American
Clinical Laboratory
Association

February 24, 2011

MEMORANDUM IN OPPOSITION

A4009/S2809
2011–2012 Proposed Health Budget, Part A, Sections 18–21

"In effect, DOH has turned the clinical laboratory reference system special revenue account into an unauthorized and unsupervised revenue stream that is limited only by the bounds of the defendant's [DOH's] creativity in characterizing the Wadsworth Center's expenses as attributable to the oversight of the plaintiffs [laboratories]."

Decision and Order of Edward A. Sheridan, J.H.O., Albany County Supreme Court, American Association of Bioanalysts v. New York State Department of Health, et al., Index No. 6225-99, (September 24, 2008, p. 26).

The American Clinical Laboratory Association (ACLA) strongly opposes the proposed amendments to sections 571, 575, 576 and 577 of the public health law set forth in Part A, Sections 18-21 of the proposed 2011-2012 health budget on the basis that it converts a regulatory fee into an unjustified tax.

Under this proposal, the components of the methodology used to determine fees that support the Department of Health's (hereinafter "DOH") oversight system for clinical laboratories and blood banks—the Clinical Laboratory Evaluation Program (hereinafter "CLEP")—would be expanded to include new cost assessments that are not part of the current methodology and unrelated to the regulation of laboratories, such as research, travel, and other costs. Doing so would not only place an unfair burden on laboratories, as they would be forced to subsidize activities of DOH unrelated to the regulation of laboratories, but would also amount to a tax, in violation of the Constitution of the State of New York.

Under current law, DOH may only collect the *actual cost* of CLEP's inspection and reference program for clinical laboratories; however, for many years, DOH collected fees that far exceeded the actual costs of the program as determined by the courts. In September 2008, the Supreme Court, Albany County ruled against DOH, ordering the agency to reassess fees wrongfully attributed to the program for fiscal years 1998–2004 and to issue refunds to laboratories based on overcharges for the program. The Third Department affirmed the trial court judgment and order on July 22, 2010[1] and the Court of Appeals on February 17, 2011 denied DOH's motion for leave to appeal to that court.

[1] *See* American Assn. of Bioanalysts v. New York State Dept. of Health, 75 A.D.3d 939 (N.Y. App. Div. 2010).

Thus, this budget proposal represents yet another effort by DOH to shunt onto laboratories costs unrelated to the inspection and reference program for laboratories. By changing the definition of "reference system," removing the phrase "actual costs," and requiring laboratories to submit reports of gross annual receipts for "all activities performed," this legislation would now authorize DOH to turn the clinical laboratory reference system special revenue account into a boundless revenue stream for DOH, contrary to the system's original intent and beyond any reasonable costs directly related to the regulatory oversight of laboratories. Since its inception in 1964, the reference system was intended only to allow DOH to cover the actual cost of evaluating laboratories. This budget proposal would institutionalize unreasonable and arbitrary taxation of a single class of citizens to pay for costs that are the responsibility of all citizens of the state.

To adopt the budget proposal as drafted would allow DOH to continue to collect the funds that the court found to be arbitrary and contrary to law. Further, it would allow the agency to continue funding non-laboratory activities with fees charged to laboratories - a single class of citizens. As has been demonstrated through the years of litigation described above, DOH has used laboratory fees to fund many activities entirely unrelated to regulating and evaluating laboratories, including salaries of persons whose jobs had nothing to do with regulating laboratories (and in some cases did not even work for DOH); trips to California and Europe; cars for the New York Commissioner of Health; the costs of developing new assays for which DOH scientists held patents and DOH would receive royalties; research into environmental pollution; and many other activities. Under the budget proposal, the authority of DOH to use laboratories' revenues would be virtually unchecked and notably ripe for open-ended abuse. The language not only creates new areas for which laboratories could be assessed, but also allows DOH to create regulations that would set forth "such other activities" that could be subject to assessment, establishing the CLEP assessment as an unchecked and unlimited stream of funding.

Finally, ACLA member laboratories simply cannot sustain this type of undefined economic impact. Given the current economic climate, a sustained fee increase, with no defined reference value or cap, will lead to loss of jobs, with a disproportionate impact on smaller local or regional laboratories.

For the foregoing reasons, ACLA urges the legislature to remove these amendments from the proposed 2011-2012 health budget.