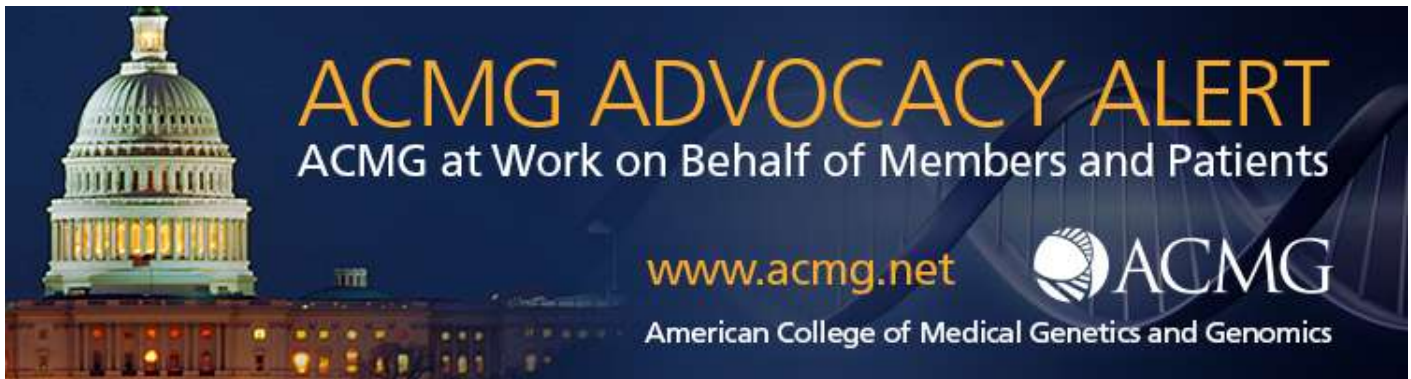


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January 12, 2018

Urgent Request: Members Urged to Submit Comments on Proposed CMS National Coverage Determination Affecting LDTs

ACMG wants to make our members aware of a recent Centers for Medicare and Medicaid (CMS) proposed National Coverage Determination (NCD) which has serious consequences for laboratories performing genetic tests and for patients who should benefit from the full range of genetic tests. The College will be providing an official response; however, members are urged to submit additional comments.

The deadline for submitting comments is January 17.

ACMG and many others are concerned that CMS in this NCD has established a coverage standard which will allow the FDA to effectively regulate Laboratory Developed Tests (LDTs), which ACMG and other organizations have long opposed. This is also contrary to FDA's long-standing policy of "enforcement discretion" in not regulating LDTs.

The CMS NCD is accessible [here](#).

The concerns about the proposed NCD are described further [here](#) (please note – this *GenomeWeb* article does require a registration).

Many stakeholders have submitted comments already, which can be viewed [here](#).

ACMG will be submitting formal comments outlining our concerns about the policy. Public comments can be submitted by anyone, including our members, using this [link](#).

ACMG Resources on LDTs

For your reference, ACMG has compiled a [comprehensive list of resources](#) regarding Laboratory Developed Tests including a webinar, a one-page summary on "The Basics of Laboratory Developed Tests", materials from the Congressional Briefing ACMG co-sponsored with AMP and ISDA on the basics of Laboratory Developed Tests and the vital role they play in patient care, ACMG's response to the FDA's proposed guidance "Framework for Regulatory Oversight of Laboratory Developed Tests," a video on the Patient Perspective on the Value of LDTs and much more. Please feel free to use these ACMG resources to help you in crafting your response.

The deadline for submitting comments is January 17.

We urge members to make their voices heard by submitting comments on this extremely important topic.



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Taking Action and Advocating for Medical Genetics

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