Changes Ahead for National Practitioner Data Bank

BY JOYCE FRIEDEN
Senior Editor

PHILADELPHIA — A new service being offered by the National Practitioner Data Bank will make it easier for hospitals and other institutions to find out when a physician with privileges at their institution has had a data bank report filed on him or her by another entity.

The new program, called the Proactive Disclosure Service, is expected to start next spring, according to Shirley Jones, senior policy analyst at the Health Resources and Services Administration, Rockville, Md., which runs the data bank. The service allows the entity—a hospital or other facility—to register all practitioners who could potentially be subjects of data bank reports. "Then, if the data bank gets a report on that practitioner, the data bank will automatically send the report to that entity," she explained, adding that the new program is "an alternative to, not a replacement for, the current querying service." Ms. Jones spoke at the annual meeting of the American Health Lawyers Association.

There will be a small charge to the facility for each person it registers, probably around $3 per practitioner, she said. Different entities can register the same practitioner.

Another change is a proposed regulation known as Section 1921, which will expand the data bank's reach, Ms. Jones continued.

"Section 1921 will expand the data that's in the data bank," she said. "State licensing authorities must [now] report all adverse licensing actions about all practitioners," not just physicians and dentists. That means hospitals and other organizations can query the data bank on other health professionals such as nurses, respiratory therapists, and massage therapists, she said.

Another part of Section 1921 would require peer review organizations to report negative actions taken against individual practitioners. However, she noted, quality improvement organizations (QIOs) would be exempt from that requirement under the proposed rule.

When it published the proposed rule earlier this year in the Federal Register, the Health Resources and Services Administration explained why it is exempting QIOs. "First, the critical mission of the QIO program is its focus on maintaining collaborative relationships with providers and practitioners to improve the quality of health care services delivered to Medicare beneficiaries," the agency noted. "The reporting of QIO sanction recommendations to the National Practitioner Data Bank will significantly interfere with the progress that has been made toward this goal and will substantially reduce the ability of QIOs to carry out their statutory and contractual obligations."

The agency also expressed concern that requiring QIOs to report recommended sanctions to the data bank "may create misconceptions about the meaning of QIO sanction recommendations," since they are only recommendations and may not always be acted on. The agency is still reviewing comments it has received on the proposed rule.

In addition to the new regulations it is proposing, the data bank also has developed a compliance program to make sure that it is getting all the reports it should. Data bank officials compare actions that have been documented on state licensing board Web sites with what is in the data bank; they also look at newspapers, magazines, and public media "to see if we're missing something," Ms. Jones said. ■

Attribute-Based Protocols Urged To Reverse 'Race-Based' Trend

BY JOYCE FRIEDEN
Senior Editor

BALTIMORE — Targeting medicines at particular 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), an antihypertensive drug that was approved specifically for use in blacks. Some experts have concluded that a good response to BiDil has more to do with attributes and genes than it does with racial identity.

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, which was 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.

Also, be aware of the limits of self-identification or identification through visual observation. "It's very hard to tell what ancestry people have if you don't ask specific questions," Ms. Hoffman said. ■

McClellan Resigns as CMS Chief

As physicians fight to avoid a proposed 5.1% payment cut under Medicare slated to take effect in January, it's unclear who will be leading the agency responsible for administering Medicare.

Dr. Mark B. McClellan resigned as administrator of the Centers for Medicare and Medicaid Services in early September after a 2½-year tenure with the agency. At press time, no acting or permanent replacement had been named by the White House.

Dr. McClellan, who previously served as commissioner of the Food and Drug Administration and as an economic adviser to President Bush, said that he is considering a move to a Washington-area think tank in the short term. He is also on leave from Stanford (Calif.) University, where he holds teaching posts in medicine and economics.

In a press briefing announcing his resignation, Dr. McClellan said he will stay on at CMS for a period to aid in the transition.

Dr. McClellan said that after several years in government service, he wanted to spend less time on the road and more time with his family. "This kind of decision is never easy and there's never a great time for it," he said.

He took the reins at CMS just months after the passage of the Medicare Modernization Act and has presided over the transition to the Medicare Part D drug benefit.

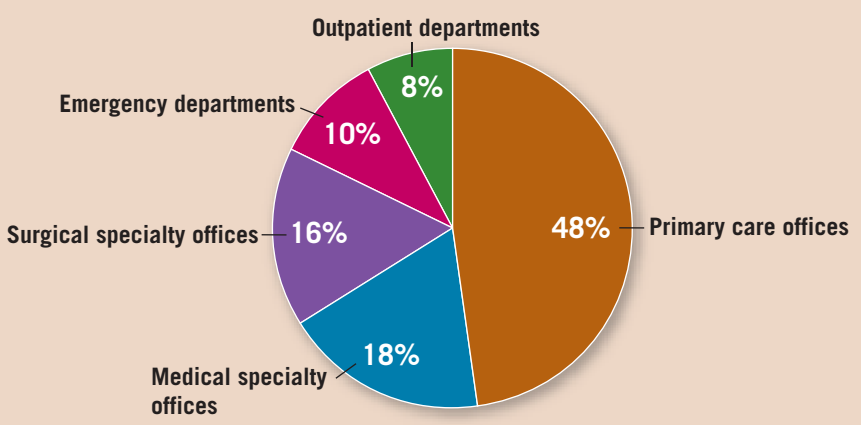
There has been momentum on all new initiatives at CMS, including the Part D benefit, he said. Dr. McClellan touted the progress of the Part D program, including lower-than-forecast beneficiary costs and an overall high rate of participation and beneficiary satisfaction.

Dr. McClellan is board certified in internal medicine and earned a PhD in economics from the Massachusetts Institute of Technology. In addition to his work in the Bush administration, Dr. McClellan served in the Treasury Department under President Clinton. Before working in the federal government, Dr. McClellan was an associate professor of economics and medicine at Stanford University.

—Mary Ellen Schneider

DATA WATCH

Almost Half of the 1.1 Billion Ambulatory Care Visits in 2004 Were to Primary Care Doctors



Source: Estimated data, Centers for Disease Control and Prevention

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