



CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

March 31, 2008

H.R. 1237

A bill to amend the Public Service Act to provide revised standards for quality assurance in screening and evaluation of gynecologic cytology preparations

*As ordered reported by the House Committee on Energy and Commerce
on March 13, 2008*

H.R. 1237 would amend the Clinical Laboratory Improvement Act (CLIA) by requiring clinical laboratories to ensure that all individuals involved in screening and interpreting cytological preparations participate in annual continuing medical education programs in gynecologic cytology. The bill would repeal the current requirement for proficiency testing for laboratory personnel performing cytology laboratory tests.

CLIA activities, which are administered by the Centers for Medicare & Medicaid Services (CMS), are funded through user fees, which cover 100 percent of the cost of implementing the program. This legislation would have a minor impact on CMS's workload. However, because the CLIA program recovers 100 percent of its costs through fees (which are accounted for in the budget as offsetting collections), any change in its administrative costs would be offset by an equal change in the fees that CMS charges. Hence, CBO estimates that implementing H.R. 1237 would have no net budgetary effect. Enacting the legislation would not affect direct spending or revenues.

The bill would require clinical laboratories, including laboratories of public and private hospitals, to comply with record-keeping and management standards for personnel performing cytology laboratory tests. That requirement would impose intergovernmental and private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA). CBO estimates, however, that the costs to laboratories would be small because compliance would probably involve minor adjustments to existing administrative procedures.

The bill also would impose a private-sector mandate on individuals who screen and interpret cytological preparations by requiring them to participate in continuing medical education programs. CBO estimates that the costs of carrying out that mandate also would be small because only several thousand individuals would be subject to the education requirements and most of them are already enrolled in such programs. Thus, CBO estimates that the costs

to governmental and private-sector entities of the mandates in the bill would be small and would not exceed the thresholds established in UMRA (\$68 million for intergovernmental mandates and \$136 million for private-sector mandates, in 2008 adjusted annually for inflation).

The CBO staff contacts for this estimate are Lori Housman (for federal costs), Lisa Ramirez-Branum (for the state and local impact), and Patrick Bernhardt (for the private-sector impact). This estimate was approved by Keith J. Fontenot, Deputy Assistant Director for Health and Human Resources, Budget Analysis Division.