Exemptions to Stark Laws Aim To Speed Health IT Adoption

BY MARY ELLEN SCHNEIDER
New York Bureau

Hospitals, health plans, and other health care organizations will soon be able to assist physicians in obtaining health information technology without running afoul of federal fraud laws under regulations issued last month by the Department of Health and Human Services.

In two final regulations published in the Federal Register on August 8, the Centers for Medicare and Medicaid Services and the HHS Office of Inspector General carved out new exceptions to the Stark physician self-referral law and the federal antikickback statute. Under these new exceptions, certain health care entities will be able to donate interoperable electronic health record (EHR) software and training. And hospitals and other health care organizations will also be able to provide hardware, software, and training services that are "necessary and used solely" for electronic prescribing.

The regulations, which go into effect in early October, did not cap the donations to physicians for electronic prescribing technology, but the government is requiring physicians to share some of the costs of donated electronic health record technology. Under the rules, physicians will be required to pay 15% of the donor's cost of the EHR technology and services.

The regulations were widely praised by physician organizations and health IT industry groups for breaking down barriers to physician adoption. But Patrick Hope, legislative counsel for the American College of Physicians, said the changes aren't likely to do a whole lot to speed physician adoption of the technologies since few hospitals will be able to afford to donate the expensive technology to physicians. "They are operating at the margins just as physician offices are," Mr. Hope said.

ACP officials are urging members of Congress to establish an add-on payment to the Medicare reimbursement for an office visit in an effort to help offset the ongoing costs of an electronic health record system, Mr. Hope said. While the regulations are helpful in removing some barriers, he said, an add-on payment would create a better business case for physician adoption of health IT.

The jury is still out as to what impact these regulations will have on physician adoption, said Chantal Worzala, senior associate director for policy at the American Hospital Association. Not all hospitals will have the financial resources to donate health IT services, she said, since only about a third of U.S. hospitals are making a profit.

But the regulations will give hospital administrators more options. "Hospitals really should have flexibility in working with community physicians," she said.

The relaxation of the Stark physician self-referral law and the antikickback statute is a good thing, said Dr. Steven E. Waldren, assistant director of the American Academy of Family Physicians' Center for Health Information Technology, since the changes will allow more health IT resources to flow to physicians. However, he cautioned physicians not to count on getting this support.

This type of support won't be available to all physicians and in some cases may not be appropriate, he said. For example, Dr. Waldren said that some hospital electronic health record systems are not designed for the ambulatory environment and may end up costing physicians more money in the long run. The bottom line is that physicians need to continue to do their "due diligence" in researching systems, he said.

The Medicare Modernization Act of 2003 mandated that the HHS Secretary create exemptions that would allow for certain health care organizations to help furnish physician practices with electronic prescribing technology. The changes were originally outlined in a proposed rule issued last October.

Under the provisions related to electronic prescribing technology, hospitals can donate hardware, software, and services to members of their medical staffs; group practices can donate to physician members; and Medicare prescription drug plan sponsors and Medicare Advantage plans can donate to pharmacies and prescribing physicians. The Stark law exemption and antikickback safe harbors have slightly different definitions of who can donate the comprehensive electronic health record system software and training.

The electronic prescribing safe harbors and exemptions allow organizations to donate hardware, software, Internet connectivity, and training and support services. The provisions for electronic health records are slightly different and do not include hardware. For EHRs, organizations can donate software, which must include an electronic prescribing component. ■

Panel Certifies First 22 Ambulatory EHR Products

The Certification Commission for Healthcare Information Technology has unveiled an initial list of 22 ambulatory electronic health record products that meet its standards for functionality, interoperability, and security.

CCHIT was formed in 2004 by three leading health IT management and technology industry associations. Since last fall, CCHIT has been under contract to the federal government to develop certification criteria for EHRs and evaluate products. The CCHIT process has also been endorsed by the American Academy of Family Physicians, the American College of Physicians, and the American Academy of Pediatrics.

The certified products are designed to serve the spectrum of physician practices.

DR. LEAVITT

In this first round, CCHIT officials gave their seal of approval to 22 products that met all certification standards. Going forward, CCHIT officials will evaluate ambulatory EHR products on a quarterly basis, and are expected to make the next announcement about newly certified EHR systems in late October. In the meantime, the group will begin work on certification for inpatient EHRs and for the network systems that support information exchange between physicians and health care institutions.

The certified products are designed to serve the spectrum of physician practices, Dr. Mark Leavitt, CCHIT chair, said during a press conference. Vendors whose products were certified in this first round received a CCHIT seal of approval that the product met 2006 standards, Dr. Leavitt said. That certification is good for up to 3 years or vendors can come back to CCHIT each year to be certified under the updated standards, he said.

"This is just a first step along a long, long path," Health and Human Services Secretary Mike Leavitt said during the press conference.

Leaders in health IT are quickly approaching the time when they will no longer have to sell people on the benefits of EHRs, he said, but there is a need to continue to talk about the importance of the interoperability of these systems. In the long term, interoperable systems will become a condition of doing business with the federal government, said Mr. Leavitt, who is not related to Dr. Leavitt.

—Mary Ellen Schneider

The full list of certified products is available at www.cchit.org.

Targeted Medicine Should Look to Attributes, Not Race

BY JOYCE FRIEDEN
Senior Editor

BALTIMORE — Targeting medicines at specific racial categories "is a misguided approach, and what we should be pursuing is attribute-based medicine," Sharona Hoffman said at the annual meeting of the American Society of Law, Medicine, and Ethics.

One example of a medicine targeted at racial categories is BiDil (fixed-dose isosorbide dinitrate and hydralazine), a heart failure drug that was approved specifically for use in blacks. Some experts say that a good response to BiDil has more to do with attributes and genes than it does with self-identified race.

Patient attributes that might be considered relevant for assessing disease vulnerability or treatment responses include genetic variations or alleles that might be more common for people who are of one ancestral origin rather than others but could still cross population lines. "Then there are other factors such as diet, exercise, stress level, and exposure to toxins" that play into treatment response, said Ms. Hoffman, a professor of law at Case Western Reserve University in Cleveland.

"The Human Genome Project showed us that race is not a biologically valid or genetically valid concept, and therefore the emergence of 'race-based' medicine is both perplexing and troubling," she said at the meeting, cosponsored by the University of Maryland. "Race doesn't mean much of anything" from a genetic perspective because "99.9% of genes are identical for all humans," and in the remaining 0.1%, 90%-95% of genetic variations are found at equal rates in every population.

Society also has difficulty defining race, with legal definitions of race varying from one state to another, Ms. Hoffman said. The race categories listed in the U.S. Census also change every decade. Almost 7 million people checked off more than one race in the 2000 census, she noted.

"If you ask people to self-identify, they may say they're African American when they are really of mixed race. And visual observation is even more misleading."

In addition to these problems, using "race-based" medicine may exacerbate health disparities, because "it's possible doctors may try to specialize in treating blacks or whites," said Ms. Hoffman. That may violate federal or state antidiscrimination laws.

Instead of pursuing race-based protocols, Ms. Hoffman recommended designing attribute-based trial protocols, and having institutional review boards and scientific review boards subject them to special scrutiny.

"Consider the genetic variations and the psychosocial, economic, cultural, environmental, and other factors, which you can measure or ask about—stress, diet, exercise, exposure to toxins, and cultural and religious barriers to treatment compliance," she said. "Maybe people aren't doing well because they are not following the protocol—because they either don't understand it [due to] a language barrier, or they have religious beliefs that prevent them from doing some of the things you need them to do.

"Don't use skin color as a proxy. What questions do you need to ask? Do you need to do further genetic testing?," she said. ■