/* These blood handling rules were proposed by the federal government in Autumn 1993. If finalized, they will be enforced in any hospital which received Medicare funds. */

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 482

Medicare Program; Hospital Standard for HIV Infectious Blood and Blood Products

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would address a blood and blood products safety issue that concerns the prompt notification of transfusion recipients who are at increased risk of HIV infection. Thus, this proposed rule would require hospitals to notify the recipient's attending physician when potentially HIV infectious blood and blood products have been administered, and ask the physician to inform the recipient of the need for HIV testing and counseling. If the physician is unavailable or declines to notify the recipient, the hospital must notify the recipient and inform the recipient of the need for HIV testing and counseling.

DATES: Written comments will be considered if we receive them at the appropriate address, as provided below, no later than 5:00 p.m. on August 30, 1993.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BPl3-633-P, P.O. Box 26688, Baltimore, MD 21207.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses: Room 309-G, Hubert H. Humphrey Building, 200 Independence Ave., SW., Washington, DC 20201, or room 132, Fast High Rise Building, 6325 Security Boulevard, Baltimore, Maryland 21207.

Due to staffing and resource limitations, we cannot accept audio, visual, or facsimile (FAX) copies of comments.

If comments concern information collection or recordkeeping requirements, please address a copy of comments to: Office of Management and Budget, Office of Information and Regulatory Affairs, Room 3206, New Executive Office Building, Washington, DC 20503, Attention: Allison Herron Eydt.

In commenting, please refer to file code BPD633-P. Comments received timely will be available for public inspection as they are received, beginning approximately three weeks after publication of this document, in Room 309-G of the Department's offices at 200 Independence Ave., SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: 202-690-7890).

FOR FURTHER INFORMATION CONTACT:

Joyce Eng, (410) 966-4619.

SUPPLEMENTARY INFORMATION:

I. Background

Hospitals must meet certain conditions of participation in order to participate in the Medicare program. These conditions are intended to protect patient health and safety and to ensure that high-quality care is provided to Medicare patients.

Regulations containing the Medicare conditions of participation for hospitals are located in the Code of Federal Regulations at 42 CFR part 482, with the conditions for hospital laboratory services at 482.27. The laboratory regulations at 482.27 are relatively general because the more detailed requirements for laboratories appear in part 493, which sets forth requirements for all laboratories participating in the Medicare, Medicaid, and Clinical Laboratories Improvement Act programs. Part 493 was added to the

CFR on March 14, 1990 (55 FR 9538).

The Human Immunodeficiency Virus (HIV) is a virus whose presence is associated with Acquired Immune Deficiency Syndrome (AIDS). Receipt of potentially HIV infectious blood and blood products does not mean that a person will get AIDS, but it indicates a likelihood that one may, depending upon the recipient's immunity and other factors.

In response to scientific data that show HIV is transmissible through blood and blood products, the Food and Drug Administration (FDA) has implemented an extensive system of additional donor screening and testing procedures, performed before, during, and after donation takes place, to help prevent the transfusion of blood and blood products that are potentially contaminated with HIV. The FDA continues to monitor blood donor issues and updates its recommendations as more information becomes available.

The Social Security Administration operates a Blood Donor Locator Service (BDLS) to enable States and authorized blood donation facilities to notify blood donors whose donations indicate that they are or may be infected with HIV. Section 205(c)(2)(D) of the Act permits States to require a blood donor to furnish his or her Social Security number (SSN) to a State agency or to an authorized blood donation facility. With the SSN, an authorized blood donation facility may request the State to contact the BDLS to obtain the donor's last known personal mailing address. The State agency may also make a request on its own behalf for this information to the BDLS.

II. Provisions of the Regulations

This proposed rule would amend the conditions of participation for hospitals to require hospitals to develop agreements which would require outside blood banks to notify the hospitals when the blood banks have made potentially HIV infectious blood and blood products available to the hospitals. We also would require that the hospitals ensure that the recipients of the blood and blood products be notified and informed of the need for HIV testing and counseling. Testing persons for HIV could allow individuals who test positive to seek medical treatment and to change behavior so as not to infect others.

This proposed rule would set forth a new standard for hospitals at 482.27, which sets forth standards for hospital laboratory services. Section 482.27(c)(1) would require that, when services are furnished to a hospital by an outside blood bank, there be an agreement governing the procurement, transfer and availability of blood and blood products specifying that the blood bank notify the hospital if potentially HIV infectious blood and blood products have been made available to the hospital. We are especially interested in receiving comments on whether this proposed requirement would be more appropriately implemented in the manner proposed, as part of a Medicare hospital standard, or as part of the FDA requirements applicable to blood banks.

Potentially infectious blood and blood products would be defined as blood and blood products from a donor whose licensed or approved screening test shows the presence of HIV and whose licensed or approved screening supplemental, more specific tests are positive or unavailable. An individual would be considered to be infected by HIV if the individual's results from the FDA's licensed or approved tests at 21 CFR 610.45 show the presence of HIV and if these screening results are confirmed by a licensed or approved supplemental, more specific test.

A new paragraph (c) (2) would require that, if a hospital has administered potentially HIV infectious blood and blood products, the hospital must first make several attempts to notify the recipient's attending physician (physician of record) and ask the physician to inform the recipient of the need for HIV testing and counseling. Then, if the physician is unavailable or declines to notify the recipient, the hospital must make several attempts to notify the recipient and inform the recipient of the need for HIV testing and counseling. The notification must be confidential. The hospital is responsible for notification, including basic explanations to the recipient and referral for counseling.

We believe that the hospital's notification effort should consist of, at the minimum, several attempts by phone or in writing to reach the attending physician and then, the recipient. The hospital's notification effort should begin immediately after receiving word from the blood bank and be completed eight weeks later. We would require that the hospital document the attempts to notify the attending physician, the attempts to notify the recipient, and indicate whether the recipient was located. We specifically invite public comment on the sufficiency of this level of effort and on

whether the notification should be done by certified mail marked "confidential".

In the proposed 482.27(c)(2), we believe that the chain of notification about the potentially infectious blood and blood products should be from the hospital to the recipient's attending physician (physician of record), and that only in rare situations would the recipient receive this notification from the hospital. We invite comment as to whether a regulation describing the mechanics of this notification is necessary and whether additional explanation is necessary to identify when the hospital should directly notify the recipient. We believe this proposed rule is self-explanatory; but that a stated time frame may be necessary to determine when the recipient should be notified by the hospital if the attending physician cannot be reached by telephone.

If a hospital furnishes HIV testing or counseling, we do not anticipate that the hospital will furnish these services without costs. It may choose to furnish the services and bill the recipient, or it may refer the recipient to a public health agency or a laboratory. Medicare and Medicaid would pay for services they cover (coverage would vary, depending on which program was used and which services were furnished). Private insurance may pay for non-Medicare or non-Medicaid patients.

We have not yet determined whether these new requirements should be independently verified by a survey or whether hospitals accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the American Osteopathic Association (AOA) can be assumed to meet these requirements. Because accreditation standards change regularly, this proposed new requirement may well be incorporated into the accreditation programs of the JGAHO and the AOA. When a final regulation is published, we will announce whether accreditation by one of these organizations creates presumptive compliance or whether a compliance survey will be performed.

This proposed rule addresses hospital requirements only, because we believe the overwhelming majority of blood and blood products are furnished in hospitals. However, we welcome public comment regarding the need to develop similar requirements for other types of facilities.

III. Regulatory Impact Analysis

Executive Order 12291 (E.O. 12291) requires us to prepare and publish a regulatory impact analysis for any proposed rule that meets one of the E.O. 12291 criteria for a "major rule"; that is, that would be likely to result in-

An annual effect on the economy of $100 million or more;

A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or

Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

In addition, we generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.& 601 through 612) unless the Secretary certifies that a proposed rule would not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, we consider all hospitals, blood banks and physicians to be small entities.

Also, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis if a proposed rule may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital with fewer than 50 beds located outside of a Metropolitan Statistical Area.

This proposed rule would add a new paragraph (c) to 482.27 regarding the notification of a patient when potentially HIV infectious blood and blood products have been administered. These proposed regulations do not affect blood testing required by 493.1269 ("Condition: Immunohematology").

From 1988 through 1991, the risk of HIV transmission via blood and blood products transfusion has been estimated to be between 1 in 38,000 and 1 in 153,000. Appropriate efforts to further reduce the risk have occurred by public education, improved tests, donor questionnaires, and revised criteria for donor self-referral. However, it remains possible, despite the best practices of a blood bank, that a person might donate blood and blood products early in infection, during the "window" period, when the test for anti-HIV remains negative but HIV is present in the person's blood. Section 482.24 ("Condition of participation: Medical record services") currently requires hospitals to maintain records for a period of 5 years. We expect hospitals would identify recipients of blood and blood products and furnish appropriate notice to the extent to which they have maintained records that permit them to do so.

As for ongoing activities, we anticipate that only a small number of cases per year can be traced to potentially HIV infectious transfused blood and blood products, and thus, we do not expect these proposed regulations would result in a substantial economic or resource burden on hospitals, blood banks or physicians. We do not have estimates of the additional cost due to the HIV counseling and subsequent testing that would be required, but since the services would be covered for those persons eligible to receive Medicare and Medicaid benefits, if they meet other eligibility and coverage requirements, we believe the effect on beneficiaries, even in high risk areas, would be minimal. To the extent possible, private insurance may also pay, or, if the State has a program, the Ryan White Comprehensive AIDS Resource Emergency Act of 1990 (Pub. L. 101- 381) may cover some of these services. In addition. since many hospitals, blood banks, and physicians are currently voluntarily complying with the requirements of these proposed regulations, new effects due to these proposed regulations are not expected to be substantial. We expect the continued cost of implementing this regulation after the initial implementation to be small because the risk of a person being transfused with potentially HIV infectious blood and blood products is declining. Even though this proposed rule would affect few people per year after initial implementation, public awareness of the HIV issue dictates that we address it by taking steps to ensure that potentially infected people are notified so they may seek appropriate medical care or consider behavior changes so as not to infect others.

As part of this proposed rule, blood banks with records that permit them to do so may notify hospitals of potentially HIV infectious blood and blood

products provided in past years. Recipients of potentialy HIV blood and blood products would need to be notified and informed of the need for HIV testing and counseling. Since it is extremely important to notify these individuals that they have the potential to transmit the HIV virus to others, it is necessary that they be identified and notified, and that their status be assessed. This is critical to the epidemiology of AIDS.

For the reasons cited above, we do not believe these proposed regulations would meet any of the criteria for a major rule, therefore we are not including an initial regulatory impact analysis.

In addition, since we have determined, and the Secretary certifies, that this proposed rule would not be likely to have a significant economic impact on a substantial number of small entities or on the operations of a substantial number of small rural hospitals, we are not preparing analyses for either the RFA or small rural hospitals.

IV. Information Collection

Requirements

Section 482.27(c)(2) of this proposed rule contains information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the authority of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). This section requires that, if potentially HIV infectious blood and blood products are administered, regardless of the source of the blood, a hospital must first make several attempts to notify the recipient's attending physician and ask the physician to inform the recipient of the need for HIV testing and counseling. Then, if the physician is unavailable, or declines to notify the recipient, the hospital must make several attempts to notify the recipient and inform the recipient of the need for HlV testing and counseling. The hospital must also document the notification or attempts to notify the attending physician and the recipient. Public reporting burden for the collection of information is estimated to be 1 hour per response. A notice will be published in the Federal Register if approval is obtained. Other organizations and individuals desiring to submit comments regarding the burden estimate or any aspect of this collection of information, including suggestions for reducing this burden, should direct

them to the OMB official whose name appears in the "ADDRESSES" section of this preamble.

V. Response to Comments

Because of the large number of items of correspondence we normally receive on a proposed rule, we are not able to acknowledge or respond to them individually. However, we will consider all comments that we receive by the date and time specified in the "DATES" section of this preamble, and if we proceed with a final rule, we will respond to the comments in the preamble of that rule.

List of subjects in 42 CFR Part 482

Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, Chapter IV, 42 CFR 482.27 would be amended as follows:

PART 482 -- Conditions of Participation for Hospitals.

1. The authority citation for Part 482 continues to read as follows:

Authority: Secs. 1102, 1136, 1138, 1814 (a)(6), 1861(e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1864, 1871, 1883, 1886, 1902 (a)(30), and 1905(a) of the Social Security Act (42 U.S.C. 1302, 1302b-6, 1338, 1395f(a)(6), 1395x(e), (f), (k), (r), (v)(1)(G), (z) and (ee), 1395aa, 1395hh, 1395tt, 1395ww, 1396a(a)(30), and 1396(a).

2. In 482.27, a new paragraph (c) is added as follows:

482.27 Condition of participation; Laboratory services.

* * * * *

(c) Standard: Infectious blood and blood products.

(1) When services are furnished by an outside blood bank, the hospital must have an agreement governing the procurement, transfer, and availability of blood and blood products. The agreement must require that the blood bank notify the hospital if potentially HIV infectious blood and blood products have been made available to the hospital. "Potentially HIV infectious blood and blood products" is defined as blood and blood products

from a donor whose licensed or approved screening test shows the presence of HIV and whose licensed or approved screening supplemental, more specific tests are positive or unavailable.

An individual would be considered to be infected by HIV if the individual's results from the FDA's licensesd or approved tests at 21 CFR 610.45 show the presence of HIV, and if these screening results are confirmed by a licensed or approved supplemental, more specific test.

(2) If a hospital has administered potentially HIV infectious blood and blood products, the hospital must make several attempts to notify the recipient's attending physician (physician of record) and ask him or her to inform the recipient of the need for HIV testing and counseling. If the physician is unavailable or declines to notify the recipient, the hospital must make several attempts to notify the recipient and inform the recipient of the need for HIV testing and counseling. The hospital is responsible for notification, including basic explanations to the recipient and referral for counseling, and nust document the notification or attempts to notify the attending physician and the recipient.

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare -- Supplementary Medical Insurance.)

Dated: March 2, 1993

William Toby, Jr., Acting Deputy Administrator, Health Care Finincing Administation.

Approved: May 19, 1993.

Doonna E. Shalala, Secretary.

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