



*HIMSS Fact Sheet:*

**Physician Self Referral Regulation Exemptions  
(Stark Exemptions)  
and Anti-kickback Safe Harbors for EHRs:  
Legislation in the 111<sup>th</sup> Congress**

*July 2010*

**Introduction**

In 2006 the Department of Health and Human Services (HHS)—in response to the Administration’s goal that all Americans have an electronic health record (EHR) by 2014—published final rules protecting eligible entities that provide EHR items and services to eligible recipients. These rules are often referred to as the Stark exemptions and anti-kickback safe harbors for EHRs (EHR Donation Rules). The EHR Donation Rules allow nonmonetary remuneration (includes items and services in the form of software or training services) necessary and used predominately to create, maintain, transmit or receive EHRs.

The “EHR Donation Rules” expire in 2013. If the rules are not made permanent, providers will face new challenges in financing EHRs in order to achieve meaningful use of certified EHR technology and engage in wide-scale electronic exchange of health information. This Fact Sheet explores the legislative landscape regulating these issues in the 111<sup>th</sup> Congress.

**Current Law**

Enacted in 1972, the anti-kickback statute makes it illegal for providers to knowingly and willfully accept remuneration or bribes in order to generate revenue from federal health programs (i.e. Medicare and Medicaid). The statute has been revised to allow for more than 20 “safe harbors,” which immunize certain payment and business practices that are implicated by the anti-kickback statute. The Stark law is a civil statute enacted in 1989; it outlaws physician referrals of a patient within a federal health program to an entity (laboratories, testing centers, etc.) in which the physician has a vested interest, such as ownership or a compensation arrangement.

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## **H.R. 3970: Medical Rights and Reform Act of 2009**

### Overview

H.R. 3970, the Medical Rights and Reform Act of 2009--to protect the doctor-patient relationship, improve the quality of health care services, lower the costs of health care services, expand access to health care services, and for other purposes—was introduced by U.S. Representative Mark Kirk (R-IL) and is co-sponsored by 12 other Representatives. The health IT provision in this bill expands the Stark and anti-kickback exceptions for EHR arrangements.

### Status

This legislation has been referred to the House Education and Labor Committee's Subcommittee on Health, Employment, Labor, and Pensions. No action has been taken.

### Summary

**Part (a) of Section 235** amends the Stark exception to the prohibition against making physician referrals for nonmonetary payment, including software, information technology, or training services, used to create, maintain, transmit, or receive electronic health records. In this case, the Secretary of Health and Human Services shall

1. Not limit the period in which the exception applies
2. Not require the physician to pay any percentage of the nonmonetary repayment
3. Apply the exception to items, such as hardware, and services, such as maintenance, in addition to the items and services already mentioned

**Part (b) of Section 235** amends the anti-kickback exception to the prohibition against making physician referrals for payment, including arrangements involving interoperable electronic health records software, information technology, or training services, used to create, maintain, transmit, or receive electronic health records. In this case, the Secretary shall

1. Not limit the period in which the exception applies
2. Not require the recipient to pay any percentage of the payment
3. Apply the exception to arrangements involving interoperable electronic health records hardware and maintenance services, in addition to the items and services already mentioned



## **H.R. 3987**

### Overview

H.R. 3987, to amend titles XI and XVIII of the Social Security Act to promote the use of health IT to better coordinate healthcare, was introduced by U.S. Representative Roy Blunt (R-MO) on November 3, 2009 and is co-sponsored by Joe Barton (R-TX), Marsha Blackburn (R-TN), Michael Burgess (R-TX), and Phil Gingrey (R-GA). This legislation helps promote the use of health IT by creating safe harbors within current anti-kickback and physician referral laws (under Stark). The language found in H.R. 3987 can also be found in a number of other bills that have been submitted to the 111<sup>th</sup> Congress:

- **H.R.1031:** Health Information Technology Promotion Act of 2009 (introduced: 2/12/2009). A bill to promote a better health information system. Status: Referred to the House Committee on Energy and Commerce and to the House Committee on Ways and Means.
- **S. 1009** and **H.R. 2520:** Patients' Choice Act (introduced: 5/20/2009). A bill to provide comprehensive solutions for the health care system of the United States, and for other purposes. Status of S. 1009: Read twice and referred to the Senate Committee on Finance. Status of H.R. 2520: Referred to the House Committee on Energy and Commerce and to the House Committee on Ways and Means.
- **S. 1679:** Affordable Health Choices Act (introduced: 9/17/2009). A bill to make quality, affordable health care available to all Americans, reduce costs, improve health care quality, enhance disease prevention, and strengthen the health care workforce. Status: Placed on Senate Legislative Calendar under General Orders.
- **H.R. 3693:** Ensuring the Future Physician Workforce Act of 2009 (introduced: 10/1/2009). A bill to amend title XVIII of the Social Security Act to modify Medicare physician reimbursement policies to ensure a future physician workforce, and for other purposes. Status: Referred to the House Committee on Energy and Commerce and to the House Committee on Ways and Means.

### Status

H.R. 3987 has been referred to the House Committee on Energy and Commerce, in addition to the House Committee on Ways and Means, and no further action has been taken.

### Summary

**Section 1** of H.R. 3987 provides protection from civil and criminal penalties. In reference to civil penalties, inducements to reduce or limit services will not apply to the benefits gained from health IT. In reference to criminal penalties, remuneration is made for the primary purpose of better coordination of care or improvement of health quality, efficiency, or research. Specifically, the language provides safe harbors for the remuneration in the form of health IT or related installation/maintenance from an entity as long as such technology is:

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1. Not limited to only those individuals receiving services at the specified entity
2. Permitted to interact with other health IT
3. Not contingent on the referral of business to the specified entity

This section also commissions a study by the Secretary of Health and Human Services to determine the impact of the exception on financial relationships, health IT adoption, quality of care, access, and cost.

The legislation defines health IT and specified entity as follows:

- Health IT: hardware, software, license, right, intellectual property, equipment, or other information technology (including new versions, upgrades, and connectivity) designed or provided primarily for the electronic creation, maintenance, or exchange of health information to better coordinate care or improve health care quality, efficiency, or research.
- Specified Entity: an entity that is a hospital, group practice, prescription drug plan sponsor, a Medicare Advantage organization, or any other such entity specified by the Secretary, considering the goals and objectives of this section, as well as the goals to better coordinate the delivery of healthcare and to promote the adoption and use of health information technology.

**Section 2** reiterates Section 1 in the context of providing an exception to certain limitations on physician referrals (under Stark) for remuneration in the form of health IT.

**Section 3** enables the formation of a group of healthcare providers, payers, employees, and other interested entities to:

1. collectively purchase and donate health information technology or
2. offer healthcare providers a choice of health information technology products that account for the varying needs of such providers receiving the products

## **Closing Remarks**

HIMSS worked to educate Congress on these issues during the 9<sup>th</sup> Annual Policy Summit. HIMSS [recommended that Congress](#) work with the Obama Administration to make permanent the current physician self-referral regulation exemptions and anti-kickback safe harbors for EHRs. HIMSS will continue to monitor these pieces of legislation for any changes and movement during the course of the 111<sup>th</sup> Congress. Questions on this fact sheet may be addressed to the HIMSS Government Relations Team at [advocacy@himss.org](mailto:advocacy@himss.org).

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