Stark Laws and the Electronic Health Record: An Unintended Paradox

Relaxing Stark laws may not help the adoption of interoperable electronic health records

The federal government currently limits what technology hospitals may provide associated practices, but loosening these rules may not help the spread of healthcare information technology.

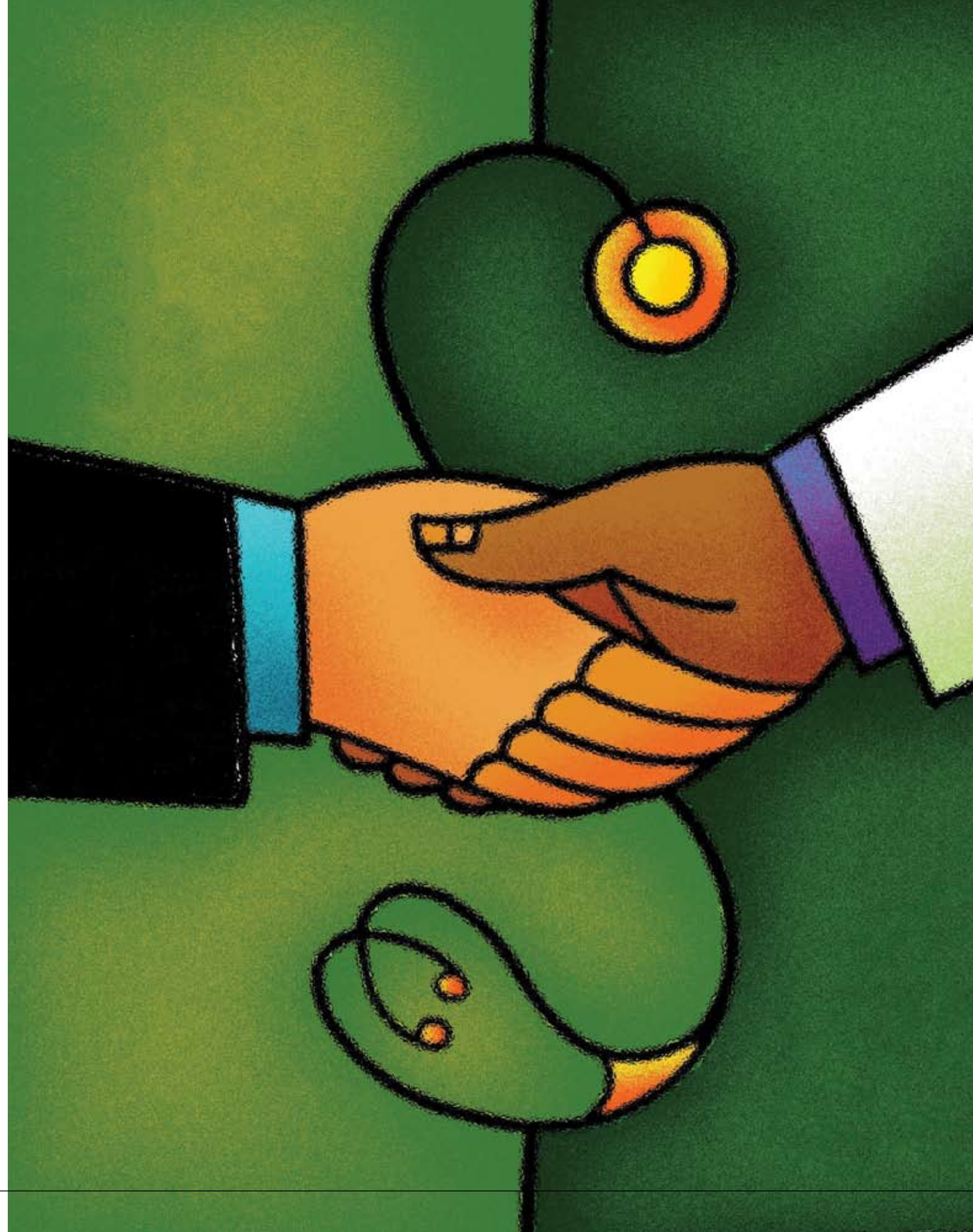
By **Dr. Allen S. Weiss**
President
NCH Healthcare System

"I'm from the government, and I'm here to help you," can be a humorous phrase with multiple and contrary meanings and connotations. In the context of healthcare information technology (HIT), the Stark law and the anti-kickback statute, this phrase highlights the phenomena of unintended consequences that come from well-intentioned laws as well as a nascent, and thus far futile, attempt by federal government to propagate the adoption of an interoperable electronic health record (EHR). In this article, we will explore these thoughts along with viable solutions for the adoption of a universally acceptable EHR.

Why an EHR?

President George W. Bush in his January 2006 State of the Union called for "wider use of electronic records and other health information technology to help control costs and reduce dangerous medical errors." Clearly, the president understands the current state of healthcare and wants to improve upon it. Modernizing healthcare will save lives and money.

We diagnose and treat using 21st century technology, but record and archive using 18th century methods. Banking, finance, transportation, communication and many other industries have embraced modern technology for quality and efficiency.



What are the Stark laws?

The Stark laws are federal anti-kickback and conflict-of-interest laws designed to keep physicians and hospitals from defrauding Medicare. Rep. Pete Stark, D-Calif. sponsored the initial legislation that passed in 1989, and a companion measure to the first law passed in 1993.

The laws, known as Stark I and Stark II, were designed to prevent physicians from self-referring patients—sending patients to facilities in which they have a direct financial stake. Penalties for violating these laws include exclusion from the Medicare program.

Stark supporters argue that the laws are needed to reduce overuse of Medicare and Medicaid. But the American Hospital Association (AHA), the Medical Group Management Association (MGMA) and the National Alliance for Health Information Technology (NAHIT) argue that the laws impede HIT adoption.

Proposed exemptions to Stark and anti-kickback laws are proceeding along two tracks—through the Department of Health and Human Services, which has the authority to establish such exemptions, and through legislation now before Congress.

Healthcare has been said to be the oldest profession and the newest industry. Healthcare is also the largest industry in the country. With more than $1.9 trillion dollars spent annually, healthcare accounts for more than 16 percent of the gross national product. If our healthcare system were a country, it would have the fifth largest economy in the world.

The United States is in a global economy. To compete with overseas manufacturers, healthcare costs must be controlled. "It is a well known fact that the U.S. auto industry spends more per car on healthcare than on steel," said Lee Iacocca, the retired chairman of Chrysler.

Consequently, General Motors and other U.S. automakers are moving manufacturing to Canada and overseas to lower total labor costs in an effort to remain competitive here and abroad.

Although healthcare has tremendous inefficiencies and waste, the industry now has the important opportunity to improve quality by using information technology. Nothing trumps quality, and improved quality decreases costs. Quality may be improved by providing the right information to the right person at the right time.

In 1960, there were 600 commonly prescribed medicines; in 2000 there were 6,000. No human can keep straight this quantity of information, including side effects and interactions.

Error prevention also can improve quality and efficiency. Hospitals have reported decreases in medication errors by using information technology. But the tools available to improve quality are not yet fully utilized. Evidence-based medicine has been shown to improve outcomes and decrease cost by decreasing variability. Total Medicare reimbursement (age, sex, illness and price adjusted) ranges from a low of $3,404 in Appleton, Wis., to a high of $9,033 in McAllen, Texas, according to the *Dartmouth Atlas*, 1999. IT would facilitate evidence-based medicine that in turn would decrease variation, improve quality and lower cost.

Thus far, HIT has been maturing at a faster rate in larger institutions such as hospitals and systems such as the Veterans' Administration Hospitals than in smaller entities. Small groups (less than 10) and solo-practice physicians provide more than half of the healthcare in the United States today. There is general agreement that the critical mass needed for economies of scale and scope requires these rank-and-file medical practices to adopt an interoperable EHR.

What can the government do to facilitate EHR adoption by small groups and solo practitioners? An early response has been to relax the Stark laws as this body of regulations relates to IT. This proposal has been named the Anti-Kickback Safe Harbors for e-Prescribing and EHRs. Simultaneously, Senate Finance Committee Chair Charles Grassley (R-Iowa) and ranking member Max Baucus (D-Mont.) have proposed the Medicare Value Purchasing Act of 2005. These initiatives should be understood as they relate to the EHR so that possible solutions can be presented.

The Stark laws

On Jan. 1, 1992, and Jan. 1, 1995, Stark laws I and II, respectively, were implemented. Stark II refined the earlier version. One portion of these laws is relevant for this discussion. The Stark laws prohibit physicians from referring Medicare patients to an organization that is paying the physician for the referral. This portion of the Stark law is straightforward.

Additional subjects covered by the Stark laws include provisions relating to physicians or groups of physicians referring patients to services directly owned by the physicians. Examples include an in-office laboratory, radiology unit or physical therapy service. If the physicians disclose their financial interest to the patients, the patients can decide whether to proceed with the service. Parts of the law are difficult to understand, interpret and enforce. Given these difficulties, the government took six years to release interpretations. At least 20 other topics not germane to the current discussion are contained in the Stark laws.

What is pertinent to this discussion is the fact that under Stark I or II, hospitals or other healthcare organizations may not give IT hardware, software or support worth more than $300 to a physician referring Medicare patients to that hospital. Thus, under the initial Stark I and II rules, hospitals must rely on physicians to independently implement office EHRs that will be interoperable with hospital systems, as well as other physicians, in the region or nation.

Congress recognizes the benefits along with the costs and difficulties of EHR implementation in communities. In an effort to ameliorate these challenges, the Stark Law Exceptions and Anti-Kickback Safe Harbors for e-Prescribing and EHRs were recently proposed.

Proposed safe harbors

On Oct. 11, the Office of the Inspector General of the Department of Health and Human Services (HHS) and the Centers for Medicare and Medicaid Services (CMS) jointly asked for comments on proposed rules covering more than 55 areas in which large healthcare systems, hospitals, pharmaceutical plans and Medicare Advantage could provide support for physicians to implement interoperable IT in their practices. The comments were due Dec. 12. This is an important step to gather opinions from IT support providers and those who want to implement IT.

These proposed regulations cover three levels, building one on another. The first, already in existence, is the Medicare Modernization Act of 2003 (MMA). This beginning step mandates electronic prescribing when IT is used to transmit and receive electronic prescriptions (e-prescribing). Although this requirement seems like a useful start, it potentially complicates existing office practices by creating a stand-alone system within pre-existing business or clinical software systems. Moreover, any start-up software must be created to permit a broader scope without rewriting itself.

The second, proposal, the "Pre-Interoperability Electronic Health Records Exception," calls for a dedicated EHR containing e-prescribing but no billing information or business support.

The third proposal, "Post-Interoperability Electronic Health Records Exception," includes both e-prescribing and the EHR as well as integrated billing and business data.

All three levels encourage adoption prior to mandating use as a requirement. The federal government has yet to specify how much money it would spend on any of the three. Under these proposed regulations, hospitals or other IT providers would not be able to choose recipients, namely physicians, on the basis of referral patterns.

The options above are only a few steps toward the adoption of an interoperable EHR. Simultaneous to collecting comments on the proposed Anti-Kickback Safe Harbors for e-Prescribing and EHRs, Sens. Grassley and Baucus have introduced the Medicare Value Purchasing Act of 2005. A pay-for-performance bill, the legislation also contains a provision that would reduce legal barriers to HIT adoption with exemptions to the anti-kickback and Stark laws.

Potential solutions

Two general approaches are available to the federal government and healthcare payers to encourage HIT. The knee-jerk response of legislating rules, which subsequently need exceptions, is usually not as effective as economic motivation. In the case of healthcare, the federal government has the option of using one or both vehicles. Advantages and disadvantages to both have been used successfully in other industries and countries.

Many factors will determine the speed and course of HIT adoption. Typically, change occurs over years and is driven by market forces. Adam Smith made this point in 1776 in his work, *Wealth of Nations*. It was later modified by John Nash's work, which won the Nobel Prize for economics. Nash showed that teams working together with individuals are more powerful change agents than individuals working alone. Nash's theory, combined with the federal government's dual role as sole legislative body and dominant payer in the market, should accelerate IT adoption.

The federal government traditionally leads change through legislation or taxation policy. However, in the case of healthcare, the federal government has one very unusual and powerful advantage—it is the single largest payer in the country, sharing an oligopsony (few buyers and many sellers) with private insurance companies. Medicare, Medicaid, and other public spending for healthcare account for 45.1 percent of the total spending in 2004, according to *Health Affairs*, January 2006.

While federal regulations are influential, ultimately financing IT adoption by large payers will be the most effective way to encourage technology use. HHS would be required to pay for providers' IT use, as recommended by Sens. Grassley and Baucus

Stark and Anti-Kickback Statute Proposed Exceptions

Proposed Exceptions	MMA mandated electronic prescribing exception	Pre-interoperability electronic health records exception	Post- interoperability electronic health records exception
Covered Technology	**Proposed:** Hardware, software, Internet connectivity, and training and support services that are necessary and used solely to transmit and receive electronic prescription information	**Proposed:** Software (must contain e-prescribing component to qualify for safe harbor) and training used solely for the purpose of EHRs	**Proposed:** Certified EHR software (must contain e-prescribing component to qualify for safe harbor) and related training. Possible inclusion of billing and registration with EHR software
Standards: Technology Must Comply	**Proposed:** Standards for e-prescribing as adopted by the Secretary of Health and Human Services	**Proposed:** Standards for e-prescribing as adopted by the Secretary of Health and Human Services	**Proposed:** Product certification and e-prescribing standards as adopted by Secretary of Health and Human Services
Interoperability	**Proposed:** To ensure competition in the marketplace donors are prohibited from limiting interoperability or otherwise imposing barriers to connectivity	**Proposed:** Same as e-prescribing exception	**Proposed:** Same as e-prescribing exception
Permissible Donors (only hospitals and managed care providers)	**Proposed:** Hospitals to members medical staffs, group practices to physician members, prescription drug plan sponsors, and MA organizations to physicians	**Proposed:** Same as e-prescribing exception	**Proposed:** Same as e-prescribing exception
Selection of Recipients	**Proposed:** Donors may not take into account volume/value of referrals from the recipient	**Proposed:** Same as e-prescribing exception	**Proposed:** May use criteria to select recipients but not take into account volume/value of referrals
Value of Protected Technology	**Proposed:** Specific dollar cap not yet determined	**Proposed:** Specific dollar cap not yet determined	**Proposed:** Specific dollar cap not yet determined

in the Medicare Value Purchasing Act of 2005. The legislation requires HHS to develop and implement value-based purchasing programs under Medicare for acute-care hospitals, physicians and practitioners, Medicare Advantage plans, end-stage renal disease providers and home health agencies. The bill would also require the department to take some initial steps toward value-based purchasing in skilled-nursing facilities.

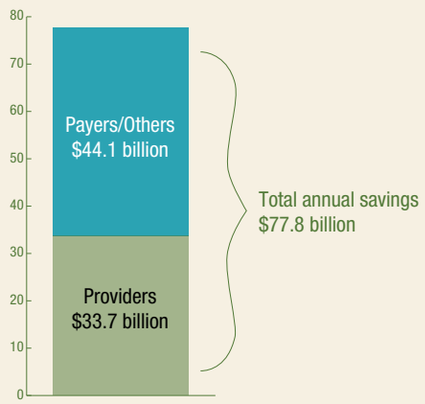
In the first stage, Medicare reimbursement updates will be tied to reporting data on quality measures. An intangible reward would be the increased efficiency and quality from IT use.

Because private insurers, who pay for 34.6 percent of healthcare, would also benefit, presumably they would follow suit by paying for IT use in clinical practices. This increased utilization of IT could be facilitated by governmental regulations and standards for interoperability, but the economic force still remains much greater than the regulatory force.

The beauty, now quantified, of paying for IT implementation is that the payback for the patient, payer and provider is huge and grows with adoption. Return on investment has been demonstrated conclusively in the recent RAND Corporation study by Richard Hillestad, Ph.D., and colleagues in *Health Affairs*, September/October 2005.

In general, as stated above, the federal government should encourage free enterprise by allowing the market to solve problems efficiently. However, the federal government is excellent at defining standards when a particular industry is ineffective in doing so. For example, early in the development of the railroad system in the United States, time zones were not standardized, leading to confusion when a train traveled across the country. The federal government established four time zones, solving the problem.

Potential Savings with an Interoperable EHR



Source: RAND Study, *Health Affairs*, Sept./Oct. 2005

Banking is an example of an industry taking an initiative, servicing its clients, and growing market share. The banking industry established communication standards so that ATM machines can be shared across banks and continents with modest fees. Banks maintain and grow market share by differentiating themselves on the basis of quality, responsiveness and service, not by maintaining stand-alone systems. Financial institutions have also established common standards so that money can be transferred safely and efficiently across the world. Banking used a combination of economic and regulatory forces to create change that was beneficial to all.

Entire countries such as Singapore have been very successful developing national information infrastructures using defined standards to respond to economic reality. As mentioned earlier using General Motors' unfortunate example, we compete in a global economy. We can and should learn best practices from other countries now and in the future. Ethnocentric pride, or the NIH syndrome—"Not Invented Here"—is deleterious to the economic health of our nation. We will need to interact with other countries in different ways than we do today. These approaches may include sharing healthcare information for patient care and/or supporting diagnosis or therapy.

For example, picture archiving and communication systems (PACS) have allowed higher-quality nighttime reading of radiographs on the other side of the world, which has a reverse diurnal pattern. Clinical and economic reasons abound for developing an HIT system that communicates facilely with other countries in addition to being seamless within the United States.

Singapore's success as a prototype city-state began with the quest for an incorporated digital infrastructure in 1992. IT connects citizens, businesses and government which, in turn, enhance Singapore's position as a global exchange for commerce. In this example, the government was successful in leading change using both legislation and direct financial support. Currently, the National Health Information System of Singapore is mature and robust, based on its 13 years of experience and centralized governmental structure. Small in size, Singapore had more motivation than the United States to develop other core competencies such as IT. Singapore's size and organized structure made this goal obtainable.

Hopefully, IT providers will realize that the whole market will grow when systems are interoperable. This would lead each system to compete on quality, efficiency, service and other defining competencies, while allowing for healthcare efficiency.

Potential problems

Who pays?

Is the payment mechanism and/or source of payment for IT implementation holding back its adoption nationally?

Thus far, caregivers have paid for their IT systems. These caregivers have benefited somewhat—but not as much as the patients and payers. Patients cared for in a functioning IT environment have a safer, higher-quality experience, while not having any additional out-of-pocket expense. Payers with implemented IT have lower costs due to fewer duplicate tests and improved quality. Similar to patients, payers have not had any additional expense for their cost savings. Lastly, caregivers who have paid for the installation and maintenance of IT have benefited by avoiding medical errors. However, these caregivers ultimately may lose revenue due to decreased utilization of services as the power of IT improves efficiency.

Policy changes such as the proposed Anti-Kickback Safe Harbors for e-Prescribing and EHRs have limitations. Because the typical profit margin of major not-for-profit hospital systems is less than 3 percent, the cost of implementing IT systems in physicians' offices could be overwhelming. Software and hardware costs, though high, are tangible and easy to estimate. However, training costs are less predictable due to high employee turnover and loose supervision in many physicians' offices. A hospital implementing

IT in a private setting is at a distinct disadvantage. The hospital, though not having control, would be blamed for any implementation frustrations or failures.

In addition, typically 20 percent of physicians on a hospital staff provide 80 percent of the admissions. However, current regulations require all physicians on staff to be offered the IT system. This requirement may be democratic, but is it cost effective? Overall, poorer communities would not have the resources to share technology due to capital expense.

Can policies effectively lead change?

Whether change can be mandated by government without an unforeseen consequence is another major area of concern. Rules gone awry include rent control in New York City, which exacerbated slum conditions (according to *Basic Economics: A Citizen's Guide to Economics* by Thomas Sowell); immigration quotas, which have prevented healthcare workers from entering the United States; draft laws, which pushed young men out of the country; and prohibition, which encouraged illegal activities—just to mention a few.

The Stark laws' provisions to stop fraud and abuse were well intentioned but created unintended consequences. First, interpretation and enforcement have created an economic boom for a cottage industry of attorneys conversant with this aspect of healthcare law, misdirecting limited resources. Second, Stark I needed to be modified by Stark II due to unforeseen ambiguities. Third, the law took six years to implement. Additionally, a patch—safe harbor legislation—to the revised law is currently being written and commented upon as a further "tweaking" of the original Stark law. Will a fourth revision be needed? This governmental law-making process is not nearly as effective or efficient as economic motivation, namely, paying caregivers more who use IT who, in turn, will be more productive, thus lowering costs.

Why is change so difficult?

Change is very difficult as examples throughout history illustrate. ATM machines were invented in 1939 and revived in the mid-1960s. Widespread acceptance, however, has been over the last 15 years. Why? Banks and bank tellers have a vested interest in maintaining the old system even though a face-to-face transaction costs about $25 compared to about $5 for an ATM transaction and less than a dollar for an Internet transaction.

"We've been through this before" said Alissa Spielberg in 1998 and as recaptured by Jeff Goldsmith in *Digital Medicine—Implications for Healthcare Leaders*. The telephone was first resisted because of lost privacy and security, intrusion into personal space, increased solicitations, eavesdropping facilitation, unwavering dependency on technology and incredibly, the fear of "wire-transmitted germs." Now the phone is passé—one has only a 25 percent chance of connecting with the person being called. E-mail is favored. However, healthcare is having trouble converting clinical communication to e-mail.

Similarly, bar coding, available for more than 50 years, has been used in healthcare only recently. Fortunately, the rest of the world is becoming digital, so the workforce is familiar and comfortable with this technology. Thomas Friedman makes this important point in his bestseller, *The World is Flat*. Stopping an old process is harder than starting a new process. Laws and legislation do work, but slowly. Economic "carrots" are more effective. In healthcare, positive feedback, namely payment for IT, is more effective than laws or safe harbors within these laws that prohibit or subsequently allow behaviors.

Summary

Ultimately, the right thing to do in caring for patients is to provide quality using the best tools (IT) available for operational efficiency. During evolutionary times, market share will shift as will profit margins for hospitals, caregivers and payers. Those with the most to lose will resist the most; but in the free market with the exchange of information, change is inevitable.

The unintended paradox is that the Stark laws and the safe harbor regulations will probably have little influence on EHR adoption. The free market, led by the largest payers, namely Medicare and Medicaid, will have a greater influence. By paying providers a premium for IT use, the payers will save money and lead change. No one needs to be economically punished; just let the free market work. Using Nash's principle, individuals and teams of individuals, namely physicians or hospitals and regions or whole countries, together will win the race to use IT in healthcare.

Changing or relaxing governmental regulations will add confusion and will not reverse the unintended paradox of the Stark law and safe harbors. Payment toward caregivers who embrace IT will make a change. If one believes IT creates quality and efficiency in healthcare, then both the providers using IT and the payers benefiting from IT will benefit. Both entities should share in the cost of implementation. TCQ

Dr. Allen Weiss
President
NCH Healthcare System

Dr. Allen Weiss is president of NCH Healthcare System in Naples, Fla. He joined the NCH medical staff in 1977 specializing in internal medicine/rheumatology and geriatrics and was named to the leadership post in 2000.

In July, Weiss testified to the Health Subcommittee of the House Committee on Ways and Means in Washington, D.C., on his current role helping to lead a major HIT implementation to improve quality and efficiency. He shared his experience to demonstrate the critical importance of increased widespread use of HIT.

As president of NCH, Weiss works with the board and management to establish long-range goals, strategies, plans and policies. He works individually with executive staff to assist in the development of institutional policies and objectives; coordinate efforts to integrate services and programs; and oversee and direct the medical staff in planning and implementing services to meet the community's needs.

Weiss received his medical degree from the College of Physicians and Surgeons of Columbia University in New York City. He is board certified in rheumatology, internal medicine and geriatrics. He is a fellow of the American College of Physicians and a fellow of the American College of Rheumatology. In 2001, he received his master's degree in business administration from Florida Gulf Coast University in Fort Myers, Fla.