AdvaMedDx
Vital Insights | Transforming Care

November 13, 2012

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2012-N-0937; Agency Information Collection Activities; Proposed Collection; Comment Request; Clinical Laboratory Improvement Amendments of 1988 Waiver Applications

Dear Sir or Madam:

On behalf of AdvaMedDx, a Division of the Advanced Medical Technology Association (AdvaMed), we provide these comments in response to the comment request regarding Food and Drug Administration (FDA) collection of information associated with Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications.

AdvaMedDx member companies produce advanced, *in vitro* diagnostic tests that facilitate evidence-based medicine, improve quality of patient care, enable early detection of disease and reduce overall health care costs. Functioning as an association within AdvaMed, AdvaMedDx is the only multi-faceted, policy organization that deals exclusively with issues facing *in vitro* diagnostic companies in the United States and abroad. Our membership includes manufacturers of innovative CLIA waived tests used by health care professionals in in settings including doctors' offices, clinics, and emergency rooms.

GENERAL COMMENTS

AdvaMedDx appreciates the opportunity to comment. These tests play an important public health role in equipping health practitioners with timely patient health status and care options and helping address the spread of infectious disease through portable and often rapid response. Despite their valuable role in health care delivery, regulatory challenges remain as manufacturers seek to navigate CLIA waiver regulatory expectations, which are outlined in the FDA guidance document entitled " Guidance for Industry and FDA Staff: Recommendations for Clinical Laboratory Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices." While there is useful information that can be gathered from these studies, there are conditions that are often difficult to achieve in practice and medical decision points that do not necessarily reflect clinical requirements based on medical use of the test.

701 Pennsylvania Avenue, NW | Suite 800 | Washington, DC 20004
T - 202.783.8700 F - 202.783.8750 AdvaMedDx.org

Unfortunately, only a small number of CLIA waiver applications have been submitted while, non-incidentally, there has been a significant increase in both cost and resources necessary for such applications along with a record rate of regulatory delays and denials. While these elements are not the subject of this docket and we appreciate FDA's recent commitment to quantitative and qualitative goals aimed to improve and speed the CLIA waiver submission process as part of the recent user fee reauthorization, we note the relation of this guidance with today's realistic and conservative estimates of the actual costs of CLIA waiver submissions.

In review of the proposed estimates, we recommend reexamination and reconsideration to reflect accurate estimates of the time and costs associated with the preparation and completion of CLIA waiver applications. In addition, we note several categories of activities that are not expressly referenced in the estimates and may be useful for more true estimates for purposes of this data collection.

SPECIFIC COMMENTS

In response to the specific question listed in the *Federal Register*, AdvaMedDx provides the following response focused on the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used (Question 2).

The estimated annual reporting burden requires significant revision to reflect more accurate figures for the collection of information. We note that based on FDA's own CLIA waiver application data, there has been an average of 6 submissions per year since 2009. From an innovator perspective, this is concerning and in stark contrast to the 40 estimated annual responses. We will assume, however, that the number of responses will ultimately return to more reasonable levels (e.g., 40 annual responses). Most importantly, the average burden per response is grossly underestimated.

Based on prior CLIA waiver submissions to FDA, average time required to prepare and submit a waiver application, including the time needed to assemble supporting data, has been approximately 1200 hours per response (in contrast to 780 hours in proposed Table 1). This takes into account multiple individuals (rather than one full-time employee) for approximately 5 months, which includes preparation and completion of clinical studies along with clinical data analysis, report documentation, and submission preparation. It should be noted that this does not include time associated with preparation and completion of 510(k) submission requirements or time of different staff to respond to questions following submission of a CLIA waiver application. Thus, Table 1 should be revised with respect to the average burden per response and total hours.

Based on previous years' manufacturer experience with CLIA waiver applications, total average cost associated with a waiver application has been $350,000 (in contrast to $66,200 cited in the proposed FR notice). This cost is largely attributed to clinical study costs incurred, which include site selection and qualification, protocol review, and study execution

(initiation, monitoring, closeout, and clinical site/subject compensation—including specimen collection for study as well as shipping and supplies). This does not include costs also incurred with 510(k) submissions and reflects average cost of completed CLIA waiver applications. FDA's estimated burden does not accurately reflect cost associated with a waiver application and requires significant revision to reflect more realistic estimates of the operating and maintenance cost associated with waiver applications.

In conclusion, AdvaMedDx recommends re-review of the proposed information collection and key revision as noted. We believe these changes are necessary to assure accurate estimate of the burden of proposed collection of information regarding CLIA waiver applications and overall utility of the information. If you have any questions, please do not hesitate to contact me at 202-434-7267 or kcalleja@advamed.org.

Sincerely,

Khatereh Calleja

Khatereh Calleja
Vice President
Technology and Regulatory Affairs