



AMERICAN UROLOGICAL ASSOCIATION, INC.®

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August 28, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20850

Re: August 14-15, 2000 Public Workshop on CLIA Waiver Criteria
Docket No. 00N-1394

Dear Sir/Madam:

On behalf of the 9,200 members of the American Urological Association (AUA), we would like to express our strong opposition to any further restrictions of the criteria for laboratory tests qualifying for a certificate of waiver under the Clinical Laboratory Improvement Act of 1998.

If the waived test category criteria is made more stringent, this will decrease the number of waived tests performed in physician offices that have been performed safely and efficiently for the past five years.

The AUA strongly feels this would adversely affect patient access to care. Patients who can now receive the results of their test immediately and receive timely treatment would often be forced to make a separate trip to a laboratory with a possible follow-up visit to the physician's office. This can delay diagnosis by several days, effectively delaying treatment for patients that could have had their illnesses identified earlier. Further, more restrictive criteria would increase the burden of regulatory compliance that physicians already face. We fear this would simply cause physicians to scale back the number of tests that they can safely perform in their office or eliminate their in office lab testing altogether.

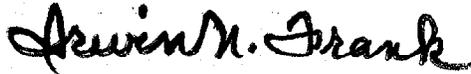
Urologists are particularly sensitive to any change, as numerous waived tests are commonly performed by urologists during their standard work-up of patients presenting with lower urinary tract symptoms.

If there are concerns that some physician office laboratories are not adequately following manufacturer instructions, we believe that instructing end users concerning the proper use of the equipment is the answer, and not further restriction of the waiver category. Moreover, we think this education effort should target just those physician office laboratories with problems, so that more regulation is not imposed on labs already following manufacturer instructions.

00N-1394

I appreciate your consideration of our views. If you have any questions, please call Scott Reid, AUA Government Relations Manager, at 410-223-4324.

Sincerely,

A handwritten signature in black ink that reads "Irwin N. Frank". The signature is written in a cursive, slightly slanted style.

Irwin N. Frank, M.D, FACS

President

American Urological Association

Cc: Clara A. Sliva, FDA

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