

§ 408.24 Individuals who enrolled or reenrolled before April 1, 1981 or after September 30, 1981.

(a) * * *

(10) For premiums due for months beginning with January 1, 2007, the following:

(i) Any months after December 2006 during which the individual met the conditions under § 407.21(a) of this chapter.

(ii) Any months of Part B (SMI) coverage for which the individual enrolled during a special enrollment period as provided in § 407.21(b) of this chapter.

(b) * * *

(2) * * *

(i) Any of the periods specified in paragraph (a) of this section; and

* * * * *

■ 10. Section 408.28 is added to read as follows:

§ 408.28 Increased premiums due to the income-related monthly adjustment amount (IRMAA).

Beginning January 1, 2007, Medicare beneficiaries must pay an income-related monthly adjustment amount in addition to the Part B (SMI) standard monthly premium, plus any applicable increase for late enrollment or reenrollment, if the beneficiary's modified adjusted gross income exceeds the threshold amounts specified in 20 CFR 418.1115.

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

Dated: January 31, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: April 7, 2008.

Michael O. Leavitt,

Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 482

[CMS–3014–F]

RIN 0938–AJ29

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

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

ACTION: Final rule.

SUMMARY: This final rule finalizes the hospital conditions of participation requirements for hospitals that transfuse blood and blood components. It requires hospitals 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. 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:* The interim final rule amending 42 CFR part 482 published August 24, 2007 at 72 FR 48562 and effective on February 20, 2008, is adopted as final June 27, 2008.

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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 (CoPs).

The CoPs for hospital laboratory services currently specifies the steps hospitals must take when they become aware they have administered potentially human immunodeficiency virus infectious blood or blood components to a patient. All laboratories must be CLIA-certified to participate in Medicare and Medicaid. 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.

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.

On November 16, 2000, we published in the **Federal Register** a proposed rule (65 FR 69416). In that proposed rule, we discussed in detail the steps that had been taken since the late 1980's to avoid the transmission of HCV infection and to create opportunities for disease prevention that, in most cases, can occur many years after recipient exposure to a donor.

On August 24, 2007, we published an interim final rule with comment period in the **Federal Register** (72 FR 48562). The interim final rule with comment period incorporated the provisions of the November 16, 2000 proposed rule, responses to public comments, and changes to further conform our regulation to FDA's final rule that was also published on August 24, 2007. For a detailed discussion of this information, we refer the reader to the August 24, 2007 interim final rule (72 FR 48562 through 48565).

II. Provisions of the Interim Final Rule With Comment Period

In order to have consistent industry standards for potentially infectious blood and blood components, on August 24, 2007, we published in the **Federal Register** an interim final rule with comment period (72 FR 48562) entitled, "Medicare and Medicaid Programs; Hospital Conditions of Participation: Laboratory Services". The provisions of the interim final rule were effective on February 20, 2008. The interim final rule with comment period addressed the comments CMS received regarding the proposed rule that was published on November 16, 2000 (65 FR 69416). Since our proposed rule was published in conjunction with the FDA's rule, we coordinated our responses with the FDA's responses in its "lookback" rule (72 FR 48766) 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”). In the interim final rule with comment period, we implemented the following provisions—

- Changed the reference of “blood establishments” to “blood collecting establishments” (BCE). Under this requirement, a BCE must notify a hospital if it supplies such hospital with potentially HCV infectious blood.

- Amended the hospital conditions of participation to require hospitals 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.

- Required 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.

- Required blood banks to notify a hospital of potentially infected blood within 3 calendar days after testing. We also require hospitals to make at least three attempts to notify the patient, or to notify the attending physician who ordered the blood or blood components.

- Required hospitals to destroy and re-label previous collection of blood or blood components held in quarantine if the results of the testing were indeterminate.

- Required 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.

III. Analysis of and Responses to Public Comments and Provisions of the Final Regulation

We did not receive any public comments on the August 24, 2007 interim final rule with comment period. Therefore, the provisions of this final rule are identical to the provisions of the August 24, 2007 interim final rule with comment period (72 FR 48562).

IV. 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 solicited public comment on each of these issues for the following sections of this document that contain information collection requirements.

Condition of Participation: Laboratory Services (§ 482.27)

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 aforementioned information collection requirements referenced are subject to the Paperwork Reduction Act, the associated burden is captured and discussed in the Food and Drug Administration’s (FDA) 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” (72 FR 48766).

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.

In the interim final rule with comment period, we assigned 1 token hour of burden to these requirements; however, we are no longer assessing 1 token burden hour for the information collection requirements because, as stated earlier, the burden associated with the information collection requirements contained in this final rule was addressed in the FDA’s final rule (72 FR 48766). The burden associated with the FDA’s final rule was approved under OMB control number 0910–0610 with an October 31, 2010, expiration date.

We have submitted a copy of this final rule to OMB for its review of the information collection requirements. These requirements are not effective until they have been approved by OMB.

V. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this final rule 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), Executive Order 13132 on Federalism and the Congressional Review Act (5 U.S.C. 804(2)).

In the August 24, 2007 interim final rule with comment period, we presented a full regulatory impact analysis that discussed the costs and benefits of the rule. The provisions of the interim final rule with comment period became effective on February 20, 2008. For a full description of the regulatory impact analysis, we refer the reader to the August 24, 2007 interim final rule (see 72 FR 48570 through 48574). We did not receive any comments on the August 24, 2007 interim final rule with comment period; and therefore, we have not made any changes to the regulatory impact analysis in this final rule. This rule merely finalizes, without change, the interim final rule, which is already in effect. Therefore, we have determined that this final rule has no economic impact.

Executive Order 12866 (as amended) 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 must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). The August 24, 2007 interim final rule with comment period estimated a one-time cost of \$41.6 million and an annual cost of \$1.7 million. Because the estimated cost falls below the threshold for a major rule, we have determined that this final 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 the Secretary has determined that this final 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") and has fewer than 100 beds. As stated above, the Secretary has determined that this final rule will not have a significant impact on a substantial number of small rural hospitals.

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 impose spending costs on State, local, or tribal governments in the aggregate, or by private sector in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately \$130 million. We believe this final rule will not be an economically significant rule as described in the Executive Order, or a significant action as defined in the Unfunded Mandates Reform Act. Aggregate impacts and expenditures imposed by this final rule, will not reach \$130 million for State, local, or tribal governments in the aggregate, or by the private sector.

We did not receive any comments on the August 24, 2007 interim final rule with comment period, and as previously stated above, we have not made any changes to the impact analysis in this final rule. As summarized, the impacts in the interim rule with comment period presented an overall one-time cost of \$41.6 million and an annual cost of \$1.7 million. The one-time cost of \$41.6 million consists of \$2.7 million for the development of HCV lookback procedures and \$38.9 million for the historical record review (retrospective lookback effort). The annual cost of \$1.7 million consists of \$1.4 million for record retention (retain records for 10 years) and \$0.3 million for prospective reviews.

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. 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 final rule also requires hospitals to have in their agreements with BCEs, that BCEs notify hospitals after performing their own FDA-mandated lookback.

In accordance with the provisions of Executive Order 12866, this final rule was not 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.

■ The interim final rule with comment period amending 42 CFR Part 482, which was published on August 24, 2007, in the **Federal Register** at 72 FR 48562 through 48574, is adopted as a final rule.

(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: April 25, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: May 22, 2008.

Michael O. Leavitt,

Secretary.

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