

MINTZ LEVIN
COHN FERRIS
GLOVSKY AND
POPEO PC

Boston
Washington
Reston
New York
Stamford
Los Angeles
London

701 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
202 434 7300
202 434 7400 fax
www.mintz.com

Thomas S. Crane

Direct dial 202 661 8787
TCrane@mintz.com

February 8, 2005

Office of Inspector General
Department of Health and Human Services
Room 5246, Cohen Building
330 Independence Avenue, S.W.
Washington, DC 20201

Re: OIG-91-N
 Health Systems Supported Electronic Health Record - Request for Safe Harbor

To Whom It May Concern:

We are writing on behalf of the providers and groups listed in Attachment A to request that the Office of Inspector General develop a safe harbor to protect the support that hospitals, health systems, and multi-specialty physician group practices^{1/} provide to their affiliated physicians^{2/} for implementation of electronic health record (“EHR”) systems. We will discuss the case for health system supported EHR development, the specific features and protections for a protected EHR system, and the OIG’s criteria for new safe harbors.

A. THE CASE FOR HEALTH SYSTEM SUPPORTED EHR DISSEMINATION AND MAINTENANCE

The President of the United States has called for making electronic health records available to most Americans in the next 10 years. When David Brailer, M.D., Ph.D., National Coordinator for Health Information Technology, testified before Congress in 2004 he said that he will be “working with the Administration, Congress and the private sector to bring together the resources and talent to drive the adoption of HIT [health information technology] in the health care system.” In a report issued in 2004, the Government Accountability Office found that

^{1/} For simplicity, the use of the term “health systems” will include hospitals, health systems, and multi-specialty physician practices.

^{2/} The use of the terms “physicians” will include other independent practitioners, such as nurse practitioners and physician assistants.

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various laws, including both the Physician Self-Referral law and the Anti-kickback statute (the “Statute”):

[P]resent barriers by impeding the establishment of arrangements between providers—such as the provision of IT resources—that would otherwise promote the adoption of health IT. Because the laws frequently do not address health IT arrangements directly, health care providers are uncertain about what would constitute violation of the laws or create a risk of litigation. To the extent there are uncertainties and ambiguity in predicting legal consequences, health care providers are reluctant to take action and make significant investments in health IT.

Government Accountability Office, GAO-04-991R, *HHS' Efforts to Promote Health Information Technology and Legal Barriers to Its Adoption*, pp. 2-3 (Aug. 13, 2004), available at <http://www.gao.gov/new.items/d04991r.pdf>. For these reasons and because the EHR support contemplated in this proposal should not be considered to be remuneration, an EHR safe harbor should be created.

1. EHR Is The Cornerstone Of A New Health Care Paradigm Based on Quality and Patient Safety

Many initiatives are underway to transform today’s health care system in the way patients receive care, with a focus on integration and a goal of eliminating fragmentation. Incentives are being developed to reward quality of care and improve patient safety.

These changes can reach their full potential only with substantial HIT that can support patient care-focused strategies, many of which are now being considered or have been recently implemented. Electronic clinical support can now provide error reporting and other error mitigation capabilities, including adverse drug surveillance that can identify drug-to-drug interactions. Decision support systems are also coming on-line to assist providers in the often complicated array of treatment choices and in controlling high-cost prescriptions and diagnostic testing while also improving outcomes. HIT systems are also central to many disease management programs that identify and track high-risk, high-cost patients and thereby help reduce avoidable utilization of services.

The backbone making these clinical strategies possible is the EHR. Simply put, an EHR is a patient-centric software system that plays many important roles.^{3/}

1. It provides a view of the patient’s health history, . . . and serves as the legal document describing the healthcare services provided to the patient.
2. It provides a method for clinical communication and care planning among the individual healthcare practitioners and institutional providers serving the patient.

^{3/} From “Practice Brief: Definition of the Health Record for Legal Purposes,” American Health Information Management Association, 2001.

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3. It provides supporting documentation for the reimbursement of services provided to the patient.
4. It documents and substantiates the patient's clinical care and serves as a key source of data for outcomes research and public health purposes.
5. It serves as a major resource for healthcare practitioner education.
6. It serves as a logical guidance tool for clinical decision-making, and documents evidence of the quality of patient care.
7. It serves as the business record for a healthcare organization and is used in support of business decision making.

An integrated EHR system is the most straightforward way of combining all of the roles in a way that benefits both the patient and the health care system as a whole. For example, EHR is the platform for meaningful e-prescribing capabilities.^{4/} EHR also connects office-based and hospital records to transmit clinical information as the patient moves between care providers and settings. Such EHR capability can reduce the need for repeat diagnostic tests, immediately inform a provider of all drugs the patient is taking to avoid drug allergies or potentially dangerous drug interactions, and alert caregivers to medical conditions that might affect treatment decisions.

In addition to all of the above, an integrated EHR in a large health system or academic medical center with a large physician network has the potential, through its extensive database, to perform important clinical and epidemiological research studies. Finally, a robust EHR system could facilitate the kind of collaboration between clinicians and researchers that leads to the creation of personally tailored drug treatment regimens.

2. Private Sector Leadership Is Essential For the Full Deployment of EHR Technology

Dr. Brailer's Office of National Coordinator for Health Information Technology ("ONCHIT") issued a report in 2004, entitled "The Decade of Health Information Technology: Delivering Consumer-centric and Information-rich Health Care" ("Strategic Framework Report") which is available on the Department's website. The report identified the weak EHR business model that makes it unlikely that physicians alone will adopt EHR technology: "A large gap remains, however, between the promise of EHR and the capacity and willingness of clinicians to use them. Data from EHR adoption studies show only modest rates of EHR adoption by health systems and physician groups." Strategic Framework Report, *Framework for Strategic Action at 2*.

The Administration is focusing on ways to encourage EHR development through new funding and recently announced pay-for-performance demonstration grants, some of which are

^{4/} We recognize that a physician could prescribe electronically using a personal digital assistant, but the clinical advantages of e-prescribing are largely lost without an electronic interface to the patient's medical record.

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linked to advances in EHR capabilities. However, the Department also clearly recognizes that private sector leadership is essential.^{5/}

While the federal government plays an important role in HIT adoption, the effective use of, and value creation from, this technology lies predominantly with the private sector. . . . The private sector must develop the market institutions to deliver the products and services that can transform the paper-based health care system into an electronic, consumer-centered, and quality-based system. The private sector can best ensure that HIT products are successfully implemented in ways that meet the varying needs of American health care across settings, cultures, and geographies. The private sector can also continue constant innovation in HIT and ensure that products are delivered on an affordable basis.

Strategic Framework Report, *Public-Private Leadership* at 1.

The Department's recognition of the central role of the private sector in EHR technology diffusion is in keeping with hospitals' historic role as providers of services beyond the four corners of their institutions. Central to the mission of hospitals and health systems is providing health care services to the communities they serve. But hospitals do not operate in a vacuum. It is the medical staffs that provide the care, order tests, and admit patients. Meaningful programs require clinical collaboration with the medical staff and, as discussed above, many of these clinical programs can be optimized when made available through an EHR platform. Additionally, a health system's implementation of EHR systems in coordination with its affiliated physicians promotes the integration of such systems. Thus, the ability of affiliated physicians to expand their HIT capabilities, including the adoption of EHR technology, is not a separate or peripheral activity for health systems. It is therefore appropriate for the Department to recognize that funding from all public sources generally will need to be supplemented with private sector funding, including that supplied by health systems, for EHR deployment.

In some areas of the country, private payors are contributing to EHR adoption through various programs and contracting mechanisms, but given the inadequacies of public sources of funding there remains a significant gap in funding. Consequently, driven by the promises in improving patient care, health systems are offering to play the leadership role that the ONCHIT stressed is needed.

3. Fraud and Abuse Rules Need to Be Modified For Health System Support For EHR Dissemination and Maintenance

Echoing Dr. Brailer's testimony before Congress, The Strategic Framework Report finds that the existing fraud and abuse rules present a significant barrier to EHR development:

^{5/} As a comparison of the availability of Federal funding to the enormity of the financial need, the new funding of \$125 million in Federal fiscal year 2006 that the President requested is lower than the individual health information operating budgets of several large hospital systems.

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The physician self-referral prohibition and the anti-kickback statute provide important protection against fraud and abuse, assuring that taxpayer and beneficiary dollars are spent appropriately and preventing patient harm. However, these statutes did not anticipate interoperable HIT that necessarily involves relationships among different providers. While the in-kind provision of EHRs, hardware, or support by hospitals and other providers or suppliers to physicians could accelerate physician adoption of EHRs, this action could face unintended conflicts with the physician self-referral prohibition and the anti-kickback statute in some circumstances. HHS could explore safe harbors or exceptions to these laws that could accelerate EHR adoption without creating inappropriate conflicts of interest or potential for abuse.

Strategic Framework Report, *Framework for Strategic Action* at 4.

The need for widespread EHR technology deployment is driven by a new paradigm of health care delivery focusing on integrated clinical services and improved quality of care and patient safety. As will be discussed more fully below in our analysis of the OIG's criteria for new safe harbor development, health system support for EHR adoption is not related to referral considerations or any of the historic concerns that led Congress to enact the Statute. Nor is it seen as a way to "game" the reimbursement system, as some fear. Regardless of whether patient information is stored electronically or in a paper format, the best health care is delivered when the medical record contains accurate information, and when that information also is used to document accurate claims for reimbursement, thereby improving the ability to audit. Moreover, new strategies centered on EHR technology hold significant promise to improve access and care. Health system support for EHR will also not involve any excessive payments because the incentive is to use the most economical and efficient systems possible so that unnecessary funds will not be diverted from direct patient care and other activities that benefit the community. Finally, there is a low risk of health systems abusing EHR technology by creating compatibility barriers that tie-in physicians. Not only would the market not accept such exclusionary systems, but such a strategy would defeat the purpose of sharing medical information through extensive connectivity as patients move across providers, and would be contrary to the Federal policy of widespread information sharing via national standards.

B. SPECIFIC FEATURES AND PROTECTIONS

We propose a safe harbor protecting health system support for EHR implementation and maintenance with the following features and protections.

1. EHR Development and Compliance with Standards Set by Independent Organizations

Health systems either would develop the EHR system internally or negotiate with approved vendors for favorable pricing through volume buying. The EHR systems would not impose compatibility barriers creating difficulties in interfacing with different hospital and regional systems. This issue will likely be addressed through the market because incompatible systems would receive significant physician resistance. In addition, national organizations such

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as the Certification Committee for Healthcare Information Technology and the Commission on Systemic Interoperability are already making progress in EHR standard-setting.

Additionally, the EHR system would be for the use for a physician's patients irrespective of payor status. Finally, the EHR system would, of course, meet all HIPAA requirements.

2. Physicians Would Be Eligible To Receive Health System Support For EHR Dissemination and Maintenance

Health systems would be protected in their support for EHR dissemination and maintenance among the following categories of affiliated physicians:

- Physicians who are on the medical staff of one of the hospitals in the health system;
- Physicians whose practice a component of the health system owns, controls, or manages;
- Physicians who are on the faculty of the medical school affiliated with the health system;
- Physicians who participate in research involving data collected in the EHR;
- Physicians involved in follow-up care even if not members of the medical staff of one of the hospitals in the health system; or
- Physicians who participate in managed care contracting with the health system.^{6/}

The health system could make support available for the EHR system to physicians in any one or all of the above categories, and the availability for physicians to participate would not otherwise be restricted based on any referral considerations, including the volume or value of referrals or business otherwise generated by the physician.

3. Features of Health System Support For EHR Dissemination and Maintenance

Health systems would either use their own EHR technology or pay approved vendors. Therefore, the support to affiliated physicians would be in the form of non-monetary or in-kind benefits, and would not involve any direct payments to physicians. The level of support would not be based on any referral considerations, but rather would reflect costs to the health system of the EHR dissemination and maintenance.

Among the non-monetary support physicians would be provided are the installation and maintenance support for the hardware, software, and related support necessary to implement and maintain the EHR system, including but not limited to connections to the regional health information organization, licensing fees, maintenance agreement, transfer and conversion costs for the practice's existing hard-copy medical records, training, etc. The support could come from any component of the health system, such as from a hospital within the system, a parent

^{6/} We have not included employed physicians in this list because we assume there is no question that health systems support for this group is protected by existing exceptions and safe harbors.

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organization, a foundation or other practice plan, or other affiliate. Physicians who wished to purchase additional enhancements beyond those determined to be necessary by the health system could do so at their own expense.

C. ANALYSIS OF OIG'S CRITERIA FOR NEW SAFE HARBORS

The OIG has set forth seven criteria for assessing the appropriateness of safe harbor proposals. Using these criteria in an analysis of the proposed EHR safe harbor demonstrates the existence of compelling policy reasons for permitting health systems to provide non-monetary support to affiliated physicians for the deployment of EHR technology, with minimal risk of abuse.

1. Access To Health Care Services

The proposed EHR safe harbor may increase access to care, including to specialists. For example, an efficient EHR may allow providers to see more patients. Patients in remote locations or who are homebound may be able to use the EHR technology as a platform for distance monitoring of their conditions so that they receive better and more timely care.

2. Quality of Care

For the reasons set out more fully in Section A above, there is a compelling case that EHR technology promises to play a significant role in improving quality of care and patient safety. Consequently, a safe harbor that protects private sector support for this technology will help accomplish these important policy objectives.

3. Patient Freedom of Choice

With the protections discussed in section B above, limiting safe harbor protection to EHR systems that do not impose compatibility barriers, patient freedom of choice will be preserved, and may be enhanced. If a patient changes providers, the process of physically moving the patient's records could be replaced by the more efficient method of merely granting the new provider electronic access to the patient's records.

4. Competition Among Health Care Providers

Competition based on improved quality and patient safety and more efficient delivery of care should only be considered a good thing. EHR systems serve as the platform for measuring quality of care, and making available risk-adjusted results that are used to evaluate individual physician, hospital and health system performance. Therefore, widespread EHR deployment would make it easier for insurers and consumers to determine which providers bring the highest value to the marketplace. Competition will also be promoted in that once a physician installs an EHR infrastructure in his/her practice, the costs are lower for the next health system because that second system would need only to install the EHR system internally and then, at most, assist the physicians with EHR software configuration in their offices.

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In addition, EHR technology is in its infancy. Private sector support for start-up technologies has historically been a catalyst for innovation, which ultimately improves competition.

5. Cost to Federal Health Care Programs

For the reasons discussed more fully in Section A above, EHR technology is the backbone for several creative cost-saving strategies. For example, decision support for high-cost prescriptions and diagnostic testing help drive more cost-effective behavior in physicians' clinical decision-making. Pay-for-performance contracting has already proven itself in the private sector as an effective vehicle to lower costs. Experience with managed care has shown that changes in physician behavior are likely to apply to all of the physician's patients, including Federal Health Care Program beneficiaries.

6. Overutilization of Services

For the reasons discussed immediately above regarding costs of care, the dissemination of EHR technology can be equally expected to improve the efficiency and cost-effectiveness of services, and reduce overutilization of services.

7. Medically Underserved Areas

The proposed EHR safe harbor may serve as a basis for increasing services to medically underserved areas. EHR systems are already expanding ways in which patients in those areas can access providers through telemedicine, and for those providers to give better care.

8. Other Considerations

The OIG also states that it will take into account other considerations, including potential referral considerations. We offer the following comments.

a. Referral considerations

As discussed in Section A above, health system support for EHR technology deployment is not driven by referral considerations. Specifically, the benefits would be made available to physicians in one or more of the specified categories of affiliated physicians identified in Section B(2), and would not be related to the volume or value of referrals. Therefore, health system support for EHR development is not intended to influence physicians' referral decisions as to where and when to refer patients or order services. Rather, EHR systems allow medical information to follow the patient as he/she moves between care providers and settings. To further minimize any potential for referral considerations, we recommend that protected EHR support programs not impose compatibility barriers that would impede access to another health system.

b. Financial benefits/remuneration

Under the proposed safe harbor, physicians would receive only non-monetary benefits and no direct payments. The intended beneficiaries of this technology are patients. In many

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other contexts, for example with disease management programs, the OIG has determined that, where programs primarily benefit patients, remuneration is deemed not to exist.

Whatever remuneration might technically be said to exist involves none of the classic payment schemes that were of historic concern to Congress in enacting the Statute. Not only will physicians receive no direct payments, they will not personally gain. Moreover, costs will be self-regulated because health systems will have no incentive to overpay itself if internally created EHR is used or vendors for technology purchased for the needed hardware and software. Rather, there will be every reason to deploy EHR technology in as cost-efficient a manner as possible. Thus, these costs are inherently fair market value payments.

c. The proposed safe harbor will encourage e-prescribing deployment

Although Congress has mandated the Department to develop a safe harbor for non-monetary support for e-prescribing technology, Congress's directives will frustrate such technology unless the Department establishes wider protections for the EHR platform on which e-prescribing technology best operates. Unfortunately, Congress did not understand the dependence of e-prescribing technology on an EHR platform. Congress apparently thought it could encourage e-prescribing by protecting only non-monetary support "necessary and used solely to receive and transmit electronic prescription information." SSA § 1860D-4(e)(6). However, as the foregoing discussion has made clear, e-prescribing needs to sit on top of and be integrated into an EHR platform to fully maximize its benefits. Thus, unless the Department addresses the need to protect support for EHR deployment at the same time as support for e-prescribing, it will frustrate and hold back the widespread use e-prescribing.

d. Overwhelming public policy reasons exist to support an EHR safe harbor

ONCHIT has already identified the important public policy reasons for widespread dissemination of EHR technology and determined the need for safe harbor protection. Hospitals have historically understood the importance to their missions to collaborate with their affiliated physicians to enhance patient care. The protection health systems are seeking to support their physicians in EHR implementation is fully in keeping with such historic collaborations.

D. CONCLUSION

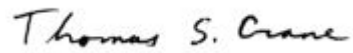
Because the Statute is so facially broad, Congress authorized the Department in 1987 to promulgate safe harbors to permit "certain non-abusive arrangements, while encouraging beneficial and innocuous arrangements." 56 FR 35958; July 21, 1991. Health systems support for dissemination and maintenance of EHR systems to affiliated physician practices precisely fits this description and should be protected.

MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C.

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We would be happy to meet with the OIG to discuss this important matter more fully.
We reserve the right to submit supplemental materials as part of this filing.

Respectfully submitted,

A handwritten signature in cursive script that reads "Thomas S. Crane".

Thomas S. Crane

Attachment

LIT 1502719v4

**ACADEMIC MEDICAL CENTERS, HEALTH SYSTEMS AND
ORGANIZATIONS SUPPORTING THE PROPOSED EHR SAFE
HARBOR^{7/}**

- American Medical Group Association
- Association of American Medical Colleges
- Deaconess Billings Clinic
- Intermountain Health Care
- Partners HealthCare System, Inc.

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^{7/} Some of the groups may send additional separate comments as well.