Dated: December 3, 1999.

Jane E. Henney,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 00–28907 Filed 11–15–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 482

[HCFA–3014–P]

RIN 0938–AJ29

Medicare and Medicaid Programs; Hospital Conditions of Participation: Laboratory Services

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would require hospitals that transfuse blood and blood products to prepare and follow written procedures for appropriate action when it is determined that blood and blood products the hospitals received and transfused are at increased risk for transmitting hepatitis C virus (HCV); quarantine prior collections from a donor who is at increased risk for transmitting HCV infection; notify transfusion recipients, as appropriate, of the need for HCV testing and counseling; and extend the records retention period to 10 years.

These changes are based on recommendations by the Secretary's Advisory Committee on Blood Safety and Availability. The intent is to aid in the prevention of HCV infection and to create opportunities for disease prevention many years after recipient exposure to a donor.

DATES: We will consider written comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on or before January 16, 2001.

ADDRESSES: Mail written comments (one original and three copies) to the following address: Health Care Financing Administration, U.S. Department of Health and Human Services, P.O. Box 8010, Attention: HCFA–3014–P, 7500 Security Boulevard, Baltimore, Maryland 21244–8010.

If you prefer, you may deliver your written comments (one original and three copies) to one of the following addresses:

Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or,

Room C5–09–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Because of staffing and resource limitations, we cannot accept audio, visual, or facsimile (FAX) copies of comments. In commenting, please refer to file code HCFA–3014–P. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in room 443–G of the Department's offices at 200 Independence Avenue, 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: Mary Collins, (410) 786–3189.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 1861(e) of the Social Security Act (the Act), 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 Medicare conditions of participation.

Regulations containing the Medicare conditions of participation for hospitals are located in the Code of Federal Regulations at 42 CFR part 482. The condition of participation for hospital laboratory services at § 482.27 (c) currently specifies the steps hospitals must take when they become aware they have administered potentially human immunodeficiency virus (HIV) infectious blood or blood products to a patient. The more detailed requirements for laboratories appear in 42 CFR part 493, which sets forth requirements for all laboratories participating in the Medicare, Medicaid, and Clinical Laboratory Improvement Amendments (CLIA) programs.

The Health Care Financing Administration (HCFA) and the Food and Drug Administration (FDA) are responsible for 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, 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). Laboratories in hospitals are also subject to the hospital conditions of participation for adequacy of laboratory services (42 CFR 482.27). HCFA coordinates inspections of hospital-based blood banks with the FDA to minimize duplication of effort and reduce the burden on affected facilities.

Hepatitis C virus (HCV) was first discovered and established as a causative agent of transfusion-associated hepatitis in the late 1980s. In October 1989, FDA's Blood Products Advisory Committee (BPAC) first discussed steps to identify and quarantine potentially HCV infectious blood and blood products remaining in storage and notify recipients of the blood. (These steps are known as ''lookback.'') BPAC advised that there was insufficient information available concerning HCV infection to propose either product quarantine or notification of recipients transfused with products prepared from prior collections from donors later determined to be at increased risk for transmitting HCV.

In 1996, the Tenth Report of the U.S. House of Representatives Committee on Government Reform and Oversight (H. Rpt. No. 104–746) focused attention on the significant public health problem that HCV infections pose for the nation. HCV infection is the most common blood-borne infection in the United States. The Centers for Disease Control and Prevention (CDC) estimate that during the 1980s, as many as 180,000 new HCV infections occurred each year. Since 1989, the annual number of new infections has declined by 80 percent. Currently approximately 4 million individuals in the United States are believed to be chronically infected with HCV.

In 1996, however, data from the Third National Health and Nutritional Examination Survey conducted from 1988 to 1994 indicated that chronically infected persons may not be aware of their infection. Despite progression of the disease, HCV infection is usually asymptomatic for about 20 years, but in many cases causes serious liver injury that is thought to be the leading cause of late stage liver failure and cirrhosis in the United States. HCV is also thought to play a significant role in the development of liver cancer. Between 8,000 and 12,000 deaths annually result from HCV-related chronic liver disease.

HCV can be transmitted in a number of ways, including sharing of drug use equipment among injection drug users, blood transfusion and solid organ

transplants from infectious donors, hemodialysis, occupational exposure to blood, perinatal exposure of infants to infected mothers, and unprotected sex.

In response to scientific data that show that HCV 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 HCV.

Blood establishments are currently testing each donation of blood and blood components for the antibody to HCV. FDA restricts the use, for transfusion or further manufacture, of donations testing repeatedly reactive for the antibody to HCV. Repeatedly reactive means that the initial HCV antibody screening test is reactive (in which case it is retested in duplicate), and that 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 HCV infections through blood transfusion is very low. Despite the best practices of blood establishments, however, a person may donate blood early in the infection process when the antibody to HCV is not detectable by the screening test but is nevertheless 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 HCV may at that time be repeatedly reactive. Under these circumstances, previously collected blood and blood products would be at increased risk for transmitting HCV, and a recipient of a blood product collected during the window period would not know whether the donor was infected with HCV at the time of the previous donations. Approximately 7 percent of the 3.9 million Americans believed to be chronically infected with HCV were infected as a result of transfusion of blood components before the availability of donor screening tests or due to past use of non-viral-inactivated plasma derivative products. [1]

As a result of advances in identifying the presence of HCV, the window period continues to shrink. The FDA proposed rule titled ''Current Good Manufacturing Practice for Blood and Blood Components: Notification of Consignees and Transfusion Recipients Receiving Blood and Blood Components at Increased Risk of Transmitting HCV Infection ('Lookback'),'' published elsewhere in this issue of the **Federal Register,** provides more information on the length of the window period and discusses various diagnostic modalities for HCV infection.

The incidence of transfusion-transmitted HCV infection has decreased markedly since the implementation of donor screening for HCV and viral inactivation of clotting factors and intravenous immune globulins. Blood establishments implemented donor screening tests after a single antigen, enzyme linked immunosorbent assay (EIA) for antibody to HCV (HCV EIA 1.0 screening test) was licensed in May 1990. FDA issued a memorandum to all registered blood establishments in November 1990, ''Testing for Antibody to Hepatitis C Virus Encoded Antigen (Anti-HCV),'' recommending use of approved donor screening tests for antibody to HCV. A lookback program was not recommended because: (1) Screening tests available at the time could not distinguish between on-going infection and recovery, thus rendering unclear the meaning of a reactive test for any one individual; (2) donor screening for antibody to HCV did not include confirmatory testing, and most notification would have been based on false positive donor test results; (3) there was limited knowledge of routes of transmission for HCV other than parenteral; and (4) no potential long-term benefits of therapy were known.

A significantly more sensitive multiantigen screening test (HCV EIA 2.0 screening test) was licensed in March 1992. In June 1993, FDA licensed an HCV 2.0 strip immunoblot assay (HCV RIBA 2.0), also known as recombinant immunoblot assay (RIBA), a supplemental test for antibody to HCV. Supplemental tests for antibody to HCV are used to distinguish false positive test results from true repeatedly reactive screening test results. Following the December 1993 BPAC meeting, BPAC recommended product quarantine of prior collections from a donor who later tests repeatedly reactive for the antibody to HCV and tests positive or indeterminate on a supplemental test; however, BPAC only marginally endorsed consignee notification for the purpose of transfusion recipient notification because the public health benefit of the notification was not clear.

The Public Health Service Advisory Committee on Blood Safety and Availability (PHS Advisory Committee) discussed improvements in the treatment and management of HCV infection and improvements in testing for the antibody to HCV at public meetings held on April 24, 1997 and on August 11 and 12, 1997. The PHS Advisory Committee also discussed the public health benefits of notifying transfusion recipients receiving prior collections from a donor who subsequently tests repeatedly reactive for evidence of HCV infection. Following the Department of Health and Human Services' acceptance of recommendations from the PHS Advisory Committee, the FDA developed guidance, published in March 1998, regarding procedures for testing blood for HCV, quarantining blood and blood products, and notifying patients who may have received HCV-infected blood and blood products.

At public meetings on November 24, 1998 and January 28, 1999, the PHS Advisory Committee reconsidered the issue of recipient notification related to repeatedly reactive results on the single antigen screening test. The PHS Advisory Committee recommended that targeted lookback should be initiated based on a repeatedly reactive HCV EIA 1.0 screening test result on a repeat donor unless a supplemental test was performed and the result did not indicate increased risk of HCV infection, or, in the absence of a supplemental test result, unless the signal to cut off value of the repeatedly reactive HCV EIA 1.0 screening test was less than 2.5 or follow-up testing of the donor was negative.

FDA published a notice in the **Federal Register** on June 22, 1999 (64 FR 33309) announcing the availability of a draft guidance titled ''Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Prior Collections from Donors with Repeatedly Reactive Screening Tests for Hepatitis C Virus (HCV); (2) Supplemental Testing, and the Notification of Consignees and Transfusion Recipients of Donor Test Results for Antibody to HCV (Anti-HCV).'' Consistent with the recommendations of the PHS Advisory Committee, this revised draft guidance addressed lookback actions related to donor screening by HCV EIA 1.0 and also recommended that the search of historical testing records of prior donations from donors with repeatedly reactive EIA 1.0, EIA 2.0, or EIA 3.0 screening tests for HCV should extend back indefinitely to the extent that electronic or other retrievable records exist.

In the proposed rule titled ''Medicare and Medicaid Programs; Hospital Conditions of Participation; Provider Agreements and Supplier Approval'' (HCFA–3745–P), published on

[1] M.J. Alter, ''Epidemiology of Hepatitis C,'' Hepatology 26.3 (1997): 62s–65s.

December 19, 1997 in the **Federal Register** (62 FR 66726), we proposed to revise the hospital conditions of participation to focus on patient care outcomes, reflect a cross-functional view of the hospitals' organization and patient treatment, encourage flexibility in meeting quality standards, and eliminate outdated and redundant evaluation criteria. The lookback requirement for HIV infectious blood and blood products was the only lookback under this proposed condition. The HIV requirement was restated without change in the existing § 482.27(c). This requirement would merely be redesignated under this proposed rule. We are still in the process of analyzing comments we received on the December 19, 1997 proposed rule as we develop the final rule.

Should the restructuring of part 482 in the December 19, 1997 proposed rule become final before we publish this proposed rule (HCFA–3014–P) as a final rule, the provisions dealing with potentially HCV infectious blood and blood products would be set forth in the final rule (HCFA–3014–F) as a revision to § 482.145.

II. Provisions of This Proposed Rule

In order to have consistent industry standards for potentially infectious blood and blood products, we propose to adopt as our requirements for hospitals the procedures for HIV and HCV proposed by the FDA published elsewhere in this issue of the **Federal Register**. Since our proposed rule is in concert with the FDA's proposed rule, we will consider comments we receive in conjunction with the FDA. We specifically request comments on the reasonableness of our adopting the FDA requirements.

The FDA proposed rule for HCV lookback would require the search of historical testing records of prior donations from donors with repeatedly reactive EIA 1.0, EIA 2.0, or EIA 3.0 screening tests for HCV to extend back indefinitely for computerized electronic records and to January 1, 1998 for other retrievable records. Under the FDA rule, the blood establishment would notify the hospital if it supplied the hospital with potentially HIV or HCV infectious blood.

Our proposed rule would amend the hospital conditions of participation to require a hospital to develop agreements with outside blood banks under which the blood bank would notify the hospital when it has supplied the hospital with potentially HCV infectious blood and blood products. This proposed rule would establish a lookback, similar to that now in effect for HIV, requiring hospitals, when notified by blood banks, to quarantine prior collections from a donor who later tests repeatedly reactive for evidence of HCV infection, and to notify transfusion recipients based on further testing of such a donor, as appropriate.

In existing § 482.27, we propose to remove the designation for paragraph (a) and redesignate paragraphs (b) and (c) as (a) and (b), respectively. In addition, we would add a definition of potentially HCV infectious blood and blood products as prior collections from a donor who tested repeatedly reactive for evidence of HCV infection on a single antigen screening test with a signal to cut off value equal to or greater than 2.5 for at least two of the three EIA tests, or the signal to cut off value cannot be calculated, and with no record of further testing; who tests or tested repeatedly reactive for evidence of HCV infection and positive on a multiantigen supplemental test licensed at an earlier or later date by FDA; who tested repeatedly reactive for evidence of HCV infection and indeterminate on a supplemental test for HCV, unless an indeterminate RIBA 3.0 supplemental test result was obtained or a negative EIA 3.0 or negative RIBA 3.0 test result was subsequently obtained; who tested repeatedly reactive for evidence of HCV infection on a multiantigen screening test with no record of further testing; or who tested repeatedly reactive for evidence of HCV infection on a single antigen screening test and repeatedly reactive on a subsequent multiantigen screening test, unless a negative supplemental test result or an indeterminate RIBA 3.0 supplemental test result was obtained. (See proposed § 482.27(b)(2).)

Our regulations currently require that a hospital that regularly uses the services of an outside blood bank have an agreement with the blood bank that requires the blood bank to notify the hospital if the blood bank has supplied the hospital with potentially HIV infectious blood. This proposed rule would amend that provision to also require notification in the case of potentially HCV infectious blood. (See proposed § 482.27(b)(3).) In addition, we would revise our regulations to include HCV-relevant testing required by FDA. (See proposed § 482.27(b)(3)(ii).)

As a new provision, we would require hospitals to include in agreements with blood banks that the blood bank notify the hospital under FDA's proposed 21 CFR 610.48(h)(3)(i) and (h)(3)(ii), and (i)(3)(i) and (i)(3)(ii). The FDA's proposed rule would require hospitals to perform a lookback of blood or blood products collected from a donor extending back indefinitely for computerized electronic records and to January 1, 1998 for other retrievable records, or to the date 12 months before the donor's most recent negative multiantigen screening test for the antibody to HCV, whichever is the later date. (See proposed § 482.27(b)(3)(ii) and (b)(3)(iii).)

We would also revise our regulations to apply the provisions regarding the quarantine of potentially HIV infectious blood and blood products currently set forth at § 482.27(c)(3) to potentially HCV infectious blood and blood products. In addition, we would require hospitals to destroy or label prior collections of blood or blood products held in quarantine as set forth in FDA's proposed 21 CFR 610.48(k). (See proposed § 482.27(b)(4).)

Hospitals are currently required to maintain clinical records on all patients for 5 years. We would add a new provision requiring hospitals to maintain adequate records of the source and disposition of all units of blood and blood products for at least 10 years from the date of disposition. Hospitals would be required to increase the record retention period yearly until 10 years of records from the date of disposition have accrued. (For example, the first year after the effective date of this regulation, hospitals would have 6 years of records, the second year after the effective date, 7 years, etc., until 10 years have been reached.) Hospitals would then be able and expected to maintain 10 years of patient records. (See proposed § 482.27(b)(5).) This is necessary to increase opportunities for disease prevention or treatment years after a recipient has been exposed to a donor later determined to be at risk of transmitting a disease through transfusion.

The FDA has proposed changes in its requirement for patient notification to allow transfusion services to make three attempts to either notify patients directly or notify the attending physician or the physician who ordered the blood. We are proposing that hospitals follow the same notification procedures with regard to potentially HIV and HCV infectious blood and blood products. For consistency, we are also proposing that the HIV lookback requirements be changed to conform to the requirements for HCV lookback. (See proposed § 482.27(b)(6).)

We propose to add a new paragraph (c) requiring hospitals to comply with FDA regulations pertaining to the appropriate testing and quarantining of infectious blood and blood products and to the notification and counseling of

recipients that may have received infectious blood and blood products.

Note that our Medicaid regulations at § 441.17 (''Laboratory services'') provide that the State plan must pay for laboratory services furnished by a hospital-based laboratory meeting the requirements for Medicare participation set forth in § 482.27. Therefore, the provisions of this proposed rule would also affect the Medicaid program. That is, in order for the laboratory services furnished by a hospital-based laboratory under Medicaid to be covered under the State plan, the hospital would have to meet the new requirements set forth in this proposed rule.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, agencies are required to provide a 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, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3506(c)(2)(A)) 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.

Therefore, we are soliciting public comment on each of these issues for the provisions summarized below that contain information collection requirements:

Section 482.27 Condition of participation: Laboratory services

In summary, § 482.27(b)(3) requires a hospital that regularly uses the services of an outside blood bank to establish and maintain a written agreement with the blood bank that governs the procurement, transfer, and availability of blood and blood products. This section also requires the blood bank to notify the hospital within 3 calendar days after the date on which the donor tested repeatedly reactive for evidence of HCV infection or after the date on which the blood establishment was made aware of other test results indicating evidence of HCV infection, as outlined in (i) through (iii).

In summary, § 482.27(b)(5) requires a hospital to maintain, in a manner that permits prompt retrieval, adequate records of the source and disposition of all units of blood and blood products for at least 10 years from the date of disposition. In addition, this section requires a hospital to maintain a fully funded and documented plan that demonstrates how the hospital will transfer these records to another hospital or other entity if the former hospital ceases operation for any reason.

In summary, § 482.27(b)(6) requires a hospital that has administered potentially HIV or HCV infectious blood or blood products (either directly through its own blood bank or under an agreement), or released the blood or blood products to another entity or individual, to make at least three attempts to notify the patient, or to notify the attending physician or the physician who ordered the blood or blood product and ask the physician to notify the patient, that potentially HIV or HCV infectious blood or blood products were transfused to the patient. Time frame and notification requirements are outlined in §§ 482.27(b)(6), (b)(7), and (b)(8).

In summary, § 482.27(b)(9) requires a hospital to maintain policies and procedures for notification and documentation that conform to Federal, State, and local laws, including requirements for confidentiality and medical records.

In summary, § 482.27(b)(10) requires a physician or hospital, if the patient has been adjudged incompetent by a State court, to 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. If the patient is a minor, the legal guardian must be notified.

While all of the information collection requirements referenced above are subject to the Paperwork Reduction Act, the burden associated with these requirements is captured and discussed in the FDA's proposed regulation titled ''Current Good Manufacturing Practice for Blood and Blood Components: Notification of Consignees and Transfusion Recipients Receiving Blood and Blood Components at Increased Risk of Transmitting HCV Infection ('Lookback'),'' Docket No. 98N–0609. Therefore, we are assigning 1 token hour of burden to these requirements.

The FDA's rule assigns a one-time burden of 16 hours for hospitals to develop procedures to conduct lookback activities. HCFA also requires hospitals that currently receive blood from an outside blood bank to have an agreement with the blood bank that governs the procurement, transfer, and availability of blood and blood products for HIV. Our proposed rule would require those hospitals to modify their current agreements to include HCV. Although the FDA does not require hospitals to have this agreement, we believe that the time necessary to perform this task would be minimal and is already captured in the 16 hours allotted in the FDA rule.

We have submitted a copy of this proposed rule to OMB for its review of the information collection requirement. These requirements are not effective until they have been approved by OMB. A notice will be published in the **Federal Register** when approval is obtained.

If you comment on any of these information collection and record keeping requirements, please mail copies directly to the following:

Health Care Financing Administration, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Room N2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850. Attn: John Burke, HCFA–3014–P, Fax number: (410) 786–0262,

and,

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503. Attn.: Allison Herron Eydt, HCFA Desk Officer, Fax numbers: (202) 395–6974 or (202) 395–5167.

IV. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, if we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of the proposed rule as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA) (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more annually). Because the projected cost of this proposed rule falls below the threshold for a major rule, we have determined that this proposed rule is not a major rule.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $5 million or less annually. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare an RIA 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 603 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.

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in any one year. We believe that this proposed rule is not an economically significant rule as described in the Executive Order, nor a significant action as defined in the Unfunded Mandates Reform Act. Aggregate impacts of the rule, and aggregate expenditures caused by the rule, would not reach $100 million for either the public or the private sector. As discussed in the following paragraphs, because of the lack of information to characterize the number and volumes of affected blood and blood products in hospitals that might qualify as small business entities, the impact on small business establishments is uncertain.

It is clear that a number of hospitals that provide blood transfusions will be affected by the implementation of this proposed rule and that a substantial number of those entities will be required to make changes in their operations. For these reasons, we have prepared the following voluntary analysis. This analysis, in combination with the rest of the preamble, is consistent with the analysis set forth by the RFA.

B. Anticipated Effects

1. Effects on Hospitals

This proposed rule would require hospitals that transfuse blood and blood products to (1) prepare and follow written procedures for appropriate action when it is determined that blood and blood products the hospitals received and transfused are at increased risk for transmitting HCV; (2) quarantine prior collections from a donor who is at increased risk for transmitting HCV infection; (3) notify transfusion recipients, as appropriate, of the need for HCV testing and counseling; and (4) extend the records retention period to 10 years.

The proposed rule would affect hospitals that transfuse blood and blood components. We estimate that there are approximately 6,200 Medicare- and Medicaid-participating hospitals. The CDC estimates that 303,676 recipients may need to be notified due to the historical review.

As indicated previously, the proposed rule would require hospitals to notify transfusion recipients who received prior collections from a donor at increased risk for transmitting HCV. The hospital may notify the attending physician or notify the recipient directly. If the transfusion recipient is a minor or adjudged incompetent by a State court, the hospital or physician would be required to notify the recipient's legal representative. The proposed rule is expected to generate one-time costs and some additional annual costs for hospitals. One-time costs include the development of procedures and policies for recipient notification and the agreement a hospital should have with a blood bank if it uses the services of an outside bank. We assume that these tasks will involve a review of current procedures and policies (for example, for HIV lookback) and the adaptation or modification of current procedures and policies to address the provisions of this rule, and we estimate, in consultation with the FDA, that the tasks will require an average of 16 hours per facility. The Bureau of Labor Statistics estimates that the total hourly compensation in 1997 for a staff medical technologist performing the review would be $25.67. Thus, we estimate the total one-time cost for all 6,200 hospitals to develop HCV lookback procedures to be $2,546,464 (16 x $25.67 x 6,200). (See Table in this section.)

For notifications resulting from donors tested on or after the effective date of the final rule under FDA's proposed § 610.48(a)(b), the hospital's required notification effort must include a minimum of three attempts to notify the transfusion recipient, and the hospital must complete the process within a maximum of 12 weeks from the time it receives from the blood establishment the results of the donor's supplemental test for HCV. The following estimated cost for compliance with provisions concerning the prospective review and recipient notification is based on: (1) FDA's estimation of the number of recipient notification multiplied by the unit cost of each notification. First, the number of annual affected blood donations was calculated as the product of 12 million donations, an 80 percent donor rate, and a 12 percent HCV positive donor rate. (2) The resulting 11,520 figure was then adjusted upward to 12,816 to reflect the difference found between the number of donors triggering lookback and the component notifications reported as interim results from a recent survey conducted by the Centers for Disease Control and prevention (CDC). (3) The cost per attempted notification is estimated at $165, which reflects the average cost quoted by a third party contractor for matching, notifying, testing, counseling, and documenting lookback efforts for over 100 hospitals.[2] Although the proposed rule does not specifically require hospitals to perform testing and counseling services many do. These assumptions yield an annual cost of $2,114,640 (12,816 × $165) for hospitals to conduct prospective lookback activities. (See Table in this section.)

For notifications resulting from donors tested before the effective date of the final rule under FDA's proposed § 610.48(c)(d), the hospital must complete the notification effort within 1 year from the time it receives notification from the blood establishment. The recipient notification provided by the hospital

[2] Richard Quattrocchi, Home Access Health Corporation.

must include a basic explanation to the recipient, referral for counseling and further testing, and documentation of the notification or attempts to notify the attending physician or recipient. Notification resulting from the review of historical testing records and the identification of prior collections are to be completed by the hospital within one year of receipt of notification from the blood establishment. The recipient notification provided by the hospital would include a basic explanation to the recipient, referral for counseling and further testing and documentation of the notification or attempts to notify the physician of record or recipient. The estimated one-time cost of recipient notification associated with the review of historical testing records is $50,106,540. This is based on the CDC estimate of blood components of about 303,676 recipients identified for notification produced from donations (188,448 from 1990 to mid-1992 and 115,228 from 1990 to mid-1992), and the average cost of $165 of staff time per component for recipient notification. Thus, the total one-time cost to hospitals for conducting the historical ''lookback'' efforts is estimated to be $52,653,004 ($2,546,464 to develop procedures and $50,106,540 for recipient notification). (See Table in this section.)

SUMMARY OF ESTIMATED COST OF PROPOSED RULE

Type of cost	Total one-time cost	Total annual cost
Development of HCV Lookback Procedures	[1] $2,546,464.00	.....
Prospective Review	.....	[3] $2,114,640.00
Historical Review	[2] 50,106,540.00	.....
Total	52,653,004.00	2,114,640.00

[1] Based on 6,200 hospitals.
[2] Based on the CDC estimate of the total number of blood products (303,676).
[3] Based on the CDC estimate of 12,816 repeat-donor repeatedly reactive donations per year.

2. Effects on Beneficiaries

Timely notification of HCV infection benefits beneficiaries, both directly and indirectly, in several important ways. First, although factors predicting the severity of liver disease due to HCV have not been well defined, recent data indicate that increased alcohol intake is associated with more severe liver disease. According to CDC, even moderate amounts of alcohol in patients with chronic HCV might exacerbate liver disease. Consequently, an HCV-infected patient identified by the proposed lookback program could minimize liver damage associated with alcohol consumption by restricting his or her intake.

Furthermore, while other percutaneous exposures currently represent the most common means of infection, some case-control studies have also reported that HCV can be transmitted through sexual contact. In fact, 15 to 25 percent of the acute HCV patients who were reported to CDC's sentinel counties surveillance system have a history of sexual exposure in the absence of other risk factors. Infected patients identified through the proposed lookback procedures could take steps to protect sexual partners from the risk of infection.

It is also important to note that identified infected patients would benefit from counseling and treatment with available therapies. Studies of patient characteristics and responsiveness to therapy indicate that best results are achieved if treatment is initiated earlier in the disease, when patients are younger and have not yet developed cirrhosis.[3] For example, Bennett et al. estimated the cost effectiveness of a single course (6 months) of treatment with interferon alfa and found that patients at age 20 gained an average of 3.1 years of life, at $500 per year of life extended (YLE); 30-year-old patients gained an average of 1.9 years of life, at $1200/YLE; patients starting treatment at age 50 gained 6 months of life, at $2900/YLE; and 70-year-old patients gained an average of 22 days, at $62,000/YLE.[4]

Another benefit of timely notification is that care providers for the infected patient would be aware of the infection and could use additional precautions to avoid the risk of exposure to blood or wounds when providing care.

Finally, infected patients would be informed that they must not donate blood. The proposed lookback program would, therefore, help to ensure the safety and continued availability of the national blood supply.

3. Effects on Medicaid and Medicare Programs

We expect this proposed rule to generate a one-time cost to develop procedures for recipient notification. We estimate that this cost will be less than $5 million. Finally, the total one-time cost for the development of HCV lookback procedures and for recipient notification associated with the review of historical testing records is estimated to be $52,653,004 ($2,546,464 + $50,106,540). These one-time costs would likely be distributed among health programs as follows: Medicare, 33.3 percent; private health insurance, 30.5 percent; Federal Medicaid, 9.8 percent; State Medicaid, 5.8 percent; other private funds, 7.9 percent; other Federal funds, 6.9 percent; and other State and local funds, 5.7 percent. The total Federal distribution would be 50 percent; that is, 33.3 percent for Medicare, 9.8 percent for Medicaid, and 6.9 percent for other Federal sources. The degree to which the Federal programs fund these amounts will vary: Medicaid providers may be able to pass on costs through the States depending on the method of payment the State Medicaid program has adopted, while Medicare payments could be limited because of the hospital outpatient prospective payment system and increase only in accordance with specific rules regarding coverage of HCV testing for patients who have been exposed to HCV-infected blood, including those identified through the FDA lookback process.

It is important to note that, although this proposed rule presents the costs that would be imposed on all payers of hospital services, including the Medicare and Medicaid programs, it merely conforms to the FDA's proposed rule and has no additional economic impact. It simply repeats the analysis performed in the FDA companion rule

[3] G.L. Davis and J.Y.N. Lau, ''Factors Predictive of a Beneficial Response to Therapy of Hepatitis C,'' Hepatology 26.3 (1997): 122s–126s.

[4] W.G. Bennett et al., ''Estimates of the Cost-Effectiveness of a Single Course of Interferon-alfa2b in Patients with Histologically Mild Chronic Hepatitis C,'' Annals of Internal Medicine, 127.10 (1997): 855–865.

and presents the same total costs to hospitals.

C. Alternatives Considered

The PHS Advisory Committee discussed improvements in the treatment and management of HCV infection and improvements in testing for the HCV antibody at public meetings held in April and August 1997. The Advisory Committee recommended that blood establishments and hospitals notify previous recipients of blood components from donors who tested positive for HCV upon a subsequent donation.

Following the Department of Health and Human Services' acceptance of recommendations from the PHS Advisory Committee, FDA developed industry guidelines for testing blood for HCV, quarantining blood and blood products, and notifying patients who may have received HCV-infected blood and blood products. We explored the possibility of using a program memorandum to notify hospitals that they are required to follow FDA guidelines. We believe, however, that we should promulgate an enforceable regulation.

The following discussion considers some key elements of successful lookback efforts, describes certain challenges identified in lookback programs already in operation, and reviews the value of targeted recipient notification and treatment efforts.

The lookback provisions of the proposed rule can be characterized as a ''targeted lookback'' program, meaning that the notification of infection risk is limited to, or targeted at, individuals identified as recipients of blood from donors subsequently found to be infected with HCV. This program is distinct from ''general lookback'' programs, which are aimed at all patients who received blood before the onset of screening and which include the recommendation that the patients be tested for evidence of infection. General and targeted lookback programs may be complementary. General lookback can be conducted in a variety of ways, including use of the broadcast media, education, and letter campaigns addressed to physicians or patients. By contrast, targeted lookback can only be performed successfully if the transfusion service is aware that the donor subsequently tested positive, if donor and product disposition records are available to link blood components with the identified donors, and if the physician or hospital knows the recipient's current whereabouts. Hospitals would locate recipient records for all transfused units from an affected donor and would have current recipient or physician address information available so that the hospitals could deliver notifications. Ideally, the recipient would still be alive and would respond to the notification for testing and treatment, if appropriate.

However, recent experiences among Canadian facilities implementing HCV lookback suggest that the effectiveness of targeted lookback may vary depending on the extent to which conditions for success exist within a community. For example, an analysis of targeted lookback in Quebec province found that, because the records were inadequate or the whereabouts of recipients were unknown, hospitals could provide information on only approximately 50 percent of the components involved.[5] A Canadian Red Cross Center in Toronto reported on another lookback challenge. Although the establishment was able to identify 5,301 affected components, trace 3,209 of those to hospitals, obtain responses for 2,807 (87 percent) of the units, and identify 2,437 as having been transfused, 45 percent of the transfused patients had already died. Of those remaining, the Canadian facilities finally tested only 184 patients (8 percent of the transfused patients) as a result of the lookback effort although as many as 68 percent of those tested were found to be HCV positive.[6]

Despite the difficulties of implementing targeted lookback, it is considered a valuable means of reaching patients at high risk for HCV. For example, a comparison of Canadian efforts in targeted lookback with general lookback through physician and public education found that a large number of patients and families were unaware of the transfusion episode. These recipients would not have been reached through the general lookback effort.[7]

Timely notification is important because studies of patient characteristics and responsiveness to therapy indicate that the best results are achieved if patients receive treatment when they are younger and have not yet developed cirrhosis.[8] The primary treatment for chronic HCV is alfa interferon therapy.[9] Of those patients who undergo interferon treatment, a reported 10 to 20 percent show a sustained response (SR) after 6 months of therapy, and 20 to 30 percent show an SR if therapy is continued for 12 months. However, alfa interferon produces a wide array of adverse side effects,[10] and some patients experience a relapse after therapy. Still, the benefits for patients identified for treatment through HCV lookback are likely to continue to increase as improved therapies are developed. For example, recent reports based on pilot studies and completed randomized controlled trials indicate that the combination of interferon alfa and ribavirin leads to higher virological SR rates (40 to 50 percent) than interferon alfa alone, which was administered in 6-month clinical trials.[11] FDA has recently approved the use of this combination therapy for HCV patients who suffer a relapse after initial therapy with interferon alone.

As discussed in section I of this document, the BPAC and PHS Advisory Committee have met a number of times to discuss HCV testing and other issues related to ''HCV lookback.'' The PHS Advisory Committee made recommendations after considering alternative procedures to notify transfusion recipients. Alternative approaches for lookback are available but are not considered fully effective. Because of the importance of a safe national blood supply and because our mission is to protect the public health, we accepted the recommendations of the PHS Advisory Committee and did not select an alternative approach.

D. Conclusion

In addition to the prospective HIV lookback that hospitals are currently required to perform, hospitals would be required to conduct a lookback of transfusion recipients of potentially HCV-infected blood. This proposed rule would also require hospitals to have in their agreements with blood banks that blood banks notify hospitals after performing the FDA-mandated lookback. Therefore, we have prepared a voluntary analysis consistent with the analysis set forth by the RFA. We solicit public comments on the extent that any of the entities would be significantly economically affected by these provisions.

[5] M. Goldman *et al.*, ''Hepatitis C Lookback,'' Transfusion Medicine Review 12.2 (1998): 84–93.

[6] A. Wall *et al.*, ''Hepatitis C Virus (HCV) Targeted Lookback Program,'' Transfusion 37 (1997): 392s.

[7] M. Goldman *et al.*, ''Hepatitis C Lookback,'' Transfusion Medicine Review 12.2 (1998): 84–93.

[8] G.L. Davis and J.Y.N. Lau, ''Factors Predictive of a Beneficial Response to Therapy of Hepatitis C,'' Hepatology 26.3 (1997): 122s–126s.

[9] A. Wall *et al.*, ''Hepatitis C Virus (HCV) Targeted Lookback Program,'' Transfusion 37 (1997): 392s.

[10] G. Duscheiko, ''Side Effects of Alpha interferon in Chronic Hepatitis C,'' Hepatology 26.3 (1997): 112s–119s.

[11] National Institutes of Health (NIH) Consensus Development Conference Panel Statement: Management of Hepatitis C, Hepatology 26.3 (1997): 2s–10s.

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by OMB.

We have reviewed this proposed rule under the threshold criteria of Executive Order 13132, Federalism. We have determined that it would not significantly affect the rights, roles, and responsibilities of States.

List of Subjects in 42 CFR Part 482

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

Accordingly, for the reasons set forth in the preamble, 42 CFR part 482 would be amended as set forth below:

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).

2. In § 482.27, the designation for paragraph (a) is removed; paragraphs (b) and (c) are redesignated as paragraphs (a) and (b), respectively; redesignated paragraph (b) is revised; and a new paragraph (c) is added to read as follows:

§ 482.27 Condition of participation: Laboratory services.

* * * * *

(b) *Standard: Potentially infectious blood and blood products*—(1) Definition. Potentially human immunodeficiency virus (HIV) infectious blood and blood products are prior collections from a donor—

(i) Who tested negative at the time of donation but tests repeatedly reactive for the antibody to HIV on a later donation;

(ii) Who tests positive on the FDA-licensed, more specific test or other followup testing required by FDA; and

(iii) For whom the timing of seroconversion cannot be precisely estimated.

(2) *Definition.* Potentially hepatitis C virus (HCV) infectious blood and blood products are prior collections from a donor—

(i) Who tested repeatedly reactive for evidence of HCV infection on a single antigen screening test with a signal to cut off value equal to or greater than 2.5 for at least two of the three enzyme linked immunosorbent assay (EIA) tests, or the signal to cut off value cannot be calculated, and with no record of further testing;

(ii) Who tests or tested repeatedly reactive for evidence of HCV infection and positive on a multiantigen supplemental test licensed at an earlier or later date by FDA;

(iii) Who tested repeatedly reactive for evidence of HCV infection and indeterminate on a supplemental test for HCV, unless an indeterminate recombinant immunoblot assay (RIBA) 3.0 supplemental test result was obtained or a negative EIA 3.0 or negative RIBA 3.0 test result was subsequently obtained;

(iv) Who tested repeatedly reactive for evidence of HCV infection on a multiantigen screening test with no record of further testing; or

(v) Who tested repeatedly reactive for evidence of HCV infection on a single antigen screening test and repeatedly reactive on a subsequent multiantigen screening test, unless a negative supplemental test result or an indeterminate RIBA 3.0 supplemental test result was obtained.

(3) *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 notify the hospital—

(i) Within 3 calendar days if the blood bank 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 or HCV on a later donation or who is determined to be at increased risk for transmitting HIV or HCV infection;

(ii) Within 45 days of the test, of the results of the FDA-licensed, more specific test for HIV or HCV, as relevant, or other followup testing required by FDA; and

(iii) Within 3 calendar days if the blood bank supplied blood and blood products collected from a donor, whenever records are available, as set forth in FDA's 21 CFR 610.48(h)(3)(ii) and (i)(3)(ii), in instances in which the donor—

(A) Tested repeatedly reactive on the screening test and positive on a supplemental test for HCV performed on the repeatedly reactive sample;

(B) Tested repeatedly reactive on the screening test and indeterminate on a supplemental test for HCV; or

(C) Tests repeatedly reactive on the screening test with no record of a supplemental test for HCV performed on the repeatedly reactive sample and no record of a negative licensed screening test performed on the same donor.

(4) *Quarantine and disposition of blood and blood products pending completion of testing.* If the blood bank (either internal or under an agreement) notifies the hospital of the repeatedly reactive HIV or HCV screening test results, 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 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 required by FDA is positive, the hospital must—

(A) Dispose of the blood and blood products; and

(B) Notify the transfusion recipients as set forth in paragraph (b)(6) of this section.

(iii) If the blood bank notifies the hospital that the result of the FDA-licensed, more specific test or other followup testing required by FDA is indeterminate, the hospital must destroy or label prior collections of blood or blood products held in quarantine as set forth in FDA's 21 CFR 610.48(k).

(5) *Recordkeeping by the hospital.* The hospital must maintain—

(i) Adequate records of the source and disposition of all units of blood and blood products for at least 10 years from the date of disposition;

(ii) The records in a manner that permits prompt retrieval; and

(iii) A fully funded plan to transfer these records to another hospital or other entity if the former hospital ceases operation for any reason.

(6) *Patient notification.* If the hospital has administered potentially HIV or HCV infectious blood or blood products (either directly through its own blood bank or under an agreement) or released the blood or blood products to another entity or individual, the hospital must take the following actions:

(i) Make at least three attempts to notify the patient, or to notify the attending physician or the physician who ordered the blood or blood product and ask the physician to notify the patient, that potentially HIV or HCV infectious blood or blood products were transfused to the patient.

(ii) Immediately notify the patient, or other individual as permitted under paragraph (b)(10) of this section, of the need for HIV or HCV testing and counseling.

(iii) If the physician is unavailable or declines to make the notification, make at least three attempts to give this

notification to the patient or other individual.

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

(7) *Timeframe for notification.* (i) *For donors tested on or after [effective date of final regulation].* For notifications resulting from donors tested on or after [effective date of final regulation] as set forth in FDA's 21 CFR 610.48(a)(b), the notification effort begins when the blood bank notifies the hospital that it received potentially HIV or HCV infectious blood and blood products and continues for 12 weeks unless—

(A) The patient is located and notified; or

(B) 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 12 weeks.

(ii) *For donors tested before [effective date of final regulation].* For notifications resulting from donors tested before [effective date of final regulation] as set forth in FDA's 21 CFR 610.48(c)(d), the notification effort begins when the blood bank notifies the hospital that it received potentially HCV infectious blood and blood products. The hospital must make at least three attempts to give notification and must complete the actions within 1 year of the date on which the hospital received notification from the outside blood service.

(8) *Content of notification.* The notification must include the following information:

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

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

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

(9) *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 the confidentiality of medical records and other patient information.

(10) *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. If the patient is a minor, the legal guardian must be notified.

(c) *General blood safety issues.* Hospitals must comply with regulations of the FDA as they pertain to blood safety issues in the following areas:

(1) Appropriate testing and quarantining of infectious blood and blood products.

(2) Notification and counseling of recipients that may have received infectious blood and blood products.

Authority: Sections 1818(d)(2) and 1818A(d)(2) of the Social Security Act (42 U.S.C. 1395i–2(d)(2) and 1395i–2a(d)(2)).

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance)

Dated: September 22, 1999.

Michael M. Hash,

Deputy Administrator, Health Care Financing Administration.

Dated: March 27, 2000.

Donna E. Shalala,

Secretary.

[FR Doc. 00–28908 Filed 11–15–00; 8:45 am]

BILLING CODE 4120–01–P