

Feds urged to issue genetic testing rules

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Johns Hopkins scientists are urging U.S. officials to issue rules concerning genetic testing to assure the quality of such procedures.

The Genetics and Public Policy Center at the Baltimore university this week asked Mark McClellan, administrator of the Centers for Medicare and Medicaid Services, to issue a proposed rule to create a genetic testing specialty under the Clinical Laboratory Improvement Amendments of 1988.

Center researchers said the delay in issuing such a rule has allowed scientific and technological advances in genetic testing to outpace the government's ability to provide adequate oversight.

McClellan's facility administers diagnostic laboratory testing standards, such as those used for blood sugar, urinalysis, or HIV infection, to ensure the tests are accurate and reliable.

"For more than 10 years, federal advisory committees have been calling upon the government to provide more oversight of genetic tests," the letter to McClellan said.

"These genetic tests may be the basis for profound life decisions, such as whether to undergo prophylactic mastectomy, terminate a pregnancy, or take a certain drug or certain dosage of a drug," the Johns Hopkins researchers said. "It's time to move swiftly to protect the American public and publish a proposed rule."

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