



CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

September 19, 2012

S. 3391 **Taking Essential Steps for Testing Act**

*As ordered reported by the Senate Committee on Health, Education, Labor, and Pensions
on September 19, 2012*

S. 3391 would amend the Public Health Service Act to revise sanctions that the Centers for Medicare and Medicaid Services (CMS) must impose on clinical laboratories under certain circumstances. To demonstrate their proficiency, laboratories are required to perform tests on samples periodically. Under current law, if CMS determines that a laboratory has intentionally referred such a sample to another laboratory for testing, CMS is required to revoke the laboratory's certification for at least one year and may impose other intermediate sanctions, including requiring laboratories to implement plans for corrective action, pay civil penalties, or pay for the costs of onsite monitoring. S. 3391 would revise those sanctions to allow CMS the flexibility to choose whether or not to revoke the laboratory's certification. Other intermediate sanctions would continue to be available.

Enacting S. 3391 would not affect direct spending or revenues; therefore, pay-as-you-go procedures do not apply. While the legislation could have the effect of increasing the number of laboratories retaining certification compared with current law, CBO estimates that the bill would result in a shift of laboratory services among certified laboratories rather than increasing the number of laboratory services provided. Therefore, programs funded by the federal government, such as Medicare and Medicaid, would not be affected.

The bill would not impose intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act and would impose no costs on state, local, or tribal governments.

The CBO staff contact for this estimate is Lisa Ramirez-Branum. The estimate was approved by Holly Harvey, Deputy Assistant Director for Budget Analysis.