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November 15, 2006

Ms. Lois G. Lerner
Director, Exempt Organizations
Internal Revenue Service
1111 Constitution Ave., NW
Washington, DC 20224

Dear Ms. Lerner:

The American Hospital Association (AHA), on behalf of our nearly 5,000 hospital, health system and other health care organization members, and our 37,000 individual members, is seeking guidance for hospitals and health care systems that are poised to implement health information technology (IT) sharing with physicians.

Recently issued Department of Health and Human Services (HHS) regulations have minimized the obstacles to such transfers under anti-kickback and self-referral statutes, and as a result offer hospitals and health systems a clearer roadmap for helping physicians access and use health IT. However, hospitals and health systems may effectively be deterred from proceeding with beneficial arrangements that would comply with the requirements of the new HHS regulations because they are concerned that such arrangements may trigger Internal Revenue Service (IRS) interest and ultimately impact the organization's tax exempt status.

Based on the rules established in the HHS regulations and well-established standards of federal tax law, we believe the provision of health IT by hospitals and health care systems would be allowable without resulting in risk to the exempt status of such organizations. We urge the IRS to consider health IT arrangements between hospitals and physicians as a priority for developing and issuing general guidance and we hereby request a meeting, at your earliest convenience, to discuss these important and time-sensitive issues.

BACKGROUND

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173) amended Title XVIII of the Social Security Act to establish the Voluntary Prescription Drug Benefit Program. Certain provisions of the MMA directed HHS to promulgate regulations that provide a safe harbor under the anti-kickback statute and an exception under the physician



self-referral statute for certain nonmonetary remuneration related to e-prescribing IT and services. The HHS issued final regulations (HHS regulations) on August 8, 2006, which addressed those issues. HHS also used general authority provided in section 1877(b)(4) of the Social Security Act to establish provisions related to electronic health records (EHRs).

The HHS regulations provide limited relief to hospitals and health systems, allowing hospitals to provide health IT resources to physicians without violating the anti-kickback or self-referral rules. Before these regulations were finalized, hospitals were reluctant to provide physicians with health IT resources for fear that they would be violating the physician self-referral statute if the physician subsequently made a referral to the hospital. ^{1/} And fearing that such resources might be viewed as remuneration that would be in violation of the anti-kickback statute, physicians were reluctant to accept health IT resources from hospitals. ^{2/} Both hospitals and physicians face severe penalties for violating these legal prohibitions.

The final HHS regulations provide an exception to the physician self-referral law and a similar safe harbor under the anti-kickback law, specifically to facilitate donations of electronic health record (EHR) technology to physicians. The promulgation of such regulations is a critical step in expanding the distribution and use of health IT to improve the delivery and quality of health care. Executive Order 13335, signed by President Bush in April 2004, established widespread adoption of EHRs and the development of a national health information network (NHIN) as national policy priorities. The Executive Order fixed a 10-year timeframe for accomplishing this ambitious goal.

The Executive Order specifically calls for a system for the electronic exchange of clinical health information that would allow clinical data to follow the patient across care settings, including physicians' offices, because sharing of clinical information through a widespread electronic network is key to alleviating the fragmented delivery of health care with its concomitant

^{1/}The physician self-referral statute was enacted to establish an enforceable rule against physician "self-referrals" and avoid the potential harm that may be caused if a physician's economic interest in an entity to which the physician refers patients influences decisions about a patient's care. The law is a strict liability statute that prohibits a physician from referring Medicare and Medicaid patients for certain designated health services, including inpatient and outpatient care, to an entity if the physician --- or a member of the physician's immediate family -- has a financial relationship with that entity.

^{2/}The anti-kickback statute is a criminal statute that makes it a felony for anyone knowingly and willfully to offer or pay anything of value to induce another individual or entity to make a referral for; to purchase, lease or order; or to arrange for or recommend the purchase or order of services reimbursable by federal or state health care programs, including Medicare and Medicaid. Under the anti-kickback statute, it is also illegal to "solicit" or "receive" payment for such purposes.

potential adverse impact on the quality of healthcare. Greater use of health IT to share patient information electronically is expected to facilitate providers' access – whether in or out of the hospital – to relevant information at the time and location of treatment, and thereby improve the quality and efficiency of patient care.

The experiences of hospitals and health systems, in fact, have demonstrated the value of using health IT. Electronic order-entry systems with clinical decision support functions, for example, have shown documented reductions in adverse drug events and medication errors. Medication bar-coding also has produced documented reductions in drug-related errors.

In addition, health IT has been shown to help improve efficiency in health care delivery. Applications such as digital imaging software can decrease radiology costs, while order-entry medication functions have saved some hospitals and health systems substantial amounts by encouraging greater use of formulary drugs. Health IT systems also are expected to save money and time for the health care system as a whole by lowering the incidence of repeated laboratory and radiology tests and improving outcomes.

Hospitals have expanded health IT use and integrated it into routine care processes, but to realize the full promise of health IT requires the direct involvement of physicians and physicians' offices. Many physicians, however, do not have the financial or technical resources needed to navigate the complex health IT market, and do not otherwise have the capability to assess interoperable options within the timeframe for implementing health IT sharing. As a result, those hospitals in a position to do so want to provide physicians with software, connectivity, or other assistance that would allow them to share their patients' clinical data with the hospital.

THE HHS REGULATIONS

Pursuant to the HHS regulations, hospitals may (but are not required to) donate identified health IT items and services to any physician who treats patients in the community without violating the physician self-referral and anti-kickback statutes.

Under the HHS regulations, the direct benefit to the physicians involved in the transaction is limited. The regulations mandate that in determining the physicians who will receive the donated health IT resources and the amount or type of the donation, the donating hospital cannot directly take into account the volume or value of referrals or other business from the physician to the hospital. Also, the physician or the physician practice, including its employees and staff members, cannot compel the donation, or the amount or type of the donation as a condition of doing business with the hospital.

Permissible donations include software, interfaces, connectivity services, training, and help-desk and other types of maintenance and support services. The regulations do not permit the donation of hardware, or the provision of staffing for physicians' offices. Donated health IT cannot duplicate what the physician already has. A donation is permissible only where the donor “does

not have actual knowledge of, and does not act in reckless disregard of, the fact that the physician possesses or has obtained items or services equivalent to” those the donor intends to provide.

The benefit from the donation of approved health IT is the exchange of relevant information necessary for patient care and quality improvement. The HHS regulations explicitly require that the donated health IT be “necessary and used predominately to create, maintain, transmit, or receive electronic health records.” The donated EHR software also must “contain electronic prescribing capability,” either through a direct prescribing component or an electronic interface with the physician’s existing prescribing system.

Donated health IT may not be used “primarily to conduct personal business or business unrelated to the physician’s medical practice.” This particular prohibition is further reinforced by requirements of the medical privacy rule created under the Health Insurance Portability and Accountability Act (HIPAA) of 1996. The HHS regulations do not affect or alter application of the HIPAA medical privacy rule when patient information is shared electronically by means of health IT donated by a hospital to a physician. The HIPAA medical privacy rule continues to limit access, use and further disclosure of a patient’s health information, including any such health information that is part of the electronic health record. Absent a patient’s explicit authorization or an applicable legal mandate, the HIPAA medical privacy rule generally restricts the use and disclosure of a patient’s protected health information to the minimum necessary for treating the patient, facilitating payment for that care, or conducting certain health care operations related to quality assessment and performance improvement of the health care provider.

The HHS regulations also require that donated health IT be capable of transmitting and receiving relevant information from the larger health care system rather than solely between the parties participating in a specific health IT arrangement. Donated health IT must be “interoperable” at the time it is provided to the physician. Technology is interoperable if it is able to “communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks, in various settings; and exchange data such that the clinical or operational purpose and meaning of the data is preserved and unaltered.” The donating hospital cannot alter or modify the technology in any way that would “limit or restrict its use, compatibility, or interoperability with other electronic health records or electronic prescribing systems.” Where the technology can be used for patients without regard to payor status, the donor cannot “restrict or take any action to limit the physician’s right or ability to use the technology for any patient.”

Finally, the HHS regulations require that physicians share the costs of purchasing and using the health IT received. Physicians must pay at least 15 percent of the donor’s costs of the donated health IT before the physician receives any of the items or services. The receiving physician’s share cannot be paid or financed, including through loans to the physician to pay for any items or services, by the donating hospital or by any party related to the donating hospital.

GUIDANCE FROM THE INTERNAL REVENUE SERVICE

The IRS has not yet offered guidance specific to health IT arrangements between a hospital and physicians that would assist hospitals in understanding precisely how arrangements that comply with the requirements of the HHS regulations are to be evaluated. As we understand the facts, the following analysis is how we think the Service should apply well-established standards of federal tax law:

Section 1.501(c)(3)-1(d)(1)(ii) of the Treasury Regulations provides that an organization is not organized or operated exclusively for charitable purposes unless it serves a public rather than a private interest, and that an organization must establish that that it is not organized or operated for the benefit of private interests. If an organization serves a public interest and also serves a private interest other than incidentally, it is not entitled to exemption under section 501(c)(3). If the private benefit is only incidental to the exempt purposes served, and not substantial, such benefit will not result in a loss of exempt status.

It is a well-established principle that for purposes of determining whether a private benefit is more than incidental, both the qualitative and quantitative aspects of the term are important. *See* GCM 39598 (Feb. 04, 1987); GCM 37789 (Dec. 18, 1978). To be incidental in the qualitative sense, the private benefit must be a necessary concomitant of the activity which benefits the public at large, i.e., the benefit to the public cannot be achieved without necessarily benefiting certain private individuals. To be incidental in the quantitative sense, the private benefit must not be substantial after considering the overall public benefit conferred by the activity.

The HHS regulations permit hospital and health care systems to provide software and other health IT and support services (but not hardware) to physicians for the purpose of promoting health by improving patient safety, and the efficiency and effectiveness of care. Accordingly, the provision of such health IT directly furthers the exempt purposes of hospitals and health care systems. To achieve these exempt purposes, the provision of health IT is necessary and used solely to receive and transmit electronic patient information in accordance with standards established by HHS. Moreover, physicians are required to share in the costs by contributing at least 15-percent before they receive any health IT items and services.

The important public policy goal of promoting health care through the effective and efficient use of health IT that allows the most current detailed patient information to be available seamlessly from hospital to physician and vice versa can only be achieved if both hospitals and physicians have compatible technology that is capable of transmitting and exchanging clinical information. By providing the technology, hospitals promote health care and to the extent physicians are benefited, it is merely incidental to the public benefit.

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We believe that the HHS regulations and well-established standards of federal tax law permit hospitals to provide health IT to physicians without resulting in risk to the exempt status of these hospitals. We look forward to discussing these issues with you, at your earliest convenience.

Sincerely,

Rick Pollack
Executive Vice President