



December 8, 2010

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

Docket No. FDA-2010-N-0308

Dear Sir/Madam:

The American Association for Clinical Chemistry (AACC) appreciates the opportunity to comment on the September 17, 2010 *Federal Register* notice, which outlines a process for the Food and Drug Administration (FDA) and Centers for Medicare and Medicaid Services (CMS) to coordinate their regulatory and reimbursement responsibilities regarding medical device manufacturers. AACC supports this initiative.

Initially, the two agencies are planning a pilot study to examine the feasibility of this concept. AACC agrees with this approach. We think it's essential that the FDA and CMS fully evaluate whether this proposal will meet its objective—to reduce the regulatory burden and costs on manufacturers—prior to implementation. If the pilot fails in this endeavor, AACC does not believe the project should go forward.

AACC also suggests that CMS, in conjunction with the American Medical Association (AMA), develop an interim payment process that allows reimbursement for newly cleared or approved devices while awaiting AMA issuance of a CPT code. Currently, it can take up to two years--from application for a CPT code to implementation of the approved code. This delay is one of the barriers that the parallel process needs to address.

AACC further recommends that the parallel review approach should be a voluntary option available to manufacturers. The final policy should also reiterate that FDA decisions are based on the safety and efficacy of the drug/device under review and should not be influenced by issues under discussion by CMS during the national coverage determination process.

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By way of background, AACC is the principal association of professional laboratory scientists--including MDs, PhDs and medical technologists. AACC's members develop and use chemical concepts, procedures, techniques and instrumentation in health-related investigations and work in hospitals, independent laboratories and the diagnostics industry worldwide. The AACC provides international leadership in advancing the practice and profession of clinical laboratory science and its application to health care. If you have any questions, please call me at (919) 966-3724, or Vince Stine, PhD, Director, Government Affairs, at (202) 835-8721.

Sincerely,

A handwritten signature in black ink that reads "Catherine Hammett-Stabler". The signature is written in a cursive, flowing style.

Catherine A. Hammett-Stabler, Ph.D., DABCC, FACB
President, AACC