

September 16, 2005

The Honorable Nancy Johnson
Chairman
House Ways and Means Subcommittee on Health
1136 Longworth House Office Building
Washington, D.C. 20515

Dear Mrs. Chairman:

The undersigned organizations thank you for your continued leadership on the critical health care issues facing our country, including health information technology (HIT). We would like to specifically thank you for your inclusion of a statutory exception to federal fraud and abuse laws for HIT arrangements in your draft HIT legislation. We believe that this exception will result in greater dissemination of HIT.

Legal Barriers to HIT Adoption

As you know, increased adoption and implementation of HIT, which can range from electronic patient registries to sophisticated electronic medical record systems (EMRs), has the potential to increase quality and decrease costs. However, substantial legal barriers to encourage HIT adoption exist.

Fraud and Abuse Laws

Because HIT has the potential to dramatically improve the quality and safety of patient care, some hospitals and medical groups with sophisticated HIT systems are ready to begin exchanging clinical data with community physicians. While many hospitals and medical groups already have web portals that allow physicians access to patient data, there is little two-way exchange of data. Therefore, these providers would like to assist physicians to take the next step and adopt EMRs. Increased physician adoption of HIT also begins to create a culture of use and reliance on sophisticated HIT systems, easing the transition to a wholly electronic system in the future. Of course, not all hospitals and medical groups are in a position to help physicians adopt EMRs, but those that would like to cannot, due to, in large part, the fraud and abuse laws.

Creating links between large providers and their affiliated and unaffiliated physicians involves the provision of computer hardware, software, support, education, etc. Unless these HIT items and services meet certain criteria, including that they are provided at fair market value, these arrangements implicate federal fraud and abuse laws (e.g., the Stark II law, the Anti-Kickback Statute and the Civil Money Penalties Law). Because of the draconian sanctions associated with these laws (including incarceration, financial penalties, and mandatory or permissive exclusion from Federal health care programs), providers remain reluctant to enter into these arrangements.

Notably, a number of government agencies, including the General Accountability Office (GAO), the Office of the National Coordinator for Health Information Technology, and the Congressional Research Service, have stated that federal fraud and abuse statutes present barriers to arrangements between providers that would otherwise promote adoption of HIT.

Current Fraud and Abuse Exceptions and Advisory Opinions

While these fraud and abuse statutes provide both statutory and regulatory exceptions that protect certain arrangements between health care providers, **no existing exception applies** to any HIT arrangements where items or services are provided at less than fair market value. Similarly, the Stark II “community-wide exception” for HIT, though well intentioned, is unworkable, given its requirement that an institutional provider offer HIT services to every physician, resident, and practitioner in an undefined “community” who desires them. This requirement could provide an open door to spending that no hospital or health system could afford. Additionally, the exception requires that providers only offer HIT items necessary to enable the physician to participate in the community-wide system. Most vendor EMR systems include modules for accounting, billing, collection, etc., and as such would not be covered by the exception.

In 1996, Congress established a process whereby the HHS Office of Inspector General (OIG) would issue Advisory Opinions (AOs) concerning whether or not an existing or contemplated arrangement violates the Anti-Kickback Statute. Since 1996, the OIG has issued hundreds of AOs, however, this process is extremely time-consuming and is ill suited to serve as the mechanism to lower or eliminate the legal barriers to HIT adoption. It should also be noted that the Centers for Medicare and Medicaid Services has generally declined requests to issue AOs under the Stark law.

Interoperability

We understand concerns have been raised about the need to tie an exception to interoperability standards. However, since no standards yet exist, it would be a fruitless endeavor to provide the exception on the one hand and then essentially negate it on the other. Federal law should not be allowed to continue to hinder the adoption of HIT, particularly given its potential to increase quality and patient safety. Additionally, HIT can help the government ensure that patients do not receive unnecessary health care services, one of the primary objectives of the fraud and abuse laws.

Provider – Physician Relationships

Another concern raised suggests that the provision and support of HIT will lead to subtle, yet preferred, relationships between hospitals, medical groups and providers. Many other factors influence hospital-physician relationships, such as patient preference, insurer restrictions on patient choice, perceived quality of the hospital, and special services that a particular hospital may have available. In any circumstance, the physician is still subject

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to the fraud and abuse statutes. Furthermore, a computer-based system can help federal law enforcement agencies track possible violations of law much more readily than the current paper-based environment.

Again, we thank you for your leadership on HIT issues and express our appreciation for the exception to HIT arrangements from the fraud and abuse laws in your draft HIT bill. We believe this exception will result in far greater dissemination of HIT to physicians and, as a result, patients will receive better, higher quality care.

Sincerely,

American Hospital Association
American Medical Group Association
Association of American Medical Colleges
Federation of American Hospitals
Healthcare Leadership Council
National Alliance for Health Information Technology
Partners HealthCare System, Inc.