IRS Ruling Clears the Way for Expanding Health Information Technology, But Who Benefits the Most?

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On May 11, 2007 the Internal Revenue Service (IRS) released a long-awaited memorandum providing direction to hospitals and physicians on subsidized purchases of electronic prescribing and health records systems.¹ This may be the “last piece” needed to pave the way for greater interconnectivity between hospitals, providers and pharmacies. The rationale driving this activity toward electronic health records (EHR) is that “better coordination of data begets better coordination of care [which] begets safer patient care and better clinical outcomes.”² Coordination of patient data is also driven by a shift to payment systems that measure and reimburse according to clinical outcomes and compliance with practice guidelines.³

Although the federal government has been a keen supporter of hastening the implementation of healthcare information technology (HIT),⁴ significant barriers have prevented this from occurring. For physicians and other providers, the largest barrier has been cost.⁵ Alternatively, hospitals have been hesitant to provide assistance to physicians for technology purchases due to concerns about the federal Stark Law⁶ and anti-kickback regulations.⁷ Recent final rules by the Department of Health and Human Services and now the recent IRS “field directive” may change the pace of EHR implementation.

In August of 2006 the Office of Inspector General (OIG) and the Centers for Medicare and Medicaid Services (CMS) of the U.S. Department of Health and Human Services (DHHS) issued final rules⁸ adding two new exceptions or safe harbors to these two key federal fraud and abuse laws. The final rules define the circumstances under which hospitals and other health care providers would be protected when entering into: 1) ¹

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² David Burda, Hey, You Asked for IT; IRS OKs Not-for-Profits Subsidizing Docs’ System, or Why All the Long Faces? 37 MODERN HEALTHCARE 25 (June 4, 2007).
⁵ Heather Havenstein, Hospitals Seek IRS Ruling on E-health Software Sales, 41 COMPUTERWORLD 1-2 (2007) (noting acquisition costs for the average electronic medical record system are between $10,000 to $12,000 per year per physician).
⁷ 42 U.S.C. § 1320a-7b(b) (2000).
arrangements involving electronic prescribing technology and 2) arrangements involving electronic health records software. The CMS rule creates two new exceptions to the Stark Law for furnishing and receiving health information technology donations of software or information technology and training services if they are used for electronic prescribing and electronic health records. The OIG final rule establishes two new safe harbors under the anti-kickback statute that exempt from enforcement action arrangements involving the provision of items and services used for electronic prescribing and electronic health records.

The electronic prescribing safe harbor under the anti-kickback statute and a similar exception under the Stark Law, permit donations of items and services that are “necessary and used solely to transmit and receive electronic prescription information.” Items and services are not “necessary” if the subsidized technology would replicate technology a physician already possesses in her medical practice. In addition, donors may also provide hardware, internet connectivity, and training and support necessary for electronic prescribing.

According to the statute, protected donors and recipients are: (1) hospitals to members of their medical staffs; (2) group practices to physician members; (3) Prescription Drug Plan (“PDP”) sponsors and Medicare Advantage (“MA”) organizations to network pharmacists and pharmacies and prescribing health care professionals. The final rules make clear that donors may not select recipients using any method that takes into account the volume or value of referrals from the recipient or other business generated between the parties. Neither may recipients make the receipt of electronic prescribing technology or services a condition of doing business with the donor. The rules place no limit on the value of donations of electronic prescribing technology, nor do they contain any expiration date for their provisions.

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11 Specifically, this is an exception to the physician self-referral prohibition in section 1877 of the Social Security Act for certain arrangements in which a physician receives compensation in the form of items or services that are necessary and used solely to receive and transmit electronic prescription information.
12 This is an exception for certain arrangements involving the provision of nonmonetary remuneration in the form of electronic health records software or information technology and training services necessary and used predominantly to create, maintain, transmit, or receive electronic health records.
14 Medicare Program; Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements, 71 Fed. Reg. 45140, 45144 (Aug. 8, 2006) (codified at 42 C.F.R. pt. 411) (To ensure compliance, DHHS proposes that physicians certify in writing that they did not already possess the same technology that is given to them).
15 Id. Items such as billing, scheduling, administrative and other general office software as well as the provision of technology for personal, non-medical purposes are excluded from protection. Id. at 45144 – 45,145.
17 42 C.F.R. 411.357(v)(5); 42 C.F.R. 1001.952(x)(6).
18 42 C.F.R. 411.357(v)(5); 42 C.F.R. 1001.952(x)(4).
The final rules also protect donations of electronic health records software or information technology and training services “necessary and used predominantly to create, maintain, transmit, or receive electronic health records.” \(^{19}\) In order to qualify for protection, the software must contain an electronic prescribing capability, either through an electronic prescribing component or ability to interface with the recipient’s existing electronic prescribing system. \(^{20}\) As with electronic prescribing, the rules do not protect software with a core functionality other than electronic health records. A notable difference from the electronic prescribing rule is that donations for electronic health records do not include hardware.

As with electronic prescribing technology, the final rule for electronic health records does not limit the total value of technology that may qualify for protection. However, recipients must pay 15 percent of the donor’s cost for the donated technology. \(^{21}\) The donor (or any affiliate of the donor) is prohibited from funding any portion of this contribution by the recipient. \(^{22}\) Finally, a sunset provision of December 31, 2013 has been instituted for electronic health record technology in order to maintain “the balance between promoting health information technology and preventing fraud and abuse.” \(^{23}\)

The details of the OIG and CMS Final Rules are summarized below:

<table>
<thead>
<tr>
<th>Authority for Exception or Safe Harbor</th>
<th>Electronic prescribing exception or safe harbor</th>
<th>Electronic health records exception or safe harbor</th>
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<tbody>
<tr>
<td><strong>Covered Technology</strong></td>
<td>Items and services that are <strong>necessary</strong> and used solely to transmit and receive electronic prescription information. Includes hardware, software, internet connectivity, and training and support services.</td>
<td>Software <strong>necessary</strong> and used <strong>predominantly</strong> to create, maintain, transmit, or receive electronic health records. Software packages may include functions related to patient administration, for example, scheduling functions, billing and clinical support. Software <strong>must</strong> include electronic prescribing capability. Information technology and training services, which cold include, for example, internet connectivity and help desk support functions. <strong>Note:</strong> does not include hardware.</td>
</tr>
<tr>
<td>Standards with Which Donated Technology Must Comply</td>
<td><strong>Electronic health records</strong> software must be interoperable. Certified software may be</td>
<td></td>
</tr>
</tbody>
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\(^{19}\) 42 C.F.R. 411.357(w); 42 C.F.R. 1001.952(y).
\(^{20}\) 42 C.F.R. 411.357(w)(11); 42 C.F.R. 1001.952(y)(10).
\(^{21}\) 42 C.F.R. 411.357(w)(4); 42 C.F.R. 1001.952(y)(11).
\(^{22}\) Id.
\(^{23}\) 42 C.F.R. 411.357(w)(13); 42 C.F.R. 1001.952(y)(13).
Electronic prescribing capability must comply with final standards for electronic prescribing adopted by the Secretary.

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<th>Donors and Recipients</th>
<th>Protected donors and recipients are hospitals to members of their medical staffs; group practices to physician members; PDP sponsors and MA organizations to network pharmacists and pharmacies, and to prescribing health care professionals.</th>
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</table>
| Selection of Recipients | Donors may not take into account directly or indirectly the volume or value of referrals from the recipient or other business generated between the parties.  
Donors may use selection criteria that are not directly related to the volume or value of referrals from the recipient or other business generated between the parties. |
| Value or Protected Technology | No limit on the value of donations of electronic prescribing technology.  
Physician recipients must pay 15 percent of the donor’s cost for the donated technology and training services.  
The donor may not finance the physician recipient’s payment or loan funds to the physician recipient for use by the physician recipient to pay for the items and services. |
| Expiration of the Exception | None  
Exception sunsets on December 31, 2013. |


Although the new exceptions and safe harbors alleviated many of the fears of regulatory violations expressed by hospitals and lessened the financial impact for physicians, there remained concern that providing electronic health record technology to physicians could lead to tax problems for some not-for-profit entities. Hospitals organized under section 501(c)(3) of tax code are prohibited from using charitable assets to benefit private individuals, such as physicians. These institutions were concerned that even with the new exceptions and safe harbors, providing physicians with information technology capabilities would be seen as private inurement and thus jeopardize their tax-exempt status. In November of 2006 the American Hospital Association submitted a letter to the IRS requesting guidance on “health IT arrangements between a hospital and physicians” and further clarification of the impact, if any, on a hospital’s tax-exempt status.24 The IRS responded to this letter by memorandum on May 11, 2007.

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The ruling by the IRS clearly states “we will not treat the benefits a hospital provides to its medical staff physicians as impermissible private benefit or inurement” as long as the “benefits fall within the range of Health IT Items and Services that are permissible under the HHS EHR Regulations.” However, the key caveat to this generosity is the requirement that “the hospital may access all of the electronic medical records created by a physician using the Health IT Items and Services subsidized by the hospital.”

This requirement is necessary for hospitals to gain access to data needed for performance analysis and measurement of clinical outcomes. These calculations are required to evaluate whether clinical practices are consistent with health care guidelines, as specified in order to obtain financial bonuses from payers through a pay-for-performance reimbursement system. Such bonuses contribute to the financial justification of a hospital’s investment in the technology of a physician’s practice. However, can hospitals rely upon the theory that “better coordination of data begets better coordination of care [which] begets safer patient care and better clinical outcomes” to support their financial justification?

Early results suggest they might not.

The results of a three-year Medicare pilot project on the pay-for-performance payment system involved 500 hospitals of which 446 acted as “control” hospitals. The findings for data collected on a total of 105,383 patients treated for myocardial infarction showed that “the pay-for-performance program was not associated with a significant improvement in quality of care or outcomes for acute myocardial infarction.” Further, there was “no evidence that improvements in mortality were incrementally greater at pay-for-performance hospitals” compared to the control hospitals.

Although data derived from the pay-for-performance system will undergo additional analysis, for now hospitals may continue to remain cautious about subsidizing health care technology for affiliated physicians, despite the green light from the DHHS and the IRS.

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25 I.R.S., supra note 1.
26 Id.
28 Meredith Rosenthal, et al., Early Experience With Pay-for-Performance: From Concept to Practice 294 JAMA 1788-93 (2005) The pay-for-performance concept was initiated and implemented by Centers for Medicare and Medicaid (CMS) through Medicare demonstration projects. Several states have adopted this quality and reimbursement initiative under Medicaid and increasingly private third-party payers are implementing similar practices. See, e.g., Suzanne Felt-Lisk, et.al., Making Pay-for-Performance Work in Medicaid, 26 HEALTH AFFAIRS w514-27 (June 26, 2007), http://content.healthaffairs.org/cgi/reprint/hlthaff.26.4.w516v1.pdf .
29 Burda, supra note 2.
30 Seth W. Glickman, et al., Pay for Performance, Quality of Care, and Outcomes in Acute Myocardial Infarction, 297 JAMA 2373, 2375 (2007).
31 Id. at 2377.
32 Id. at 2376.