5. Section 610.45 is amended by adding a new paragraph (d) to read as follows:

§ 610.45 Human immunodeficiency virus (HIV) requirements.

* * * * *

(d) For a donor whose test results for antibody to HIV are repeatedly reactive or otherwise determined to be unsuitable when tested in accordance with paragraph (a) of this section, the blood establishment shall comply, as applicable, with §§ 610.46 and 610.47.

6. New §§ 610.46 and 610.47 are added to subpart E to read as follows:

§ 610.46 ''Lookback'' requirements.

(a) *Quarantine and notification.* (1) All blood and plasma establishments are required to take appropriate action when a donor of Whole Blood, blood components, Source Plasma and Source Leukocytes tests repeatedly reactive for antibody to human immunodeficiency virus (HIV), or otherwise is determined to be unsuitable when tested in accordance with § 610.45. For Whole Blood, blood components, Source Plasma and Source Leukocytes collected from that donor within the 5 years prior to the repeatedly reactive test, if intended for transfusion, or collected within the 6 months prior to the repeatedly reactive test, if intended for further manufacture into injectable products, except those products exempt from quarantine in accordance with § 610.46(c), the blood establishment shall promptly, within 72 hours:

(i) Quarantine all such Whole Blood, blood components, Source Plasma and Source Leukocytes from previous collections held at that establishment; and

(ii) Notify consignees of the repeatedly reactive HIV screening test results so that all Whole Blood, blood components, Source Plasma and Source Leukocytes from previous collections they hold are quarantined.

(2) Consignees notified in accordance with paragraph (a)(1)(ii) of this section shall quarantine Whole Blood, blood components, Source Plasma and Source Leukocytes held at that establishment except as provided in paragraph (c) of this section.

(b) *Further testing and notification of consignees of results.* Blood establishments that have collected Whole Blood, blood components, Source Plasma or Source Leukocytes from a donor as described in paragraph (a) of this section shall perform a licensed, more specific test for HIV on the donor's blood, and in the case of distributed products, further shall notify the consignee(s) of the results of this test, within 30 calendar days after the donor's repeatedly reactive test. Pending the availability of a licensed, more specific test for HIV–2, a second, different screening test for antibody to HIV–2 shall be used along with a licensed, more specific test for HIV–1.

(c) *Exemption from quarantine.* Products intended for transfusion need not be held in quarantine if a determination has been made that the Whole Blood, blood components, Source Plasma or Source Leukocytes was collected more than 12 months prior to the donor's most recent negative antibody screening test when tested in accordance with § 610.45. Pooled Source Plasma and Source Leukocytes are exempt from quarantine.

(d) *Release from quarantine.* Whole Blood, blood components, Source Plasma and Source Leukocytes intended for transfusion or further manufacture which have been quarantined under paragraph (a) of this section may be released if the donor is subsequently tested for antibody to HIV as provided in paragraph (b) of this section and the test result is negative, absent other informative test results.

(e) Actions under this section do not constitute a product recall as defined in § 7.3(g) of this chapter.

§ 610.47 ''Lookback'' notification requirements for transfusion services.

(a) Transfusion services that are not subject to the Health Care Financing Administration's regulations on conditions of Medicare participation for hospitals (42 CFR part 482) are required to take appropriate action in accordance with paragraphs (b) and (c) of this section when a recipient has received Whole Blood or blood components from a donor determined to be unsuitable when tested for human immunodeficiency virus (HIV) infection in accordance with § 610.45 and the results of the additional tests as provided for in § 610.46(b) are positive.

(b) *Notification of recipients of prior transfusion.* If the transfusion service has administered Whole Blood or blood components as described in paragraph (a) of this section, the transfusion service shall 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 transfusion service shall notify the recipient and inform the recipient of the need for HIV testing and counseling. The notification process shall include a minimum of three attempts to notify the recipient and be completed within a maximum 8 weeks of receipt of the result of the licensed, more specific test for HIV. The transfusion service is responsible for notification, including basic explanations to the recipient and referral for counseling, and shall document the notification or attempts to notify the attending physician or the recipient, pursuant to § 606.160 of this chapter.

(c) *Notification to legal representative or relative.* If the transfusion recipient has been adjudged incompetent by a State court, the transfusion service or physician must notify a legal representative designated in accordance with State law. If the transfusion recipient is competent, but State law permits a legal representative or relative to receive the information on the recipient's behalf, the transfusion service or physician must notify the recipient or his or her legal representative or relative. If the transfusion recipient is deceased, the transfusion service or physician must continue the notification process and inform the deceased recipient's legal representative or relative. Reasons for notifying the recipient's relative or legal representative on his or her behalf shall be documented pursuant to § 606.160 of this chapter.

Dated: July 11, 1996.

David A. Kessler,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 96–22709 Filed 9–6–96; 8:45 am]

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Health Care Financing Administration

42 CFR Part 482

[BPD–633–F]

RIN 0938–AE40

Medicare and Medicaid Programs; Hospital Standard for Potentially HIV Infectious Blood and Blood Products

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

ACTION: Final rule.

SUMMARY: This final rule requires hospitals participating in the Medicare and Medicaid programs to take appropriate action when the hospitals learn that they have received whole blood, blood components (including recovered plasma), source plasma, and source leukocytes (hereafter referred to as blood or blood products) that are at increased risk of transmitting Human Immunodeficiency Virus (HIV)

infection. If the hospital learns that it has received blood or blood products collected from a donor recently exposed to HIV, before the donor has a sufficient level of antibody to be detected by the screening test for antibody to HIV, the hospital must quarantine any blood or blood products remaining in inventory pending confirmatory testing. If the presence of HIV is confirmed by more specific testing, the hospital must notify patients who received the blood or blood product.

This final rule is intended to ensure that proper health and safety steps are taken to minimize further spread of HIV infection. A final rule published elsewhere in this Federal Register by the Food and Drug Administration applies the same requirements to entities furnishing transfusion services that do not participate in the Medicare and Medicaid programs and clarifies the responsibilities of blood establishments to identify and notify the transfusion service that received affected blood and blood products.

EFFECTIVE DATES: This rule is effective on November 8, 1996.

FOR FURTHER INFORMATION CONTACT: Janet Samen, (410) 786–9161.

SUPPLEMENTARY INFORMATION:

I. Background

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

Regulations containing the Medicare conditions of participation for hospitals are located in the Code of Federal Regulations at 42 CFR part 482, with the condition for hospital laboratory services at § 482.27. Section 482.27 contains general requirements for hospital laboratories. 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 (CLIA) programs.

In the Department of Health and Human Services, the Food and Drug Administration (FDA) and HCFA are responsible for different aspects of ensuring the safety of blood and blood products. Blood banks (referred to as blood establishments in FDA regulations) are subject to the FDA regulations for current good manufacturing practices and additional standards for the manufacture of blood and blood components under 21 CFR parts 211 and 600, 601, 606, 610, and 640. Laboratories that provide transfusion services are subject to CLIA requirements for quality control and health and safety standards (42 CFR part 493, subpart K) and laboratories in hospitals are also subject to the hospital conditions of participation for adequacy of laboratory services (§ 482.27). FDA and HCFA coordinate inspections of hospital-based blood banks to minimize duplication of effort and reduce the burden on affected facilities.

Human Immunodeficiency Virus (HIV) is a virus whose presence is associated with Acquired Immune Deficiency Syndrome (AIDS). In response to scientific data that show HIV is transmissible through infectious blood and blood products, FDA has implemented an extensive system of donor screening and testing procedures performed before, during, and after a donation takes place to help prevent the transfusion of blood and blood products that are infected with HIV.

Existing FDA regulations require each donation of blood to be tested and found negative for the antibody to HIV and restrict the use, for transfusion or further manufacture, of a donation testing repeatedly reactive for the antibody to HIV. Repeatedly reactive means that the initial HIV antibody screening test is reactive, retested in duplicate, and one or both of the duplicate tests are reactive. As a result of the FDA blood donor screening and testing procedures, the risk of transmitting HIV infection through blood transfusion is very low. However, despite the best practices of blood establishments, a person may donate blood early in infection when the antibody to HIV is not detectable by the screening test, but HIV is present in the donor's blood (a so-called ''window'' period). If the donor attempts to donate blood at a later date, the test for the antibody to HIV may at that time be repeatedly reactive. Under such circumstances, previously collected blood and blood products would be at increased risk for transmitting HIV and a recipient of a blood product collected during the ''window'' period would not know whether the donor was infected with HIV at the time of the previous donation. Steps taken to identify and quarantine remaining blood and blood products in storage and notify recipients of the blood are known as ''lookback.''

As a result of advances in identifying the presence of HIV, the ''window'' period continues to shrink. The FDA final rule published elsewhere in this Federal Register provides more information on the length of the window period and discusses various diagnostic modalities for HIV infection.

II. Proposed Regulations

FDA and HCFA published proposed regulations in the Federal Register on June 30, 1993 (58 FR 34962 and 58 FR 34977, respectively) to require lookback by blood establishments and transfusion services when it is later determined that potentially HIV infectious blood or blood products might have been collected and administered.

FDA proposed to require blood establishments (that is, facilities involved in the manufacture of blood and blood components) to quarantine previously collected blood and blood products collected from a donor who tested negative at the time of a previous donation but tests repeatedly reactive for the antibody to HIV on a later donation. A donor would be considered to be infected by HIV if the results of the FDA's licensed tests described at 21 CFR 610.45 show the presence of the antibody to HIV and if the screening results are confirmed positive by a licensed, more specific test. Blood establishments would be required to promptly notify the hospital transfusion service of the need to quarantine the potentially HIV infectious blood or blood products that were distributed.

In the HCFA regulation, we proposed to add a new paragraph (c) to § 482.27 (''Conditions of participation: Laboratory services.'') to set forth the standard for potentially HIV infectious blood and blood products. Under the proposed rule, when the hospital learns that it has administered blood that may have been collected during the ''window'' period, the hospital would be required to make several attempts to notify the patient's attending physician (physician of record) and ask the physician to inform the patient of the need for HIV testing and counseling. If the physician is unavailable or declines to notify the patient, the hospital must make several attempts to inform the patient of the need for HIV testing and counseling. We proposed that the notification include basic explanations to the patient and referral for counseling and that the hospital document the notification or attempts to notify the attending physician and the patient.

In addition, we proposed to require that, when services are furnished to a hospital by an outside blood bank, there must be an agreement governing the procurement, transfer, and availability of blood and blood products specifying that the blood bank promptly notify the hospital if potentially HIV infectious blood or blood products have been made available to the hospital.

Notification would enable the hospital to take proper health and safety steps to minimize further spread of HIV infection.

III. Analysis of and Responses to Public Comments

In response to the June 1993 HCFA proposed rule, we received 28 timely items of correspondence from national organizations, nurses, hospital administrators, State offices, law firms, and various organizations representing infection control officers and blood banks. A summary of individual comments we received on the June 1993 proposed rule, our responses, and the changes we have made are discussed below.

Coordination of FDA and HCFA Efforts

When HCFA and FDA published the June 1993 proposed rules, we intended that all blood banks (that is, blood establishments involved in the manufacture of blood and blood components) and transfusion services (that is, consignees that receive blood and blood products from blood banks/blood establishments and perform compatibility testing) comply with the quarantine and patient notification requirements. However, based on public comments received by both agencies, it appears that there was public misunderstanding of the mission of each agency and the scope of the rulemaking, as discussed below.

Comment: One commenter indicated that terminology used by HCFA and FDA is not consistent. In the FDA regulation, the terms ''consignees'' and ''transfusion services'' are used while the HCFA regulations refer to ''hospitals'' and ''blood banks.'' The commenter requested more consistent use of the terms. In addition, the commenter noted that the term ''blood banks'' may refer to a transfusion service or a freestanding community blood center. Finally, the commenter noted that the term ''consignee'' may mean the facility providing the transfusion service and that the term ''recipient'' may refer to the transfused patient. The commenter asked that ''transfusion service'' and ''transfused patient'' be the preferred terms.

Response: While we agree that the use of different terms can be confusing, we do not believe it would be appropriate to revise the terminology used in the HCFA regulation because it is consistent with that used elsewhere in title 42 of the Code of Federal Regulations, including the hospital conditions of participation and the CLIA regulations. Likewise, although the FDA terminology is different, it is understood by the entities regulated by FDA and described by FDA as follows.

- A transfusion service is a facility that is part of either a hospital or an independent clinical laboratory, that performs compatibility tests, stores and distributes blood components, but is not engaged in the routine collection or preparation of blood or plasma except for therapeutic collections or separation of recovered plasma or red blood cells.
- A blood establishment is an FDA registered facility or portion of a facility registered as such with FDA pursuant to 21 U.S.C. section 510 and 21 CFR part 607 that manufactures blood or blood products. These include hospital and non-hospital blood banks, plasmapheresis centers, donor centers, and the laboratories performing testing for these establishments.

To avoid confusion concerning whether FDA requirements regarding lookback and quarantine apply to hospital transfusion services, we are adding those requirements to the hospital conditions of participation. We have added a paragraph (c)(3) to § 482.27 to include the following requirements:

- Upon notification by the blood bank (blood establishment) that certain blood and blood products are at increased risk for transmitting HIV infection, the hospital (transfusion service) must determine the disposition of the blood or blood product and if it is holding any of the blood or blood product in inventory. If so, the hospital must quarantine the blood or blood products until notified by the blood bank of the results of an FDA-licensed, more specific test or other followup testing recommended or required by FDA.
- The hospital may release the blood or blood product from quarantine only after notification by the blood bank that the additional testing was negative for the HIV antibody, absent other informative test results. If the testing confirms the presence of the antibody for HIV, the hospital must dispose of the blood and blood products in accordance with FDA regulations at 21 CFR 606.40 and notify any patients who received the affected blood or blood products of the need for HIV testing and counseling. (The FDA final regulation requires the blood bank to complete the licensed, more specific test for the antibody to HIV within 30 days and promptly notify the hospital transfusion service of the test results.)

Comment: Several commenters suggested that any facility receiving and administering blood or blood products be required to comply with the same notification requirements as set forth in the proposed rule. Two commenters also suggested this standard for ambulatory surgical centers.

Response: When we published the proposed regulation, we specifically requested public comment regarding the need to develop similar requirements for other facilities that provide transfusion services. Although we did not receive specific suggestions, we have revised § 482.27(c)(4) to clarify that when a hospital (transfusion service) furnishes blood or blood products to another entity or appropriate individual, the hospital retains responsibility for patient notification.

We believe this approach is reasonable and consistent with the usual path followed by blood from donation to transfusion. As clarified in FDA regulations, blood establishments (defined in 21 CFR 607.3(c)) collect, screen, and test the blood, prepare blood components or process blood for further manufacture, and label blood components for distribution to a transfusion service. The transfusion service is the entity responsible for determining compatibility with the patient's sample and sending the blood to the patient's location (for example, the hospital, clinic, nursing facility, or home setting). In order to release the blood and blood products for transfusion, the hospital must crossmatch the blood for compatibility with the patient's sample. In doing so, the hospital would obtain enough information to enable them to notify the patient. Thus, the hospital has patient information and a notification system in place and is in the best position to perform patient notification.

We note that FDA is adopting the patient notification requirements for hospitals that do not participate in Medicare and Medicaid. Thus, all hospitals that administer blood and blood products or release the blood and blood products must comply with the same patient notification requirements.

Timeframe for Completing Notification

In the proposed rule, we did not require a specific timeframe for completion of the notification effort. Rather, we required the hospital to make several attempts to notify the patient's attending physician and, if the physician is unavailable or declines to notify, make several attempts to notify the patient. We indicated in the preamble that the hospital's notification effort should begin immediately after receiving the information from the blood bank and be completed within 8 weeks. Although we specifically invited public comment on the sufficiency of this level of effort, we did not receive enough information to draw any

conclusions about existing patient notification activities. In addition, the information we received indicated fundamental differences in the viewpoints of the commenters as described below.

Comment: Two commenters agreed with the approach contained in the proposed rule and did not want the hospital's search for the patient's physician or the patient to be bound by a specific timeframe. One commenter suggested that we only include the following requirements in the final rule: (1) Require that hospitals have written procedures for notifying patients; (2) provide for an appropriate, knowledgeable person to talk with the patient if the physician cannot be reached or chooses not to be involved; and (3) require that the notice be expeditious and confidential and include recommendations to seek HIV testing and counseling. Another commenter suggested that we require only that the hospital exercise due diligence and document its notification efforts.

Response: In order to respond to these commenters, we consulted with FDA on the best approach to the notification timeframe. We have decided to include a specific timeframe for completion of the notification effort in order to prevent hospitals from making sporadic efforts over a protracted period of time and to provide a reasonable minimum standard (§ 482.27(c)(5)). We believe requiring at least three attempts to notify the physician and, as necessary, three attempts to notify the patient within 8 weeks is reasonable. Since patient notification by the hospital rarely will be necessary, we do not believe that requiring as many as six notification attempts will be burdensome to hospitals.

Comment: One commenter asserted that the search could be performed in less than 8 weeks depending on a hospital's ability to locate records and contact the patient by mail. Still another commenter questioned whether we had considered the possible delay in starting treatment that may occur because of the 8-week period allowed for notification and expressed concern that an 8-week delay could contribute to individuals unknowingly transmitting HIV. One commenter indicated that four or five attempts over a 3- to 5-day period would be sufficient while another commenter suggested that we require a 12-week timeframe based on their concern that the physician might decline at the end of the 8 weeks and leave little time for the hospital to perform the notification.

Response: We believe that most, if not all, notifications would be accomplished with relatively little effort and that three attempts should be sufficient in most cases. On the other hand, if a hospital has made a good faith effort of at least three attempts but is not able to locate the patient within 8 weeks, we do not expect the hospital to continue its search. Of course, there is no limit on how much time a hospital may choose to expend on this effort.

We do not intend for the hospital to use the entire 8 weeks to attempt to locate a physician who, at the end of the 8-week period, may be determined to be unavailable. Rather, we intend that the majority of the 8 weeks be used to locate and notify the patient. We recommend that the hospital promptly make three attempts within one week to notify the physician. If the hospital is unable to locate the physician or the physician does not agree to notify the patient, the hospital should promptly start attempts to locate the patient.

In addition, it would be inappropriate for the physician to wait until the end of the 8-week period to inform the hospital that he or she is unwilling to notify the patient. In most cases, we believe that the hospital will contact the physician by telephone and the physician will make an immediate decision to agree or decline to notify the patient. However, if the physician is not able to make an immediate decision, the physician should indicate his or her decision within 1 week of the hospital's request. In this way, it is reasonable to expect the hospital to locate and notify the patient in the remaining 7 weeks.

We are aware that there may be instances where the hospital's notification efforts will extend beyond the 8-week period due to circumstances beyond the hospital's control. For example, a physician who agrees to notify the patient may later inform the hospital that he or she was unable to notify the patient or the patient may not respond timely to notification efforts because he or she is away from home. In these cases, the hospital must document in the patient's medical record the extenuating circumstances that prevented patient notification within the 8-week timeframe (§ 482.27(c)(5)).

Comment: One commenter questioned whether patient notification is necessary if several years have passed after receipt of a transfusion, or whether the hospital can establish timeframes after which patient notification need not be made.

Response: Section 610.46(a) of the FDA regulation published elsewhere in this Federal Register defines the quarantine and notification process to be followed by blood establishments supplying blood to hospitals. Under this rule, when a blood establishment learns of a change in the HIV status of a donor, the blood establishment must determine if any prior donations meet the quarantine and notification requirements set forth in 21 CFR 610.46(a) and, as appropriate, inform the hospital(s) that received any prior donations from the donor. Once the blood establishment notifies the hospital(s), we do not believe that there is ever a time that patient notification need not be attempted. It is only when the physician or the hospital cannot locate the patient that the process may come to an end.

Role of the Physician in the Notification Process

Comment: One commenter suggested that we require any physician who wishes to participate in the Medicare or Medicaid program to assume the responsibility for notifying the patient and providing or making available appropriate HIV counseling to the patient. Another commenter requested that we indicate the consequences for physicians who fail to notify the patient.

Response: Although we believe that it is appropriate for attending physicians to notify their patients, we do not have authority under current law to require that physicians do so. Thus, while it is true that there are no Federal penalties imposed on physicians who decline or do not take appropriate steps to notify the patient, we believe most physicians will choose to notify the patient and voluntarily inform the hospital whether notification occurred. Since we have an agreement with each Medicare and Medicaid participating hospital and the law authorizes us to include provisions such as these under the hospital conditions of participation, we have determined that if the physician does not agree to notify the patient, the hospital must assume responsibility for patient notification.

Comment: Several commenters wanted clarification regarding when a physician could decline to notify the patient. Many commenters disagreed with permitting the physician the option to decline notification. Four commenters stated that this policy contradicts principles of continuity of care and sound medical practice. One commenter asserted that no physician will notify patients if given the option and that the requirement for hospitals to notify patients when physicians decline removes any incentive for the physicians to participate in the notification process.

Response: In the interest of continuity of care and sound medical practice, we believe that most physicians will notify

their patients. However, we continue to believe there could be legitimate reasons why a physician might refuse to notify the patient; for example, the physician determines that the patient has moved to another State and it would be difficult for the physician to identify HIV counseling and testing programs in the patient's new location, or the physician has had very limited or no contact with the patient in several years.

Comment: Several commenters asked us to publish a definition of ''attending physician'' to clarify who should be responsible for patient notification.

Response: In § 482.27(c)(4), we have included the phrase ''physician of record'' in parentheses next to the term ''attending physician.'' Although many physicians may have contact with a patient in the course of a hospital stay, the admitting physician is identified on the admission form. We believe that this physician is the ''physician of record'' and should be responsible for the notification. However, if the physician who orders the transfusion is not the same physician as the physician identified on the admitting form, the hospital may ask either physician to perform the notification.

Comment: One commenter questioned the role the hospital plays in determining whether a physician provided information and referred the patient for counseling. One commenter asked that we specify whether the hospital is obligated to complete any part of the notification that the physician fails to carry out. Additionally, the commenter questioned how the hospital would know what the physician had done.

Response: Under this regulation, when the physician accepts responsibility for the notification, the hospital is not required to follow up with the physician to determine whether patient notification occurred. Since the hospital may not be aware of the information the physician provides, we cannot require that the hospital complete the notification. In light of physicians' professional relationship with hospitals, we believe physicians will inform the hospital whether notification occurred. If the physician informs the hospital that he or she was unable to notify the patient, the hospital must proceed with patient notification.

Comment: One commenter wanted to know at what point the hospital resumes responsibility for notification if the physician is unable to contact the patient. Two commenters questioned whether the physician is required to inform the hospital of the results of notification, for example, whether the physician was unable to locate the patient, whether the patient was tested, and the results of the testing.

Response: Although we believe that the physician, as part of his or her professional responsibility, will inform the hospital of the results of notification, he or she is not required to do so. If the physician accepts responsibility for notification, and later informs the hospital that the patient was not notified, the hospital must attempt notification, regardless of the time that elapsed after the hospital first notified the physician.

Some State or local health groups may require further followup and other epidemiological information but release of information is dependent upon State and local laws, the medical practice, and the patient-physician relationship. Finally, having the physician notify the hospital of the results of testing of the referred patient is outside the scope of the notification requirements of this regulation.

Comment: One commenter noted that the laws in his State require the physician to provide information to the patient regarding blood products in advance of any non-emergency transfusion and, when the physician orders an HIV test, to obtain the patient's informed consent.

Response: While these precautions are indeed important to the risk management of blood and blood products, they do not remove the need for notification by the hospital or physician of possible contamination.

Comment: One commenter indicated that assigning patient notification responsibility to the hospital means that a clinician must be identified to handle the cases declined by the physician. Several commenters questioned whether the appropriate individual to notify the patient should be limited to someone with medical experience or whether the hospital may designate any nonmedical personnel to perform these notifications. One commenter indicated that the physician is the only individual who should notify the patient, while another commenter noted that the infection control representative in his facility is responsible for notification. Another commenter requested that we permit the hospital to bypass the doctor/patient relationship if the physician resists the hospital's request to notify the patient. One commenter suggested that when the physician declines to notify the patient, the hospital should use the mail system, rather than have a hospital employee unknown to the patient, to provide the notification.

Response: We continue to believe it is preferable that notification be made by a physician with whom the patient has a professional relationship, such as the attending physician who coordinated the care during the patient's hospitalization or the physician who ordered the blood or blood product. Nevertheless, the hospital may designate another physician or an appropriate hospital representative to inform the patient. We believe that the hospital in its policies and practices will designate an appropriate, competent individual to perform this type of notification such as an infection control officer, a nurse, a clinical laboratory scientist, an individual with medical expertise who is not a physician, or a social worker. We note that the hospital must review any voluntary notification procedures to ensure that they conform to the requirements of this regulation.

Comment: Several commenters indicated that hospitals should develop policies to identify the appropriate physician to assist in notification and counseling, in the event efforts to locate the attending physician are unsuccessful.

Response: We have revised the regulation to require hospitals to establish policies and procedures for notification (§ 482.27(c)(6)). The final regulation does not require a hospital to provide HIV testing or counseling, but merely to refer the patient for testing and counseling. We expect that the referral for testing and counseling will be made to a physician or organization that provides high quality HIV testing and has extensive experience in providing HIV counseling.

Notification Requirements

Comment: We invited comment on whether our proposed rule should be implemented as part of a Medicare hospital standard or as part of the FDA requirements applicable to blood establishments. While most commenters indicated that hospitals, not blood banks, should be responsible for assuring that patients are properly notified of the possibility that they have received infectious blood, some commenters recommended that blood banks should be required to make notification.

Response: Based on the comments we received, we have determined that the hospital could best perform the notifications since it has access to medical records. Blood banks that are not departments of hospitals do not routinely receive hospital patient information. If the blood bank were a department within the hospital or performed compatibility testing for the hospital, it would have access to patient information and could perform the

notification as designated by hospital policy. Under this final regulation, blood banks must notify the hospital of receipt of potentially HIV infectious blood and blood products and hospitals are responsible for patient notification.

Comment: Two commenters recommended that specific operational issues should be developed at the hospital level within general guidelines established by regulation. Another commenter suggested that the regulation describe what hospitals are expected to accomplish and let hospitals determine, based on their own experience and circumstances, how best to notify patients. However, two others requested that the mechanics of notification be spelled out for standardization.

Response: As noted previously, we added § 482.27 (c)(4) and (c)(5) to require three attempts to notify the physician, and, as necessary, three attempts to notify the patient with 8 weeks. We believe that, within these parameters, the hospital retains flexibility to develop its own policies and procedures in order to meet the notification requirements.

Comment: One commenter indicated that the language of proposed § 482.27(c)(2) is inconsistent with the preamble because it implies that the hospital is obligated to notify both the physician and the patient.

Response: We are clarifying in this final rule that the hospital must notify the patient only if the physician is unavailable, declines, or later informs the hospital that he or she was unable to notify the patient (§ 482.27(c)(4)).

Comment: One commenter indicated that a search should be terminated only after a review is conducted by a hospital-sponsored ''lookback advisory committee'' composed of relevant specialists and expert staff members.

Response: While we support the use of an advisory committee to determine when it is appropriate for patient notification efforts to cease, we have decided not to adopt this suggestion in the regulation. We would prefer to allow a hospital flexibility to develop responsible policies and procedures. Of course, a hospital may choose to incorporate the commenter's suggested approach into its policies and procedures.

Comment: Four commenters indicated that there are no requirements that identify the information to be released during patient notification. The commenters suggested that we establish uniform and standard minimum requirements for disclosing information to patients during the notification process.

Response: We agree and have added § 482.27(c)(6)(iii) to clarify that when a physician or hospital notifies a patient about the need for HIV testing and counseling, the patient will also be given the names of several programs or places in the area where the patient resides that provide these services. In addition, the patient will be told about any requirements or restrictions the programs may impose such as whether the program requires a fee, a physician request form, identification or public assistance cards, or a residency requirement. In some situations, the hospital, in conjunction with its advisory groups, will provide the materials for the physician to use or identify programs that provide the HIV testing and counseling. Some groups have developed packages of materials, brochures, and information about the risks of blood and blood products and how HIV infection is transmitted. The Centers for Disease Control and Prevention (CDC) National AIDS Hotline operates a toll-free number (1–800–342–2437) 24 hours a day that the hospital or physician can give to the patient for more assistance. (The Hotline offers anonymous, confidential AIDS information to the American public. Trained information specialists answer questions about HIV infection and AIDS. The physician or hospital can give the patient the Hotline number (1–800–342–AIDS/2437 (English); 1–800–344–7432 (Spanish) and 1–800–243–7889 (TDD/Deaf Access)). We encourage physicians and hospitals to make available to the patient any additional information that would be useful to the patient and consult with and obtain resource materials from programs that are funded by the Ryan White Comprehensive AIDS Resources Emergency Act, the CDC, county and State health departments, and AIDS awareness groups.

Privacy and Recordkeeping

Comment: One commenter expressed concern that the proposed regulation did not address the issue of privacy in recordkeeping, including access to the information from the Blood Donor Locator Service (BDLS) operated by the Social Security Administration (SSA), and blood bank and hospital records. The commenter suggested that, even though these issues may be addressed elsewhere, they needed to be restated in this regulation.

Response: Hospital requirements for confidentiality in recordkeeping are already in existing regulations at § 482.24. Documents related to notification become part of the patient's medical record and are subject to the normal safeguards for access, information release, patient consent, and other precautions for confidential information, whether in hard copies, films, or computer records. If there is any doubt about confidentiality or disclosure, a medical record administrator can be consulted to provide adequate instructions. In addition, the hospital must establish procedures that conform to all Federal, State and local laws regarding confidentiality.

Comment: One commenter suggested that the hospital send the physician a return postcard and ask that the postcard be sent back to the hospital indicating whether the patient was notified, and, if so, the date the physician notified the patient.

Response: As noted earlier, we have revised the regulation to require hospitals to establish policies and procedures for notification, including requirements for confidentiality (§ 482.27(c)(7)). We have concerns about maintaining patient confidentiality through use of postcards to convey information about potentially HIV infectious blood and blood products. Although this final rule affords the hospital the flexibility to establish policies and procedures for the notification process, the policies and procedures must protect patient confidentiality.

Comment: In addition to any State requirements or laws concerning HIV confidentiality, many commenters recommended that all written patient notifications be marked ''confidential'' and be sent only by certified mail. Two commenters asked for a ''return receipt.''

Response: While we would support efforts by hospitals to use certified mail when written patient notification is necessary, we have decided not to incorporate this requirement in the regulation. Similarly, although use of a return receipt would provide the hospital with confirmation that the individual received the information, incorporating this specific requirement may conflict with State laws that require ''marking for confidentiality'' and would limit the hospital's flexibility to develop a process based on its experience and circumstances.

Comment: One commenter did not want all patients notified based on a concern that once a patient's HIV status is known, the patient may be subjected to ostracism and discrimination in receiving care. Since many hospitals use universal precautions for infection control, the commenter believed that there is no need to know the HIV status of patients. However, information about

the HIV status could be retained by the patient's physician.

Response: We believe it is important for the patient to know of his or her potential exposure to HIV so that he or she will be informed of the need for testing and counseling in order to promote behavior changes that will reduce the risk for transmission of HIV and to detect HIV infection in persons so that their need for medical treatment and other services can be assessed.

Comment: One commenter recommended that we clarify the documentation needed to be filed by the attending physician and materials to be developed and retained by the hospital. Another commenter wanted to know which steps in the process should be documented, that is, the attempts to notify patients, counseling, patient referral, etc. One commenter questioned whether compliance can be evaluated by Medicare, the FDA, or the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) without specific documentation requirements for notifying patients of potentially infectious blood or blood products.

Response: We are not looking for lengthy documentation, but sufficient recordkeeping that indicates when attempts were made to notify the patient and the results of those attempts. We are not prescribing forms that a hospital must use; however, a hospital may develop its own record forms. We do not believe that additional files or new systems of data should be kept on this matter. The surveyor, in determining compliance, must be able to determine satisfactorily that the manner in which the hospital performs notifications comports with the regulation.

Comment: One commenter requested that we clarify the type of information regarding the patient, for example, patient testing results, that can be shared between physician and hospital.

Response: The hospital and the physician may determine if any information should be shared. This rule does not require the sharing of information between the physician and the hospital. Patient testing results are outside the scope of this regulation.

Comment: One commenter asked for standardized recommendations for record retention by blood banks and by institutions accepting and administering blood and blood products. The commenter asserted that his facility requires that employee health records be kept for 30 years after terminating employment.

Response: Although a facility may require that employee health records be kept for 30 years after the employee leaves employment, this is not the current Federal standard for records involving blood and blood products. The hospital conditions of participation require that hospital medical records must be kept at least 5 years (§ 482.24(b)(1)). The notification records and blood bank records are subject to the same 5-year requirement. Additionally, the FDA regulations at 21 CFR 606.160(d) require that blood and blood product records be kept for at least 5 years after processing, or 6 months after the latest expiration date, whichever is later. Under CLIA, the laboratory regulations on quality control records for blood and blood products (§ 493.1221) reflect the FDA regulation. Any longer timeframe for retention of medical records is dependent upon hospital policies, State laws, computerization, storage space, and investigational studies.

Comment: Two commenters interpreted the proposed rule as requiring notification by the hospital when the patient is terminally ill, debilitated, or celibate, and is not (and has not been) an infection risk to others. The commenters expressed concern that these patients would be adversely affected by the notification. The commenter interpreted the proposed rule to require the hospital to inform the patient even if the physician caring for the patient, either alone or in consultation with relatives, believes the harmful effects of notification exceed the benefits of notification.

Response: We have revised the regulation at § 482.27(c)(8) to clarify that the physician or hospital may notify a legal representative designated in accordance with State law. Further, if the patient is competent, but the physician believes the information should not be given to the patient and State law permits a legal representative or relative to receive information on the patient's behalf (for example, when the patient is under age 18), then the physician must notify the patient's representative or relative. Upon learning of the death of a transfusion patient, the hospital must pursue the notification process to inform the patient's family. Public health concerns would warrant that the notification process continue and include the deceased patient's legal representative or relative. It would not be appropriate for a physician or hospital to determine that the patient or someone acting on his or her behalf need not be informed.

Comment: Three commenters wanted epidemiologic information, demographics, or other information to be provided to the State health department or other appropriate entity for patient followup. Another commenter requested that the blood bank notify the physician and the regional health departments about potentially HIV infectious blood and blood products being administered. The commenter referred to the health department's ability to track various diseases and to provide pre- and post-counseling of possible HIV-infected individuals.

Response: Disclosure of information to entities other than the hospital, the patient, and, as appropriate, the patient's legal representative or relative, is governed by State law and hospital policies and is outside the scope of this rulemaking.

Comment: One commenter suggested that the notification about a patient's HIV status be given to good samaritan bystanders. The commenter stated that there are circumstances when an individual injured in an accident or fire requires subsequent medical care. When that care is given and the patient is found to be HIV positive, the commenter stated that all those who have given the patient medical care should be informed of the patient's status. The commenter wants State and Federal regulations to protect health care workers, emergency medical technicians, and public safety officials.

Response: The comment, while addressing an important public health and safety issue, is beyond the scope of this regulation. However, the CDC published a final rule on March 21, 1994 to address this issue (59 FR 13418).

Comment: One commenter wanted the hospital to be informed promptly by outside blood sources if there is any doubt about its blood supplies possibly being infected by the HIV virus.

Response: The issue raised by the commenter is addressed in the FDA final regulation published elsewhere in this Federal Register.

Hospital Agreements With Blood Banks

Comment: One commenter indicated that government intrusion in mandating agreements between hospitals and blood banks would not permit the organizations to work out their own agreements. Another commenter stated that if hospitals are required by regulation to have an agreement for procurement, transfer, and availability of blood and blood products, the blood banks would be in a position to impose additional terms through the agreements that the hospital would not otherwise wish to accept, for example, an agreement under which a hospital would never seek indemnification from the blood bank for infectious blood or

blood products. Another commenter suggested that his facility occasionally obtains blood or blood products from a source other than the blood bank that regularly supplies it. The commenter questioned whether the hospital is required to have an agreement with all sources supplying blood to the hospital.

Response: The laboratory requirements at § 493.1277 already require that in the case of services regularly furnished by an outside blood bank, the hospital laboratory must have an agreement reviewed and approved by the director that governs the procurement, transfer, and availability of blood and blood products. We note that a blood bank that is part of a hospital is not required to have an agreement with the hospital administration, but the laboratory still would have policies of proper practice that meet the FDA regulations and requirements of other regulatory and accrediting bodies. We intend that the details of the agreements or practice policies that are worked out between the blood bank and the hospital be consistent with Federal, State and local laws. Finally, we recognize that, under certain circumstances, hospitals may receive blood from a source other than the blood bank that has an agreement with the hospital. For example, during a blood emergency, a hospital may receive blood from another blood bank that may have a surplus of a special blood type that is needed by the hospital's patient. In this situation, if the blood bank becomes aware that the blood it furnished the hospital is potentially infected with HIV, the FDA regulations require the blood bank to notify the hospital.

Comment: One commenter indicated that the blood bank obligations are better achieved through regulations by the FDA. Further, the commenter suggested that since requirements change from time to time, all agreements would need to be changed every time. The commenter also concluded that establishing requirements by regulation alone is more flexible and efficient than regulations and contractual agreements.

Response: As noted previously, FDA and HCFA are responsible for different aspects of ensuring the safety of blood and blood products. Blood banks are subject to FDA regulations for current good manufacturing practices and additional standards for the manufacture of blood and blood components under 21 CFR parts 211 and 600, 601, 606, 610, and 640. HCFA regulations cover quality control, health and safety issues, and adequacy of laboratory services. Since the hospital has access to medical records and it is preferable that the notification is made by an individual with whom the patient has a professional relationship, such as the attending physician who coordinated the care during the patient's hospitalization, we believe that the requirements of this regulation should be addressed through the hospital conditions of participation. Agreements can be written flexibly so that any changes in FDA or HCFA requirements can be incorporated into operating procedures rather than by constructing a new contractual agreement.

Comment: One commenter recommended that the SSA BDLS be expanded and adapted to provide assistance in mandated lookback programs to locate patients. Another commenter asked that the SSA BDLS program be available for locating the last address of known sexual partners of lookback patients if notifying them is determined to be necessary.

Response: The SSA BDLS was implemented 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 8008 of the Technical and Miscellaneous Revenue Act of 1988 (Pub. L. 100–647) provides for furnishing only to participating States and authorized blood donation facilities at their request the last known personal mailing address of blood donors whose blood donation shows that they are or may be infected with HIV, if the State or authorized blood donation facility has been unable to locate the donors. The SSA BDLS cannot be used for any other purpose. To expand the program to include obtaining information on the patient or known sexual partner would require a legislative amendment.

Comment: One commenter stated that the rule did not address requirements for hospitals that have their own blood banks.

Response: We have clarified in § 482.27(c)(4) that if the hospital has administered potentially HIV infectious blood and blood products directly through its own blood bank or under an agreement with an outside blood bank, the hospital must promptly notify the patient's physician. We note that a hospital transfusion service that also functions as a blood establishment, that is, collects and manufactures blood and blood products, is subject to HCFA's final rule as a transfusion service and FDA's final rule as a blood establishment.

Contracting for Notification

Comment: Four commenters recommended that we permit a hospital to formally contract with a blood center to supervise the notification of the patient, testing, and counseling procedures, if the physician is unavailable or declines to do so. One commenter mentioned that the departments of health in three States perform notification and tracing of HIV/AIDS patients and contacts. Another commenter suggested public health departments as an alternative for notification and counseling because of the expertise and mechanisms that are already in place.

Response: There is no barrier to a hospital contracting with another organization to perform the notification, testing, and counseling. However, under this rule, the hospital is responsible for the notification and referral. We are aware that a number of State departments of health provide notification and tracing of HIV/AIDS patients and contacts. Nonetheless, we continue to believe that the hospital and the physician are in a better position to perform the notification because of their prior involvement with the patient. A hospital that delegates notification must ensure that the notification and referral for counseling are performed in accordance with this regulation. If the blood center or organization fails to comply with the conditions of participation, the hospital would be subject to a noncompliance action.

Counseling

Comment: Two commenters stated that some State laws require specific counseling procedures and clinical information for those undergoing counseling for HIV testing.

Response: We believe individual State laws should be followed to provide information and counseling procedures following the notification process. The notification and referral requirements in the rule do not conflict with any such State laws.

Enforcement

Comment: One commenter urged us to recognize the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the American Osteopathic Association (AOA) standards to avoid a second survey by Medicare.

Response: We have been in contact with the JCAHO and AOA and have evaluated their standards to ensure comparability with the requirements in this final regulation. Both organizations plan to incorporate the new requirements into the 1996 update to their accreditation standards. Therefore, a hospital accredited by the JCAHO or the AOA would be deemed to meet the Medicare requirement for the standards

on potentially HIV infectious blood and blood products. A second survey by HCFA would not be routinely required. However, if a complaint was filed regarding a look-back situation and HCFA decided the situation warranted an investigation, HCFA may authorize a complaint investigation.

Burden on Hospitals

Comment: One commenter disputed the estimate in the proposed rule of 1 hour of public reporting burden (58 FR 34980) and suggested that notification takes more than 1 hour to complete.

Response: We estimated the 1-hour timeframe based on several assumptions: (1) The records on the patient had already been retrieved, (2) the physician of record was noted on the admission sheet, and (3) the hospital had the physician's correct phone number or address. We anticipated that the phone conversation between the hospital representative and physician would last approximately 10 minutes. We inflated this figure to 1 hour because we wanted to include any time necessary for recalls and wrong numbers. We also considered time necessary for preparation of written notices and delivery of notices to the mail room. We expect that a hospital will rarely need to notify a patient directly, although we recognize that it would take additional time. We did not receive any comments that cited examples of the time involved to notify a patient. Some hospitals have computer linkup between departments and can easily retrieve information. The time involved for each case also may differ depending upon whether it was a single unit of blood given to one patient versus a unit of blood that was separated into several blood products and given to several patients. If a single unit of blood is separated into several components or blood products, each individual affected by the donor represents a separate notification case.

Comment: Two commenters stated that the cost associated with an additional standard would add an unnecessary regulatory burden.

Response: We disagree that the cost of this standard would be burdensome. Although initial implementation of notification procedures will require some expenditure of time and effort, we believe most hospitals, blood banks, and physicians are currently voluntarily complying with the requirements of this final regulation. We estimate that the ongoing cost of complying with this regulation will be small because the risk of a person being transfused with potentially HIV infectious blood and blood products is small and declining.

IV. Provisions of the Final Regulations

After consideration of the public comments, we are adopting the June 1993 proposed rule with the following changes.

- We have clarified that when the blood bank notifies the hospital that certain blood and blood products are at increased risk for HIV infection, the hospital must determine if it is holding any of the blood or blood product in inventory. If so, the hospital must quarantine the blood or blood products until notified by the blood bank of the results of a licensed, more specific test or other followup testing recommended or required by FDA. The hospital may release the blood or blood product from quarantine only after notification by the blood bank that the licensed, more specific test was negative for HIV antibody, absent other informative test results. (§ 482.27(c)(3))
- We have clarified that when patient notification is necessary, hospitals are required to make three attempts to notify the patient's attending physician or the physician who ordered the blood or blood product and ask the physician to notify the patient. If the physician is unavailable, declines, or later informs the hospital that he or she was unable to notify the patient, the hospital must make three attempts to notify the patient. (§ 482.27(c)(4)
- We have clarified that when a hospital releases blood and blood products to another entity or appropriate individual for transfusion, the hospital is responsible for the patient notification process. (§ 482.27(c)(4))
- We have specified that notification to a legal representative or relative of the patient may be appropriate in those instances permitted by State law or where the patient is deceased. (§ 482.27(c)(8))
- We have clarified that we are not requiring the physician to make the actual counseling appointment for the patient and expanded the description of the content of notification. (§ 482.27(c)(6)(ii) and (iii))
- We have clarified that a hospital's steps to notify must be initiated promptly and completed within 8 weeks. (§§ 482.27(c)(4)(i) and (c)(5))
- We have required that hospitals establish policies and procedures for notification and documentation that conform to Federal, State, and local laws, including requirements for confidentiality and for medical records. (§ 482.27(c)(7))
- We clarified that, if the hospital uses the services of an outside blood bank, the agreement governing the procurement, transfer, and availability of blood and blood products must require the blood bank to promptly notify the hospital about potentially HIV infectious blood and blood products. (§ 482.27(c)(2))

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), agencies are required to provide 60-day notice in the Federal Register and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- Whether the information collection is necessary and useful to carry out the proper functions of the agency;
- The accuracy of the agency's estimate of the information collection burden;
- The quality, utility, and clarity of the information to be collected; and
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Since this final rule contains information collections that are subject to OMB review under the Paperwork Reduction Act of 1995, we are soliciting public comment on these information collections as discussed below.

As discussed in detail section III. of this preamble, we are requiring in § 482.27(c) that Medicare participating hospitals undertake certain activities when they learn that they have received blood or blood products that are at increased risk of transmitting HIV infection. These activities include the identification and quarantine of affected blood and blood products that remain in inventory pending confirmatory testing. If the testing confirms that blood or blood products the hospital received are potentially HIV infectious, the hospital must promptly make at least three attempts to notify the patient's attending physician and ask the physician to inform the patient of the need for HIV testing and counseling. If the physician is unavailable, declines, or later informs the hospital that he or she was unable to notify the patient, the hospital must promptly make at least three attempts to notify the patient, the patient's surviving relative, or other person designated in accordance with State law. The hospital must document in the patient's medical record the notification

or attempts to give the required notification. Hospitals must establish policies and procedures for patient notification and documentation that conform to Federal, State, and local laws, including requirements for confidentiality. Finally, if the hospital uses the services of an outside blood bank, the agreement governing procurement, transfer, and availability of blood and blood products must be revised to require the blood bank to promptly notify the hospital about potentially HIV-infectious blood or blood products. We note that the burden associated with these requirements involves the establishment of a system to facilitate information collection (that is, the notification and documentation of notification), but are not themselves information collections.

These changes would not increase significantly the paperwork and information collection burden on the approximately 6,400 Medicare-participating hospitals. We estimate that development of policies and procedures for handling potentially HIV-infectious blood and blood products and revision of agreements between hospitals and their blood banks will increase each hospital's recordkeeping burden by approximately 2 hours. Since this 2 hour burden is a one-time occurrence for each hospital, the total burden associated with this particular requirement is 12,800 hours.

We further estimate that notifying patients and documenting notification efforts in patients' medical records will take approximately 1 hour per occurrence. As indicated in section III. of this preamble, we based this estimate on several assumptions: (1) The records on the patient had already been retrieved; (2) the physician of record was noted on the admission sheet; and (3) the hospital had the physician's correct telephone number or address. The time involved for each lookback case also may differ depending upon whether it was a single unit of blood given to one patient versus a unit of blood that was separated into several blood products and given to several patients. We considered each individual affected by the donor to be a separate notification case. FDA has estimated that approximately 60 lookback cases occur annually, with 16 involving patient notification. These cases are spread over approximately 6,600 hospitals, including approximately 200 hospitals that do not participate in the Medicare program. If we assume that all 16 cases involving patient notification were to occur in Medicare-participating hospitals, this requirement would increase the recordkeeping burden on these hospitals by a total of 16 hours.

The total paperwork and reporting burden on Medicare participating hospitals as a result of the information collection requirements in this rule is, therefore, estimated to be 12,816 (12,800+16) hours.

Organizations and individuals were given an opportunity to comment on these information collection requirements at the time the June 30, 1993 rule was published. However, because of the new estimate of the two-hour recordkeeping burden on hospitals resulting from the need to establish policies and procedures and to amend agreements with blood banks, we are again soliciting public comment on these information collection requirements and providing the 60-day notice. As also stated in the June 30, 1993 rule, a document will be published in the Federal Register after Office of Management and Budget approval is obtained.

Organizations and individuals desiring to submit comments on these information collection and recordkeeping requirements should send them to HCFA, OFHR, MPAS, C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

VI. Regulatory Impact Statement

Consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), we prepare a regulatory flexibility analysis unless we certify that a rule will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, we consider hospitals, blood banks, and physicians to be small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

This final rule expands the scope of the notification requirements to include hospitals that release blood and blood products to another entity or appropriate individual. Physicians will be asked to inform the recipient of a potentially HIV infectious blood or blood product of the need for HIV testing and counseling. If the physician is unavailable, declines, or informs the hospital that he or she was unable to notify the patient, the hospital is responsible for notification. It also requires hospitals to quarantine blood or blood products collected during the ''window'' period pending completion of more specific testing.

The most recent estimates of the current HIV risk per unit is 1 in 420,000. These estimates are a dramatic improvement over the 1 in 487 odds that prevailed before HIV testing of the blood supply began in 1985. 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, the time it takes a recently infected person to develop the antibodies that screening tests are designed to detect. That window period is estimated to range from a few weeks to 6 months. Section 482.24 (''Condition of participation: Medical record services.'') currently requires hospitals to maintain records for a period of 5 years. We expect hospitals will identify recipients of blood and blood products and meet the requirements of this rule to the extent the hospitals have 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 blood and blood products, and thus, we do not expect these final regulations will result in a substantial economic or resource burden on small entities. In addition, since most hospitals, blood banks, and physicians are currently voluntarily complying with the requirements of these final regulations, the ramifications of these final regulations are not expected to be substantial. Because of the small number of cases detected, individual hospitals will be required to quarantine blood and blood products and notify blood recipients in only a few, if any, cases. Nevertheless, the policies and procedures must be written and periodically updated to ensure that appropriate and timely quarantine and patient notification take place. Though not significant, there will be an additional burden of time and resources on hospitals not currently involved in the notification process.

We believe the ongoing cost of notification after implementation of this regulation will not be significant or burdensome because the risk of a person being transfused with potentially HIV infectious blood and blood products is declining. Even though this final rule will affect few people per year, it is

important that we ensure that potentially infected people are notified so they may seek appropriate medical care or consider behavior changes so as not to infect others.

Therefore, we are not preparing analyses for either the RFA or small rural hospitals since we have determined, and we certify, that this final rule will not likely have a significant economic impact on a substantial number of small entities or have a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this regulation was not reviewed by the Office of Management and Budget.

Under the provisions of Public Law 104–121, we have determined that this final rule is not a major rule.

List of Subjects in 42 CFR Part 482

Grant programs—health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR part 482 is 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 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart C—Basic Hospital Functions

2. Section 482.27 is amended by adding a new paragraph (c) to read as follows:

§ 482.27 Condition of participation: Laboratory services.

* * * * *

(c) *Standard: Potentially infectious blood and blood products*—(1) *Potentially HIV infectious blood and blood products* are prior collections from a donor who tested negative at the time of donation but tests repeatedly reactive for the antibody to the human immunodeficiency virus (HIV) on a later donation, and the FDA-licensed, more specific test or other followup testing recommended or required by FDA is positive and the timing of seroconversion cannot be precisely estimated.

(2) *Services furnished by an outside blood bank.* If a hospital regularly uses the services of an outside blood bank, it must have an agreement with the blood bank that governs the procurement, transfer, and availability of blood and blood products. The agreement must require that the blood bank promptly notify the hospital of the following:

(i) If it supplied blood and blood products collected from a donor who tested negative at the time of donation but tests repeatedly reactive for the antibody to HIV on a later donation; and

(ii) The results of the FDA-licensed, more specific test or other followup testing recommended or required by FDA completed within 30 calendar days after the donor's repeatedly reactive screening test. (FDA regulations concerning HIV testing and lookback procedures are set forth at 21 CFR 610.45-et seq.)

(3) *Quarantine of blood and blood products pending completion of testing.* If the blood bank notifies the hospital of the repeatedly reactive HIV screening test results as required by paragraph (c)(2)(i) of this section, the hospital must determine the disposition of the blood or blood product and quarantine all blood and blood products from previous donations in inventory.

(i) If the blood bank notifies the hospital that the result of the FDA-licensed, more specific test or other followup testing recommended or required by FDA is negative, absent other informative test results, the hospital may release the blood and blood products from quarantine.

(ii) If the blood bank notifies the hospital that the result of the FDA-licensed, more specific test or other followup testing recommended or required by FDA is positive, the hospital must dispose of the blood and blood products in accordance with 21 CFR 606.40 and notify patients in accordance with paragraph (c)(4) of this section.

(4) *Patient notification.* If the hospital has administered potentially HIV infectious blood or blood products (either directly through its own blood bank or under an agreement described in paragraph (c)(2) of this section) or released such blood or blood products to another entity or appropriate individual, the hospital must take the following actions:

(i) Promptly make at least three attempts to notify the patient's attending physician (that is, the physician of record) or the physician who ordered the blood or blood product that potentially HIV infectious blood or blood products were transfused to the patient.

(ii) Ask the physician to immediately notify the patient, or other individual as permitted under paragraph (c)(8) of this section, of the need for HIV testing and counseling.

(iii) If the physician is unavailable, declines to make the notification, or later informs the hospital that he or she was unable to notify the patient, promptly make at least three attempts to notify the patient, or other individual as permitted under paragraph (c)(8) of this section, of the need for HIV testing and counseling.

(iv) Document in the patient's medical record the notification or attempts to give the required notification.

(5) *Timeframe for notification.* The notification effort begins when the blood bank notifies the hospital that it received potentially HIV infectious blood and blood products and continues for 8 weeks unless—

(i) The patient is located and notified; or

(ii) The hospital is unable to locate the patient and documents in the patient's medical record the extenuating circumstances beyond the hospital's control that caused the notification timeframe to exceed 8 weeks.

(6) *Content of notification.* The notification given under paragraphs (c)(4) (ii) and (iii) of this section must include the following information:

(i) A basic explanation of the need for HIV testing and counseling.

(ii) Enough oral or written information so that the transfused patient can make an informed decision about whether to obtain HIV testing and counseling.

(iii) A list of programs or places where the patient can obtain HIV testing and counseling, including any requirements or restrictions the program may impose.

(7) *Policies and procedures.* The hospital must establish policies and procedures for notification and documentation that conform to Federal, State, and local laws, including requirements for confidentiality and medical records.

(8) *Notification to legal representative or relative.* If the patient has been adjudged incompetent by a State court, the physician or hospital must notify a legal representative designated in accordance with State law. If the patient is competent, but State law permits a legal representative or relative to receive the information on the patient's behalf, the physician or hospital must notify the patient or his or her legal representative or relative. If the patient is deceased, the physician or hospital must continue the notification process and inform the deceased patient's legal representative or relative.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; Program No. 93.774, Medicare—Supplementary Medical Insurance; and Program No. 93.778, Medical Assistance Program)

Dated: July 11, 1996.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

Dated: July 11, 1996.

Donna E. Shalala,

Secretary.

[FR Doc. 96–22708 Filed 9–6–96; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF THE INTERIOR

Office of Hearings and Appeals

43 CFR Part 4

Department Hearings and Appeals Procedures

AGENCY: Office of Hearings and Appeals, Interior.

ACTION: Final rule.

SUMMARY: This document eliminates redundant words in 43 CFR 4.1(a) addressing authority of Administrative Law Judges to hold hearings within the Department of the Interior.

EFFECTIVE DATE: September 9, 1996.

FOR FURTHER INFORMATION CONTACT: James P. Terry, Deputy Director, Office of Hearings and Appeals, U.S. Department of the Interior, 4015 Wilson Blvd., Arlington, VA 22203 Telephone: (703) 235–3810.

SUPPLEMENTARY INFORMATION: Because this action reflects agency management in deleting non-substantive, redundant language relating to scope of actions for which Administrative Law Judges within the Department of the Interior have existing hearing responsibility, the Department has determined that the provisions of the Administrative Procedures Act, 5 U.S.C. 553 (b) and (d), allowing for public notice and comment and a 30-day delay in the effective date of a rule, are unnecessary and impracticable.

List of Subjects in 43 CFR Part 4

Administrative practice and procedure, Scope of authority, Applicable regulations.

Therefore, under the authority of the Secretary of the Interior contained in 5 U.S.C. 301, section 4.1(a) in Subpart A in Part 4 of Title 43 of the Code of Federal Regulations, is amended as follows:

PART 4—[AMENDED]

Subpart A—General; Office of Hearings and Appeals

1. The authority citation for Part 4 continues to read:

Authority: R.S. 2478, as amended, 43 U.S.C. 1201, unless otherwise noted.

2. Section 4.1(a) is revised to read as follows:

§ 4.1 [AMENDED]

* * * * *

(a) A Hearings Division comprised of administrative law judges who are authorized to conduct hearings in cases required by law to be conducted pursuant to 5 U.S.C. 554, and hearings in other cases arising under statutes and regulations of the Department, including rule making hearings, and

* * * * *

Dated: August 28, 1996.

Bonnie R. Cohen,

Assistant Secretary—Policy, Management and Budget.

[FR Doc. 96–22815 Filed 9–6–96; 8:45 am]

BILLING CODE 4310–79–M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 68

Connection of Terminal Equipment to the Telephone Network

AGENCY: Federal Communications Commission.

ACTION: Correcting amendments.

SUMMARY: This document contains corrections to the final regulations which related to the connection of terminal equipment to the telephone network.

EFFECTIVE DATE: September 9, 1996.

FOR FURTHER INFORMATION CONTACT: William von Alven, (202) 418–2342.

SUPPLEMENTARY INFORMATION:

Background

The final regulations that are the subject of these corrections relate to the means of connection of data terminal equipment to the telephone network and to the on-hook impedance limitations for all types of terminal equipment.

Need for Correction

As published, the final regulations contain errors which may prove to be misleading and are in need of clarification.

List of Subjects in 47 CFR Part 68

Communications equipment, Telephone.

PART 68—CONNECTION OF TERMINAL EQUIPMENT TO THE TELEPHONE NETWORK

Accordingly, 47 CFR Part 68 is corrected by making the following correcting amendments:

1. The authority citation for Part 68 continues to read as follows:

Authority: Secs 4, 5, 201–5, 208, 15, 218, 226, 227, 303, 313, 314, 403, 410, 602 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154, 155, 201–5, 208, 215, 218, 226, 227, 303, 313, 314, 403, 404, 410, 602.

§ 68.104 [Corrected]

2. In § 68.104, paragraph (b), in the first sentence, the reference to ''§ 68.308(a)(4) (i) or (ii)'' is revised to read ''§ 68.308(b)(4) (i) or (ii)''.

§ 68.312 [Corrected]

3. In § 68.312, paragraph (b)(2), the reference to ''paragraph (a)(1)(v)'' is revised to read ''paragraph (b)(1)(v)''.

4. In § 68.312, paragraph (c)(2), in the tenth sentence, the reference to ''paragraph (a)(2)'' is revised to read ''paragraph (b)(2)''.

5. In § 68.312, paragraph (d)(1)(iv), the reference to ''paragraph (a)(1)(iv)'' is revised to read ''paragraph (b)(1)(iv)''.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 96–22701 Filed 9–6–96; 8:45 am]

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47 CFR Part 73

[MM Docket No. 95–14; RM–8552]

Radio Broadcasting Services; Leavenworth, Othello, and East Wenatchee, WA

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of Ronald A. Murray, d/b/a Murray Broadcasting, substitutes Channel 266A for Channel 249A at Leavenworth, Washington, and modifies Station KLVH(FM)'s construction permit accordingly. To accommodate the substitution, we also downgrade Channel 248C1 to Channel 248C3 at Othello, Washington, and modify Station KZLN-FM's construction permit accordingly; and substitute Channel 249A for Channel 266A at East Wenatchee, Washington, and modify Station KYSN(FM)'s license accordingly. *See* 60 FR 6689, February 3, 1995. Channel 266A can be allotted at Leavenworth in compliance with the Commission's minimum distance