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ADVOCATES DEMAND CMS RULEMAKING ON GENETIC TESTING LABS

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A coalition of researchers and consumer advocates is petitioning **CMS** to increase its oversight of, and set performance standards for, genetic testing laboratories in a move that may hint at upcoming litigation. The push comes as HHS touts genomics as a way to cut health care costs and personalize care, and **CMS** is deferring to FDA's authority to approve safe genetic testing procedures.

In a separate petition, the Washington Legal Foundation (WLF) recently criticized FDA for sending out about two dozen warning letters to clinical labs over the summer, telling them their diagnostic tests are subject to premarket approval by FDA as medical devices. Such "new substantive policy" requires a proper rulemaking process that allows public comment, the legal watchdog claims.

Senate health committee Ranking Democrat Edward Kennedy (MA) is working on legislation that would clarify that FDA has the authority to regulate genetic tests, which the lawmaker said Sept. 22, in an apparent reference to WLF, "some have questioned."

It would direct FDA how to exercise this authority, and clarify that when FDA has cleared or approved a diagnostic, similar lab tests must also be cleared or approved by the agency, according to a Kennedy press release.

While WLF questions FDA's role in approving testing procedures, the coalition of researchers and consumer advocates criticizes **CMS** for not ensuring these tests are properly conducted, potentially putting patients and medical professionals in danger.

The research organization Genetics and Public Policy Center and advocacy groups Public Citizen and Genetic Alliance signed the Sept. 26 petition.

The coalition wants **CMS** to resume a rulemaking process that never really got off the ground, and create a "genetic testing specialty" under the Clinical Laboratories Improvement Amendments (CLIA) of 1988, which **CMS** administers. Currently, many genetic testing labs forgo CLIA certification or seek certification as a chemistry or other type of lab, according to an expert.

But, the source said, "testing of blood for salt levels is very different from conducting genetic tests. It requires totally different skills."

Genetic researchers may fear that the public will lose confidence in their work without clear performance standards, and that insurers will stop paying for their services, the source suggested.

However, at a National Institutes of Health committee meeting in June -- two months after placing a proposed rule on genetic testing labs on its semiannual regulatory agenda -- a **CMS** official declared that current regulations were adequate to ensure the accuracy and reliability of genetic testing labs.

"A CLIA regulation would not resolve the problem that these tests are not currently FDA-approved and therefore, not necessarily clinically validated," a **CMS** spokesperson said. "**CMS** has no data that indicates there are any more problems in these [genetic testing] labs compared to labs performing other types of tests.

"Since the field is so dynamic, it would be impossible to write prescriptive standards for these tests that would not go out of date before they were published."

CMS continues to review tests and oversee labs with the help of FDA and the Centers for Disease Control

and Prevention, the spokesperson said. The agency is also working with accrediting organizations, surveyors and other partners to increase education and compliance.

The issue was said to become a major point of discussion at the **American Society of Human Genetics'** Oct. 9-13 conference in New Orleans, LA, where coalition members were expected to rally support among industry stakeholders.

Sen. Barak Obama (D-IL) introduced legislation Aug. 3 that would require FDA to assess its regulation of genetic tests, task the Institute of Medicine to suggest improvements to government regulations of genetic tests, and develop a "biobank" database that would store and evaluate genomic information.

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