AMERICAN
ASSOCIATION
OF BLOOD BANKS

January 15, 2001

Health Care Financing Administration
U.S. Department of Health and Human Services
Room 443-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: 42 CFR part 482 Medicare and Medicaid Programs; Hospital Conditions of Participation: Laboratory Services; Proposed Rule

To Whom It May Concern:

These comments are filed on behalf of the interorganizational task force created to provide assistance to the blood banking community for HCV lookback. The task force consists of the American Association of Blood Banks, America's Blood Centers and the American Red Cross, and represents all of the blood collecting organizations and over 80 percent of the blood transfusion services in the United States. The task force appreciates the opportunity to comment on this proposed rule.

The F*ederal Register* notice indicates that the Health Care Financing Administration (HCFA) proposed rule is in concert with the Food and Drug Administration's (FDA's) proposed rule and HCFA will consider comments they receive in conjunction with the FDA. Please be advised that the interagency task force will be filing comments on the FDA proposed rule. Some of these comments will also affect the HCFA rule, so it is imperative that HCFA consider the comments received at the FDA.

HCFA specifically requested comments on the reasonableness of HCFA adopting the FDA requirements. We believe it is imperative that the HCFA requirements and the FDA requirements for HCV and HIV look back are identical so that the requirements are the same for all participants regardless of whether they are regulated primarily by FDA or by HCFA. This will ensure that targeted look back is carried out in a uniform manner throughout the United States.

The HCV task force generally agrees with the proposed rule. We agree that requiring hospitals to maintain adequate records of the source and disposition of all units of blood and blood products for at least ten years from the date of disposition 482.27 (b) (5) is appropriate and should be phased in as described in Section II. Provisions of This Proposed Rule.

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We do, however, have the following concerns about specific provisions in the rule:

- Section 482.27 (b)(6).We agree that direct notification of the patient or notification to the attending physician or the physician who ordered the blood or blood product should all be permissible. However, we disagree that at least three attempts to notify the patient must be made. We request that this provision be changed to permit one attempt made using a traceable method, such as certified mail, return receipt requested. A signed returned receipt or a returned letter should be proof that notification was attempted and was unsuccessful, and that further attempts will also be unsuccessful.

- Section 482.27 (b)(10). This section states, "If the patient is deceased, the physician or hospital must continue the notification process and inform the deceased patient's legal representative or relative." The FDA proposed rule section 610.49 (c) does not contain this provision. In the discussion of the highlights of the proposed rule the FDA explains that "Proposed 610.49 (c) would not require notification efforts to continue if the recipient is deceased because, as previously discussed, direct percutaneous exposure to infectious blood, particularly in the setting of drug abuse, accounts for the majority of HCV infections acquired in the United States. Secondary transmission of HCV to sexual partners, care providers or others with close contact is very unlikely." We agree with the FDA proposal and request that that the HCFA proposed rule conform to the FDA proposed rule by deleting 482.27 (b)(10).

- We also note what we believe is a significant typographical error that appears in both the FDA and the HCFA proposed rules. The time frame for other retrievable records (those that are not computerized electronic records) should be January 1, **1988** rather than January 1, 1998.

Once again, the interorganizational HCV lookback task force appreciates the opportunity to comment on the HCV lookback proposed rule. Any questions or comments for the task force may be directed to Kay Gregory, director, Regulatory Affairs, AABB, at 301-215-6522 or kayg@aabb.org.

Yours truly,

Ramona L. Walker
Chair, HCV Task Force