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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 411

[CMS-1454-F]

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: Final rule.

SUMMARY: This final rule revises the exception to the physician self-referral law that permits certain arrangements involving the donation of electronic health records items and services. Specifically, this final rule extends the expiration date of the exception to December 31, 2021, excludes laboratory companies from the types of entities that may donate electronic health records items and services, updates the provision under which electronic health records software is deemed interoperable, removes the electronic prescribing capability requirement, and clarifies the requirement prohibiting any action that limits or restricts the use, compatibility, or interoperability of donated items or services.

DATES: With the exception of the amendment to § 411.357(w)(13), this regulation is effective on [Insert date 90 days after the date of publication in the Federal Register].

The amendment to § 411.357(w)(13) is effective on December 31, 2013.

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SUPPLEMENTARY INFORMATION:**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 the requirements of an exception are satisfied; and (2) prohibits the entity from submitting claims to Medicare for those referred services, unless the requirements of an exception are satisfied. 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 our statutory authority, we published an exception to the physician self-referral law 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

expire on December 31, 2013 (see 42 CFR 411.357(w)(13)). In the April 10, 2013 **Federal Register** (78 FR 21308), we published a proposed rule that would update certain aspects of the electronic health records exception and extend the expiration date of the exception. The purpose of this final rule is to address the public comments received on the proposed rule and to finalize certain aspects of the proposed rule.

B. Summary of the Final Rule

This final rule amends the current exception in several ways. First, this final rule extends the expiration date of the exception to December 31, 2021. Second, it excludes laboratory companies from the types of entities that may donate electronic health records items and services. Third, this rule updates the provision under which electronic health records software is deemed interoperable. Fourth, this rule clarifies the requirement at § 411.357(w)(3) prohibiting any action that limits or restricts the use, compatibility, or interoperability of donated items or services. Finally, it removes from the exception the requirement related to electronic prescribing capability.

C. Costs and Benefits

This final rule modifies an existing exception to the physician self-referral law. The exception permits certain entities to provide to physicians certain software and information technology and training and services necessary and used predominantly to create, maintain, transmit, or receive electronic health records. The 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 will not have a significant effect on program expenditures and there are no additional substantive

costs to implement the resulting provisions. We expect the exception, as modified by this final rule, to continue to facilitate the adoption of electronic health records technology.

II. Background

A. Physician Self-Referral Statute and Exceptions

Section 1877 of 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 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 the requirements of an exception are satisfied; and (2) prohibits the entity from submitting claims to Medicare for those referred services, unless the requirements of an exception are satisfied. The statute at 42 U.S.C. 1395nn(b)(4) 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.

B. The Electronic Health Records Items and Services Exception

On August 8, 2006 (71 FR 45140), we published a final rule that, among other things, finalized at § 411.357(w) an exception to the physician self-referral law for protecting certain arrangements involving interoperable electronic health records software or information technology and training services (the “electronic health records exception”). Also in the August 8, 2006 **Federal Register** (71 FR 45110), the Department of Health and Human Services' (HHS) Office of Inspector General (OIG)

published similar final regulations at § 1001.952 that, among other things, adopted a safe harbor under the Federal anti-kickback statute (section 1128B(b) of the Act, codified at 42 U.S.C. 1320a-7b(b)) for certain arrangements involving interoperable electronic health records software or information technology and training services. As set forth at § 411.357(w)(13) and § 1001.952(y)(13), the physician self-referral law electronic health records exception and the Federal anti-kickback electronic health records safe harbor, respectively, are scheduled to expire on December 31, 2013.

On April 10, 2013 (78 FR 21308), we published a proposed rule that would set forth certain proposed changes to the electronic health records exception. First, we proposed to update the provision under which electronic health records software is deemed interoperable. Second, we proposed to remove from the exception the requirement related to electronic prescribing capability. Third, we proposed to extend the expiration date of the exception. In addition to these proposals, we solicited public comment on other possible amendments to the exception, including our proposal to limit the types of entities that may donate electronic health records items and services under the exception and to add or modify conditions to limit the risk of data and referral lock-in. Elsewhere in the same issue of the **Federal Register** (78 FR 21314), OIG proposed almost identical changes to the Federal anti-kickback statute safe harbor. Within the limitations imposed by the differences in the respective underlying statutes, we attempted to ensure as much consistency as possible between our proposed modifications to the exception at § 411.357(w) and OIG's proposed modifications to the safe harbor. We noted in the proposed rule that, due to the close nexus between our proposed rule and the

OIG's proposed rule, we might consider comments submitted in response to OIG's proposal in finalizing this rule.

This final rule adopts some of the proposed changes to the electronic health records exception to the physician self-referral law. First, this final rule extends the expiration date of the exception to December 31, 2021. Second, it excludes laboratory companies from the types of entities that may donate electronic health records items and services under the exception. Third, this rule updates the provision under which electronic health records software is deemed interoperable. Fourth, this rule clarifies the requirement at § 411.357(w)(3) prohibiting any action that limits or restricts the use, compatibility, or interoperability of donated items or services. Finally, it removes from the exception the requirement related to electronic prescribing capability.

Elsewhere in this issue of the **Federal Register**, the OIG is finalizing almost identical changes to the electronic health records safe harbor¹ under the Federal anti-kickback statute. We attempted to ensure as much consistency as possible between our changes to the physician self-referral law exception and OIG's safe harbor changes. We have considered and responded to the timely comments we received as well as those received by OIG. Similarly, OIG considered comments submitted in response to our proposed rule in crafting its final rule. For purposes of this final rule, we treat comments that were made with respect to the Federal anti-kickback statute as if they had been made with respect to the physician self-referral law, except where they relate to differences in the underlying statutes.

¹ 42 CFR 1001.952(y).

III. Provisions of the Proposed Regulations and Analysis of and Responses to Public Comments

We received approximately 110 timely items of correspondence for the proposed rule. We summarize and respond to comments later in this section of the final rule. For ease of reference, we divided the comments and responses into the following categories: the deeming provision; the electronic prescribing provision; the “sunset” provision; and additional proposals and considerations.

A. The Deeming Provision

Our current electronic health records exception requires at § 411.357(w)(2) that the donated software must be “interoperable” (as defined at § 411.351) at the time it is provided to the physician. This provision further provides that 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 proposed two modifications to § 411.357(w)(2), which is known as the “deeming provision.” Both modifications to the deeming provision were proposed to reflect recent developments in the Office of the National Coordinator for Health Information Technology’s (ONC) certification program.

The first proposed modification would reflect ONC’s responsibility for authorizing certifying bodies. The second would modify the timeframe during which donated software must be certified. Currently, to comply with the deeming provision, the exception requires donated software to be certified no more than 12 months prior to the date of donation.

After the issuance of the August 2006 final rule, ONC developed a regulatory process for adopting certification criteria and standards which is anticipated to result in a cyclical rulemaking process. (For more information, see ONC's September 4, 2012 final rule entitled "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).) Our proposal would have modified the deeming provision to track ONC's anticipated regulatory cycle. As a result, software would be eligible for deeming if, on the date it is provided to the physician, 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. By way of example, for 2013, the applicable definition of Certified EHR Technology includes 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 would have satisfied the requirement of the exception as we proposed to modify it. Additionally, we solicited comments on whether removing the current 12-month certification requirement would impact donations and whether we should retain the 12-month certification period as an additional means of determining eligibility under the deeming provision.

After consideration of the public comments received, we are finalizing the proposed revisions to § 411.357(w)(2) with one clarification to our proposed regulatory text to ensure that the deeming provision closely tracks ONC's certification program. We are revising § 411.357(w)(2) to state that software is deemed to be interoperable if,

on the date that it is provided to the physician, it has been certified by a certifying body authorized by the National Coordinator for Health Information Technology to an edition of the electronic health record certification criteria identified in the then-applicable 45 CFR part 170. As we stated in the August 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 that our final rule with respect to this requirement is consistent with that understanding and our objective of ensuring that software is certified to the current required standard of interoperability when it is donated.

Comment: All of the commenters that addressed this issue in their comments supported the proposed modification that would amend the exception to recognize ONC as the agency responsible for authorizing certifying bodies on behalf of the Secretary, with one commenter requesting that we clarify that software need not be certified to ONC’s standards to be eligible for donation.

Response: We appreciate the commenters’ support for this modification. With respect to the request for clarification, the commenter is correct that § 411.357(w)(2) does not require software to be certified to ONC’s standards in order to be eligible for donation. As we discussed in the August 2006 final rule (71 FR 45156), the deeming provision offers one way for parties to be certain that the interoperability requirement of § 411.357(w)(2) is met at the time of donation. Even if donated software is not deemed

to be interoperable, the arrangement would satisfy the interoperability requirement of the exception if the software meets the definition of “interoperable” at § 411.351.

Comment: One commenter expressed concerns about linking the interoperability requirement of the exception to ONC’s certification criteria and standards because they do not, in the commenter’s assessment, reflect contemporary views of interoperability. The commenter suggested that we instead implement a broad definition of interoperability adopted by the International Organization for Standardization or, alternatively, that we adopt interoperability functional definitions developed by the American National Standards Institute.

Response: Although we are mindful that other non-governmental organizations may be developing their own standards to encourage the adoption of interoperable electronic health records technology, ONC’s certification criteria and standards are the core policies the Department is utilizing to accelerate and advance interoperability and health information exchange. On March 7, 2013, ONC and CMS jointly published a Request for Information (78 FR 14793) to solicit public feedback on a set of possible policies “that would encourage providers to routinely exchange health information through interoperable systems in support of care coordination across health care settings.” The process by which ONC considers the implementation of new certification criteria and standards is a public, transparent effort that allows the Department’s electronic health records technology experts to consider appropriately the comments submitted in light of the goal “to accelerate the existing progress and enhance a market environment that will accelerate [health information exchange] across providers”

(78 FR 14795).

We believe that it is reasonable and appropriate to link the deeming provision to ONC's certification criteria and standards because of ONC's expertise and its public process for considering and implementing its criteria and standards. ONC is the agency within the Department with expertise in determining the relevant criteria and standards to ensure that software is as interoperable as feasible given the prevailing state of technology. ONC expects to revise and expand such criteria and standards incrementally over time to support greater interoperability of electronic health records technology. (See the September 4, 2012 final rule (77 FR 54269).) Additionally, we believe that utilizing ONC's certification criteria and standards, which are implemented through a public process, affords the best opportunity for interested parties to comment on, understand, and ultimately implement those criteria and standards. Therefore, we are not adopting the commenter's suggestion.

Comment: One commenter stated that many electronic health records systems lack the capabilities to function within a patient-centered medical home. The commenter suggested that we finalize policies that further strengthen the use of core electronic health records features.

Response: We are not adopting the commenter's suggestion. As discussed, ONC is the agency within the Department with expertise in determining the relevant criteria and standards for electronic health records technology, including those related to the use of core features. The public process through which ONC's certification criteria and standards are implemented affords the best opportunity for interested parties to comment

on, understand, and ultimately implement those criteria and standards.

Comment: Of the commenters that addressed the deeming provision, most supported our proposal to modify the timeframe within which donated software must have been certified to track more closely the current ONC certification program. Commenters asserted that aligning the exception's certification timeframe with ONC's certification program will provide donors and physician recipients more certainty about the deemed status of donated software because the software must be certified to meet only one set of standards on the same certification cycle to comply with both ONC's certification criteria and the deeming provision of the exception. One commenter supported the modification, but suggested that the 12-month certification timeframe also be retained or, alternatively, that we allow software to be deemed to be interoperable if it has been certified to any edition of ONC's electronic health record certification criteria.

Response: We agree that aligning the exception's certification timeframe with ONC's certification program provides more certainty to donors and physician recipients. We believe that the modification we are making to the requirement at § 411.357(w)(2) will support the dual goals of the deeming provision: (1) to ensure that donated software is as interoperable as feasible given the prevailing state of technology at the time it is provided to the physician recipient; and (2) to provide donors and physician recipients a means to have certainty that donated software satisfies the interoperability requirement of the exception.

We are not persuaded to adopt the commenter's suggestion to retain the 12-month certification timeframe, as this would not ensure that software is certified to the current

required standard of interoperability. In the course of evaluating the commenter's suggestion, however, we realized that our proposed regulatory text may be too narrow to satisfy the dual goals of the deeming provision. Under our proposed regulatory text, software would be deemed interoperable if it was certified to an edition² of certification criteria referenced in the then-applicable definition of "Certified EHR Technology" at 45 CFR 170.102. That definition applies only to the Medicare and Medicaid Electronic Health Record Incentive Programs (the EHR Incentive Programs). See generally, 42 CFR part 495. However, ONC also has the authority to adopt into its regulations in 45 CFR part 170 certification criteria for health information technology, including electronic health records, that may not be referenced in the definition of "Certified EHR Technology" because they are not related to the EHR Incentive Programs. If we finalize the proposed regulatory text, software certified to criteria in editions not included in the definition "Certified EHR Technology" would not be eligible for deeming under the exception. Further, we have recently learned that ONC intends to retire outdated editions of certification criteria by removing them from the regulatory text in 45 CFR part 170. Accordingly, software certified to an edition identified in the regulations in effect on the date of the donation would be certified to a then-applicable edition, regardless of whether the particular edition was also referenced in the then-applicable definition of Certified EHR Technology. Thus, we are finalizing revisions to § 411.357(w)(2) to track more closely ONC's certification program in the deeming provision. We are finalizing a modification to our regulatory text to provide that software is deemed to be interoperable

² ONC has recently begun characterizing sets of adopted certification criteria as "editions."

if, on the date it is provided to the physician recipient, it has been certified by a certifying body authorized by the National Coordinator for Health Information Technology to an edition of the electronic health record certification criteria identified in the then-applicable version of 45 CFR part 170. We believe that this is consistent with our intent, as articulated in the proposed rule, to modify the deeming provision by removing the 12-month timeframe and substituting a provision that more closely tracks ONC's certification program. Further, we believe that the regulatory text, as modified, will support the goals of the deeming provision described previously.

Comment: One commenter suggested that, for deeming purposes, we should require that software be certified to the latest edition of electronic health record certification criteria rather than any edition then applicable. This commenter also suggested that the electronic directory of service (e-DOS) standard should be a certification requirement for donated software, and asserted that both recommendations would help ensure electronic health records software is interoperable.

Response: We decline to adopt the commenter's suggested requirements for the exception at § 411.357(w). We believe that requiring donated software to be certified to editions that are adopted and not yet retired by ONC through its certification program ensures that the software is certified to interoperability standards updated regularly by the agency of the Department with the relevant expertise. Further, adding requirements to the ONC certification criteria and standards is outside the scope of this rulemaking. Therefore, we are not implementing the commenter's suggestions.

B. The Electronic Prescribing Provision

At § 411.357(w)(11), our current electronic health records exception 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), Pub. L. 108-173].” We also noted that it was “our understanding that most electronic health records systems already include an electronic prescribing component” (71 FR 45153).

We continue to believe in the critical importance of electronic prescribing. However, in light of developments since the August 2006 final rule, we proposed to delete from the exception the requirement at § 411.357(w)(11). Based on our review of the public comments and for the reasons stated in the proposed rule, we are finalizing our proposal to eliminate the requirement that electronic health records software contain electronic prescribing capability in order to qualify for protection under the exception at § 411.357(w).

Comment: Two commenters disagreed that it is no longer necessary to require the inclusion of electronic prescribing capability in donated electronic health records software. One of the commenters stated that it was encouraged by the growth in the

number of physicians using electronic prescribing between 2008 and 2012, but believed that the requirement should remain for patient safety reasons because electronic prescribing is critical to lowering the incidences of preventable medication errors.

Response: Like the commenters, and as we stated in the proposed rule (78 FR 21311), we believe in the importance of electronic prescribing. However, we are persuaded that other existing policy drivers, many of which did not exist in August 2006 when the exception was promulgated, sufficiently support the adoption of electronic prescribing capabilities. We do not want to undermine important public policy goals by requiring redundant and sometimes expensive software capabilities that may not contribute to the interoperability of a given system. As we discussed in the proposed rule, electronic prescribing technology will remain eligible for donation under the electronic health records exception or under the electronic prescribing exception at § 411.357(v). We do not believe that removing this requirement would increase the risk of fraud or abuse posed by donations made pursuant to the exception.

Comment: Many commenters supported our proposal to eliminate the requirement that donated software must include electronic prescribing capability at the time it is provided to the physician recipient, agreeing that developments since the promulgation of the exception make it unnecessary to retain this requirement. One of the commenters asserted that the goal of the requirement for the inclusion of electronic prescribing technology in donated electronic health records software—that is, increasing the use of electronic prescribing—had been achieved through the electronic prescribing incentive program authorized by the Medicare Improvements for Patients and Providers

Act of 2008.

Response: We appreciate the commenters' support and, for the reasons explained in more detail previously in this final rule, we are eliminating the requirement at § 411.357(w)(11) that donated electronic health records 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.

C. The "Sunset" Provision

Protected donations under the current electronic health records exception must be made on or prior to December 31, 2013. In adopting this requirement of the electronic health records exception, we acknowledged in the August 2006 final rule (71 FR 45162), "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."

As we discussed in the proposed rule, although the industry has made great progress in the adoption and meaningful use of electronic health records technology, the use of such technology has not yet been adopted nationwide. Continued use and further adoption of electronic health records technology remains an important goal of the Department. We continue to believe that, as progress on this goal is achieved, the need for an exception for donations of electronic health records items and services should continue to diminish over time. Accordingly, we proposed to extend the expiration date

of the exception to December 31, 2016, selecting this date for the reasons described in the proposed rule (78 FR 21311). We also specifically sought comment on whether we should, as an alternative, select a later expiration date and what that date should be. For example, we stated that we were considering an expiration date of December 31, 2021 (78 FR 21311). In response to comments, we are extending the expiration date of the exception to December 31, 2021.

Comment: Numerous commenters urged us to make permanent the exception at § 411.357(w). According to these commenters, a permanent exception could: (1) provide certainty with respect to the cost of electronic health records technology for physicians; (2) encourage adoption by physicians who are new entrants into medical practice or have postponed adoption based on financial concerns regarding the ongoing costs of maintaining and supporting an electronic health records system; (3) encourage adoption by providers and suppliers that are not eligible for incentive payments through the Medicare and Medicaid programs; and (4) preserve the gains already made in the adoption of interoperable electronic health records technology, especially where hospitals have invested in health information technology infrastructure through protected donations of such technology. According to some commenters, although the exception was implemented to encourage the adoption of health information technology, it is now a necessity for the creation of new health care delivery and payment models. Some commenters also stated their support for a permanent exception because the adoption of electronic health records technology has been slower than expected, and allowing the exception to expire in 2016 would adversely affect the rate of adoption. Some of these

commenters requested that, if CMS is not inclined to make the exception permanent, we extend the availability of the exception through the latest date noted in the proposed rule—December 31, 2021.

Response: We agree with the commenters that the continued availability of the exception at § 411.357(w) plays a part in achieving the Department's goal of promoting electronic health records technology adoption. However, we do not believe that making the exception permanent is required or appropriate at this time. The permanent availability of the exception could serve as a disincentive to adopting interoperable electronic health records technology in the near-term. Moreover, as described in the proposed rule (78 FR 21312) and elsewhere in this final rule, we are concerned about inappropriate donations of electronic health records items and services that lock in data and referrals between a donor and physician recipient, among other risks. A permanent exception might exacerbate these risks over the longer term without significantly improving adoption rates. However, in light of other modifications we are making in this final rule to mitigate such ongoing risks, including removing laboratory companies as protected donors of electronic health records items and services, we are persuaded to permit use of the exception for more than the additional 3-year period that we proposed.

The adoption of interoperable electronic health records technology still remains a challenge for some providers and suppliers despite progress in its implementation and meaningful use since the August 2006 promulgation of the exception at § 411.357(w).

(See ONC's Report to Congress on Health IT Adoption (June 2013) at

http://www.healthit.gov/sites/default/files/rtc_adoption_of_healthit_and_related_efforts.pdf

[f](#) and the U.S. Department of Health and Human Services Assistant Secretary for Planning and Evaluation's EHR Payment Incentives for Providers Ineligible for Payment Incentives and Other Funding Study (June 2013) at <http://aspe.hhs.gov/daltcp/reports/2013/ehрпи.shtml>.) Although we believe that the protection afforded by the exception encourages the adoption of such technology, its permanence is not essential to the achievement of widespread adoption. It is only one of a number of ways that physicians are incented to adopt electronic health records technology, including the incentives offered by the EHR Incentive Programs and the movement in the health care industry toward the electronic exchange of patient health information as a means to improve patient care quality and outcomes.

Balancing our desire to encourage further adoption of interoperable electronic health records technology against our concerns about potential disincentives to adoption and the misuse of the exception to lock in referral streams, we are establishing a December 31, 2021 expiration date for the exception. We believe that this expiration date will support earlier adoption of electronic health records technology, provide a timeframe that aligns with the financial incentives for electronic health records adoption currently offered by the Federal government, and safeguard against foreseeable future fraud risks, while still providing adequate time for donors and physician recipients to maximize the financial incentives currently offered by the Federal government.

Comment: Two commenters agreed that the availability of the exception at § 411.357(w) should be extended, but not beyond December 31, 2016. One of these commenters asserted that a relatively short extension of the sunset date for the exception

would allow a wider range of people to obtain access to health information technology services while not diminishing the incentive for providers to acquire, implement and standardize the necessary electronic health records systems. Another commenter supported our proposal to extend the availability of the exception through December 31, 2016, and encouraged us to consider an additional extension as that date approaches. One commenter suggested that we extend the availability of the exception for at least 6 years, although a shorter or longer time period could be established after review of adoption rates across the range of providers that may or may not be eligible for meaningful use incentives under the EHR Incentive Programs. Other commenters supported our alternative proposal to extend the availability of the exception through December 31, 2021, which corresponds to the statutory end of the Medicaid incentive program. These commenters noted that more remains to be done to promote electronic health records technology adoption, and suggested that maintaining the exception through this date will help maximize the incentives for eligible physicians to adopt electronic health records technology and thereby increase use of electronic health records. Two other commenters suggested tying the expiration of the exception to the corresponding date for assessing “penalties” under the Medicare EHR Incentive Program in order to align appropriately Federal regulation of electronic health records technology adoption and use.

Response: We share the commenter’s concerns regarding diminishing incentives for providers to acquire, implement and standardize the necessary electronic health records systems. However, after consideration of all of the comments on this issue, we

believe that an extension of the exception would advance the Department's goals regarding the adoption of interoperable electronic health records technology and improvements in patient care, while providing an incentive for providers to adopt electronic health records technology in the near-term. Therefore, we are extending the availability of the exception at § 411.357(w) through December 31, 2021, which corresponds to the end of incentive payments under the Medicaid EHR Incentive Program.

We note that the two commenters that suggested tying the expiration of the exception to the corresponding date for assessing penalties under the Medicare EHR Incentive Program appear to misunderstand the duration of the downward payment adjustments under this program, which will continue until an eligible participant adopts and meaningfully uses appropriate electronic health records technology. (For additional information, see the July 28, 2010 (75 FR 44448) final rule entitled "Medicare and Medicaid Programs; Electronic Health Record Incentive Program.") The practical effect of the commenters' suggestion would be to extend permanently the exception at § 411.357(w). For the reasons stated elsewhere in this final rule, we do not believe that making the exception permanent is required or appropriate at this time, and we are not adopting the commenters' suggestion.

Comment: A few commenters expressed general support for extending the availability of the exception, but did not specify whether the extension should be for 3 years, 8 years, or some other length of time. Commenters noted that failure to extend the availability of the exception would negatively impact the adoption of electronic health

records technology, as well as its continued use.

Response: As described previously, we are finalizing our alternative proposal to extend the exception through December 31, 2021.

Comment: A number of commenters urged us to let the exception at § 411.357(w) expire on December 31, 2013. Some of the commenters asserted that the exception permits the exact behavior the law was intended to stop, namely, referrals tied to financial relationships between physicians and entities furnishing DHS, in this case, entities that donate electronic health records items and services. Other commenters asserted that the exception permits “legalized extortion” or provides “legal sanction to trample the competition.” Another commenter asserted that the inclusion of “non-market factors” (that is, the influence of donors, rather than end users) in the decision to adopt electronic health records technology may result in lower quality products or services and/or higher costs, often with an adverse impact on technology adoption and innovation. Still others asserted that, given the financial incentives that the government itself has provided, it is no longer necessary to spur the adoption of electronic health records technology through the underwriting of the cost of electronic health records technology by outside entities.

Response: Although we appreciate the commenters’ concerns, we continue to believe that the exception serves to advance the adoption and use of interoperable electronic health records. However, we caution that a compensation arrangement involving the donation of electronic health records technology runs afoul of the physician self-referral law unless it satisfies each requirement of the exception at § 411.357(w).

Arrangements that disguise the “purchase” or lock-in of referrals and donations that are solicited by the physician recipient in exchange for referrals would fail to satisfy the requirements of the exception. We disagree with the commenters that asserted that encouragement for the “underwriting” of electronic health records technology by organizations other than the government is no longer necessary, particularly in light of the developments in integrated patient care delivery and payment models.

Comment: Numerous commenters suggested that the exception at § 411.357(w) should sunset as scheduled on December 31, 2013, but only with respect to laboratories and pathology practices, “ancillary service providers,” entities not listed in section 101 of the MMA (authorizing an exception for certain donations of electronic prescribing items and services), or entities that are not part of an accountable care organization or not integrated in a meaningful manner.

Response: We consider these comments to be related to “protected donors” and address them in section III.D.1. of this final rule.

D. Additional Proposals and Considerations

1. Protected Donors

As we discussed in the proposed rule, despite our goal of expediting the adoption of electronic health records technology, we have concerns about the potential for abuse of the exception by certain types of providers and suppliers (including suppliers of ancillary services that do not have a direct and primary patient care relationship and a central role in the health care delivery infrastructure). The OIG indicated that it has concerns related to the potential for laboratories and other ancillary service providers to abuse its safe

harbor, as it has received comments suggesting that abusive donations are being made under the electronic health records safe harbor. In order to address these concerns, we proposed to limit the scope of protected donors under the electronic health records exception.

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

Many commenters raised concerns about donations of electronic health records items and services by laboratory companies and strongly urged us to adopt our proposal to eliminate protection for such donations, either by excluding laboratory companies from the scope of protected donors (if we extend the availability of the exception), or by letting the exception sunset altogether. (For more detailed discussion of comments concerning the sunset provision, see section III.C. of this final rule.) Other commenters raised similar concerns, but did not suggest a particular approach to address them.

We carefully considered the comments that we received on this proposal and, based on the concerns articulated by commenters and the wide-ranging support from the entire spectrum of the laboratory industry (from small, pathologist-owned laboratory companies to a national laboratory trade association that represents the industry's largest laboratory companies), we are finalizing our proposal to exclude laboratory companies from the types of entities that may donate electronic health records items and services under the exception. We believe this decision is consistent with and furthers our continued goal of promoting the adoption of interoperable electronic health records technology that benefits patient care while reducing the likelihood that the exception will be misused by donors to secure referrals. We also believe that our decision will address situations identified by some of the commenters involving physician recipients conditioning referrals for laboratory services on the receipt of, or redirecting referrals for laboratory services following, donations from laboratory companies.

Comment: Many commenters raised concerns that, notwithstanding a clear prohibition in the exception, laboratory companies are, explicitly or implicitly,

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

Response: The current requirement at § 411.357(w)(6) prohibits determining the eligibility of a physician recipient or the amount or nature of the items or services to be donated in a manner that directly takes into account the volume or value of referrals or other business generated between the parties. Accordingly, the quid pro quo arrangements and targeted donations described by the commenters would not satisfy this requirement of the exception. Such arrangements are not consistent with the purpose of the exception and can result in the precise types of harm the physician self-referral law is designed to prevent, such as financial self-interest that may affect a physician's medical decision making. We urge those with information about such arrangements to contact the OIG's fraud hotline at 1-800-HHS-TIPS or visit <https://forms.oig.hhs.gov/hotlineoperations/> to learn of other ways to report fraud.

We appreciate the commenters' support for our proposal to remove donations by laboratory companies from the protection of the exception. We believe that our decision to exclude laboratory companies from the scope of protected donors is the best way to encourage and facilitate the adoption of interoperable electronic health records technology without risk of program or patient abuse.

Comment: Several commenters raised concerns about laboratory company arrangements with electronic health records technology vendors. The commenters described agreements involving laboratory companies and vendors that result in the vendors charging other laboratory companies high fees to interface with the donated technology or prohibiting other laboratory companies from purchasing the technology for donation to their own clients. One of the commenters also raised a concern that volume discount arrangements between laboratory companies and vendors of electronic health records technology are resulting in donations of electronic health records items and services that may not best suit the needs of the physician recipient. The commenter asserted that donor laboratory companies are pushing a particular vendor's specific electronic health records system onto physician recipients because of the donor's close relationship with the vendor.

Response: Excluding potential competitors of the donor from interfacing with donated items or services, as described by the commenters, can result in data and referral lock-in. We discuss the issue of lock-in elsewhere in this final rule in more detail. We believe that our determination to exclude laboratory companies from the scope of protected donors will help address the data and referral lock-in risks posed by

arrangements such as those described by the commenters. We also believe that the changes to § 411.357(w)(1) that we are finalizing regarding the types of entities that may donate electronic health records items and services will help address the commenter's concern about the negative impact of relationships between laboratory companies and vendors on the selection of electronic health records technology by physicians. We stated in the August 2006 final rule that, although physician recipients remain free to choose any electronic health records technology that suits their needs, we do not require donors to facilitate that choice for purposes of the exception. However, as we also stated in the August 2006 final rule (71 FR 45157), our regulations require donors to offer interoperable products and donors must not impede the interoperability of any electronic health records software they decide to offer. Any agreement between a donor and a vendor that precludes or limits the ability of competitors to interface with the donated electronic health records software would raise significant questions regarding whether the donation meets the requirement at § 411.357(w)(3).

Comment: Many commenters noted that several states—including Missouri, New Jersey, New York, Pennsylvania, Tennessee, Washington, and West Virginia—have prohibited or restricted donations of electronic health records technology by laboratory companies to address fraud and abuse concerns. Some of the commenters urged us to effectuate a similar prohibition or restriction by removing laboratory companies as potential donors under the exception. One of these commenters asserted that laboratory companies licensed in states that strictly prohibit them from donating to referring physicians all or part of the costs of electronic health records technology are put at a

considerable disadvantage in the marketplace because of “the need for [electronic health records technology] subsidies to compete for business.”

Response: We believe that our determination to exclude laboratory companies from the types of entities that may donate electronic health records items and services under the exception will address the fraud and abuse concerns referenced by the commenters. With respect to the commenter’s concern about being disadvantaged, we note that our decision to prohibit laboratory companies from utilizing the exception applies equally to all laboratory companies, regardless of their location.

Comment: Several commenters, including a national laboratory trade association that represents the industry’s largest laboratory companies, took exception to what they perceived as an allegation that laboratory companies are solely responsible for problematic donations of electronic health records items and services. Some of these commenters asserted that electronic health records technology vendors are encouraging physicians to seek or demand donations from laboratory companies, and that physicians are threatening to withhold referrals or send laboratory business elsewhere if donations are not made. According to one commenter, because physicians are not paying for a significant portion of the cost of these items and services, electronic health records technology vendors are able to charge high prices and the size of donations (in dollars) has increased exponentially in recent years. The commenter also suggested that vendors may be manipulating pricing to maximize the amount a laboratory company pays for donated items and services while minimizing or eliminating any physician responsibility. Another commenter raised a related concern that electronic health records technology

vendors have increased the costs of their products because they know that laboratories are paying for them. Generally, commenters raising concerns about the conduct of electronic health records technology vendors and physicians recommended that we remove laboratory companies from the universe of permissible donors under the exception.

One commenter asserted that physicians are no longer choosing electronic health records technology based on which system is most appropriate, but rather based on which will produce the largest donation of items and services. Another commenter asserted that many physicians will change laboratory companies and seek a new donation once an existing donor laboratory company ceases to subsidize the physicians' electronic health records technology costs. This commenter stated that such conversions to different electronic health records technology are not only inefficient, but undermine the spirit of the regulatory requirement that physicians do not possess the same or equivalent items or services as those being donated.

Response: Our proposed modification related to the universe of donors potentially covered under the exception; thus, the focus of our discussion in the proposed rule was on donor conduct. Some of the comments we describe in this final rule also raise concerns about the conduct of physician recipients. In response, we are clarifying that we do not believe that problematic donations involving laboratory companies are solely the result of questionable conduct by laboratory companies. We believe that our decision to exclude laboratory companies from the universe of protected donors is the best way to reduce the risk of misuse of the exception at this time and addresses the

concerns identified by the commenters.

We note that § 411.357(w)(5) prohibits the physician recipient and the physician recipient's practice from making the receipt, amount or nature of the donated items or services a condition of doing business with the donor. This provision recognizes the program integrity risk posed by a potential physician recipient who demands a donation in exchange for referrals. This type of quid pro quo arrangement is no less troubling than quid pro quo arrangements that originate with the donor and would not satisfy the requirements of the exception. Whether a quid pro quo donation is for an initial installation of a donated item or service or a conversion to a different donated item or service would not change our analysis. Additionally, we caution those engaging in conversion arrangements to be mindful of the limitations in the exception at § 411.357(w)(8) concerning the donation of equivalent items or services.

Comment: Several commenters suggested that laboratory companies should be prohibited from donating electronic health records items and services to physicians or that physicians should pay for their own electronic health records technology. Other commenters asserted that laboratory companies do not share an essential interest in their referring clients having electronic health records technology. Still other commenters stated simply that laboratory companies represent a high risk of fraud and abuse.

Response: Based on the complaints previously received by OIG, which are described in more detail in the proposed rule, and the information provided by the commenters regarding some of the arrangements between laboratory companies and physician recipients of donated electronic health records items and services, we agree

that donations of electronic health records items and services by laboratory companies present a high risk of fraud and abuse. Exceptions promulgated using our authority under section 1877(b)(4) of the Act may provide protection from the physician self-referral law's prohibitions only for those financial relationships that pose no risk of program or patient abuse. We do not believe that continuing to permit laboratory companies to make protected donations under the exception at § 411.357(w) would meet this standard.

Therefore, we are modifying the requirements of the exception to eliminate laboratory companies from the types of entities that may provide donations under the exception. We do not agree with the commenters that laboratory companies necessarily do not have an essential interest in their referring clients having electronic health records technology. It is the behavior of laboratory companies and physician recipients of donations from laboratory companies of which we are aware that drives our determination to finalize our proposal to eliminate laboratory companies from the types of entities that may provide donations under the exception.

Comment: A few commenters noted that, rather than electronic health records, laboratory companies typically use a laboratory information system (LIS), anatomic pathologist information system, and/or blood banking system to store and share patients' laboratory results, and that these systems should not be confused with an electronic health record that includes a patient's full medical record comprised of information from many medical specialties, including pathology. One of these commenters asserted that laboratories already bear the cost of establishing LIS interfaces that they provide to physicians in order to exchange laboratory services data electronically, and that clinical

and anatomic laboratories could continue to do so legally even if they were no longer protected donors under the exception. One commenter lamented the costs associated with interfaces, other commenters requested that CMS clarify its position on the donation of interfaces by laboratory companies, and one commenter asserted that interfaces were not analogous to facsimile machines, which we have stated in the past may be provided to physicians under certain circumstances.

Response: We appreciate the general information provided by the commenters regarding the various types of technology that laboratory companies generally use or do not use. The more relevant technology in the laboratory setting is the interface that exchanges data electronically between the laboratory and its referral sources. These comments provide us an opportunity to discuss more fully our position on the donation of interfaces by laboratory companies.

Our decision to exclude laboratory companies from the universe of protected donors under the exception does not affect our interpretation of the physician self-referral law as it relates to whether the provision of an item or service qualifies as “remuneration” that establishes a compensation arrangement that implicates the law’s referral and billing prohibitions. In section 1877(h)(1)(A) of the Act, “compensation arrangement” is defined as “any arrangement involving any remuneration” between a physician (or an immediate family member of such physician) and an entity furnishing DHS. Section 1877(h)(1)(B) of the Act defines “remuneration” to include “any remuneration, directly or indirectly, in cash or in kind.” However, under section 1877(h)(1)(C) of the Act, “remuneration” does not include “the provision of items, devices, or supplies that are

used solely to: (i) collect, transport, process, or store specimens for the entity providing the item, device, or supply; or (ii) order or communicate the results of tests or procedures for such entity.” Therefore, the provision of such items, devices or supplies does not result in a compensation arrangement that implicates the physician self-referral law’s referral and billing prohibitions. We discussed this further in CMS Advisory Opinion 2008-01, which can be found at <http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-AO-2008-01.pdf>. Accordingly, the provision of certain interfaces, such as those described by the commenters, need not satisfy the requirements of § 411.357(w).

We disagree with the commenter that asserted that interfaces are not sufficiently analogous to facsimile machines. We believe that a limited-use interface (as described previously) is the contemporary analog to the limited-use computer or facsimile described in the example from the 1998 proposed rule preamble (63 FR 1693 and 1694 (January 9, 1998)). Moreover, the mode of technology is not restricted by the language of section 1877(h)(1)(c) of the Act nor is its cost, which is, in any event, outside the scope of this rulemaking.

Comment: Several commenters inquired whether our proposal to prohibit use of the exception for donations of electronic health records items and services by laboratory companies would apply to suppliers of both anatomic and clinical pathology services, and suggested that our proposal should apply to both. Commenters also inquired about the application of this proposal to hospitals that operate laboratory companies for non-hospital affiliated customers. Raising concerns about an uneven playing field, some

of these commenters urged us to exclude such hospitals from the universe of protected donors if we determined to exclude laboratory companies. One commenter suggested that we effectuate this limitation by restricting protected hospital donations to those made to the hospital's employed physicians and the hospital's wholly-owned physician practices.

Response: Our proposal applied to "laboratory companies" and did not distinguish between those that provide anatomic pathology services and those that provide clinical pathology services. We intend that references to "laboratory company" or "laboratory companies" include entities that furnish both types of DHS.

With respect to the commenters' suggestion to limit or prohibit hospital donations of electronic health records items and services, we appreciate the concerns articulated by the commenters, but are not adopting their suggestion at this time. We continue to believe that hospitals have a substantial and central stake in patients' electronic health records. Further, the types and prevalence of the concerns that have been brought to the OIG's attention and discussed elsewhere in this final rule about donations by laboratory companies have not arisen, to our knowledge, in the hospital-donation context.

We are also clarifying that, if a hospital furnishes clinical laboratory services through a laboratory that is a department of the hospital for Medicare purposes (including cost reporting), and the hospital bills for the services through the hospital's provider number, then the hospital would not be a "laboratory company" and would continue to qualify as a protected donor under the modified exception. However, if a hospital-affiliated or hospital-owned company with its own supplier number furnishes

clinical laboratory services that are billed using a billing number assigned to the company and not to the hospital, the company would be a “laboratory company” and would no longer qualify as a protected donor. The ability of the affiliated hospital to avail itself of the exception would be unaffected. We remind readers that it is the substance, not the form, of an arrangement that governs under the physician self-referral law.

Comment: One commenter requested that, if we finalize our proposal to exclude laboratory companies from the universe of protected donors, we specifically clarify that “[laboratory companies] are prohibited from providing [] software to physicians unless they comply with another one of the existing exceptions.” The commenter went on to cite examples of software leases and sales at fair market value that could potentially qualify for protection under an exception other than the one at § 411.357(w).

Response: We decline the commenter’s invitation to make this clarification. Exceptions set forth specific requirements that, if satisfied, assure the parties involved that physician referrals to the entity for DHS are not prohibited and that the entity may bill Medicare for the services furnished pursuant to those physician referrals. As we have stated in prior rulemakings, an arrangement need not satisfy the requirements of a particular exception. Rather, the parties to an arrangement may avail themselves of any applicable exception to protect the physician’s referrals to the DHS entity with which he or she (or an immediate family member) has a financial relationship.

Comment: One commenter shared its concerns about a practice that it described as “post-donation in-sourcing.” The commenter stated that it is aware of situations in which laboratory companies are donating electronic health records technology to

referring physicians only to have those physicians in-source their laboratory services shortly after the donation. The commenter suggested that the donations enable referring physicians to avoid bearing the full cost of electronic health records technology without continued referrals to the donating laboratory company.

Response: We are not modifying the exception to address the commenter's concern. We remind stakeholders that the exception does not require the physician recipient to make referrals to the donor. To the contrary, § 411.357(w)(5) prohibits the physician recipient and his or her practice from making the receipt, amount, or nature of the donated items or services a condition of doing business with the donor. Moreover, § 411.357(w)(6) prohibits determining the eligibility of a physician recipient or the amount or nature of the items or services to be donated in a manner that directly takes into account the volume or value of referrals or other business generated between the parties. Whether protection is afforded under the exception to the types of arrangements described by the commenter will depend on whether all of the requirements of the exception are satisfied.

Comment: Two commenters raised issues regarding the type of remuneration permissible under the exception at § 411.357(w). One commenter characterized the exception as allowing laboratory companies to donate funds to physician recipients to help them implement electronic health records technology. Another commenter noted that some donations from laboratory companies have included hardware.

Response: We remind stakeholders that the exception at § 411.357(w) applies only to the donation of nonmonetary remuneration (in the form of software or

information technology and training services) necessary and used predominantly to create, maintain, transmit, or receive electronic health records. As stated in the preamble to the August 2006 final rule (71 FR 45161), reimbursement for previously incurred expenses is not protected, as it poses a substantial risk of program and patient abuse. We also remind stakeholders that the exception does not protect the donation of hardware.

Comment: Although the majority of commenters supported excluding laboratory companies from the types of entities that may donate electronic health records items and services under the exception, some commenters made other recommendations related to protected donors. A number of commenters recommended that we maintain our current scope of protected donors; that is, allow any entity (as defined at § 411.351) to provide electronic health records items and services to a physician. Some of these commenters stated that limiting the scope of protected donors could have an impact on specialists, who, according to the commenters, still have relatively low rates of electronic health records adoption. Along the same lines, one commenter stated that limiting the categories of donors that may seek protection under the exception will negatively impact physician recipients by preventing certain entities from helping to move the entire healthcare system toward more interoperable electronic health record systems. Others cautioned that restricting the universe of permissible donors will stymie innovation and restrict learning from the technology. Finally, some commenters contended that laboratory companies and other ancillary service providers have a legitimate clinical interest in donating electronic health records technology and that many physician practices depend on it.

Some commenters, while acknowledging our concerns regarding abusive donation practices, suggested alternative means to address the concerns we articulated in the proposed rule. These commenters variously recommended that we strengthen interoperation requirements, provide physician education materials, or adopt enforcement policies to prevent abuses rather than limiting the universe of potential donors of

electronic health records items and services.

Response: We agree with many of the reasons articulated by the commenters supporting a fully expansive universe of protected donors under the exception. We recognize that limiting the universe of potential donors could constrain the ability of many physicians to adopt electronic health records technology. However, we are persuaded by the commenters that cited examples or patterns of program abuse by laboratory companies and are amending the exception to limit permissible donors under § 411.357(w) by excluding laboratory companies. Other than with respect to laboratory companies, the universe of protected donors will remain the same. We will continue to monitor and may, prior to the end of 2021, reconsider in a future rulemaking the risk of program or patient abuse relating to the use of the exception by other donors or categories of donors.

We appreciate the suggestions from commenters regarding alternative means of addressing abusive donation practices. However, our authority under section 1877(b)(4) of the Act permits us to establish exceptions to the physician self-referral law only where protected financial relationships would pose no risk of program or patient abuse. We do not believe that adopting the commenters' alternative suggestions for addressing our concerns would meet this standard.

Comment: We received a number of comments requesting that we retain certain categories of providers and suppliers within the universe of permissible donors of electronic health records items and services under the exception at § 411.357(w). For example, commenters that provide dialysis services specifically requested that they

remain protected donors. One of the dialysis-provider commenters noted that excluding this specialty would have a chilling effect on the development and availability of the specialized electronic health records systems used by nephrologists. A few commenters requested that we continue to include hospitals and health systems as protected donors in order for them to retain the ability to assist physicians in adopting electronic health records technology. Other commenters requested that we explicitly retain home health agencies as permissible donors. In support of retaining home health agencies, one commenter stated that the depth, breadth, and frequency of communications between home health agencies and other direct care providers makes the use of interoperable electronic health records technology essential to improving clinical outcomes and financial efficiencies. We also received comments in support of retaining safety net providers and pharmacies as protected donors.

Response: We agree generally with the thrust of these comments. We recognize the value of permitting entities that participate directly in the provision of health care to patients and that have a need to coordinate with care providers to donate electronic health records items and services to facilitate those interactions. We take no action in this final rule to prohibit entities other than laboratory companies from utilizing the exception.

Comment: Some commenters agreed with the option we presented in the proposed rule to retain the ability of any DHS entity to donate electronic health records items and services, except suppliers of ancillary services associated with a high risk of fraud and abuse. A few of these commenters suggested that a targeted approach would minimize the risk of unintended consequences. One of these commenters asserted that

we should exclude the particular individuals or entities that have been the subject of complaints. Another of these commenters specifically recommended that we target categories of suppliers with a history or pattern of abusive behavior.

Other commenters variously recommended excluding laboratories, DME suppliers, home health agencies, or safety net providers from the types of entities that may donate electronic health records items and services under the exception. One commenter asserted that entities like laboratory companies and DME suppliers do not have an overarching and essential interest in having physicians use electronic health records, nor do they coordinate the patient's care. In contrast, one commenter objected to singling out a provider or supplier type to exclude from the scope of protected donors. This commenter stated that such an action unjustly: (1) penalizes a whole category of providers or suppliers when most, in the commenter's assessment, are law-abiding; and (2) supports other providers or suppliers that may have similar motivations.

Response: We respond elsewhere in this final rule to the commenters who expressly recommended removing only laboratory companies from the universe of permissible donors. With respect to the other commenters, we note that, in the proposed rule (78 FR 21312), we specifically requested comments, "with supporting reasons," regarding whether particular provider or supplier types should be prohibited from utilizing the exception at § 411.357(w). Some commenters suggested that we prohibit other types of entities from donating electronic health records items and services under the exception, but the comments did not provide specific examples of abusive practices with respect to donations of electronic health records items and services by such donors,

nor did the comments indicate problems with other types of entities comparable to those that are arising in the context of laboratory companies. Finally, we do not agree with the commenters that laboratory companies, DME suppliers, home health agencies, safety net providers, or, for that matter, any other “ancillary” service providers necessarily do not have an overarching and essential interest in having physicians use electronic health records, or that they do not coordinate the patient’s care. It is the behavior of laboratory companies and physician recipients of donations from laboratory companies of which we are aware that drives our determination to finalize our proposal to exclude laboratory companies from the types of entities that may provide donations under the exception. We have not heard the same concerns about other categories of donors or types of donation arrangements and, therefore, believe it is premature to exclude potential donors (other than laboratory companies). We also decline to identify particular individuals or organizations in the regulation.

Comment: A few commenters recommended restricting the entities that may donate electronic health records items and services under the exception to those types listed in the MMA. These commenters also suggested imposing additional restrictions on donations from this limited universe of donors. For example, one commenter recommended limiting the application of the exception to hospitals and providers operating in an integrated setting and to MA plans and providers under contract with them. Another commenter suggested limiting the application of the exception to a similar integration model, and to hospitals that donate electronic health records items and services to their employed physicians and the physician groups that they own. In

contrast, one commenter suggested that limiting the protected donor types to the original MMA list would be too restrictive. The commenter believed that some provider types not listed in the MMA should have the opportunity to make donations (for example, ambulatory surgical centers that now perform many procedures previously only performed in hospitals).

Response: We agree that providers and suppliers operating in an integrated environment need interoperable electronic health records. However, we do not believe that the need for this technology is limited to those individuals and entities in an integrated care setting. Patients may receive care from providers and suppliers that are not in the same integrated system, and the patient's medical records need to be shared with those providers and suppliers that also care for the patient. The Department's goal continues to be fostering broad adoption of interoperable electronic health records technology. In furtherance of that goal, we seek to limit the applicability of the exception vis-à-vis permissible donors only to the extent necessary to prevent program and patient abuse. At this time, we believe that excluding laboratory companies from the types of entities that may utilize the electronic health records exception, rather than limiting the universe of permissible donors to the MMA list of donors (or some other subset of permissible donors) strikes the right balance between furthering the Department's goal and preventing program and patient abuse.

2. Data Lock-In and Exchange

We solicited comments on what new requirements could be added to, or how we could modify existing requirements of, the exception at § 411.357(w) in order to achieve

our goals of: (1) preventing misuse of the exception that results in data and referral lock-in; and (2) encouraging the free exchange of data (in accordance with protections for privacy). Additionally, we requested comments on whether such requirements, if any, should be in addition to, or in lieu of, our proposal to limit the entities whose donations of electronic health records items and services may qualify for protection under the exceptions. Finally, we solicited comments on possible modifications to § 411.357(w)(3), which requires that, in order to qualify for the protection of the exception, “[t]he donor (or any person on the donor’s behalf) does 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 solicited these comments to explore whether this requirement could be modified to reduce the possibility of data and referral lock-in.

Comment: Many commenters asserted that the current requirements of the exception provide adequate safeguards to prevent donations of electronic health records items and services that result in data or referral lock-in between the donor and physician recipient. These commenters expressed general support for the investigation of arrangements that may not satisfy the requirements of the exception. Several of these commenters were also concerned that adding or modifying requirements may increase the burden of compliance and, therefore, lead to fewer entities willing to make appropriate donations of electronic health records items and services.

Response: In general, we agree with these commenters. We are not persuaded to adopt significant new requirements or modifications to the exception to address the issue

of data or referral lock-in. In addition, we do not wish to take any action that inadvertently discourages donors and physician recipients from entering into appropriate donation arrangements. However, we are making limited clarifications to § 411.357(w)(3) to reflect our intended meaning of this requirement and our interpretation of existing requirements for interoperability as it pertains to potential data or referral lock-in. We also remain committed to assisting our law enforcement partners in the investigation of potentially abusive arrangements that purport to satisfy the requirements of the exception but, in fact, do not.

Comment: Several commenters expressed concerns about donations of electronic health records items and services that lead to data lock-in. As described elsewhere in this final rule, some commenters suggested that, although some donated electronic health records software has the ability to be interoperable, vendors may charge providers who do not use the same donated software high fees to interface with it. The commenters contended that these business practices result in electronic health records software that is not practically interoperable because non-donor providers cannot afford to connect to the donated electronic health records items and services. Other commenters expressed general concerns that donated electronic health records items or services are capable of interoperation, but that physician recipients implicitly agree to send referrals using the technology only to the donor. These commenters did not provide specific recommendations to modify the data lock-in requirements of the exception, but generally supported our efforts to prevent data lock-in.

Two commenters representing laboratory companies expressed specific concerns

about a feature of donated software that may lead to data lock-in. These commenters explained that some software is designed to limit the accessibility of data that is received from an electronic health records system that is different than the donated software. Most often, data sent from the non-donated electronic health records system cannot populate automatically in a patient's electronic health record or other limits are placed on the portability of data sent from the non-donated electronic health records system. According to these commenters, the limited accessibility of the data makes it harder for the physician recipient to access and use it for clinical purposes. As a result, a physician recipient is more likely to utilize only the donor's services to make sure that necessary data is easily accessible. These commenters asserted that there are no technical solutions to reducing the possibility of data lock-in; rather, the only solution is to remove laboratory companies from the types of entities whose donations may be protected under § 411.357(w).

Several other commenters generally endorsed our efforts to prevent data and referral lock-in. These commenters evidenced strong support for the free exchange of health information across different provider types to better coordinate care for patients. However, apart from supporting our efforts to ensure that electronic health records systems are interoperable, the commenters made no specific recommendations regarding modifications to the exception.

Response: We share the commenters' concerns about the interoperability of donated electronic health records software. Arrangements involving the donation of electronic health records software that has limited or restricted interoperability due to

action taken by the donor or by any person on the donor's behalf (which could include the physician recipient acting on the donor's behalf) would fail to satisfy the requirement at § 411.357(w)(3) and would be inconsistent with an important purpose of the exception, which is to promote the use of technology that is able to communicate with products from other vendors. For example, arrangements in which the donor takes an action to limit the use, communication, or interoperability of the electronic health records items or services by entering into an agreement with the physician recipient to preclude or inhibit any competitor from interfacing with the donated items or services would not satisfy the requirement of § 411.357(w)(3). Other donation arrangements described by the commenters in which electronic health records technology vendors charge high interface fees to non-recipient providers or competitors may also fail to satisfy the requirements of § 411.357(w)(3). We believe that any action taken by a donor (or any person on behalf of the donor, including the electronic health records technology vendor or the physician recipient) to limit the use of the donated electronic health records items or services by charging fees to prevent non-recipient providers and the donor's competitors from interfacing with the donated items or services would pose legitimate concerns that parties were improperly locking in data and referrals, and that the arrangement in question would not satisfy the requirements of the exception. However, whether a donation actually satisfies the requirements of the exception depends on the specific facts of the donation arrangement.

Comment: One commenter expressed concern regarding data lock-in and supported ensuring that donations of electronic health records items and services are

transparent and free of any attempts to steer future business. Although it denied knowledge of any specific abuse of the exception, the commenter requested that we allow individuals or entities to remedy noncompliance with the physician self-referral law due to a donation that may not be protected by the exception. The commenter suggested that the remedy for violation of the physician self-referral law due to an arrangement's failure to satisfy the requirements of the exception at § 411.357(w) should be to make physician recipients pay the fair market value of any costs for ongoing support of the donated electronic health records items or services. The commenter suggested allowing 3 years for the physician recipient to either pay full value for the donated electronic health records items and services or transition to a new system.

Response: We appreciate the commenter's concern and recommendation; however, we decline to make the suggested modification. Implementing the commenter's suggestions would be outside the scope of our statutory authority under section 1877(b)(4) of the Act to promulgate exceptions to the physician self-referral law that pose no risk of program or patient abuse.

Comment: A few commenters urged us to amend the exception to require the physician recipient or the donor to participate in health information exchange with an electronic health records system that is different from the one donated. One commenter specifically suggested that the physician recipient should have to demonstrate exchange with at least one other electronic health records system within a certain timeframe after receipt of the donation. Another commenter suggested that the donor should have to—upon request—enable the physician recipient of the donation to engage in bi-directional

exchange of data with competitors not using the same electronic health records system.

Response: We appreciate the commenters' recommendations; however, we are not modifying the exception to require the parties to an arrangement for the donation of electronic health records items and services to demonstrate interoperation. We question whether adequate demonstration of interoperation could occur only after the donation has been made, which would create uncertainty about whether the donation satisfies the requirements of the exception. This uncertainty would undermine the Department's broad goal for the exception—that is, to support widespread adoption of interoperable electronic health records technology. However, it is our intent and expectation that interoperation of donated items and services will, in fact, occur, and we believe the requirements of the exception, in their entirety, promote such interoperation. Moreover, routine interoperation with systems other than those of the donor may be evidence that neither the donor nor any person on the donor's behalf has taken 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, as required under § 411.357(w)(3).

Further, we note that the Department is considering a number of policies to accelerate and advance interoperability and health information exchange. As part of this process, ONC and CMS issued a notice requesting input from the public on possible policies and programmatic changes to accelerate electronic health information exchange among individuals and entities that furnish health care items and services, as well as new ideas that would be both effective and feasible to implement (78 FR 14793). We believe

that the process through which ONC and CMS will jointly act is better-suited than this exception to consider and respond to evolving functionality related to the interoperability of electronic health records technology. The paper that addresses the public comments we received and outlines the Department's strategy for accelerating health information exchange is available at: <http://www.healthit.gov/policy-researchers-implementers/accelerating-health-information-exchange-hie>.

Comment: In response to our solicitation of comments, some commenters provided suggestions as to how we could broaden the current requirements related to data lock-in. Two commenters suggested amending § 411.357(w)(3), which prohibits the donor (or any person on the donor's behalf) from taking 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." Specifically, the commenters suggested that we replace the reference to "electronic prescribing or electronic health records systems" with "health information technology platforms or other health care providers." The commenters asserted that this proposed change reflects the development of health information technology that may not be classified as an electronic health records system, but supports the free exchange of health information. These two commenters also suggested that we modify § 411.357(w)(3) to state that neither the donor nor the physician recipient may take any action to limit the interoperability of donated electronic health records items or services and that we require that the modified condition be included as part of the written agreement required under § 411.357(w)(7).

Another commenter suggested amending § 411.357(w)(3) by providing a

non-exhaustive list of actions that would cause a donation not to satisfy this requirement and by establishing a process for entities to provide the Department with information about potential abuses of the exception. A representative of several health plans suggested modifying the exception to ensure that, in the context of health information exchange, the interoperability requirement of the exception requires that all key stakeholders, including health insurance plans, have access to the health information exchange. The commenter suggested that we modify the interoperability condition at 42 CFR 411.357(w)(2) to prohibit restrictions on the communication and exchange of data with any covered entity as defined at 45 CFR 160.103.

Response: The language in the existing regulatory text prohibits donors (or persons on the donor's behalf) from taking any action to limit or restrict the use, compatibility, or interoperability of donated items or services with other "electronic prescribing or electronic health records systems." The term "electronic prescribing or electronic health records systems" was intended to be broad in order to account for developments in the health information technology industry. Based on the commenters' suggestions it appears, however, that stakeholders may have read this term more narrowly. This narrow reading is inconsistent with our intended meaning. We have always believed and continue to believe that an action taken by a donor (or on behalf of the donor) that limits the use, compatibility, or interoperability of donated items or services with any other health information technology may impede the free exchange of data and limit the ability of providers and suppliers to coordinate care, which is inconsistent with the goals of the exception. Therefore, we are clarifying

42 CFR 411.357(w)(3) by adding, by way of example and without limitation, a non-exhaustive list of some of the forms of technologies that we believe are included within the meaning of the existing regulatory language. We are not adopting the commenters' suggested edit, as we do not believe that it is necessary in light of our clarification. We also decline to modify 42 CFR 411.357(w)(2) to prohibit restrictions on the communication and exchange of data with any covered entity as defined at 45 CFR 160.103. We believe that existing 42 CFR 411.357(w)(3), which we have clarified in this final rule as including health information technology applications, products, or services, promotes interoperability with a variety of providers and suppliers, as well as other health care entities that may play a role in the coordination of care, including health plans that operate health information technology applications, products, or services.

We are also not adopting the commenters' suggestion to modify the exception to state that neither the donor nor the physician recipient may take any action to limit the interoperability of donated electronic health records items or services. The requirement at § 411.357(w)(3) prohibits the donor (or any person on behalf of the donor) from taking any action that limits or restricts the use, compatibility, or interoperability of the donated electronic health records items or services. To the extent that a physician recipient takes an action on the donor's behalf to limit the use, compatibility, or interoperability of donated items or services, that donation would fail to qualify for protection under the exception. Because we see no obvious reason, other than at the behest of the donor or as a condition of the donation, why a physician recipient would take action to limit the use,

compatibility, or interoperability of donated items or services, we believe that any action of this type by a physician recipient would be suspect. We are not making the suggested modification because we believe the concern articulated by the commenters is already addressed by the existing regulatory language and the policies we are adopting in this final rule. Accordingly, we are not making any corresponding revisions to require that the recommended provision be incorporated into the written agreement required under § 411.357(w)(7).

Finally, we are not revising the exception to provide in regulation text examples of actions that may cause a donation not to satisfy the requirements of § 411.357(w)(3). Whether a donation satisfies the requirements of the exception requires a case-by-case analysis and depends on the specific facts of the donation.

Comment: One commenter objected to the use of the exception to address the issue of data lock-in. The commenter contended that data lock-in may arise in response to legitimate concerns, such as the Health Insurance Portability and Accountability Act (HIPAA) privacy and security rules, liability issues, licensing requirements, and antitrust issues. Further, according to the commenter, data lock-in conditions may cause uncertainty for donors because parties may not be able to determine whether a donation satisfies the requirements of the exception until after donation.

Response: Nothing in this final rule is intended to prohibit legitimate actions taken to ensure that electronic health records items and services appropriately protect data, including measures to ensure the privacy and security of health information data. We recognize that there may be appropriate security, privacy and other business reasons

to protect data. This final rule addresses only actions that inappropriately lock in data, for example, locking in data to secure future referrals.

Comment: One commenter expressed support for preventing electronic health records data lock-in and the free exchange of data. However, the commenter did not agree that additional requirements designed to promote these goals would be effective. Instead, the commenter suggested that we adopt payment models that continue to foster care coordination activities.

Response: We appreciate the commenter's suggestion; however, changes to our payment models are outside the scope of the proposed rule. We note that, in our joint Request for Information, we and ONC solicited input on options for improving several different CMS payment models to support better the adoption of interoperable electronic health records technology (78 FR 14797). As noted earlier, the paper that addresses the public comments we received and outlines the Department's strategy for accelerating health information exchange is available at: <http://www.healthit.gov/policy-researchers-implementers/accelerating-health-information-exchange-hie>.

Comment: Two commenters suggested data lock-in could be limited by requiring electronic health records software to be open or "open source." Both commenters asserted that open source software would limit data lock-in due to the transparent nature of open source software. In addition, it would lead to greater interoperability of electronic health records systems. One commenter also suggested that we require mandatory advance disclosure of the operational and business policies and practices associated with the electronic health records technologies. One commenter suggested

that we adopt the e-DOS standard as certification criteria for electronic health records.

Response: Although we share the commenters' support for the free exchange of health information where appropriate protections for privacy and security exist, we are not adopting their recommendations because software certification criteria and standards are determined by ONC and are, therefore, outside the scope of this rulemaking.

3. Covered Technology

In the proposed rule, we noted that we received questions concerning whether certain items or services fall within the scope of the technology potentially covered under the exception at § 411.357(w). There, we stated that the answer to such questions depends on the exact items or services being donated. We referenced our discussion in the August 2006 final rule regarding our interpretation of the term “software, information technology and training services necessary and used predominantly.” We stated that we believe that the current regulatory text, when read in light of the preamble discussion, is sufficiently clear concerning the scope of covered technology. Nonetheless, because we received suggestions from stakeholders to modify § 411.357(w) to reflect explicitly this interpretation, in the proposed rule (78 FR 21313), we sought comments from the public regarding this issue. After considering the public comments with respect to this issue, we determined not to make any changes to the regulation text to address the scope of covered technology.

Comment: Several commenters stated that the regulatory text describing the scope of technology covered by the exception, when read in light of the August 2006 final rule preamble, is sufficiently clear. One of these commenters urged us not to revise

the regulation in any way that might limit the scope of covered technology, limit the ability of donors and physician recipients in the design and selection of items and services, or create barriers to achieving interoperability. Other commenters agreed that the current definition of covered technology is appropriate, with two of these commenters suggesting that we revisit the definition in the future as health information technology evolves. Still other commenters asserted that the existing regulatory language can be interpreted to include “services that enable the interoperable exchange of electronic health records data;” thus, no revisions to the regulatory text are required. In contrast, one commenter suggested that we incorporate into the regulatory text the preamble language from the August 2006 final rule where we discussed examples of items and services that would qualify for coverage under the exception. Another commenter suggested that we revise the regulatory text to include as many examples of covered “software, information technology and training services” as possible while emphasizing that the list is not exhaustive.

Response: We agree that maintaining flexibility is important, particularly as health information technology evolves. We endeavor to avoid revisions to the regulation text that could inadvertently narrow the exception, which is intended to promote the adoption of interoperable electronic health records technology. Moreover, our interpretation of what is covered by the exception has not changed. As we stated in the proposed rule (78 FR 21313), whether specific items or services fall within the scope of covered technology under the exception depends on the exact items or services that are being donated. If the “services that enable the interoperable exchange of electronic

health records data” are of the type that do not meet the requirements for covered technology (for example, because they include hardware, storage devices, or have core functionality other than electronic health records), they would not be eligible for protection under the exception at § 411.357(w).

For these reasons, we are not revising the regulation text at § 411.357(w) to identify any specific types of items or services that may be donated if the other requirements of the exception are satisfied. We are also not modifying the examples identified in the preamble discussion in the August 2006 final rule (71 FR 45151). The exception continues to protect nonmonetary remuneration in the form of software, information technology and training services necessary and used predominantly to create, maintain, transmit, or receive electronic health records.

Comment: A few commenters requested clarification regarding whether third-party fees related to the exchange of health information, such as health information exchange service charges for interconnectivity, are “covered technologies” under the exception.

Response: The exception protects only nonmonetary remuneration, in the form of software and information technology and training services, that is necessary and used predominantly to create, maintain, transmit, or receive electronic health records. Whether particular items or services, such as interconnectivity services, may be donated under the exception depends on the exact items or services being donated.

Comment: One commenter suggested that, in addition to maintaining as much flexibility as possible, we broaden the scope of the technology covered by the exception

to include software and services used for care coordination, quality measurement, improving population health, or improving the quality or efficiency of health care delivery among parties. The commenter noted that some of these items may be covered by the waivers issued in connection with the Medicare Shared Savings Program (MSSP); however, because those waivers extend only to parties participating in that program, protection for the donation of items or services that advance the Department's goal of encouraging the adoption of health information technology that supports public policy objectives is not available to other health care industry stakeholders. To advance these goals in a broader way, the commenter suggested that the exception be expanded to include items potentially covered by the MSSP pre-participation waiver, such as electronic health information exchanges that allow for electronic data exchange across multiple platforms, data reporting systems (including all-payer claims data reporting systems), and data analytics (including staff and systems, such as software tools, to perform analytic functions). Another commenter suggested that we broaden the scope of technology covered by the exception to include software separate from the certified electronic health records software as long as it is interoperable with the electronic health records software. The commenter gave as examples of such electronic health records-associated components "patient portals that support patient engagement, direct and other standards-compliant means for secure patient information exchange between providers, solutions to support transition care, and tools that may assist in inter- and intra-patient matching." A third commenter urged us to consider a broader array of covered technologies, provided that they support policy goals such as reducing hospital

readmissions and coordinated care across settings outside of traditional office settings, including telemonitoring and telemedicine. Another commenter suggested that we expand the protection of the exception to cover “any additional items or services that will be required or helpful in meeting Stage 2 or Stage 3 requirements for [the EHR Incentive Programs].”

Response: As stated previously, whether specific items or services fall within the scope of covered technology under the exception at § 411.357(w) depends on the exact items or services that are being donated. Some of the particular items and services that may be included within the broad categories identified by the commenters may be eligible for donation. For example, if a particular software product related to transitions of care was necessary and used predominantly to create, maintain, transmit, or receive electronic health records, then it would be eligible for donation, provided that the donation satisfied all of the other requirements of the exception. As noted previously in this final rule, software is not required to be certified to ONC certification criteria in order to be donated under the exception at § 411.357(w). Thus, software that is separate from certified software may still be eligible for donation if it satisfies the definition of “interoperable” at § 411.351.

To the extent that the commenters suggested that we expand the scope of the exception to protect items and services that are not already eligible for donation, we note that revision of the exception to include such items or services would be outside the scope of this rulemaking. In the proposed rule (78 FR 21313), with respect to the scope of technology potentially covered by the exception, we sought input from the public

regarding the singular issue of “whether the current regulatory text, when read in light of the preamble discussion, is sufficiently clear concerning the scope of covered technology.” With regard to whether the scope of the technology covered under the exception should be broadened—as opposed to clarified—we are mindful of the important issues raised by the commenters and may consider them in the future. Further, we note that other exceptions to the physician self-referral law exist to protect financial relationships between physicians and entities furnishing DHS. Depending on the circumstances, some of the arrangements described by the commenters may satisfy the requirements of another exception or may not implicate the physician self-referral law.

Comment: One commenter suggested that we define “equivalent technology” for purposes of the requirement in the exception that the donor of electronic health records items or services may not have actual knowledge of, or act in reckless disregard or deliberate ignorance of, the fact that the physician recipient possesses or has obtained items or services equivalent to those being donated. This commenter also suggested that we prohibit a physician from seeking or accepting a donation of electronic health records technology before a certain period of time has elapsed since the receipt of a previous donation. Another commenter urged us to eliminate maintenance and service agreements from the scope of potentially protected donations under the exception. In the alternative, the commenter suggested that we impose a restriction on the time period that donations of such services would be permitted. The commenter noted concerns that donors may use ongoing donations of maintenance and service agreements to lock in referrals from physician recipients. A commenter that urged us not to extend the availability of the

exception suggested that we prohibit the donation of all technology except interfaces for reporting of laboratory results.

Response: Although we appreciate the commenters' suggestions, we are not making the requested changes. We believe that the modifications to and clarifications of § 411.357(w) adopted in this final rule and the clarifications offered in this preamble address the concerns raised by these commenters.

Comment: One commenter asserted that the prohibition on donating equivalent items or services currently included in the exception locks physician practices into a vendor, even if they are dissatisfied with the technology, because the physician recipient must choose between paying the full amount for a new system and continuing to pay 15 percent of the cost of the substandard system. The commenter asserted that the cost differential between these two options is too high and effectively locks physician practices into electronic health records technology vendors.

Response: Although we appreciate the commenter's concern, we continue to believe that items and services are not "necessary" if the physician recipient already possesses equivalent items or services. As we stated in the August 2006 final rule (71 FR 45154), "the provision of equivalent items and services poses a heightened risk of abuse, [because] such arrangements potentially confer independent value on the physician recipient (that is, the value of the existing items and services that might be put to other uses) unrelated to the need for electronic health records technology." Therefore, we are retaining the regulatory preclusion of protection for donation arrangements where the donor has actual knowledge of, or acts in reckless disregard or deliberate ignorance

of, the fact that the physician recipient possesses or has obtained equivalent items or services. We expect that physicians would not select or continue to use a substandard system if it posed a threat to patient safety.

Comment: One commenter referenced the proposed rule's statement that "software or information technology and training services necessary and used predominantly for electronic health records purposes" included "information services related to patient care (but not separate research or marketing support services)" (78 FR 21313). The commenter requested that we retract that statement and clarify that it is appropriate for health researchers to use data in electronic health records for research that is related to, for example, evidence-based medicine, population management, or other research, provided that the use complies with applicable Federal, state, and institutional requirements.

Response: We decline to retract our statement in the proposed rule. To promote adoption of electronic health records without risk of abuse, the scope of items and services permitted to be donated under the exception is limited to electronic health records items and services in the form of software and information technology and training services that are "necessary and used predominantly to create, maintain, transmit, or receive electronic health records." Donations of software used for research that is separate from clinical support and information services related to patient care are not consistent with the primary goals of the exception.

The exception at § 411.357(w) addresses only the donation of electronic health records items and services, and not the use of data. Thus, the portion of the comment

related to data use is outside the scope of this rulemaking. We note, however, that nothing in the exception prohibits the use of data in electronic health records systems for research purposes (assuming the parties comply with all other applicable laws, including HIPAA privacy protections).

Comment: One commenter requested that CMS confirm that patient portals are within the scope of the technology potentially protected by the exception.

Response: We are not certain what the commenter precisely means by “patient portals.” Patient portals come in a variety of forms; the key to the analysis is whether the specific item or service donated is: (1) in the form of software, information technology and training services and; (2) necessary and used predominantly to create, maintain, transmit or receive electronic health records. As we stated in the August 2006 final rule in response to a commenter’s recommendation that the exception specifically protect the provision of patient portal software that enables patients to maintain on-line personal medical records, including scheduling functions (71 FR 45152), nothing in the exception precludes protection for patient portal software if it satisfies all of the requirements of the exception.

E. Comments Outside the Scope of this Rulemaking

In addition to the comments described and to which we responded previously, we received several comments from stakeholders, including suggestions on policy changes, that are outside the scope of this rulemaking. For example, one commenter raised concerns about a private insurer’s proposed fee schedule for laboratory services. Another commenter expressed concern about “outrageous bills” the commenter received from a

laboratory company. Although we appreciate the commenters taking the time to present these concerns, we do not address them here, as they are outside the scope of this rulemaking.

IV. Provisions of the Final Regulations

For the most part, this final rule incorporates the proposed revisions stated in the proposed rule. Specifically, we are revising the exception to exclude laboratory companies from the types of entities that may donate electronic health records items and services under the exception, and are modifying the regulation text at § 411.357(w)(1) to effectuate this change. We are also amending § 411.357(w)(2) by deleting the phrase “recognized by the Secretary” and by replacing it with the phrase “authorized by the National Coordinator for Health Information Technology” and replacing the 12-month timeframe for certification of electronic health records software with a requirement that the software be certified to an edition of the electronic health record certification criteria identified in the then-applicable version of 45 CFR part 170 (ONC’s certification program). We are clarifying the requirement at § 411.357(w)(3) prohibiting any action that limits or restricts the use, compatibility, or interoperability of donated items or services. In addition, we are eliminating the requirement at § 411.357(w)(11) that donated electronic health records software include electronic prescribing capability. Finally, we are modifying § 411.357(w)(13) to extend the expiration of the exception from December 31, 2013 to December 31, 2021.

V. Waiver of the Delay in the Effective Date

Ordinarily, we provide a delay of at least 30 days in the effective date of a final

rule after the date that the rule is issued. However, the 30-day delay in effective date can be waived if the rule grants or recognizes an exemption or relieves a restriction. We believe that it is appropriate to waive the 30-day delay in effective date for § 411.357(w)(13), which relieves a restriction on donations of electronic health records items and services. Specifically, this final rule amends § 411.357(w)(13) to extend the expiration of the existing exception from December 31, 2013 to December 31, 2021. Without a waiver of the requirement for a delayed effective date, the entire exception will expire on December 31, 2013 and will not be available to protect any ongoing donation arrangements or new donations of electronic health records items and services made to physicians after December 31, 2013. By waiving the 30-day delay in effective date, the exception will not expire, thereby allowing parties to continue utilizing the exception to protect donations of electronic health records items and services. We stress, however, that donations of electronic health records items and services that occur between January 1, 2014 and the effective date of the remaining provisions of this final rule (**[Insert date 90 days after the date of publication in the Federal Register]**) will need to satisfy all of the requirements of the existing exception. The waiver of the 30-day delay in effective date simply serves to maintain the status quo until the rest of this final rule becomes effective.

The 30-day delay in effective date can also be waived if the agency finds for good cause that the delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the findings and reasons in the rule issued. We find that it is unnecessary to provide a 30-day delay in effective date for

§ 411.357(w)(13) because an earlier effective date simply allows parties to continue making donations under the existing electronic health records items and services exception; it does not impose any new requirements or restrictions on potentially affected parties. Moreover, we find that a 30-day delayed effective date for § 411.357(w)(13) is impracticable because it would cause the entire exception to expire, thereby nullifying this final rule.

VI. Collection of Information Requirements

The provisions in this final rule will 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.

VII. Regulatory Impact Analysis

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 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 that this final rule does not reach the economic threshold for being considered economically significant and, thus, is not considered a major rule. It is 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 rule modifies an existing exception to the physician self-referral law, and the modifications would not impose additional substantive costs on those seeking to utilize the exception. Further, the donation of electronic health records items or services and the use of the exception to protect such donations is entirely voluntary. In section III. of this final rule, we provide a detailed discussion and analysis of the alternatives considered in this final rule, including those considered for extending the expiration date of the electronic health records exception, limiting the types of entities that may donate electronic health records items and services, and tying the timeframe for deeming electronic health records software to ONC's certification program. Finally, we received no public comments specific to the RIA set forth in the proposed rule.

This final rule extends the exception's expiration date to December 31, 2021; excludes laboratory companies from the types of entities that may donate electronic health records items and services; updates the provision under which electronic health records software is deemed interoperable; clarifies the requirement at § 411.357(w)(3) prohibiting any action that limits or restricts the use, compatibility, or interoperability of

donated items or services; and removes the requirement related to electronic prescribing capability. Neither this final rule nor the regulations it amends requires any entity to donate electronic health records items and services to physicians, but we expect these changes to continue to facilitate the adoption of electronic health records technology by eliminating perceived barriers 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 final 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 the passage of two laws encouraging adoption of electronic prescribing and electronic health records: (1) the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), Pub. L. 110-275; and (2) 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. In addition, there has been an increase over the past few years in the rate of electronic health records-based electronic prescribing capabilities.³

As discussed in more detail in the preamble to the proposed rule, section 132 of MIPPA authorized an electronic prescribing incentive program (starting in 2009) for

certain types of eligible professionals. The HITECH Act authorized us to establish the EHR Incentive Programs for certain eligible professionals, eligible hospitals, and critical access hospitals. Also, the HITECH Act required that eligible professionals under the EHR Incentive Programs demonstrate meaningful use of certified electronic health records technology, including the use of electronic prescribing. Specifically, the final rule for Stage 2 EHR Incentive Programs (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 2015, an eligible professional risks a reduction in the Medicare Physician Fee Schedule payment amount that will otherwise apply for covered professional services if he or she is not a meaningful electronic health records technology user for a 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 records items and services that advance the adoption and use of electronic health records. Lastly, according to ONC, electronic prescribing by physicians using electronic health records technology has increased from 7 percent in December 2008 to approximately 48 percent in June 2012.⁴ 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. However, due to data limitations, we are unable to estimate accurately how much the electronic health records exception has contributed to

³ See, for example, 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.

the increase in electronic prescribing. Nevertheless, we believe that, as a result of recent developments, physician adoption of electronic prescribing and electronic health records technology will continue to increase despite removal of 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 less than \$7.0 million to less than \$35.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. This final rule does not result in an economic effect on small entities of 3 to 5 percent or more of their total revenues or costs. As a result, the Secretary has determined that this final rule will 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 604 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 final rule would not have a significant economic impact on the operations of a substantial

⁴ See, for example, State Variation in E-Prescribing Trends in the United States, available at

number of small rural hospitals (that is, an effect of more than 3 to 5 percent of their total revenues or costs).

Section 202 of the Unfunded Mandates Reform Act of 1995 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 final rule imposes no mandates and, as a result, will have no consequential effect on State, local, or tribal governments, or on the private sector, of \$141 million or more.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. For the reasons stated earlier, this final rule will not have a substantial effect on State or local governments, nor does it preempt State law or have Federalism implications.

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 amends 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 as follows:

A. Revising paragraphs (w)(1) through (3).

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

C. In paragraph (w)(13), removing the date “December 31, 2013” and adding the date “December 31, 2021” in its place.

The revision reads as follows:

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

* * * * *

(w) * * *

(1) The items and services are provided to a physician by an entity (as defined at §411.351) that is not a laboratory company.

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

(3) The donor (or any person on the donor's behalf) does 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 (including, but not limited to, health information technology applications, products, or services).

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CMS-1454-F

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

Dated: September 5, 2013

Marilyn Tavenner,

Administrator,

Centers for Medicare & Medicaid Services.

Approved: December 12, 2013

Kathleen Sebelius,

Secretary,

Department of Health and Human Services.

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