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Medicare slammed for not improving lab-quality rules

By Joyce Howard Price
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Some scientists and consumer health groups are angry that the U.S. Centers for Medicare and Medicaid Services (CMS) has decided not to write new rules designed to improve the quality of laboratories that perform genetic testing, keeping in place current guidelines.

"We're very disappointed," said Rick Borchelt, spokesman for the Genetics and Public Policy Center. "After years of saying they were going to do this, they did a complete about-face ... with no justification. We're mystified."

Late last month, the Genetics and Public Policy Center -- along with the Genetic Alliance and the Public Citizen Health Research Group -- filed a petition with CMS demanding the agency create a "genetic testing specialty" under the provisions of the Clinical Laboratories Improvement Amendments (CLIA) of 1988, which CMS administers.

The groups argued that additional regulation was necessary to ensure high-quality genetic test results, which they say are now used to diagnose more than 900 diseases.

"Making sure that laboratories can accurately and reliably perform genetic tests is a fundamental requirement for the success of genetic medicine, and a fundamental obligation of CMS," said Kathy Hudson, director of the Genetics and Public Policy Center.

"In 2000, CMS thought the creation of rulemaking with CLIA was a good idea," said Catherine D. O'Connell, a senior scientist with Tetracore Inc., a biotechnology research and development firm in Rockville. Until just a few months ago, she and others said, CMS said new rules to strengthen and ensure the quality of genetic labs should be under CLIA.

But now CMS says it "will focus on beefed-up oversight of genetic testing labs under current rules," Miss O'Connell said.

CMS recently informed an advisory panel that oversees CLIA that it has "scrapped the rulemaking effort," even though work to establish "specialty requirements for genetic testing" had been under way for years.

In an e-mail, CMS confirmed it has decided "there will not be a CLIA genetic testing standard" and offered a half-dozen explanations.

Key among them, CMS said, is that a "CLIA regulation would not resolve the problem that these tests are not currently FDA-approved, and, therefore, not clinically validated."

Besides, CMS said, it has no data indicating genetic testing labs "have any more problems than labs doing other kinds of testing."

Furthermore, the federal agency said, it is still not clear how such rules would address a host of sensitive moral issues, such as when doctors use tests that could show a patient is suffering from an incurable disease predict how long that patient will live.

CLIA standards "would not fix ethical, legal and social issues associated with genetic testing," CMS said.

What's more, CMS said, the genetic testing field is "so dynamic, it would be impossible to write prescriptive standards for these tests that would not go out of date before they are published."

Meanwhile, the Food and Drug Administration (FDA), which says it wants to take over the regulation of genetic testing, has been sending letters to clinical labs that do such testing. The letters warn the labs that they are violating federal law by providing these "unapproved medical devices (tests)" to clinicians, said Richard A. Samp, chief counsel of the Washington Legal Foundation. The labs were told they can "either submit voluntarily to FDA regulations" or stop providing the tests, he said.

The public interest law firm recently filed a citizen petition with the FDA, calling on the agency to cease its efforts to enforce its "medical device" regulations.

An FDA spokeswoman said the agency has fully explained why it thinks it should be regulating genetic tests in congressional hearings.