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Kickbacks and Contradictions: The Anti-Kickback Statute and Electronic Health Records

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Kickbacks and Contradictions: The Anti-Kickback Statute and Electronic Health Records

ABSTRACT

The Obama Administration has made the universal adoption of electronic health records a major policy priority, passing the Health Information Technology for Economic and Clinical Health (HITECH) Act, which creates incentives for physicians and hospitals to computerize their medical records. This effort has been largely successful, as evidenced by the significant increase in medical providers who have adopted electronic health records. However, for the President to achieve his goal of computerizing all medical records in the United States, he will need to ensure that other federal laws do not conflict with the incentive structure created by the HITECH Act. The Anti-Kickback Statute has the potential to limit the effectiveness of the HITECH Act by prohibiting hospitals from donating electronic health record technology to physicians. In order to ensure that the entire federal regulatory scheme incentivizes the adoption of electronic health records, the Department of Health and Human Services should draft a broad safe harbor that allows hospitals to donate the full cost of purchasing, implementing, and maintaining electronic health record technology to physicians.

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Electronic health records are an important advancement in the medical field that, if fully implemented, have the potential to drastically reduce health care costs and improve patient outcomes.¹ Accordingly, the Obama Administration has strongly advocated for the universal adoption of electronic health records.² The administration views electronic health records as a mechanism to achieve two of its major goals: improving the nation's infrastructure and reducing the country's unsustainable level of health care spending.³

In order to achieve the goal of computerizing all medical records in the United States, the President included significant funding for electronic health records in the stimulus package, his first major legislative achievement after taking office.⁴ The funds included in the stimulus package are designed to incentivize both physicians and hospitals to rapidly transition to electronic health records.⁵

However, the complex regulatory scheme governing health care providers in the United States may inadvertently prevent physicians from computerizing their medical records.⁶ Specifically, the Anti-Kickback Statute may limit the ability of hospitals to help physicians achieve this goal by prohibiting hospitals from donating electronic health record technology to physicians.⁷

In order to prevent the Anti-Kickback Statute from impeding the adoption of electronic health records, the Department of Health

1. See David Goldman, *Obama's Big Idea: Digital Health Records*, CNN MONEY (Jan. 12, 2009, 4:05 AM), http://money.cnn.com/2009/01/12/technology/stimulus_health_care/.

2. *Id.*

3. *See id.*

4. American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, §§ 4101, 4102, 123 Stat. 115, 353-72.

5. *Id.*

6. *See United States v. Greber*, 760 F.2d 68, 69-70 (3d Cir. 1985).

7. *See* 42 C.F.R. § 1001.952(y) (2014).

and Human Services (HHS) created a regulatory safe harbor, allowing hospitals to donate electronic health record technology to physicians.⁸ However, it is unclear if this safe harbor is broad enough to overcome the obstacles created by the Anti-Kickback Statute.⁹

This Note examines how the Anti-Kickback Statute may impede the adoption of electronic health records. Part I of this Note will provide background information on the portion of the stimulus package designed to promote the adoption of electronic health records and will explain the broad scope of the Anti-Kickback Statute.¹⁰ Part II of this Note will analyze how the Anti-Kickback Statute may impede the adoption of electronic health records and whether the safe harbor established by HHS is sufficient to overcome this impediment.¹¹ Part III of this Note argues that the safe harbor for electronic health records should be expanded.¹²

I. THE ANTI-KICKBACK STATUTE AND THE HITECH ACT

The federal government is committed to incentivizing physicians and hospitals to adopt electronic health records. Computerizing the nation's health records is a major policy priority of the Obama Administration.¹³ This commitment to the universal adoption of electronic health records is evidenced by the President's stimulus package, which created significant financial incentives for physicians and hospitals to computerize their medical records.¹⁴ However, the Anti-Kickback Statute, a law designed to prevent fraud by physicians and hospitals, may unintentionally prevent medical providers from adopting electronic health records.¹⁵

A. *The HITECH Act*

Shortly before taking office, President Barack Obama announced a plan to computerize all health records in the United States by 2014.¹⁶ The President touted the ability of electronic health records to improve health care outcomes and reduce costs,

8. *Id.*

9. See Medicare and State Health Care Programs: Fraud and Abuse; Electronic Health Records Safe Harbor Under the Anti-Kickback Statute, 78 Fed. Reg. 79,202 (Dec. 27, 2013) (to be codified at 42 C.F.R. pt. 1001).

10. American Recovery and Reinvestment Act §§ 4101, 4102; *Greber*, 760 F.2d at 69.

11. See *Greber*, 760 F.2d at 72; 42 C.F.R. § 1001.952(y).

12. See 42 C.F.R. § 1001.952(y).

13. Goldman, *supra* note 1.

14. American Recovery and Reinvestment Act §§ 4101, 4102.

15. See *Greber*, 760 F.2d at 72.

16. Goldman, *supra* note 1.

stating: “This will cut waste, eliminate red tape, and reduce the need to repeat expensive medical tests. It just won’t save billions of dollars and thousands of jobs—it will save lives by reducing the deadly but preventable medical errors that pervade our health care system.”¹⁷ The United States is well on its way to meeting this goal, due largely to the significant investment in health information technology and electronic health records included in the President’s stimulus package.¹⁸

The Health Information Technology for Economic and Clinical Health (HITECH) Act, which was part of the economic stimulus package known as the American Recovery and Reinvestment Act of 2009 (ARRA), was designed to promote the adoption of health information technology (HIT) and the utilization of qualified electronic health records (EHRs).¹⁹ Sections 4101 and 4102 of ARRA created financial incentives for physicians and hospitals to adopt and use EHR technology.²⁰ Early adopters of EHR technology received bonus payments from the federal government in addition to their standard Medicare payments.²¹ However, after an adjustment period, physicians and hospitals that fail to adopt and use EHR technology will face a reduction in their level of Medicare reimbursement.²²

Beginning in 2011, the Federal Supplementary Medical Insurance Trust Fund began making bonus payments, in addition to their standard Medicare payment rates, to eligible professionals (EPs), who were determined to be meaningful EHR users.²³ These bonus payments reached their cap of \$18,000 in 2011 and have decreased in each subsequent year.²⁴ Beginning in 2015, the Medicare fee schedule will reduce for EPs who are not meaningful EHR users.²⁵ These physicians will receive only 99 percent of the rate typically paid by Medicare in 2015, 98 percent in 2016, and 97 percent in 2017 and subsequent years.²⁶

17. *Id.*

18. See HIT Policy Comm., *Medicare & Medicaid EHR Incentive Programs*, CENTERS FOR MEDICARE & MEDICAID SERVICES (Sept. 3, 2014), http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/September2014_HITPCFullDeck-.pdf.

19. 42 C.F.R. §§ 412, 413, 422, 495 (2014).

20. American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, §§ 4101, 4102, 123 Stat. 115, 353–72.

21. American Recovery and Reinvestment Act § 4101(a).

22. *Id.*

23. *Id.*

24. *Id.* § 4101(a)(o).

25. *Id.* § 4101(b)(7).

26. *Id.*

The HITECH Act creates a similar incentive structure for hospitals.²⁷ Beginning in 2011, hospitals determined to be meaningful EHR users became entitled to receive bonus payments from the Federal Hospital Insurance Trust Fund.²⁸ In some instances, bonus payments were over \$1 million in 2011, depending on the number of Medicare patients served by the hospital. These payments were reduced in each subsequent year.²⁹ In 2015, hospitals that have not achieved meaningful EHR use will have their annual Medicare payment update reduced.³⁰ Seventy-five percent of the payment increase that the hospital would normally receive will be reduced by 33.3 percent in 2015, 66 percent in 2016, and 100 percent in 2017 and subsequent years.³¹

The HITECH Act also provides full federal financing to states offering incentive payments to Medicaid providers who demonstrate meaningful EHR use.³² This creates more opportunities for physicians and hospitals to receive bonus payments and further increases the pressure to adopt EHRs.³³

To receive incentive payments, providers must demonstrate meaningful use of EHRs.³⁴ The Centers for Medicare and Medicaid Services (CMS) defined meaningful use in a 2010 final rule implementing the HITECH Act.³⁵ CMS stated that the goal of the regulation was “improving health care quality, encouraging widespread EHR adoption, promoting innovation, and avoiding imposing excessive or unnecessary burdens on health care providers”³⁶ CMS opted to use a phased approach to meaningful use, giving providers time to develop and gain experience with EHR technology.³⁷

To reach the initial stage of meaningful use and begin receiving incentive payments, providers must focus on developing functional

27. *Id.* § 4102.

28. *Id.* § 4102(a)(1).

29. *Id.*

30. *Id.*

31. *Id.*

32. *Id.* § 4201(a).

33. *Id.*

34. 42 C.F.R. § 495.6 (2014).

35. Medicare and Medicaid Programs; Electronic Health Record Incentive Program, 75 Fed. Reg. 44,313, 44,321 (July 28, 2010) (to be codified at 42 C.F.R. pts. 412, 413, 422, 495).

36. *Id.*

37. *Id.*

EHR technology.³⁸ Functionalities in EHR technology allow providers to meet the Stage 1 meaningful use criteria.³⁹

The structure of the HITECH act gives physicians and hospitals strong financial incentives to adopt EHR technology. Significant use of EHR technology is on the rise as a result of this incentive structure.⁴⁰ According to CMS, as of September 2014, more than 414,000 health care providers had received bonus payments from the EHR Incentive Program.⁴¹ This represents more than half of all medical providers eligible for bonus payments and exceeded the HHS's goal for meaningful EHR use.⁴²

This success is due to the rapid growth in EHR use since the passage of ARRA.⁴³ According to the Centers for Disease Control (CDC), only 17 percent of physicians utilized EHRs in 2008.⁴⁴ This number rose to over 50 percent in 2012.⁴⁵ Additionally, only 9 percent of hospitals utilized EHRs in 2008.⁴⁶ This number rose to over 80 percent in 2012.⁴⁷ This trend led Secretary of HHS, Kathleen Sebelius, to state that the United States had "reached a tipping point in adoption of electronic health records."⁴⁸ Despite the Secretary's confidence, legislative and financial impediments could prevent the universal adoption of EHR technology.

38. 42 C.F.R. § 495.6.

39. See Medicare and Medicaid Programs; Electronic Health Record Incentive Program, 75 Fed. Reg. at 44,321. Stage 1 meaningful use criteria includes:

[E]lectronically capturing health information in a structured format; using that information to track key clinical conditions and communicating that information for care coordination purposes (whether that information is structured or unstructured, but in structured format whenever feasible); implementing clinical decision support tools to facilitate disease and medication management; using EHRs to engage patients and families and reporting clinical quality measures and public health information.

Id.

40. See EHR Incentive Program, Summary Report *September 2014*, CMS (2014), http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/September2014_SummaryReport.pdf.

41. See *id.*

42. *Doctors and Hospitals' Use of Health IT More Than Doubles Since 2012*, U.S. DEP'T HEALTH & HUMAN SERVICES (May 22, 2013), <http://www.hhs.gov/news/press/2013pres/05/20130522a.html> (noting that HHS's goal was "for 50 percent of doctor offices and 80 percent of eligible hospitals to have EHRs by the end of 2013").

43. *Id.*

44. *Id.*

45. *Id.*

46. *Id.*

47. *Id.*

48. *Id.*

B. The Anti-Kickback Statute

Despite the rapid growth in EHR use since the passage of ARRA, the United States will still likely fail to meet the President's goal of computerizing all health records by 2014.⁴⁹ One potential impediment to universal EHR adoption is the complex regulatory structure employed by the United States to combat health care fraud and abuse.⁵⁰ One piece of this structure is the Anti-Kickback Statute, a law designed to prevent payments to doctors in exchange for referring patients to hospitals or other health care providers.⁵¹ The US Court of Appeals for the Third Circuit significantly expanded the scope of the Anti-Kickback Statute when it decided *United States v. Greber* in 1985.⁵² The court established the "One Purpose Test," holding that if one purpose of a payment was to induce future referrals, the arrangement violated the Anti-Kickback Statute.⁵³

In *Greber*, Cardio-Med, Inc., an organization that supplies medical technology and provides diagnostic services to physicians, received funding from the federal health insurance program, Medicare.⁵⁴ After Cardio-Med received payment for its services, the company forwarded a portion of the Medicare payment to the physician who had referred the patient to the company.⁵⁵ These payments were called interpretation fees.⁵⁶ The CEO of Cardio-Med stated that the company paid the physicians these interpretation fees as reimbursement for their initial consultation services and for explaining test results to patients.⁵⁷

The CEO admitted that inducing referrals to Cardio-Med was also a reason for offering interpretation fees, stating: "[I]f the doctor didn't get his consulting fee, he wouldn't be using our service. So the doctor got a consulting fee."⁵⁸ However, the CEO claimed that he believed the fee was legitimate because Cardio-Med and the referring physicians shared the responsibility of explaining test results to patients.⁵⁹

49. *Id.*

50. Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93, § 14(a), 101 Stat. 680.

51. *Id.*

52. *United States v. Greber*, 760 F.2d 68, 69 (3d Cir. 1985).

53. *Id.*

54. *Id.*

55. *Id.*

56. *Id.*

57. *Id.*

58. *Id.*

59. *Id.*

The Third Circuit began its analysis of the case by reviewing the text of the Anti-Kickback Statute, which states:

[W]hoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly in cash or in kind to induce such person—

(B) to purchase, lease, order, or arrange for or recommend purchasing . . . or ordering any . . . service or item for which payment may be made . . . under this title, shall be guilty of a felony.⁶⁰

The Third Circuit also analyzed the legislative history of the 1977 Amendment to the Anti-Kickback Statute.⁶¹ The legislative history demonstrated that Congress was focused on “the practice of giving ‘kickbacks’ to encourage the referral of work.”⁶² Based on this area of focus, the court stated that the primary purpose of the statute was to prevent the inducement of referrals.⁶³ Consequently, the court found that “[e]ven if the physician performs some service for the money received,” a violation of the Anti-Kickback Statute can still occur because “the potential for unnecessary drain on the Medicare system remains.”⁶⁴

The court also stated that Congress’s addition of the term “remuneration” to the Anti-Kickback Statute further supported this conclusion.⁶⁵ The definition of remunerates is “to pay an equivalent for service.”⁶⁶ Therefore, the court reasoned that “[b]y adding ‘remuneration’ to the statute in the 1977 Amendment, Congress sought to make it clear that, even if the transaction was not considered to be a ‘kickback’ for which no service had been rendered, payment nevertheless violated the Act.”⁶⁷

Based on this broad reading of the Anti-Kickback Statute, the Third Circuit held that the test to determine liability under the Anti-Kickback Statute is: “If the payments were intended to induce the physician to use Cardio-Med’s services, the statute was violated, even if the payments were also intended to compensate for professional services.”⁶⁸ Under this standard, a defendant is liable if they make a payment and even “one purpose” of that payment is to “induce future referrals.”⁶⁹

60. *Id.* at 71 (alterations in original).

61. *Id.*

62. *Id.*

63. *Id.*

64. *Id.*

65. *Id.*

66. *Id.*

67. *Id.* at 72.

68. *Id.*

69. *Id.* at 69.

Courts throughout the country have followed the One Purpose Test articulated in *Greber*.⁷⁰ The Tenth Circuit noted this trend, stating: “The only three Circuits to have decided this issue have all adopted the ‘one purpose’ test.”⁷¹ The court noted that its decision to deny a challenge to the One Purpose Test was based on “review of, and agreement with, the ‘sound reasoning’ of the Third Circuit in *Greber*.”⁷²

In 1987, Congress amended the Anti-Kickback Statute, directing HHS to develop regulatory safe harbors to immunize certain socially beneficial business practices.⁷³ Business practices covered by safe harbors are shielded from liability under the Anti-Kickback Statute, despite potentially involving remuneration with some intent to induce referrals.⁷⁴ Congress intended the amendment to provide security to businesses by ensuring that their agreements do not make them liable under the Anti-Kickback Statute.⁷⁵

The 1987 Amendment preserved the One Purpose Test.⁷⁶ While socially beneficial conduct that falls within a statutory or legislative “safe harbor” is immune from liability under the Anti-Kickback Statute, courts still evaluate transactions that do not meet the requirements of a specific safe harbor under the broad standard laid out in *Greber*.⁷⁷ The First Circuit held that *Greber* was still good law after the passage of the 1987 Amendment, stating “[t]he fact that Congress, in reenacting the substantive sections of the Medicare Fraud statute did not change them, implies that Congress approved prior interpretations such as *Greber*.”⁷⁸

II. THE ANTI-KICKBACK STATUTE CREATES A BARRIER TO ACHIEVING THE GOALS OF THE HITECH ACT

The broad scope of the One Purpose Test has the potential to create liability under the Anti-Kickback Statute for hospitals that provide EHR technology or services to physicians.⁷⁹ Anticipating this

70. *E.g.*, United States v. LaHue, 261 F.3d 993, 1003 (10th Cir. 2001).

71. *Id.* (quoting United States v. McClatchey, 217 F.3d 823, 835 (10th Cir. 2000)).

72. *Id.*

73. *See id.*

74. *See id.*

75. *See id.*

76. *See id.*

77. *See id.*

78. United States v. Bay State Ambulance & Hosp. Rental Serv., Inc., 874 F.2d 20, 31 (1st Cir. 1989).

79. *See* United States v. Greber, 760 F.2d 68, 69 (1985).

issue, HHS created a safe harbor for EHRs.⁸⁰ However, it is unclear whether this safe harbor is enough to overcome the obstacles created by the Anti-Kickback Statute.⁸¹

A. The One Purpose Test has the Potential to Implicate the Adoption of Electronic Health Records

The broad scope of the Anti-Kickback Statute, as interpreted in *Greber*, may be a barrier to the HITECH Act's goal of universal EHR adoption.⁸²

The purpose of the Anti-Kickback Statute is "to prevent drains on the public fisc."⁸³ However, "the statute does not require that there be a drain on the public fisc in order for payments to be illegal."⁸⁴ Therefore, parties can be liable under the Anti-Kickback Statute even if they pay fair market value for services that were actually performed and would not cause the federal government to pay any additional money in Medicare fees.⁸⁵ This extends the reach of the Anti-Kickback Statute beyond its primary purpose of preventing drains on the public fisc and potentially creates liability for actions that pose no risk of financial harm to the government.⁸⁶

Parties can also be liable under the Anti-Kickback Statute even if their actions cause no tangible harm to patients.⁸⁷ If one purpose of a hospital payment is to induce referrals, liability can exist under the One Purpose Test even if there was no effect on the quality or cost of the services provided.⁸⁸ Therefore, the Anti-Kickback Statute, as interpreted in *Greber*, is significantly broader than under traditional fraud statutes that require the government to show that actual harm occurred.⁸⁹

Hospital physician recruitment agreements provide an example of a relationship that has the potential to violate the Anti-Kickback Statute, despite not creating a drain on the public fisc or causing

80. 42 C.F.R. § 1001 (2014).

81. *Id.*

82. *Greber*, 760 F.2d at 69.

83. *Bay State Ambulance*, 874 F.2d at 32. Merriam-Webster defines fisc as "a state or royal treasury." Definition *Fisc*, MERRIAM WEBSTER (2014), available at <http://www.merriam-webster.com/dictionary/fisc>.

84. *Bay State Ambulance*, 874 F.2d at 32 n.21.

85. *See id.* at 31.

86. *See id.* at 32 n.21.

87. *See United States v. Jain*, 93 F.3d 436, 442–43 (8th Cir. 1996).

88. *See id.*

89. *See id.*

tangible harm to patients.⁹⁰ If a hospital offers a physician any remuneration to join its staff, intending that the doctor will refer Medicare patients to the hospital, it risks violating the One Purpose Test.⁹¹ The District Court for the Eastern District of Texas held that a hospital had violated the Anti-Kickback Statute by offering a physician remuneration in the form of an interest-free loan, free office space, and reimbursement for the expense of relocation and obtaining malpractice insurance to induce the physician to move his practice to the hospital.⁹²

Recruitment agreements, many of which offer guarantees of income or payment of relocation expenses, are a standard tool used by businesses to recruit top professionals. This practice does not fall into the conventional definition of fraud and is not prosecutable under the mail fraud statute or any other traditional fraud statute.⁹³ However, due to the scope of the One Purpose Test, payments for recruitment of health care professionals can be found fraudulent under the Anti-Kickback Statute.⁹⁴

Additionally, courts have invalidated physician recruitment agreements, despite the fact that they have the potential to benefit the community by increasing the quality of medical care available to residents.⁹⁵ Many hospitals in rural areas have a difficult time attracting physicians and rely on recruitment incentives to ensure that they can provide adequate medical care to their patients. The Texas district court acknowledged this phenomenon, stating “the hospital may well have been motivated to a greater or lesser degree by a legitimate desire to make better medical services available in the community.”⁹⁶ However, the court invalidated the contract because one purpose of the agreement was to induce referrals to the hospital, demonstrating that socially beneficial agreements can violate the Anti-Kickback Statute.⁹⁷

The broad interpretation of the Anti-Kickback Statute advanced by courts could frustrate the purpose of the HITECH Act to incentivize physicians to computerize their medical records. For example, hospitals can use EHR technology as another tool to recruit

90. See *Polk Cnty., Tex. v. Peters*, 800 F. Supp. 1451, 1456 (E.D. Tex. 1992) (internal citations omitted).

91. See *id.*

92. *Id.* at 1455–56.

93. See *Jain*, 93 F.3d at 441–42.

94. See *Peters*, 800 F. Supp. at 1456.

95. See *id.*

96. *Id.*

97. See *id.*

physicians.⁹⁸ Hospitals can offer to provide EHR technology to physicians or compensate physicians for the cost of adopting EHRs in return for the physician agreeing to move his or her practice to the hospital.⁹⁹ Compensating physicians for the cost of adopting EHR technology could be considered analogous to reimbursing physicians for moving expenses, which has previously been found to violate the Anti-Kickback Statute.¹⁰⁰

Given the financial pressure put on physicians by the HITECH Act, many independent practitioners not currently affiliated with hospitals will have a strong incentive to move their practices.¹⁰¹ These unaffiliated physicians may lack the capital necessary to pay the upfront costs of computerizing their medical records and likely would incorporate their practices with that of a local hospital in return for the hospital providing the physicians with EHR technology.¹⁰² Additionally, if hospitals do not provide their current staff physicians with EHR technology, those physicians will have a strong incentive to move their practices to other hospitals that will compensate them for adopting EHRs.¹⁰³

Despite the fact that the federal government identified the adoption of EHRs as socially beneficial, providing EHR technology to physicians creates a potential violation of the Anti-Kickback Statute.¹⁰⁴ When hospitals recruit physicians, there is an expectation that the physicians will refer their existing patients to the hospital.¹⁰⁵ If the hospital provides remuneration to the recruited physician, it can be held liable under the Anti-Kickback Statute.¹⁰⁶ The statute states that remuneration can "be in cash or in kind."¹⁰⁷ This definition of remuneration would include providing EHR technology to physicians even if the hospital's recruitment agreement did not require it to pay any money to the physicians it recruited.¹⁰⁸ Therefore, hospitals require legal protection in order to provide EHR technology to physicians without violating the Anti-Kickback Statute.¹⁰⁹

98. See 42 C.F.R. § 1001 (2014).

99. See *id.*

100. See *Peters*, 800 F. Supp. at 1455–56.

101. 42 C.F.R. § 1001.

102. *Id.*

103. *Id.*

104. See *Peters*, 800 F. Supp. at 1456.

105. See *id.*

106. See *id.*

107. Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93 § 14(a), 101 Stat. 680.

108. See *id.*

109. See *id.*

B. The Government has Taken Steps to Limit Liability for Socially Beneficial Agreements Including Electronic Health Records

Recognizing the need to protect hospitals when they provide EHR technology to physicians, HHS created a safe harbor regulation for EHRs. However, it is unclear whether the safe harbor is broad enough to immunize the socially beneficial practice of adopting EHR technology.

Regulatory safe harbors are drawn narrowly.¹¹⁰ If an agreement does not meet the exact requirements of a safe harbor regulation, it is not immunized from liability under the Anti-Kickback Statute.¹¹¹ HHS clarified that an agreement is subject to the One Purpose Test if it does not fit precisely into a safe harbor, even if it is in substantial compliance with the requirements of the regulation.¹¹²

Additionally, safe harbor regulations fail to immunize all agreements that create no risk of tangible harm to patients or risk of drain on the public fisc.¹¹³ HHS rejected a proposed safe harbor for “business arrangements that technically may violate the statute, but do not increase costs to the Medicare or Medicaid programs, or otherwise injure beneficiaries.”¹¹⁴ This demonstrates that even after the promulgation of safe harbor regulations, the scope of the Anti-Kickback Statute is still far broader than that of traditional fraud statutes.¹¹⁵

Many arrangements will not fit into the narrow requirements of a specific safe harbor, forcing the parties to rely on HHS’s prosecutorial discretion.¹¹⁶ It is common for agreements in the health care field to technically violate the Anti-Kickback Statute, but HHS has no motivation to challenge these agreements if they create no risk of tangible harm to patients or drain on the public fisc.¹¹⁷ However, because the arrangements are not immunized from liability, the parties cannot be certain that they will not be subject to felony charges.¹¹⁸

110. See Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952, 35,954 (July 29, 1991) (to be codified at 42 C.F.R. pt. 1001).

111. See *id.*

112. See *id.*

113. See *id.* at 35,954–55.

114. *Id.*

115. See *id.*

116. *Id.*

117. *Id.*

118. *Id.*

The parties' uncertainty is furthered by the False Claims Act, which allows a private party to bring a lawsuit alleging a violation of the Anti-Kickback Statute on behalf of the United States.¹¹⁹ Private parties, such as former hospital employees, often have access to the information necessary to demonstrate technical violations of the Anti-Kickback Statute.¹²⁰ These private parties can bring suit, even if HHS would have exercised prosecutorial discretion and chosen not to pursue the case because the agreement in question created no risk of harm to either patients or the federal government.¹²¹

In an effort to prevent the Anti-Kickback Statute from interfering with the incentive structure created by the HITECH ACT, HHS promulgated regulations creating an "Electronic Health Records Safe Harbor Under the Anti-Kickback Statute."¹²² HHS published the final rule establishing the safe harbor in December 2013.¹²³ The EHR safe harbor allows hospitals to donate up to 85 percent of the cost of purchasing, implementing, and maintaining EHR technology to physicians.¹²⁴ This safe harbor will allow hospitals to use EHR technology as a recruitment tool without violating the Anti-Kickback Statute.¹²⁵ The safe harbor will also help to achieve the goals set forth in the HITECH Act by allowing hospitals to donate costly EHR technology to physicians who otherwise may not have had the capital necessary to transition to EHRs.¹²⁶

The safe harbor had an initial sunset date of December 31, 2013.¹²⁷ However, when HHS released the final rule, it extended the safe harbor through 2021.¹²⁸ The extension of the safe harbor demonstrates that, while EHR technology use is expanding, the medical community still needs additional time to achieve the President's goal of computerizing all health records.¹²⁹

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119. See 31 U.S.C. § 3729 (2012).
120. See 56 Fed. Reg. at 35,954–55.
121. *Id.*
122. 42 C.F.R. § 1001 (2014).
123. *Id.*
124. *Id.*
125. *See id.*
126. *Id.*
127. *Id.*
128. *See id.*
129. *Id.*

C. The Safe Harbor for Electronic Health Records May Not Be Broad Enough to Overcome the Barriers Created by the Anti-Kickback Statute

While the safe harbor will allow hospitals to significantly defray the cost of adopting EHR technology, it will still leave physicians responsible for funding at least 15 percent of the cost of transitioning to EHRs.¹³⁰ While this represents only a small portion of the total cost of purchasing EHR technology, it may still prove to be too steep a price for independent practitioners who do not have the resources of a hospital or a large group practice.¹³¹

A recent study in the journal *Health Affairs* determined that the average cost of implementing an EHR system was \$162,000 for a five-physician primary care practice in Texas.¹³² The study also estimated that the practice would pay an additional \$85,000 in system maintenance costs over the first year of implementation.¹³³ Moving beyond the pure financial cost of implementing an EHR system, the study estimated that each physician and their staff would need to spend 134 hours preparing to use the EHR system in clinical encounters.¹³⁴

Based on the total cost of implementing an EHR system, *Health Affairs* estimated that the process would cost each physician in the group approximately \$32,000.¹³⁵ The journal noted that this estimate was consistent with studies from Massachusetts and New York which placed the per physician cost of adopting an EHR system in the \$34,000–39,000 range.¹³⁶

However, some studies project that the cost of implementing an EHR system will be significantly higher than the estimate provided by *Health Affairs*.¹³⁷ A study by CDW Healthcare estimated the total cost of implementing an EHR system would be \$120,000 per physician. The study also projected annual recurring costs of \$30,000

130. *Id.*

131. See Catherine M. DesRoches et al., *Electronic Health Records in Ambulatory Care—A National Survey of Physicians*, 359 *NEW ENG. J. MED.* 50, 54, 56 (2008), available at <http://www.nejm.org/doi/full/10.1056/NEJMsa0802005>.

132. Neil S. Fleming et al., *The Financial and Nonfinancial Costs of Implementing Electronic Health Records in Primary Care Practices*, 30 *HEALTH AFF.* 481, 481 (2011), available at <http://content.healthaffairs.org/content/30/3/481.full>.

133. *Id.*

134. *Id.*

135. *Id.* at 485.

136. *Id.*

137. *Physician Practice EHR Price Tag*, *CDW HEALTHCARE* 5 (Dec. 13, 2010), <http://webojects.cdw.com/webojects/media/pdf/Newsroom/CDW-Healthcare-Physician-Practice-EHR-Price-Tag.pdf>.

per physician.¹³⁸ High price estimates from health information technology companies, such as CDW, could help explain why many physicians have not yet adopted EHR technology.¹³⁹ If independent physicians with limited capital believe that they will not be able to afford EHR systems without assistance, they may choose to accept the Medicare fee reduction imposed on physicians who do not demonstrate meaningful use of EHRs.¹⁴⁰

Whether the safe harbor is broad enough to protect the adoption of EHRs will depend on which cost estimates proves to be correct. If lower cost estimates put forth by *Health Affairs* prove to be accurate, the 85 percent cap will likely not be a significant barrier to EHR adoption.¹⁴¹ However, if the higher cost estimates put forth by CDW Healthcare prove to be accurate, physicians could have difficulty affording 15 percent of the cost of adopting EHR technology.¹⁴²

A national survey conducted by the *New England Journal of Medicine* confirmed that costs were a significant reason why many physicians have not yet adopted EHR technology.¹⁴³ “Capital costs” and “uncertainty about their return on investment” were two of the reasons most commonly cited as barriers to adoption by physicians who did not have access to an EHR system.¹⁴⁴ This survey demonstrates that, regardless of which cost estimate for the adoption of EHR technology ultimately proves to be correct, physicians are clearly concerned with the potential cost of purchasing and maintaining EHR technology.¹⁴⁵

The Anti-Kickback Statute will also likely prevent hospitals from loaning money to physicians in order to cover the portion of the EHR technology that the physician is responsible for.¹⁴⁶ Courts have held that a loan to a physician represents remuneration intended to induce referrals, invalidating hospital recruitment agreements.¹⁴⁷ Therefore, recruitment agreements that offer physicians loans to fund the balance of their EHR implementation costs would likely also be invalidated by the courts.¹⁴⁸

138. *Id.*

139. *See id.* at 4.

140. *See id.*

141. *See* Fleming et al., *supra* note 132, at 485.

142. *See Physician Practice EHR Price Tag, supra* note 137, at 5.

143. DesRoches et al., *supra* note 131, at 54.

144. *Id.*

145. *See id.*

146. *See* Polk Cnty., Tex. v. Peters, 800 F. Supp. 1451, 1456 (E.D. Tex. 1992).

147. *Id.* at 1455–56.

148. *See id.*

Additionally, hospitals will likely be concerned that providing any additional help to physicians will represent a violation of the Anti-Kickback Statute.¹⁴⁹ A hospital can only receive the protection of the EHR safe harbor if its agreements with physicians meet the narrow requirements of the safe harbor.¹⁵⁰ If hospitals attempt to aid physicians beyond donating up to 85 percent of the cost of purchasing, implementing, and maintaining EHR technology, they will put themselves at risk for felony charges and significant monetary damages.¹⁵¹

The 85 percent donation cap may have the effect of limiting the number of the physicians that are financially able to adopt EHRs.¹⁵² This would represent a failure of the safe harbor regulations to immunize socially beneficial behavior.¹⁵³ EHR use is intended to improve patient care by eliminating preventable medical errors.¹⁵⁴ However, if a significant portion of physicians cannot afford to computerize their medical records, unnecessary medical errors will continue to occur.¹⁵⁵

Additionally, if the donation cap prevents physicians from adopting EHRs, it will frustrate the purpose of the Anti-Kickback Statute, which is designed “to prevent drains on the public fisc.”¹⁵⁶ Greater use of EHRs will make medical care more efficient, saving money for federal health care programs such as Medicare and Medicaid.¹⁵⁷ The donation cap could have the unintended consequence of limiting the financial savings available to the federal government through the HITECH Act.¹⁵⁸

III. A BROADER SAFE HARBOR WILL BETTER SERVE THE PURPOSES OF THE HITECH ACT AND THE ANTI-KICKBACK STATUTE

In order to ensure the HITECH Act is successful and that the President’s goal of computerizing all health records in the United

149. See Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952, 35,954 (July 29, 1991) (to be codified at 42 C.F.R. pt. 1001).

150. See 42 C.F.R. § 1001.952(x) (2014).

151. See *id.*

152. See DesRoches et al., *supra* note 131, at 54.

153. See Goldman, *supra* note 1.

154. See *id.*

155. See *id.*

156. See *United States v. Bay State Ambulance & Hosp. Rental Serv., Inc.*, 874 F.2d 20, 32 (1st Cir. 1989).

157. See Goldman, *supra* note 1.

158. See *id.*

States is met, HHS should broaden the EHR safe harbor.¹⁵⁹ The HHS should promulgate new regulations that remove the 85 percent donation cap and allow hospitals to donate the full cost of purchasing, implementing, and maintaining EHR technology to physicians.¹⁶⁰ This broader safe harbor regulation will remove the financial impediments currently preventing some physicians from adopting EHRs and encourage hospitals to take on a larger role in the process of computerizing medical records in their communities.¹⁶¹

A. A Broader Safe Harbor Will Reduce Impediments to the Adoption of Electronic Health Records

HHS can eliminate physicians' concerns about the cost of adopting EHR technology by allowing hospitals to donate the total cost of purchasing, maintaining, and implementing EHR technology to physicians.¹⁶² Hospitals can clearly afford EHR technology, as demonstrated by the fact that over 80 percent of hospitals in the United States have already adopted EHR technology.¹⁶³

Hospitals will likely take advantage of the opportunity to donate EHR technology to physicians if they are legally allowed to do so.¹⁶⁴ A hospital often offers physicians compensation in return for moving their practices to the hospital.¹⁶⁵ As physicians find themselves under financial pressure to computerize their health records, the ability to donate EHR technology to physicians will likely become an important recruiting tool for hospitals.¹⁶⁶

Additionally, a hospital is likely to see a financial benefit if the physicians it works with have adopted EHR technology that is interoperable with that of the hospital.¹⁶⁷ The use of EHR technology will increase the efficiency of hospitals by eliminating the need to repeat costly tests and procedures.¹⁶⁸ Eliminating these unnecessary

159. See 42 C.F.R. § 1001.952(x) (2014).

160. See *id.*

161. See DesRoches et al., *supra* note 131, at 54.

162. See *id.*

163. See *Doctors and Hospitals' Use of Health IT More Than Doubles Since 2012*, *supra* note 42.

164. See *Polk Cnty., Tex. v. Peters*, 800 F. Supp. 1451, 1456 (E.D. Tex. 1992).

165. See *id.*

166. See American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, § 4101, 123 Stat. 115, 353-72.

167. See Goldman, *supra* note 1.

168. See *id.*

services will help hospitals to meet the cost saving requirements included in the Affordable Care Act.¹⁶⁹

However, while hospitals have strong financial incentives to donate EHR technology to physicians, they will be unlikely to do so if they are concerned about exposure to liability under the Anti-Kickback Statute.¹⁷⁰ Hospitals risk felony charges if their actions violate the Anti-Kickback Statute.¹⁷¹ Even if HHS chooses not to pursue a claim, hospitals are still liable to suits brought by private individuals, such as disgruntled former employees, under the False Claims Act.¹⁷² Given this high danger of felony liability, hospitals are likely to be extremely careful to avoid liability under the Anti-Kickback Statute.¹⁷³ This caution may prevent hospitals from donating EHR technology to physicians because they are concerned that they will not meet the strict requirements of the safe harbor regulation.¹⁷⁴

HHS could make it significantly easier for hospitals to comply with the EHR safe harbor by eliminating the 85 percent donation cap.¹⁷⁵ If HHS made it clear that virtually all donations fit into the EHR safe harbor, hospitals could legally donate the full cost of purchasing, maintaining, and implementing EHR technology to physicians.¹⁷⁶ This would reduce the concern over liability under the Anti-Kickback Statute and encourage a greater number of hospitals to donate EHR technology to physicians in their communities.¹⁷⁷

Additionally, the current safe harbor regulation likely does not allow hospitals to donate the entire cost of purchasing EHR technology to physicians.¹⁷⁸ Courts have held that loans to physicians represent a violation of the Anti-Kickback Statute.¹⁷⁹ Therefore, a loan to a physician to cover the full cost of EHR adoption likely creates liability under the Anti-Kickback Statute.¹⁸⁰

169. See Patient Protection and Affordable Care Act, Pub. L. No. 111-148, §3022, 124 Stat. 119, 395 (2010).

170. See *United States v. Greber*, 760 F.2d 68, 69 (3d Cir. 1985).

171. See *id.*

172. See Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952, 35,954 (July 29, 1991) (to be codified at 42 C.F.R. pt. 1001).

173. See *Greber*, 760 F.2d at 69.

174. See Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. at 35,954.

175. See 42 C.F.R. § 1001.952(x) (2014).

176. See *id.*

177. See *id.*

178. See *Peters*, 800 F. Supp. at 1456.

179. See *id.*

180. See *id.*

Eliminating the 85 percent donation cap would allow hospitals to loan physicians money to cover the cost of adopting EHRs.¹⁸¹ Therefore, even if hospitals did not want to cover the entire cost of a physician's transfer to EHR technology, the hospital could still provide the initial capital investment.¹⁸² This would help ease the concern over capital costs identified in the *New England Journal of Medicine* survey.¹⁸³

Some opponents of a broader safe harbor may argue that physicians do not actually need a hospital to reimburse 100 percent of their expenses in order to adopt EHR technology. HHS echoed this view when explaining the rationale behind the 85 percent donation cap, stating that requiring physicians to contribute 15 percent of the cost of EHR adoption would not pose a significant financial burden.¹⁸⁴ If the *Health Affairs'* cost estimates are correct, computerizing their medical records should not be unduly burdensome for physicians, especially if hospitals can still cover 85 percent of their costs as currently allowed under the safe harbor.¹⁸⁵ However, the *New England Journal of Medicine* survey indicates that whatever the actual cost of adopting EHR technology, doctors have resisted computerizing their medical records because they are concerned about capital costs and return on investment.¹⁸⁶ Allowing hospitals to completely cover the cost of EHR technology would remove this concern and eliminate a major barrier to universal EHR adoption.

In explaining the rationale behind the 85 percent donation cap, HHS also pointed out the importance of physicians having a financial stake in the adoption of EHR technology.¹⁸⁷ The agency reasoned that if physicians were required to pay for a portion of their EHR technology, they would have greater incentives to select technology that was appropriate for their practice and would be more likely to actually utilize the technology.¹⁸⁸ Physician selection and utilization of the appropriate EHR technology is necessary to achieve the HITECH Act's goals of reducing the cost and improving the quality of

181. *See id.*

182. *See id.*

183. *See* DesRoches et al., *supra* note 131, at 59.

184. Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbors for Certain Electronic Prescribing and Electronic Health Records Arrangements Under the Anti-Kickback Statute, 71 Fed. Reg. 45,110, 45,132 (Aug. 8, 2006) (to be codified at 42 C.F.R. pt. 1001).

185. *See* Fleming et al., *supra* note 132, at 485.

186. *See* DesRoches et al., *supra* note 131, at 59.

187. Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbors for Certain Electronic Prescribing and Electronic Health Records Arrangements Under the Anti-Kickback Statute, 71 Fed. Reg. at 45,132.

188. *Id.*

medical care. However, no progress will be made toward the goals of the HITECH Act if physicians cannot afford to adopt EHR technology. Therefore, while HHS has raised important concerns about physicians having a financial stake in EHR adoption, those concerns are outweighed by the cost constraints that have prevented many physicians from computerizing their medical records.

B. A Broader Safe Harbor Will Further the Purpose of the Anti-Kickback Statute More Effectively

New regulations that remove the 85 percent donation cap and allow hospitals to donate to physicians the full cost of purchasing, implementing, and maintaining EHR technology would further the purpose of the Anti-Kickback Statute more effectively than the current safe harbor regulations.¹⁸⁹ The Anti-Kickback Statute is designed to save the federal government money and to prevent unnecessary federal expenditures.¹⁹⁰ EHR technology serves this goal by reducing the number of expensive tests and procedures performed by physicians and hospitals.¹⁹¹ The more efficient delivery of medical care will save the federal government money because Medicare and Medicaid will no longer be required to pay for unnecessary services.¹⁹² Therefore, widespread EHR adoption will reduce federal health care spending.¹⁹³ When the President announced the goal of computerizing all medical records in the United States, he touted these efficiency savings, noting that EHR technology can reduce waste by eliminating the need to repeat expensive medical tests and procedures.¹⁹⁴ Removing the 85 percent donation cap would cause more physicians to adopt EHR technology, leading to additional savings for the federal government.¹⁹⁵

Broader EHR safe harbor regulations would also further the purpose of the 1987 Amendment to the Anti-Kickback Statute.¹⁹⁶ This amendment, which gave HHS the authority to create regulatory safe harbors, was designed to immunize socially beneficial behavior from

189. See *United States v. Bay State Ambulance & Hosp. Rental Serv., Inc.*, 874 F.2d 20, 31 (1st Cir. 1989).

190. See *id.* at 32.

191. See Goldman, *supra* note 1.

192. See *id.*

193. See *Bay State Ambulance*, 874 F.2d at 31.

194. See Goldman, *supra* note 1.

195. See 42 C.F.R. § 1001 (2014).

196. See Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93, § 14(a), 101 Stat. 680.

liability under the Anti-Kickback Statute.¹⁹⁷ EHR technology has the ability to significantly reduce preventable medical errors, improving patient outcomes.¹⁹⁸ The President touted the socially beneficial nature of EHR technology, noting its ability to save lives by preventing unnecessary medical errors.¹⁹⁹ Saving lives by preventing medical errors is clearly socially beneficial behavior of the type that is supposed to be protected by safe harbors.²⁰⁰ However, if the 85 percent donation cap prevents some physicians from computerizing their medical records, the safe harbor will fail to stop preventable deaths from occurring.²⁰¹ A broader regulation, which allows hospitals to donate the full cost of EHR technology to physicians, would ensure that the safe harbor functioned as effectively as possible, and that the Anti-Kickback Statute did not impede progress toward improving the quality of medical care in the United States.²⁰²

Some opponents of a broader safe harbor may argue that allowing hospitals to pay for the entire cost of EHR technology serves as a kickback to physicians and encourages fraud. However, the current safe harbor already allows hospitals to pay up to 85 percent of a physician's EHR technology under the current safe harbor.²⁰³ While raising this cap to 100 percent may allow more physicians to adopt EHR technology, it is unlikely that this increase would significantly change their referral practices. Additionally, since EHR technology stands to significantly reduce costs for the federal government and improve patient care, it would not frustrate the purpose of the Anti-Kickback Statute if physicians using EHR technology referred patients to affiliated hospitals that also utilize EHR technology.²⁰⁴

In explaining the rationale behind the 85 percent donation cap, HHS also noted that requiring physicians to have a financial stake in EHR adoption prevents them from receiving a windfall if they gain financial benefits from computerizing their medical records.²⁰⁵ Physicians may gain financial benefits from adopting EHR technology, including reduced expenses and incentive payments under the

197. *See id.*

198. *See* Goldman, *supra* note 1.

199. *See id.*

200. *See* Medicare and Medicaid Patient and Program Protection Act § 14(a).

201. *See* 42 C.F.R. § 1001 (2014).

202. *See id.*

203. *Id.*

204. *See* Goldman, *supra* note 1.

205. Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbors for Certain Electronic Prescribing and Electronic Health Records Arrangements Under the Anti-Kickback Statute, 71 Fed. Reg. 45,110, 45,132 (Aug. 8, 2006) (to be codified at 42 C.F.R. pt. 1001).

HITECH Act.²⁰⁶ If physicians are not required to pay any of the cost of adopting EHR technology, these benefits could be viewed as a kickback.²⁰⁷ However, physicians will only receive these financial benefits after they have computerized their medical records. Therefore, while it may make sense to require physicians to reimburse hospitals if they receive a windfall benefit after adopting EHR technology, it does not make sense for HHS to leave the 85 percent donation cap in place if it prevents physicians from making the initial decision to adopt EHR technology.

While the United States has made great progress toward the goal of computerizing all health records, universal adoption of EHR technology will require further, significant gains.²⁰⁸ These gains will need to come largely from physicians, almost half of whom have yet to purchase EHR technology.²⁰⁹ The federal government created strong incentives through the HITECH Act to encourage these physicians to adopt EHR technology.²¹⁰ However, the federal government may also have inadvertently created a barrier to the adoption of EHR technology by allowing hospitals to donate only 85 percent of the cost of purchasing, implementing, and maintaining EHR technology to physicians.²¹¹ If the government is to succeed in the monumental goal of computerizing the entire nation's health records, the entire federal government must encourage hospitals and physicians to adopt EHR technology.²¹² For this reason, HHS should broaden the EHR safe harbor regulations, removing the 85 percent donation cap and allowing hospitals to donate the full cost of purchasing, implementing, and maintaining EHR technology to physicians.²¹³

IV. CONCLUSION

The Obama Administration chose to make universal adoption of EHR technology a major policy priority.²¹⁴ The administration dedicated significant resources to this goal, allocating a portion of its stimulus package to create incentives for physicians and hospitals to

206. *Id.*

207. *See id.*

208. *See Doctors and Hospitals' Use of Health IT More Than Doubles Since 2012, supra* note 42.

209. *See id.*

210. *See American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, § 4101, 123 Stat. 115, 353-72.*

211. *See 42 C.F.R. § 1001 (2014).*

212. *See American Recovery and Reinvestment Act § 4101.*

213. *See 42 C.F.R. § 1001.*

214. *See Goldman, supra* note 1.

computerize their medical records.²¹⁵ This effort has been largely successful, as evidenced by the significant increase in medical providers who have adopted EHR technology since the passage of the HITECH Act.²¹⁶

However, for the President to achieve his goal of computerizing all medical records in the United States, he will need to ensure that other federal laws do not conflict with the incentive structure created by the HITECH Act.²¹⁷ The Anti-Kickback Statute has the potential to limit the effectiveness of the HITECH Act by prohibiting hospitals from donating EHR technology to physicians.²¹⁸ While HHS has created a safe harbor to address this issue, it is unclear whether the safe harbor is broad enough to overcome the impediments created by the Anti-Kickback Statute.²¹⁹ In order to ensure that the entire federal regulatory scheme incentivizes the adoption of EHR technology, HHS should broaden the safe harbor, allowing hospitals to donate the full cost of purchasing, implementing, and maintaining EHR technology to physicians.²²⁰

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215. See American Recovery and Reinvestment Act § 4101.

216. See *Doctors and Hospitals' Use of Health IT More Than Doubles Since 2012*, *supra* note 42.

217. See *United States v. Greber*, 760 F.2d 68, 69 (3d Cir. 1985).

218. See *id.*

219. See 42 C.F.R. § 1001 (2014).

220. See *id.*

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