



Greater New York Hospital Association

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Kenneth E. Raske, President

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Jane E. Henney, MD
Commissioner of Food and Drugs
Dockets Management Branch (HFA-305)
U. S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 98N-0607: Proposed Rule; General Requirements for Blood, Blood Components, and Blood Derivatives; Notification of Deferred Donors

Dear Commissioner Henney:

Greater New York Hospital Association (GNYHA) represents over 175 hospitals and long-term care facilities in New York City, Westchester, Nassau, and Suffolk counties. Its members include the largest providers of health care services in the area, and we are greatly concerned that the blood supply available to consumers of these health care services be as safe as possible. In that spirit GNYHA has carefully reviewed the proposed rule that would require donor notification when the donor is deferred due to testing results or failure to meet donor suitability criteria. Our member hospitals that operate blood donor centers would be directly affected by this proposed rule. Therefore, GNYHA is pleased to have the opportunity to respond to the U.S. Food and Drug Administration (FDA) regarding this proposed rule.

GNYHA supports the intent of the proposed rule to contribute to the safety of the nation's blood supply. However, GNYHA believes that current FDA recommendations and the standards of the American Association of Blood Banks (AABB) sufficiently address issues related to donor notification of medical abnormalities detected during the screening of potential blood donors. Since these standards are widely followed, it is unclear what advantage, if any would be gained by codifying notification requirements for deferred donors. The proposed rule is very prescriptive in nature, and would impose burdens on blood banks and donor centers that, under the circumstances, cannot be justified.

The list of requirements for the notification process, as set forth in proposed section 630.6 (b) of Part 630, is unnecessarily detailed. Again, GNYHA would defer to the AABB

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standard that indicates the type of information to be provided to the potential donor, but not the specific content.

GNYHA also believes that the proposed requirement, at section 630.6 (c) of Part 630, that three attempts at notification be made and documented is excessive. If a notice is mailed to the address provided by the donor, one mailing would seem sufficient. Since the notification of deferral would be sent within a short period of the attempted donation, it is reasonable to anticipate that an unreturned notice was delivered or forwarded to the addressee. Subsequent efforts to notify the deferred donor by mail would not be expected to have a different outcome. Placing the burden of repeated efforts at notification on the donor facility will result in the added expense and inconvenience of sending all notifications by certified or registered mail. Such mail will be no more likely to reach the donor, but will serve to document the facility's effort at notification. This would be a most undesirable outcome of the proposed rule.

In conclusion, GNYHA does not oppose the notification of deferred donors, but believes that the method and specific contents of the notification should not be codified. The proposed requirement that three attempts be made to notify potential donors of a deferred status is not likely to enhance actual notification, but will place an unnecessary burden on blood banks. GNYHA will be available to answer any questions you may have regarding these comments. Thank you for your consideration of GNYHA's opinion on this important matter.

Sincerely,

A handwritten signature in cursive script that reads "Patricia O'Brien".

Patricia O'Brien, Senior Advisor
Regulatory and Professional Affairs

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359