

May Encourage EHR Adoption

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scribing, despite the fact that widespread use of electronic prescribing could save the U.S. health care system as much as \$27 billion, as estimated by the Center for Information Technology Leadership.

"Part of the problem is that the people who are being asked to take the time and to spend the money to put this in their offices—the physicians—aren't necessarily the ones who get the financial benefit," she said.

That's why the coalition has come together to offer physicians an option that is not only free, but takes 15-30 minutes to learn, said Dr. Dickey.

"It is a truly easy system," said Dr. Azar Korbey, a family physician in Salem, N.H., who has been testing the software for the past year. Even someone who is not computer savvy should be able to learn the system in under 40 minutes, Dr. Korbey guessed.

NEPSI's efforts may be just the kickstart some physicians need, said Dr. Wilson Pace, director of the American Academy of Family Physicians' National Research Network and a member of the

IOM committee that produced last year's report on medication errors.

"This appears to be a relatively safe way to try out something and get started for somebody who is not quite clear where they want to go," he said in an interview.

There also is a growing incentive to adopt electronic prescribing, Dr. Mark McClellan said at the NEPSI launch.

Part D plans already are required to support electronic prescribing and Medicare Advantage plans are moving toward adoption of similar standards. Even in traditional fee-for-service Medicare, the Centers for Medicare and Medicaid Services is expanding efforts to boost reimbursement to physicians who report quality data, said Dr. McClellan, former CMS administrator and now a senior fellow at the AEI-Brookings Joint Center, a Washington think tank.

"It all fits together in supporting the movement toward electronic prescribing to get to better quality care at a lower cost," he said.

But this is not something that the gov-

ernment can achieve alone. Partners in the private sector are crucial, he said.

To that end, the initiative is being wholly funded by the coalition of private stakeholders at an estimated cost of \$100 million for the first 5 years. That is in contrast to other free electronic prescribing software that requires physicians to market personal health records or other products to patients.

The companies that are supporting and paying for NEPSI see this as an investment in the future, said Glen Tullman, chief executive officer of Allscripts Inc., which is leading the effort.

"Down the road, we're very hopeful that this encourages adoption of full electronic health records, and Allscripts is a leading provider of those health records," he said at the briefing.

"But I want to make it very clear that our first objective is to equip every physician in the United States with electronic prescribing software that is absolutely free of charge," in an effort to improve patient safety, he added.

Such a large coalition of payers and vendors has the potential to put a real dent in the problem, said Dr. Pace.

"The primary care system in England is

Who's on Board?

Members of the National ePrescribing Patient Safety Initiative include:

- Allscripts Inc.
- Dell Inc.
- Cisco Systems
- Fujitsu Computers of America
- Microsoft Corp.
- Sprint Nextel
- Wolters Kluwer Health
- Aetna
- WellPoint
- SureScripts
- Google
- Twelve regional health care organizations

virtually all electronic. The driving force behind that initially ... was stand-alone prescription systems," he said.

It is not clear how physicians in this country will feel about adopting an electronic prescribing system that is not integrated with electronic medical records, but "there's no question it's a step up from paper," said Dr. Pace. ■

Hospitals Slow to Make Gainsharing Arrangements Due to Legal Fears

BY MARY ELLEN SCHNEIDER
New York Bureau

Hospitals are reluctant to offer physicians a portion of the savings generated by reducing clinical costs—a concept known as gainsharing—because of legal fears, D. McCarty Thornton, said during an audioconference on gainsharing sponsored by the Integrated Healthcare Association.

"It's clear, I think, that gainsharing is not on the fast track," said Mr. Thornton, a partner with the law firm of Sonnenschein, Nath, and Rosenthal LLP, based in Washington.

In the long run, gainsharing approaches that can save money without impacting patient care are likely to take hold, he said, but first hospitals need clarification from Congress, the Health and Human Services secretary, and the Office of Inspector General about what arrangements are allowed.

In 1999, the HHS Office of Inspector General issued a special advisory bulletin saying that the civil monetary penalty provision of the Social Security Act prohibits most gainsharing arrangements. Under that provision, hospitals are prohibited from making payments to physicians to reduce or limit services to Medicare and Medicaid beneficiaries.

The bulletin said that these types of arrangements could also trigger the antikickback provisions of the Social Security Act, which prohib-

it arrangements used to influence the referral of patients in federal health care programs.

"Historically, the office has been somewhat leery of gainsharing arrangements," said Catherine A. Martin, OIG senior counsel.

Since the 1999 bulletin, the OIG has issued a number of advisory opinions which outline gainsharing arrangements that would be allowable.

In general, in order to give the green light to a gainsharing arrangement, the OIG looks for transparency and accountability, quality of care controls, and safeguards against kickbacks, Ms. Martin said.

In order to be transparent, any actions taken to save costs need to be clearly and separately identified and fully disclosed to patients. Hospitals must also put in place controls to ensure that cost savings do not result in the inappropriate reduction of services. OIG officials also want to see ongoing monitoring of quality by the hospital and an independent outside reviewer, Ms. Martin said.

But OIG is not the only regulator that hospitals and physicians need to consider when embarking on gainsharing arrangements, Ms. Martin said. Hospitals and physicians must also keep from running afoul of the Stark self-referral prohibitions, which fall under the purview of the Centers for Medicare and Medicaid Services.

Gainsharing arrangements must also meet Internal Revenue Service rules, and hospitals are at risk for private lawsuits, she said.

But the industry is keeping an eye on two demonstration projects that test the gainsharing concept in the Medicare fee-for-service program. Both projects are set to begin this year.

The first project, which is required under the Deficit Reduction Act of 2005, will involve 6 hospitals and will focus on quality and efficiency in inpatient episodes and during the 30-day postdischarge period. The DRA provision waives civil monetary penalty restrictions that would otherwise prohibit gainsharing.

The second project will focus on physician groups and integrated delivery systems and their affiliated hospitals.

The demonstration will include inpatient episodes, as well as the pre- and posthospital care over the duration of the project. This demonstration was mandated the Medicare Modernization Act of 2003.

Participants in both demonstrations will be required to standardize quality and efficiency improvement initiatives, internal cost savings measurement, and physician payment methodology, said Lisa R. Waters, a project officer with the division of payment policy demonstrations at CMS.

But CMS officials are looking to test various gainsharing models so participants will have flexibility in how they choose to target savings from reducing the time to diagnosis and treatment to improving discharge planning and care coordination. ■

Agency Initiates Stricter Medical Glove Standards

The Food and Drug Administration has issued a final rule that would require medical glove makers to improve their products' ability to serve as a barrier against pathogens.

Manufacturers are being given 2 years to comply with the new regulations.

The goal is to reduce the risk of transmission of blood-borne pathogens such as HIV and hepatitis B, according to the FDA. While the agency can't quantify how many cases might be prevented with better barriers, it estimated that approximately 2.4 HIV infections occur each year due to "problems with the barrier protection properties of gloves used in health-care settings."

The FDA estimates that 140 health-care workers are infected with the hepatitis B virus (HBV) on the job each year, primarily from percutaneous injuries. About a third, or 40 cases, may be due to glove defects, according to the agency.

There is less evidence that glove defects are associated with hepatitis C, said the agency, noting that most occupational exposures are from needle sticks. The agency has inspected gloves—used for patient examinations and surgical procedures—since 1990. At that time, the International Organization for Standard-

ization (ISO), ASTM International, and the FDA had the same standards for glove quality. A few years later, the ISO and ASTM began requiring higher standards.

The agency has allowed a defect rate of 4% for gloves used during patient exams and 2.5% for gloves used in surgery.

With more and more brands of gloves being marketed and sold, the agency hopes to maintain that defect rate. To do so means increasing the quality standards, said the agency.

The FDA estimates that about 2% of the 39.2 billion gloves currently marketed are defective—some 940 million gloves. There are more than 400 manufacturers, but the number of gloves made and sold is expected to vastly increase in the next 10 years. If standards were left at their current level, 10 years from now, some 1.2 billion defective gloves would be sold.

The agency said the benefits of higher standards will outweigh the costs. It will cost about \$6.6 million a year, but will result in savings of about \$15 million due to reduced need for blood screens and fewer infected health-care workers.

The agency said it will continue to fail lots that have pinholes or visual defects.

— Alicia Ault