the 8-hour Ozone Maintenance Plan and the 2002 Base Year Emissions Inventory for the Reading, Pennsylvania Area at the end of the table to read as follows:

§ 52.2020 Identification of plan.

* * * * *

(e) * * *

(1) * * *

Name of non-regulatory SIP revision	Applicable geographic area	State submittal date	EPA approval date	Additional explanation
*	*	*	*	*
8-Hour Ozone Maintenance Plan and 2002 Base Year Emissions Inventory.	Reading Area (Berks County)	1/25/2007	8/24/2007 [Insert page number where the document begins].	

PART 81—[AMENDED]

■ 3. The authority citation for part 81 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

■ 4. In § 81.339, the table entitled ''Pennsylvania—Ozone (8-Hour Standard)'' is amended by revising the entry for the Reading, PA Area to read as follows:

§ 81.339 Pennsylvania.

* * * * *

PENNSYLVANIA—OZONE (8-HOUR STANDARD)

Designated area	Designation [a]		Category/classification	
	Date [1]	Type	Date [1]	Type
*	*	*	*	*
Reading, PA: Berks County	9/10/2007	Attainment.		
*	*	*	*	*

[a] Includes Indian County located in each county or area, except otherwise noted.
[1] This date is June 15, 2004, unless otherwise noted.

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[FR Doc. E7–16683 Filed 8–23–07; 8:45 am]
BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 482

[CMS–3014–IFC]

RIN 0938–AJ29

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

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period requires hospitals that transfuse blood and blood components to: Prepare and follow written procedures for appropriate action when it is determined that blood and blood components 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 for transfusion-related data to 10 years.

These changes are based on recommendations by the Secretary's Advisory Committee on Blood Safety and Availability and are being published in conjunction with the Food and Drug Administration's (FDA) Final Rule, ''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'') found elsewhere in this issue of the **Federal Register**. The intent is to aid in the prevention of HCV infection and to create opportunities for disease prevention that, in most cases, can occur many years after recipient exposure to a donor.

DATES: *Effective Date:* These regulations are effective on February 20, 2008.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on October 23, 2007.

ADDRESSES: In commenting, please refer to file code CMS–3014–IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.cms.hhs.gov/eRulemaking.* Click on the link ''Submit electronic comments on CMS regulations with an open comment period.'' (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid

Services, Department of Health and Human Services, Attention: CMS–3014–IFC, P.O. Box 8014, Baltimore, MD 21244–8014.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3014–IFC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by mailing your comments to the addresses provided at the end of the ''Collection of Information Requirements'' section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Mary Collins, (410) 786–3189. Jeannie Miller, (410) 786–3164.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS–3014–IFC and the specific ''issue identifier'' that precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.cms.hhs.gov/eRulemaking.* Click on the link ''Electronic Comments on CMS Regulations'' on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

This **Federal Register** document is also available from the **Federal Register** online database through *GPO Access*, a service of the U.S. Government Printing Office. The Web site address is: *http://www.access.gpo.gov/fr/index.html.*

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 (CFR) 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 components 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 Centers for Medicare & Medicaid Services (CMS) and Federal agencies that comprise the Public Health Services, including the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and the National Institutes of Health (NIH), are responsible for ensuring the safety of blood and blood components. In the November 16, 2000 proposed rule (65 FR 69416), we used the term ''blood banks'' to refer to establishments that supply blood. However, for consistency, we will use the FDA's term of ''a blood collecting establishment'' (BCE) since blood suppliers include hospital blood banks and blood donor centers. BCEs are subject to the FDA regulations for current good manufacturing practice 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). We coordinate inspections of hospital-based BCEs 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 components remaining in storage and notify recipients that they may possibly have received infectious blood or blood products. (These steps are known as a lookback.) BPAC advised that there was insufficient information available concerning HCV infection to propose either product quarantine or notification of recipients transfused with blood and blood components 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 chronic blood-borne infection in the United States. The CDC estimates that during the 1980s, as many as 230,000 new HCV infections occurred each year. Since 1989, the annual number of new infections has declined by 80 percent. The decline is in part attributed to the blood collection establishments' implementation of a donor screening test (HCV enzyme linked

immunosorbent assay (EIA) screening test) that was licensed in May 1990. In 1996, however, data from the Third National Health and Nutritional Examination Survey conducted from 1988 to 1994 indicated that approximately 3 million individuals in the United States were believed to have been chronically infected with HCV and that chronically infected persons might not be aware of their infection.

Despite progression of the disease, HCV infection is often asymptomatic for about 20 years, but in many cases eventually causes serious liver injury that is thought to be a leading cause of end stage liver disease among adults 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, exposure to infectious blood or body fluids in healthcare settings (for example, hemodialysis or occupational exposure to blood), perinatal exposure of infants to infected mothers, and possibly by unprotected sex.

In response to scientific data that show that HCV is transmissible through blood and blood components, 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 components that are infected with HCV.

Blood collecting establishments are currently testing each donation of blood and blood components for evidence of HCV infection. Current testing for HCV includes antibody screening, as well as direct viral detection through the current use of nucleic acid tests (NAT). FDA restricts the use of donations that test reactive for evidence of HCV infection for transfusion or further manufacture. (The term ''repeatedly reactive'' has been used to indicate 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.) FDA now refers to screening tests as ''reactive,'' instead of ''repeatedly reactive'' to accommodate the different testing algorithms established for NAT and other screening tests. In cases where the screening algorithm requires initial and repeat testing as part of a single screening procedure, FDA would interpret the term ''reactive'' to mean ''repeatedly reactive.''

As a result of 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 testable marker to HCV is not detectable by the test but HCV is nevertheless present in the donor's blood (called a ''window'' period).

If the donor later tests reactive for evidence of HCV infection, or when the blood collecting establishment is made aware of other reliable test results or information indicating evidence of HCV infection, previously collected blood and blood components would be at increased risk for transmitting HCV. We believe that approximately 7 percent of the estimated 3.9 million Americans ever 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.

As a result of advances in identifying the presence of HCV, most notably through screening tests based on nucleic acid amplification technology, the window period and risk of HCV transmission from blood continues to shrink. The preamble to FDA's proposed rule entitled ''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 on November 16, 2000 (65 FR 69378), and FDA's final rule published elsewhere in this issue of the **Federal Register** provide more information on the length of the window period and discuss various diagnostic modalities for HCV infection.

The incidence of transfusion-transmitted HCV infection has decreased markedly since the implementation of donor screening and testing for HCV, and viral inactivation of derivatives. 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. The FDA issued a memorandum to all registered blood establishments in November 1990, ''Testing for the 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 at that time because: (1) Screening tests available at the time could not distinguish between on-going infection and recovery, thus making unclear the meaning of a reactive test for any one individual; (2) donor screening for the 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 HCV antibodies are used to counsel and resolve the donor's status. 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 components, and notifying patients who may have received HCV-infected blood and blood components.

In response to comments received, the March 1998 guidance was withdrawn and FDA issued a revised guidance dated September 1998, which it announced in the **Federal Register** on October 21, 1998 (63 FR 56198), entitled ''Guidance for Industry: Current Good Manufacturing Practice for Blood and

Blood Components: (1) Quarantine and Disposition of Units From Prior Collections From Donors With Repeatedly Reactive Screening Test for Antibody to Hepatitis C Virus (Anti-HCV); (2) Supplemental Testing, and the Notification of Consignees and Blood Recipients of Donor Test Results for Anti-HCV'' (the September 1998 guidance). The September 1998 guidance provided recommendations to enable quarantine and disposition of blood and blood components from prior collections from donors with repeatedly reactive screening test results.

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.

The FDA published a notice in the **Federal Register** on June 22, 1999 (64 FR 33309) announcing the availability of a revised draft guidance titled ''Draft 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 October 2004 FDA issued a final guidance, ''Guidance for Industry: Use of Nucleic Acid Tests on Pooled and Individual Samples from Donors of Whole Blood and Blood Components (Including Source Plasma and Source Leukocytes) to Adequately and Appropriately Reduce the Risk of Transmission of Human Immunodeficiency Virus Type 1 and Hepatitis C Virus'' which was announced in the **Federal Register** on October 28, 2004 (69 FR 62902). The guidance informed blood collecting establishments that FDA had licensed NAT as tests to screen blood donors for HIV–1 RNA and HCV RNA, that the licensed tests could detect evidence of infection at a significantly earlier stage than was possible under previously approved tests using antibody or antigen detection technology, and that the FDA believed that these newly licensed tests were widely available and met the criteria in 21 CFR 610.40(b) for screening tests that are necessary to reduce adequately and appropriately the risk of transmission of communicable disease through blood products.

II. Provisions of the Proposed Rule

In order to have consistent industry standards for potentially infectious blood and blood components, on November 16, 2000 (65 FR 69416), we proposed to adopt as our requirements for hospitals the procedures for HCV proposed by the FDA in that same **Federal Register** (65 FR 69378). Since our proposed rule was published in conjunction with the FDA's proposed rule, we have considered comments we received in conjunction with the FDA. We specifically requested in the proposed rule comments on the reasonableness of our adopting the FDA requirements.

The FDA proposed rule for HCV lookback would require blood establishments (in this IFC we changed the reference of ''blood establishments'' to ''blood collecting establishments'' (BCE)) to search 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, extending back indefinitely for computerized electronic records, and to January 1, 1988 for other retrievable records. Under the FDA rule, a BCE would be required to notify a hospital if it supplied such hospital with potentially HCV infectious blood.

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

We proposed to remove current paragraph (a) in the existing § 482.27 and re-designate paragraphs (b) and (c) as (a) and (b), respectively. In addition, we proposed adding a definition of ''potentially HCV infected blood and blood components'' as previous collections from a donor—(1) 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 when the signal to cut off value for such donor could not be calculated, with no record of further testing; (2) who tested repeatedly reactive for evidence of HCV infection and positive on a multiantigen supplemental test licensed at an earlier or later date by FDA; (3) 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; (4) who tested repeatedly reactive for evidence of HCV infection on a multiantigen screening test with no record of further testing; or (5) 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 a hospital that regularly uses the services of an outside BCE to have an agreement with the BCE that requires the establishment to notify the hospital if the establishment has supplied the hospital with potentially HIV infected blood. We proposed to amend that provision to also require notification in the case of potentially HCV infected blood. (See proposed § 482.27(b)(3).) In addition, we proposed to revise our regulations to include HCV-relevant testing required by FDA. (See proposed § 482.27(b)(3)(ii).)

We also proposed conforming changes to the HIV requirement at § 482.27(b)(3)(i) by removing the word ''promptly'' and instead require that a blood bank notify a hospital of potentially infected blood within 3 calendar days after testing. Also, hospitals would have been required to make at least three attempts to notify the patient, or to notify the attending physician who ordered the blood or blood components.

We proposed additional conforming changes that would have required a hospital's agreement with a BCE to require the BCE to notify the hospital within 3 calendar days of testing if blood tested repeatedly reactive for HCV antibodies. This change provides further clarity of the notification requirement.

The FDA proposed a change to the maximum time permitted for a BCE to notify hospitals of the results of the further testing, from 30 to 45 days, in order to create consistency between the HIV and HCV lookback provisions. Although FDA has stated that further testing for HIV and HCV could be completed within 30 days, additional time was needed to notify hospitals following completion of the further testing. We proposed the appropriate changes to § 482.27(b)(3)(ii) to include the change from 30 to 45 days in the agreement a hospital had with a BCE.

In § 482.27(c)(3)(i) and (ii) regarding follow-up testing, we proposed deleting the words in § 482.27(b)(1)(ii) to reflect that the additional follow-up testing was an FDA requirement and not a recommendation.

As a new provision, we proposed that hospitals be required to include in agreements with BCEs a provision requiring the BCE to notify the hospital of lookback results under FDA's proposed 21 CFR 610.48(h)(3)(i) and (h)(3)(ii), and (i)(3)(i) and (i)(3)(ii). FDA proposed that hospitals perform a lookback of blood or blood components collected from a donor extending back indefinitely for computerized electronic records and to January 1, 1988 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.

We also proposed to revise our regulations to apply the provisions regarding the quarantine of potentially HIV infectious blood and blood components currently set forth at § 482.27(c)(3) to potentially HCV infected blood and blood components. (See proposed § 482.27(b)(4).) In addition, we proposed requiring hospitals to destroy or re-label previous collections of blood or blood components held in quarantine if the results of the testing were indeterminate. We proposed that hospitals re-label previous collections of blood or blood components held in quarantine if the results of the testing were indeterminate, in accordance with the FDA regulations at 21 CFR 606.121 and the HCV Lookback Guidance Documents.

We proposed a change to § 482.27(b)(4) by adding a parenthetical phrase ''(either internal or under an agreement).'' We proposed this change to clarify that a blood collecting establishment has a responsibility to notify the hospital of HIV or HCV screening results even when located at a hospital site.

Hospitals are currently required to maintain clinical records on all patients for 5 years. We proposed adding a new provision requiring hospitals to maintain adequate records of the source and disposition of all units of blood and blood components for at least 10 years after the date of disposition. The FDA also proposed to increase record retention requirements for blood establishments from 5 years to 10 years. Hospitals would be required to increase the record retention period yearly until 10 years of records from the date of disposition had accrued. (For example, the first year after the effective date of this regulation, hospitals would have had 6 years of records, the second year after the effective date, 7 years, and so on until 10 years had been reached.) Hospitals would then have been able and expected to maintain 10 years of patient records. (See proposed § 482.27(b)(5).) We believed this would be necessary to increase opportunities for disease prevention or treatment years after a recipient had been exposed to a donor later determined to be at risk of transmitting the disease through transfusion. We proposed, as is currently required at § 482.24(b)(2), that hospitals maintain the clinical records in such a manner that would permit prompt retrieval. We also had proposed that hospitals ensure that medical records would be transferred to another hospital or other entity if the former hospital ceased operation for any reason. (See proposed § 482.27(b)(5)(iii).)

The FDA had 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 proposed that hospitals follow the same notification procedures with regard to potentially HIV and HCV infectious blood and blood components. For consistency, we also proposed that the HIV lookback requirements be changed to conform to the requirements for HCV lookback.

We had proposed adding a new paragraph (c) requiring hospitals to comply with FDA regulations pertaining to the appropriate testing and quarantining of infectious blood and blood components and to the notification and counseling of recipients who may receive any infectious blood and blood components that are identified after the publication of this rule.

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 interim final rule with comment period will 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 will have to meet the new requirements set forth in this rule.

III. Analysis of and Responses to Public Comments

While we are not issuing a new proposed rule as would otherwise be required under section 1871(a)(3)(B) of the Act, we are considering comments we received on the proposed rule published on November 16, 2000 in this interim final rule with comment period. See section VI below for a more detailed discussion of our decision to publish this matter as an interim final rule with comment period.

Six types of organizations, including blood banks, blood centers, the blood industry trade association, and hospitals, submitted comments raising several issues with the proposed rule. The main concerns were with the proposed requirement to make three attempts to notify affected transfusion recipients and the requirement to notify the deceased's relative of possible HCV infection.

Both CMS and the FDA received comments related to the complex and prescriptive language in their respective proposed rules. As we stated in section II of this rule, we also reviewed the comments and responses that the FDA received, and we have coordinated our responses with the FDA.

Comment: One commenter disagreed with adding specific language about the test method in the interim final rule with comment period, stating that the methodology could be obsolete in a few years.

Response: We agree with the commenter that including specific testing methods in this interim final rule with comment period is too restrictive. We have changed the regulation at § 482.27(b)(2) to reference 21 CFR 610.47, which describes blood and blood components subject to HCV lookback.

Comment: Several commenters disagreed with our proposal to require a hospital to notify a patient's legal

guardian or relative of possible HCV exposure after a patient had already died (of any cause). They noted that there are no clear indications of risk to household contacts of patients with HCV. They request that § 482.27(b)(10) be deleted.

Response: We agree with respect to HCV. As previously discussed in both the FDA and CMS's rules, direct percutaneous exposure to infected blood, particularly in the setting of drug abuse, accounts for the majority of HCV infections acquired in the United States. Secondary transmission of HCV to sexual partners, care providers, or others with close contact is very unlikely. The proposed rule implies that notification efforts should be continued for HCV transmissions if the recipient is deceased. We will clarify that if the patient is deceased, the requirement to notify the legal guardian or relative of possible exposure applies only to HIV infection and not HCV infection. We have changed § 482.27(b)(10) to reflect the clarification.

Comment: One commenter stated that since the FDA requires that all blood donors and donated transfusions are screened, the risks of transmission through blood transfusions are currently very low. The commenter stated that there does not appear to be a need to increase the regulatory burden on hospitals because the problem of HCV transmission in hospitals by blood transfusion and tissue transplant has been effectively solved. The commenter stated that the proposed regulation should be withdrawn.

Response: We understand that due to advanced screening techniques and the fact that hospitals are currently following the FDA's industry guidelines on HCV testing and quarantining of blood and blood components that test reactive for evidence of HCV infection, the risk of transmitting HCV through blood transfusions or administration has been greatly reduced. In addition to reducing the risk of current and future HCV transmission, this rule will ensure that hospitals appropriately notify those Americans who may have been infected with HCV as a result of transfusion of blood components before the broad availability of donor screening tests in 1990. It is important that these individuals are notified of the need for HCV testing and counseling. HCV infection is usually asymptomatic for about 20 years, but may cause serious liver injury that is thought to be a leading cause of end stage liver disease among adults in the United States. HCV is also thought to play a role in the development of liver cancer. Between 8,000 and 12,000 deaths annually result from HCV-related chronic liver disease.

This interim final rule with comment period also increases the medical record retention period from 5 to 10 years. The FDA has recommended that the records retention period be increased because advances in medical diagnosis and therapy have created opportunities for disease prevention or treatment many years after recipient exposure to a donor later determined to be at increased risk of transfusion transmitted disease.

Comment: One commenter stated that the burden of 16 hours for a hospital to develop the required procedures and establish the contract with the BCE is underestimated. They also stated that the estimated cost of $52,653,004 for recipient notification is very low.

Response: As stated in the proposed rule, we currently require hospitals that receive blood from an outside BCE to have an agreement with the BCE that governs the procurement, transfer, and availability of blood and blood components for HIV. We do not envision that hospitals need a separate or different agreement for HCV. Hospitals will only need to modify their current agreement to include potentially HCV infected blood and blood components. Also, hospitals currently have procedures in place to conduct HIV lookback activities. We think that 16 hours, as stated in the proposed rule, will provide adequate time to incorporate similar procedures for conducting HCV lookback activities.

We agree with the commenter regarding the cost for recipient notification. Based on the recent Bureau of Labor Statistics estimates, we have increased the cost for recipient notification. We have increased the hourly wage for a staff medical technologist performing the review from $25.67 to $33.84. Each hospital will incur a one-time cost of $541.44, or about $2.7 million for the entire industry to develop HCV lookback procedures. Thus, the total one-time cost to hospitals for conducting the historical (retrospective) lookback efforts is estimated to be $41.6 million ($2.7 million to develop procedures and $38.9 million for recipient notification). The calculations are based on the latest data available related to hospitals and number of recipients that may need notification. There are approximately 4,980 Medicare- and Medicaid-participating hospitals, excluding 1,041 hospitals that operate blood collection centers, because they are counted among the collection establishments. The CDC estimated in 2000 that 212,000 recipients may need to be notified due to the historical review.

Comment: One commenter stated that there is no reason for blood records to be kept for 10 years, stating that there is no reason for such records to be kept on a different basis than any other medical records. Having special rules for this narrow class of records will only lead to confusion. Several commenters agreed with requiring hospitals to maintain adequate records of the source and disposition of all units of blood and blood components for at least 10 years from the date of disposition, but recommended that the retention period be phased in.

Response: We maintain that increasing the record retention period from 5 to 10 years will increase opportunities for disease prevention or treatment years after a recipient has been exposed to a donor that is later determined to be at risk of transmitting a disease through transfusion. In addition, advanced technology has improved the hospital's ability to maintain, store, and retrieve records.

The record retention period will be phased in as described above in Section II, ''Provisions of the Proposed Regulation.'' Hospitals will be required to increase the record retention period yearly until 10 years of records from the date of disposition have accrued.

Comment: Several commenters agree that the hospital should directly notify the patient, the attending physician, or the physician who ordered the blood and blood component of HCV infection. However, they disagree with requiring, at a minimum, three attempts to notify the patient. They stated that only one notification attempt should be made using a traceable method such as certified mail or return receipt. A returned letter should be proof that notification was attempted and was unsuccessful, and that further attempts would be unsuccessful as well. However, one commenter disagrees with requiring just one notification attempt by certified mail. The commenter stated that there are individuals who will not claim a certified letter.

Response: We agree that some individuals are reluctant to take possession of a certified letter. We have clarified in the interim final rule with comment period at 482.27(b)(6)(i) and (b)(7) that the hospital must make reasonable attempts to perform the notification within 12 weeks after being notified by the BCE that it has received potentially HIV or HCV infectious blood and blood components. The hospital will be required to notify the recipient, recipient's physician of record, or a legal representative or relative if the recipient is a minor or adjudged incompetent by a State court.

Comment: Several commenters stated that it is important for both CMS' and FDA's requirements for HCV and HIV lookbacks to be identical in order to ensure that the targeted lookbacks are carried out in a uniform manner throughout the United States.

Response: We appreciate the comments supporting a unified targeted lookback effort. It is important to have consistent industry standards for maintaining the safety of the nation's blood supply. As previously stated, we have collaborated with the FDA in developing and responding to the comments received on the proposed rule.

Comment: A commenter stated that the time-frame for non-computerized retrievable records should be from January 1, 1988 instead of January 1, 1998.

Response: After the effective date of this rule, whenever a hospital or other BCE receives a blood donation that tests infectious for HCV, it must perform a lookback as far back as the period described above (that is, 1988 or to the extent of electronic records), to determine if that donor had previously given blood. If the donor's most recent previous donation (before the current infectious donation) tested non-reactive (that is, uninfected), or tested reactive on a viral detection test (for instance, the nucleic acid test) but non-reactive on the associated antibody screening test on that previous occasion, the hospital and/or BCE must review the record for the 12 months previous to the earlier donation test, to determine if there were any donations during that 12-month period, and to determine if those blood products are still available for use. If so, all such blood products still available for consignment/use 12 months and less before that previous donation must be quarantined retested, and the consignees of the blood products notified.

IV. Provisions of the Interim Final Rule With Comment Period

For the most part, this interim final rule with comment period incorporates the provisions of the November, 2000 proposed rule. As discussed in section III, ''Analysis of and Responses to Public Comments,'' we have made minor changes to the proposed rule at § 482.27(b)(2), (6), (7), and (10). We have added § 482.27(b)(11) to establish a cut-off date for retrospective HCV lookback.

In § 482.27(b)(2), we removed language that we determined, based on public comment, to be too restrictive. That language was replaced with a reference to FDA's regulations in 21 CFR 610.47.

In § 482.27(b)(3)(i) through (iii), we made changes to the regulation citations to conform to the FDA rule.

In § 482.27(b)(6) and (7), we changed the proposed requirement that the hospital make three attempts to notify the patient or physician of record that potentially infectious blood was transfused to the patient. Instead, we are requiring the hospital to make reasonable attempts to notify the recipient or the physician of record. We emphasize that a hospital should continue attempting its notification efforts until it is clear that further attempts would not be successful.

In § 482.27(b)(10), we have revised the language to clarify that if a patient is deceased, the requirement to notify a legal guardian or relative of possible exposure applies only to HIV infection and not to HCV infection.

We have made changes to the interim final rule with comment period in § 482.27(b)(11) to conform with the FDA's rule at § 610.48 whereby a cut-off date has been established for the retrospective lookback. As such, we have established a cut-off date in this rule for the retrospective (historical) HCV lookback. The requirement under § 482.27(b) will remain in effect for 8 years after the date of publication in the **Federal Register**.

We clarified the regulation at § 482.27(c) by stating that the lookback activities discussed in this section are related only to new blood safety issues that are identified after the publication of this rule. Hospitals should comply with the FDA regulations pertaining to the appropriate testing and quarantining of infectious blood and blood components, and to the notification and counseling of recipients who may receive any infectious blood and blood components.

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, 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, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Waiver of Proposed Rulemaking

Section 1871(a)(3) of the Act (as added by section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)) provides that, effective December 8, 2003, the Secretary, in consultation with the Director of the Office of Management and Budget (OMB), shall establish and publish a regular timeline for the publication of Medicare final regulations based on the previous publication of a proposed regulation or an interim final regulation. Section 1871(a)(3)(B) of the Act further provides that such timelines may vary among different regulations, but shall not be longer than 3 years except under exceptional circumstances. As noted above, CMS published a proposed rule regarding Hepatitis C Virus and blood collecting establishments on November 16, 2000. On December 30, 2004, we published a notice in the **Federal Register** implementing section 1871(a)(3) of the Act (68 FR 78442). In that notice, we interpreted the effect of that section as generally rendering legally inoperative Medicare proposed rules that were over 3 years old on the MMA's effective date. Therefore, since 3 years had already elapsed since publication of the November, 2000 NPRM on December 8, 2003, we believe that the 2000 NPRM became legally ineffective as of that date. Accordingly, even though we sought and received extensive comments on this interim final rule with comment period in response to the 2000 proposed rule, we are not publishing this rule as a final rule.

Under such circumstances, we ordinarily would publish a new proposed rule in the **Federal Register** and invite public comment on the proposed rule. The proposed rule would include a reference to the legal authority under which the rule was proposed, and the terms and substance of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice and comment procedure is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and its reasons in the rule issued.

We are waiving publishing a proposed rule, and instead publishing this rule as an interim final rule with comment period. We are specifically going forward because of the importance of keeping this document coordinated with the FDA's lookback rule covering blood establishments, and the present danger to lives and health of individuals that arise from unknown contaminants in the nation's blood supply. Section 1871(a)(3) of the Act does not prohibit us from issuing an interim final rule with comment period based on the expired proposed rule, as long as we issue a final rule no later than 3 years after the interim final rule's publication

date (or publish in the **Federal Register** a notice extending the period).

The FDA's final rule and CMS's interim final rule on blood safety are very closely related and dependent upon each other. However, the FDA is not restricted by this section of the MMA (which applies only to Medicare rules) and therefore is also issuing its final rule in this issue of the **Federal Register**. We believe that it would not be in the best interest of the public for the FDA to publish a final rule requiring blood establishments to notify hospitals of infectious blood and blood products and CMS not to require hospitals to perform the necessary lookback activities of notifying transfusion recipients of the need for HCV testing and counseling.

For the FDA's rule to be effective practically, it is therefore necessary that we issue a companion interim final rule with comment period that covers transfusion services and further supports the notification of recipients of blood and blood components that are at increased risk of infection and transmission of HCV.

Therefore, we find good cause to waive the publication of a proposed rule and to issue this interim final rule with comment period. We are providing a 60-day public comment period.

VII. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment when 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 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

Section 482.27 Condition of Participation: Laboratory Services

Section 482.27(b)(3) requires a hospital that regularly uses the services of an outside BCE to establish and maintain a written agreement with the BCE that governs the procurement, transfer, and availability of blood and blood components. This section also requires the BCE to notify the hospital within 3 calendar days after the date on which the donor tested 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 (b)(3)(i) through (iii).

Section 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 components 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 will allow the hospital to transfer these records to another hospital or other entity if such hospital ceases operation for any reason.

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

Section 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 the confidentiality of medical records.

Section 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 for HIV infection 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 final 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'' published elsewhere in today's **Federal Register**. 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. We also require hospitals that currently receive blood from an outside BCE to have an agreement with the BCE that governs the procurement, transfer, and availability of blood and blood components for HIV. Our rule requires hospitals to modify their current agreements to include HCV. Although the FDA does not require hospitals to have an agreement with a BCE, we believe that the time necessary to perform this task will be minimal and is already captured in the 16 hours allotted in the FDA rule.

We received a comment that the burden of 16 hours for a hospital to develop the required procedures and establish the contract with the BCE is underestimated. This interim final rule with comment period will require a hospital to make minor modifications to the current agreement they have with the BCE for HIV. Therefore, we disagree with the comment that the 16 hours is not adequate to develop procedures to conduct lookback activities and modify their agreement with the BCE.

We have submitted a copy of this interim final rule with comment period to OMB for its review of the information collection requirements. These requirements are not effective until they have been approved by OMB. A notice will be published in the **Federal Register** when we receive approval.

If you comment on any of these information collection and record keeping requirements, please mail copies directly to the following: Centers for Medicare and Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group, Attn: Melissa Musotto, CMS–3014–IFC, Room C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850; and Office of

Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Carolyn Lovett, CMS Desk Officer, CMS–3014–IFC, *carolyn_lovett@omb.eop.gov.* Fax (202) 395–6974.

VIII. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this interim final rule with comment period as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) 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 rule falls below the threshold for a major rule, we have determined that this 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 small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $31.5 million in any 1 year. For purposes of the RFA, a majority of hospitals are considered small entities due to their non-profit status. The agency has examined the impact on small entities and has determined that this rule will not have a significant economic impact on a substantial number of small entities. 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 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 (superseded by ''core-based statistical areas'' (CBSAs)) and has fewer than 100 beds. Because of the lack of information to characterize the number and volume of affected blood and blood components in small rural hospitals, we have prepared an analysis that is consistent with section 604 of the RFA.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately $122 million. We believe that this interim final rule with comment period is not an economically significant rule as described in the Executive Order, or a significant action as defined in the Unfunded Mandates Reform Act. Aggregate impacts of the rule, and aggregate expenditures caused by the rule will not reach $120 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 components in hospitals that might qualify as small entities, the impact on small entities is uncertain.

It is clear that a number of hospitals that provide blood transfusions will be affected by the implementation of this interim final rule with comment period 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 analysis. This analysis, in combination with the rest of the preamble, is consistent with the analysis set forth by the RFA.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we have concluded that the rule does not contain policies that have federalism implications as defined in the Executive Order 13132 and, consequently, a federalism summary impact statement is not required.

B. Anticipated Effects

1. Effects on Hospitals

This interim final rule with comment period requires hospitals that transfuse blood and blood components to (1) prepare and follow written procedures for appropriate action when it is determined that blood and blood components the hospitals received and transfused are at increased risk for transmitting HCV; (2) quarantine prior collections in inventory from a donor who is at increased risk for transmitting HCV infection; (3) notify transfusion recipients (and, where required, legal representatives or relatives), as appropriate, of the need for HCV testing and counseling; and (4) extend the records retention period to 10 years.

This interim final rule with comment period will affect hospitals that transfuse blood and blood components. There are approximately 4,980 Medicare- and Medicaid-participating hospitals, excluding 1,041 hospitals that operate blood collection centers, because they are counted among the collection establishments. The CDC estimated in 2000 that 212,000 recipients may need to be notified due to the historical review.

Fixed Cost—Standard Operating Procedures and Record Review. This interim final rule with comment period 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 if it uses the services of an outside BCE. 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. We estimate, in consultation with the FDA, that the tasks will require an average of 16 hours per facility.

In the proposed rule, we estimated, based on the 1997 Bureau of Labor Statistics (BLS) estimates, that the total hourly compensation for a staff medical technologist is $25.67. We have revised the estimates to increase the hourly compensation to $33.84 to reflect the most recent BLS data. Each hospital will incur a one-time cost of $541.44 ($33.84 $\times$ 16 hours = $541.44). The total cost is about $2.7 million ($541.44 $\times$ 4980 establishments = $2,696,371.) (See the table in this section.) The proposed rule would have required hospitals to make at least three attempts to notify the

transfusion recipient. Several commenters expressed concern that it would be unnecessary to continue notification attempts if the hospital had proof that notification was attempted and was unsuccessful and that further attempts would most likely be unsuccessful. Therefore, we have changed the prescriptive language about the number of attempts. However, hospitals must make a reasonable attempt to contact any affected transfusion recipient within a maximum of 12 weeks from the time they receive from the blood establishment the results of a donor's supplemental positive test for HCV.

We did not receive comments on the initial estimate that it would cost $165 to comply with all of the lookback provisions for each affected component. However, based on a recent report the FDA received from Los Angeles County, a vendor was paid $118 per patient to abstract health records, locate and notify transfusion recipients, and to give pretest counseling. Therefore, the FDA has revised the cost for lookback activities. The FDA estimates that the product quarantine accounts for about 40 percent of the unit cost (that is, $66), and the recipient notification accounts for the other 60 percent of the unit cost (that is, $99). [EB2] Without other data from both the prospective and retrospective lookbacks, the FDA continues to use the $66 as the cost of product quarantine, but increased the cost of recipient notification from $99 to $118 based on the experience of Los Angeles County.

Prospective HCV lookback. The FDA estimates (based on prevalence levels reported by the American Red Cross for 2000) about 2,400 discrete components could trigger recipient notification (780 donations from HCV-infected donors × 3.1 components per donation). The CDC survey found that on average about 85 percent of the at-risk components sent to hospitals were transfused. For the analysis of the proposed rule, FDA assumed that no patient would receive more than one affected component. This assumption suggests that hospitals will quarantine about 2,400 components and attempt about 2,050 recipient notifications (780 HCV positive donors × 3.1 components per donor × 85 percent transfused). Because CMS inspected hospitals account for about 65 percent to 75 percent of the number of transfusions, the annual costs for consignees to conduct the prospective lookback actions range from $260,000 to $300,000 (65 percent by CMS-inspected establishments × 2,400 components annually triggering recipient notification × $66 per component quarantine plus 2050 components annually triggering recipient notification × $118 per recipient notification to 75 percent by CMS-inspected establishments × 2,400 components annually triggering quarantine × $66 per component quarantine plus 2,050 components annually triggering recipient notification × $118 per recipient notification. (See the table in this section. The numbers in the table are rounded).

Retrospective HCV lookback. For notifications resulting from donors tested before February 20, 2008 under 21 CFR 610.48(c), 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 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. The estimated one-time cost of recipient notification associated with the review of historical testing records is $41.6 million. This is based on the FDA estimate of blood components of about 212,000 recipients identified for notification produced from donations, and the average cost of $184 ($66 + $118) for staff time per component for recipient notification. Thus, the total one-time cost to hospitals for conducting the historical (retrospective) lookback effort is estimated to be $38.9 million for recipient notification). (See the table in this section.)

This interim final rule with comment period requires hospitals to increase the time they keep records from 5 to 10 years. Although we did not include the annual cost of keeping records for a longer period of time in the analysis for the proposed rule, we are including the cost in this interim final rule with comment period. The FDA has estimated in its final rule that it may take 40 hours for a computer programmer to perform routine maintenance of these additional records. At a wage of $34 per hour, including benefits, a hospital would spend an additional $1,360 annually to conform to this provision of the rule. However, according to the AABB (formerly knows as the American Association of Blood Banks), 80 percent of the establishments that transfuse blood are accredited by the AABB and already comply with their standards, including retaining records for 10 years. Taking AABB compliance into account, this analysis includes additional compliance costs for 20 percent of the transfusion facilities at a total annual cost of $1.4 million ($34.00 per hour × 40 hours × 4,980 hospitals × 20 percent). The following table shows the estimated compliance cost of this interim final rule. We believe that hospitals will incur up to $1.7 million in annual compliance costs for the prospective lookback provisions and to retain records for 10 years, and up to $42 million in one-time costs for SOPs and the retrospective lookback based on historical review of records. The annualized costs of this interim final rule over 10 years at 3 and 7 percent interest rates will be $6.5 and $7.6 million.

SUMMARY OF THE ESTIMATED COST OF THIS INTERIM FINAL RULE WITH COMMENT PERIOD

Type of cost	Number affected	One-time cost (millions of dollars)	Annual cost (millions of dollars)	Annualized costs (millions of dollars)	
				3 percent	7 percent
Development of HCV lookback Procedures	*4,980	$2.7		$0.3	$0.4
Prospective Review	4,980		0.3	0.3	$0.3
Historical Review (Retrospective lookback)	4,980	$38.9		$4.6	$5.5
Record Retention Retain records for 10 years	4,980		1.4	1.4	$1.4
Total		$41.6	$1.7	$6.5	$7.6

* Numbers are rounded. (Excluding 1,041 hospitals that operate blood collection centers, because they are counted among the collection establishments).

* The annualized cost is for a 10 year period.

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 lookback program could minimize liver damage associated with alcohol consumption by restricting his or her intake.

It is also important to note that identified infected patients will benefit from counseling and treatment with available therapies. Studies of patient characteristics and responsiveness to therapy indicate that when treatment is initiated early in an infection, the best and most cost effective outcomes are achieved. That is, best results are achieved if treatment is initiated earlier in the disease, when patients are younger and have not yet developed cirrhosis. For example, Bennett et al. showed that the years of life gained and cost effectiveness of interferon-alpha 2b treatment decreased as the age of the patient increased from 3.1 years at $500 per year of life (YLE) for 20-year-old patients to 22 days at $62,000 per YLE for 70-year-old patients. The dollar amounts of $500 and $62,000 represent the cost effectiveness of the treatment when it is given at an earlier age.

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

3. Effects on Medicare and Medicaid Programs

This interim final rule with comment period will generate a one-time cost to develop procedures for recipient notification. We estimate this cost to be $2.7 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 $41.6 million ($2.7 + $38.9). 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 interim final rule with comment period 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 final rule and has no additional economic impact. We have simply restated the analysis performed in the FDA companion rule; both rules present 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 PHS 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 guidance for testing blood for HCV, quarantining blood and blood components, and notifying patients who may have received HCV-infected blood and blood components. We explored the possibility of using a program memorandum to notify hospitals that they must follow FDA guidance. We believe, however, that in order to protect the health and safety of beneficiaries, we should publish an enforceable regulation that will enable us to ensure compliance through the survey process.

The FDA, in its final rule published elsewhere in this issue of the **Federal Register**, provides a lengthy discussion and cost-benefit analysis regarding a targeted lookback program compared to a general lookback program for HCV. Therefore, 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 this interim final rule with comment period 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 test positive for 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 be located, and would respond to the notification for testing and treatment, if appropriate.

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 that the patient had ever received a transfusion while in the hospital. These recipients would not have been reached through the general lookback effort.

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. The primary treatment for chronic hepatitis C is combination therapy with standard or pegylated interferon alpha and ribavirin. Of those patients who undergo combination treatment, a reported 40 to

50 percent show a sustained response (SR) after 12 months of therapy. However, interferon alpha produces a wide array of adverse side effects, 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. 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 are also required to conduct a lookback of transfusion recipients of potentially HCV-infected blood. This interim final rule with comment period also requires hospitals to have in their agreements with BCEs that BCEs notify hospitals after performing their own FDA-mandated lookback. Therefore, we have prepared an analysis consistent with the analysis set forth by the RFA. We solicited public comments on the extent that these provisions will significantly economically affect any of the entities.

We have reviewed this interim final rule with comment period under the threshold criteria of Executive Order 13132, Federalism. We have determined that it will not significantly affect the rights, roles, and responsibilities of States.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 482

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

■ For the reasons set forth in the preamble 42 CFR part 482 is 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. Amend § 482.27 by—

■ A. Removing the designation of paragraph (a).

■ B. Redesignating paragraphs (b) and (c) as paragraphs (a) and (b), respectively.

■ C. Revising re-designated paragraph (b).

■ D. Adding paragraph (c).

The revisions and additions read as follows:

§ 482.27 Condition of participation: Laboratory services.

* * * * *

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

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

(ii) Who tests positive on the supplemental (additional, more specific) test or other follow-up testing required by FDA; and

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

(2) *Potentially hepatitis C virus (HCV) infectious blood and blood components.* Potentially HCV infectious blood and blood components are the blood and blood components identified in 21 CFR 610.47.

(3) *Services furnished by an outside blood collecting establishment.* If a hospital regularly uses the services of an outside blood collecting establishment, it must have an agreement with the blood collecting establishment that governs the procurement, transfer, and availability of blood and blood components. The agreement must require that the blood collecting establishment notify the hospital—

(i) Within 3 calendar days if the blood collecting establishment supplied blood and blood components collected from a donor who tested negative at the time of donation but tests reactive for evidence of HIV or HCV infection 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 supplemental (additional, more specific) test for HIV or HCV, as relevant, or other follow-up testing required by FDA; and

(iii) Within 3 calendar days after the blood collecting establishment supplied blood and blood components collected from an infectious donor, whenever records are available, as set forth at 21 CFR 610.48(b)(3).

(4) *Quarantine and disposition of blood and blood components pending completion of testing.* If the blood collecting establishment (either internal or under an agreement) notifies the hospital of the 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 components from previous donations in inventory.

(i) If the blood collecting establishment notifies the hospital that the result of the supplemental (additional, more specific) test or other follow-up testing required by FDA is negative, absent other informative test results, the hospital may release the blood and blood components from quarantine.

(ii) If the blood collecting establishment notifies the hospital that the result of the supplemental, (additional, more specific) test or other follow-up testing required by FDA is positive, the hospital must—

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

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

(iii) If the blood collecting establishment notifies the hospital that the result of the supplemental, (additional, more specific) test or other follow-up testing required by FDA is indeterminate, the hospital must destroy or label prior collections of blood or blood components held in quarantine as set forth at 21 CFR 610.46(b)(2), 610.47(b)(2), and 610.48(c)(2).

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

(i) Records of the source and disposition of all units of blood and blood components for at least 10 years from the date of disposition in a manner that permits prompt retrieval; and

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

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

(i) Make reasonable attempts to notify the patient, or to notify the attending physician or the physician who ordered the blood or blood component and ask the physician to notify the patient, or other individual as permitted under paragraph (b)(10) of this section, that potentially HIV or HCV infectious blood or blood components were transfused to the patient and that there may be a need for HIV or HCV testing and counseling.

(ii) If the physician is unavailable or declines to make the notification, make reasonable attempts to give this notification to the patient, legal guardian, or relative.

(iii) 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 February 20, 2008.* For notifications resulting from donors tested on or after February 20, 2008 as set forth at 21 CFR 610.46 and 21 CFR 610.47 the notification effort begins when the blood collecting establishment notifies the hospital that it received potentially HIV or HCV infectious blood and blood components. The hospital must make reasonable attempts to give notification over a period of 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 February 20, 2008. For notifications resulting from donors tested before February 20, 2008 as set forth at 21 CFR 610.48(b) and (c), the notification effort begins when the blood collecting establishment notifies the hospital that it received potentially HCV infectious blood and blood components. The hospital must make reasonable 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 collecting establishment.

(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 an informed decision can be made about whether to obtain HIV or HCV testing and counseling; and

(iii) A list of programs or places where the person 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. For possible HIV infectious transfusion recipients that are deceased, the physician or hospital must inform the deceased patient's legal representative or relative. If the patient is a minor, the parents or legal guardian must be notified.

(11) *Applicability.* HCV notification requirements resulting from donors tested before February 20, 2008 as set forth at 21 CFR 610.48 will expire on August 24, 2015.

(c) *General blood safety issues.* For lookback activities only related to new blood safety issues that are identified after August 24, 2007, hospitals must comply with FDA regulations as they pertain to blood safety issues in the following areas:

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

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

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

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

Dated: July 22, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Approved: December 18, 2006.

Michael O. Leavitt,

Secretary.

Editorial Note: This document was received at the Office of the Federal Register on August 17, 2007.

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CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

45 CFR Parts 2510, 2522, 2540, 2551, and 2552

RIN 3045–AA44

National Service Criminal History Checks

AGENCY: Corporation for National and Community Service.

ACTION: Final rule.

SUMMARY: The Corporation for National and Community Service (Corporation) is issuing a regulation requiring grantees to conduct and document National Service Criminal History Checks on Senior Companions and Foster Grandparents, as well as on AmeriCorps State and National (including Education Award Program) participants and grant-funded staff in those programs who, on a recurring basis, have access to children, persons age 60 and older, or individuals with disabilities. A National Service Criminal History Check consists of a State criminal registry check; and a National Sex Offender Public Registry (NSOPR) check.

DATES: This final rule is effective November 23, 2007.

FOR FURTHER INFORMATION CONTACT: Amy Borgstrom at (202) 606–6930 (*aborgstrom@cns.gov*). The TDD/TTY number is (202) 606–3472. You may request this rule in an alternative format for the visually impaired.

I. Background—The October 26, 2006, Proposed Rule

On October 26, 2006, the Corporation published a proposed rule (71 FR 62573) to require its grantees to conduct and document criminal history checks on Senior Companions and Foster Grandparents, as well as on AmeriCorps State and National (including Education Awards Program) participants and grant-funded staff in those programs who, on a recurring basis, have access to children, persons age 60 and older, or individuals with disabilities. The objective of this rule is to help protect vulnerable individuals who are beneficiaries of programs that are funded by the Corporation. This update to the Corporation's criminal history check policies was prompted by a recommendation by the Corporation's Acting Inspector General in an advisory letter to the Corporation's Chief Executive Officer in January 2005.

Emphasis on Protecting Vulnerable Populations

Many national and community service programs are dedicated to