, if EPA finds that a state failed to submit the required SIP revision or if EPA disapproves the required SIP revision, or a portion thereof, EPA must promulgate a FIP no later than 2 years from the date of the finding if the deficiency has not been corrected.

IX. Statutory and Executive Order Reviews

Under the Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Act. Accordingly, this proposed action merely approves state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272) because application of those requirements would be inconsistent with the Act; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using

practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this proposed action does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Oxides of Nitrogen, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: April 1, 2013.

Judith A. Enck,

Regional Administrator, Region 2.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 411

[CMS-1454-P]

RIN 0938-AR70

Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships: Exception for Certain Electronic Health Records Arrangements

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the exception to the physician self-referral prohibition for certain arrangements involving the donation of electronic health records items and services. Specifically, it would extend the sunset date of the exception, remove the electronic prescribing capability requirement, and update the provision under which electronic health records technology is deemed interoperable. In addition, we are requesting public comment on other changes we are considering.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on June 10, 2013.

ADDRESSES: In commenting, please refer to file code CMS-1454-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1454-P, P.O. Box 8013, Baltimore, MD 21244-8013.

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

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1454-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Michael Zleit, (410) 786-2050.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

Comments received by CMS will be shared with the HHS Office of Inspector General.

I. Executive Summary

A. Purpose of the Regulatory Action

Section 1877 of the Social Security Act (the Act), codified at 42 U.S.C. 1395nn, also known as the physician self-referral statute: (1) prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership interest or compensation arrangement), unless an exception applies; and (2) prohibits the entity from submitting claims to Medicare for those referred services, unless an exception applies. The statute establishes a number of exceptions and grants the Secretary the authority to create additional regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse. Since the original enactment of the statute in 1989, we have published a series of final rules interpreting the statute and promulgating numerous exceptions.

In accordance with this authority, we published an exception to protect certain arrangements involving the provision of interoperable electronic health records software or information technology and training services. The

final rule for this exception was published on August 8, 2006 (71 FR 45140) (hereinafter referred to as the August 2006 final rule) and is scheduled to sunset on December 31, 2013 (See 42 CFR 411.357(w)(13)). The purpose of this proposed rule is to update certain aspects of the electronic health records exception and to extend the sunset date.

B. Summary of the Major Provisions

This proposed rule would amend the current exception 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 exception. Third, we propose to extend the sunset date of the exception. In addition to these proposals, we are soliciting public comment on other possible amendments to the exception, 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 exception to the physician self-referral statute. This exception 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. The proposed modifications to the exception 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 would 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, and remove the requirement related to electronic prescribing capability, and extend the exception's expiration date (currently set at December 31, 2013). We expect these proposed changes to continue to facilitate the adoption of electronic health records technology.

II. Background

A. Physician Self-Referral Statute and Exceptions

Section 1877 of the Social Security Act (the Act), 42 U.S.C. 1395nn, also known as the physician self-referral law: (1) prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to

an entity with which he or she (or an immediate family member) has a financial relationship (ownership interest or compensation arrangement), unless an exception applies; and (2) prohibits the entity from submitting claims to Medicare for those referred services, unless an exception applies. The statute at 42 U.S.C. 1395nn(b)(4), establishes a number of exceptions and grants the Secretary of the Department of Health and Human Services (the Secretary) (HHS) the authority to create additional regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse. Since the original enactment of the statute in 1989, we have published a series of final rules interpreting the statute and promulgating numerous exceptions.

B. The Electronic Health Records Items and Services Exception

In the October 11, 2005 **Federal Register** (70 FR 59182), we published a proposed rule (the 2005 proposed rule) that would promulgate two exceptions to the physician self-referral law to address donations of certain electronic health records software and directly related training services, using our authority at section 1877(b)(4) of the Act. One proposed exception would have protected certain arrangements involving donations of electronic health records technology made before the adoption of certification criteria. The other proposed exception 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 and directly related training services. In the same issue of the **Federal Register** (70 FR 59015), the HHS Office of Inspector General (OIG) proposed similar language to establish a "safe harbor" under the Federal anti-kickback statute.

On August 8, 2006 (71 FR 45140), we published a final rule that, among other things, finalized an exception at 42 CFR 411.357(w)¹ (the "electronic health records exception") to the physician self-referral prohibition for protecting certain arrangements involving interoperable electronic health records software or information technology and training services. Also, in the August 8, 2006 **Federal Register** (71 FR 45110), the OIG simultaneously published similar final regulations at 42 CFR 1001.952 that, among other things,

¹ For the reasons discussed in more detail in the preamble on August 8, 2006 final rule (71 FR 45140), we abandoned the proposal to have separate pre- and post-interoperability exceptions for electronic health records arrangements.

adopted a single safe harbor under the Federal anti-kickback statute for certain arrangements involving interoperable electronic health records software or information technology and training services. As set forth at 42 CFR 411.357(w)(13), the physician self-referral electronic health records exception is scheduled to sunset on December 31, 2013.

This proposed rule sets forth certain proposed changes to the electronic health records exception to the physician self-referral law. The OIG is proposing almost identical changes to the anti-kickback statute electronic health records safe harbor² elsewhere in this issue of the **Federal Register**. We attempted to ensure as much consistency as possible between our proposed changes to the physician self-referral exception and OIG's safe harbor changes, despite the differences in the respective underlying statutes. We intend the final rules to be similarly consistent. Also, because of the close nexus between this proposed rule and OIG's proposed rule, we may consider comments submitted in response to OIG's proposed rule when crafting our final rule. Similarly, OIG 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 exception to the physician self-referral law specifies at § 411.357(w)(2) that the donated software must be interoperable at the time it is provided to the physician. As discussed in the March 7, 2013 (78 FR 14795) request for information (RFI), "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." Additionally, as emphasized in this 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 exception. Although we have long been concerned that parties could use the donation of technology to capture referrals, we have viewed interoperability as a potential mitigating factor, or safeguard, to justify other exception 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.³ For purposes of this exception, "interoperable" (as defined at § 411.351) 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." The current provisions of the electronic health records exception state that for purposes of meeting the condition set forth in § 411.357(w)(2), "software is deemed to be interoperable if a certifying body recognized by the Secretary has certified the software no more than 12 months prior to the date it is provided to the physician." 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 § 411.357(w)(2) to reflect that ONC is responsible for "recognizing" certifying bodies, as referenced in this provision.⁴ To become a certifying body "recognized" by the Secretary, an entity must successfully complete an authorization process established by ONC. This authorization process constitutes Secretary's recognition as a certifying body. Accordingly, we propose to revise the phrase "recognized by the Secretary" in the second sentence of paragraph (w)(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 exception 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 exception, 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 electronic health record certification criteria to the next. Thus, the current 12-month timeframe is 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 exception 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 2014 editions of the electronic health record certification criteria and the 2014 edition. Therefore, in 2013, software certified to meet either the 2011 edition or the 2014 edition could satisfy the exception provision as we propose 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 (71 FR 45156), 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 the items or services are provided to the physician recipient." 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

² 42 CFR 1001.952(y).

³ See (70 FR 59186) and (71 FR 45155).

⁴ See 42 U.S.C. 300jj-11(c)(5).

comment on our proposal, including if removing the 12-month period would 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 exception at § 411.357(w)(11) specifies that the donated software must “contain [* * *] electronic prescribing capability, either through an electronic prescribing component or the ability to interface with the physician’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 August 2006 final rule (71 FR 45153), 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), Public Law 108–173].” We also noted at (71 FR 45153), it was “our understanding that most electronic health records systems already include an electronic prescribing component.”

We continue to believe in the critical importance of electronic prescribing. However, in light of developments since the August 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 exception. 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 at 42 U.S.C. 1395w–4(o), 1395ww(n), 1395f(l)(3), and 1396b(t) authorizes us to establish Medicare and Medicaid electronic health record incentive programs for certain eligible professionals, eligible hospitals, and critical access hospitals. 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. Second, the industry has made great progress related to electronic prescribing. Recent analysis by ONC notes an increase in the percentage of physicians electronic 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.⁵ Furthermore, the rules recently published to implement Stage 2 of the EHR Incentive Programs (77 FR 54198 and 77 FR 53989), continue to encourage physicians’ use of electronic prescribing technology.

In light of these developments, we propose to delete the electronic prescribing condition at § 411.357(w)(11).

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 exception or under the electronic prescribing exception at 42 CFR 411.357(v). We note that, unlike other provisions in the exception, the electronic prescribing condition was not imposed to satisfy the statutory requirement that regulatory exceptions promulgated under section 1877(b)(4) of the Act pose no risk of program or patient abuse. Rather, the condition was imposed to further the policy of encouraging donations that would produce the overall benefits of health information technology. Accordingly, we do not believe that removing the electronic prescribing condition would pose a risk of program or patient abuse for donations made under this exception.

C. The Sunset Provision

The electronic health records exception is scheduled to sunset on December 31, 2013. In adopting this condition of the electronic health records exception, we acknowledged “that the need 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.” 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, “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 an exception 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 [Guidance/Legislation/EHRIncentivePrograms/downloads/EHRIncentProgTimeline508V1.pdf](http://www.cms.gov/RegulatoryandPolicySupport/legislation/2012/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 records Medicaid incentives. 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

⁵ 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.

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 August 2006 final rule (71 FR 45156) for the electronic health records exception, “[w]e [originally] proposed to limit the scope of protected donors under the electronic health records exception to hospitals, group practices, [prescription drug plan (PDP)] sponsors, and [Medicare Advantage (MA)] organizations, consistent with the MMA-mandated donors for the electronic prescribing exception.” In the August 2006 final rule (71 FR 45156), we indicated that we selected these donors because they have a “direct and primary patient care relationship and a central role in the health care delivery infrastructure that would justify protection under the exception for the provision of electronic health records technology that would not be appropriate for other types of providers and suppliers, including providers and suppliers of ancillary services.” However, in the August 2006 final rule (71 FR 45157), we expanded the exception to permit donations by any DHS entity, stating that such an expansion “will expedite adoption of electronic records,” which was an important public policy goal. We also stated (71 FR 45157) that, “the requirements that donated software be interoperable and that physicians contribute 15 percent to the cost of the donated technology, and the limited duration of the exception * * *, if met, [would] provide adequate protection against program and patient abuse.”

Notwithstanding this conclusion, we have concerns about the potential for abuse of the exception by other types of providers and suppliers (including providers and suppliers of ancillary services who do not have a direct and primary patient care relationship and a central role in the health care delivery infrastructure). The OIG also indicated that it has concerns related to the potential for laboratories and other ancillary service providers to abuse its safe harbor. The OIG has received comments suggesting that abusive donations are being made under the electronic health records safe harbor. For example, some of the responses OIG received to its annual solicitation of safe

harbors and special fraud alerts (see the December 28, 2012 **Federal Register** (77 FR 76434)) 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. Because of the close nexus of our regulations, we believe it is also prudent for us to explore the possibility of such providers and suppliers abusing the exception.

Therefore, we propose to limit the scope of protected donors under the electronic health records exception, with the continued goal of promoting adoption of interoperable electronic health record technology that benefits patient care while reducing the likelihood that donors would misuse electronic health record technology donations to secure referrals. In this regard, we are considering revising the exception 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. We are considering excluding suppliers of ancillary services associated with a high risk of fraud and abuse, because the 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 as well, such as durable medical equipment (DME) 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 exception.

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 exception—because they are used to lock in referrals—from receiving protection

under the exception. We are also considering inclusion of new or modified conditions in the exception as an alternative or additional means of achieving that result. We are particularly interested in new or modified conditions that would help achieve two related goals. The first goal is to prevent the misuse of the exception 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 previously, in promoting the adoption of interoperable electronic health record technology that benefits patient care while reducing the likelihood that donors would misuse electronic health record technology donations to secure referrals. The August 2006 final rule requires donated software to be interoperable at the time it is donated to the physician. The software is deemed interoperable if it is certified as described previously. 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 exception for electronic health records 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, § 411.357(w)(3) requires, as a condition of the exception 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 comment 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

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. Kellerman and Spencer S. Jones, ANALYSIS & COMMENTARY: What It Will Take to Achieve The As-Yet-Unfulfilled Promises Of Health Information Technology, *Health Affairs*, January 2013 32:163–68.

health records data, fall within the scope of covered technology under the exception for electronic health records. The answer to such questions depends on the exact items or services that are being donated. In the August 2006 final rule (71 FR 45151), we explained that we interpreted “software, information technology and training services necessary and used predominantly” for electronic health records purposes to include the following, by way of example: “interface 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 (for example, permitting physicians to communicate with patients through electronic messaging); and training and support services (such as access to help desk services).” It also has been suggested that we modify the regulatory text (that is, § 411.357(w)) of the electronic health record exception 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.

III. Collection of Information Requirements

The provisions in this proposed rule would not impose any new or revised information collection, recordkeeping, or disclosure requirements. Consequently, this rule does not need additional Office of Management and Budget review under the authority of the Paperwork Reduction Act of 1995.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the “DATES” section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Statement

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation

and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 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 extend the exception’s expiration date (currently set at December 31, 2013), update the provision under which electronic health records software is deemed interoperable, and remove the requirement related to electronic prescribing capability. Neither this proposed rule nor the regulations it amends requires any entity to donate electronic health record technology to physicians, 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 physicians would adopt this technology.

The summation of the economic impact analysis regarding the effects of electronic health records in the ambulatory setting, that is presented in the August 2006 final rule (71 FR 45164) still pertains to this proposed rule. However, since the August 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 exception. 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 us 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 rule of the Stage 2 meaningful use (September 4, 2012; 77 FR 53968) includes more demanding requirements for electronic prescribing and identifies electronic prescribing as a required core measure. As a result, beginning in calendar year (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 physicians not to receive products or services they already own, but rather to receive electronic health record technology that advances their adoption and meaningful 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 rules recently published to implement Stage 2 of the EHR Incentive Programs (77 FR 54198 and 77 FR 53989), continue to encourage physicians’ use of electronic prescribing technology. Due to data limitations; however, we are unable to accurately estimate the level of impact the electronic health records exception 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

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.

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]

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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