HCFA and FDA Propose Rules to Reduce Risk of Hepatitis C Transmission for Blood Transfusion Recipients

On November 16, 2000, the Health Care Financing Administration (HCFA) and the Food and Drug Administration (FDA) each released proposed rules to prevent the spread of hepatitis C virus (HCV). The proposed rules require hospitals to notify transfusion recipients who received blood from donors at increased risk for transmitting HCV. The proposed rules seek to prevent HCV in transfusion recipients many years after exposure to the disease.

The HCFA and FDA proposed rules were issued in concert and each incorporates key provisions of the other. HCFA’s Proposed Rule alters hospital conditions of participation for laboratory services under the Medicare and Medicaid programs. The proposed rule requires hospitals that transfuse blood and blood products to establish:

1. **Written Procedures:** Prepare and follow written procedures when it is determined that blood and blood products that the hospital received and transfused are at increased risk for HCV;

2. **Quarantine and Notification:** Establish a “lookback” program similar to that in effect for human immunodeficiency virus (HIV), by:

   (i) quarantining prior collections from donors who are at increased risk for transmitting HCV infection, and

   (ii) notifying transfusion recipients of the need for HCV testing and counseling;

3. **Records Retention:** Extend the records retention period from five to ten years.

The FDA’s Proposed Rule was released as part of its “Blood Initiative” effort to review and revise rules related to blood and blood products. It is considerably more technical than HCFA’s Proposed Rule, but still focuses on HCV “lookback” as a key approach to combating the spread of HCV.

Comments on the proposed rules will be considered jointly by HCFA and the FDA and must be received by January 16, 2001 at HCFA and by February 14, 2001 at the FDA.

**Impact on Health Care Entities**

The proposed rules place administrative and financial burdens on hospitals and other entities affected by the rules. Health care entities must prepare and follow written procedures for HCV infected blood, quarantine potentially infected blood, notify transfusion recipi-
ents, as appropriate, of the need for HCV testing and counseling, and enhance recordkeeping related to HCV infected blood. The Centers for Disease Control and Prevention estimates that 303,676 recipients may need to be notified of their risk of HCV infection under the “lookback” program contemplated by the proposed rules. Time limits also apply to the notification process, which may tie up already scarce hospital staffing resources. Thus, the proposed rules impose a substantial administrative and financial burden on health care entities.

The proposed rules, however, benefit transfusion recipients who may have been exposed to HCV, permitting them to take action to reduce their risk and the risk of others contracting the disease. For example, transfusion recipients notified under the proposed rules may limit alcohol intake, protect sexual partners from the risk of infection, and refrain from donating blood, all of which will help reduce the spread of HCV. Such actions also reduce the overall cost of health care. Likewise, the notification process allows the health care workers providing care to potentially infected transfusion recipients to take additional precautions to avoid the risk of exposure. Finally, many health care entities already engage in the procedures required by the rule for HIV, and thus, must simply expand their activities to encompass HCV, somewhat limiting the administrative and financial burden of compliance.

Background

HCV is the most common bloodborne infection in the United States. HCV may be transmitted by blood transfusions and solid organ transplants from infectious donors, hemodialysis, occupational exposure to blood, perinatal exposure of infants to infected mothers, injection drug users sharing drug use equipment, and unprotected sex.

HCV is often asymptomatic for as many as 20 years. A “window period” exists for the disease, when no detectable antibody to HCV appears in screening tests. Often, HCV infection is discovered only after serious liver damage has occurred.

HCFA and the FDA are responsible for ensuring the safety of the nation’s blood and blood products. HCFA regulates hospital laboratories through conditions of participation under the Medicare and Medicaid programs. The FDA regulates good manufacturing practices for blood and blood components. The FDA’s Blood Products Advisory Committee and the Public Health Service Advisory Committee on Blood Safety and Availability have also been studying HCV issues and have made recommendations to combat spread of the disease for almost a decade. The proposed rules reflect much of this collective knowledge.

HCFA’s Proposed Rule

HCFA’s Proposed Rule revises the condition of participation related to laboratory services for hospitals participating in the Medicare and Medicaid programs. First, the rule makes the existing regulation, which covers HIV, also applicable to HCV. The proposed rule also adds additional requirements applicable to both HIV and HCV. Specifically, the proposed rule does the following:

1. Definitions: Defines potentially HCV infectious blood and blood products as prior collections from donors who test repeatedly reactive under various standards (set forth in the proposed rule) for evidence of HCV.

2. Agreements with Blood Banks: Provides that a hospital’s agreements with its blood banks require each blood bank to notify the hospital within 3 days if the blood bank supplied blood and blood products collected from a donor who is later determined to be potentially HCV infectious, and within 45 days for certain FDA licensed or required tests.

3. Quarantine: Requires the hospital to quarantine all blood and blood products that are potentially infectious until more specific, FDA-licensed tests are performed. If such tests determine the blood is likely HCV infectious, the blood and blood products must then be destroyed or labeled and transfusion recipients of such blood and blood products notified, as discussed below.
4. **Notification:** Hospitals that have administered or released potentially HCV infectious blood or blood products must:

   (i) make at least three attempts to notify the patient (or the attending or ordering physician to ask them to notify the patient) that potentially HCV infectious blood or blood products were transfused to the patient. If the physician is unavailable or declines to make the notification, the hospital must make at least three attempts to notify the patient (or the patient’s legal representative);

   (ii) immediately notify the patient (or the patient’s legal representative) of the need for HCV testing and counseling; and

   (iii) document in the patient’s medical record the notification or attempt at notification.

5. **Timeframe:** For donors tested after the effective date of a final rule, if issued, the hospital has 12 weeks from the date the blood bank notifies the hospital that it received potentially HCV infectious blood or blood products to notify the patient or to document in the patient’s medical record the extenuating circumstances that caused the notification timeframe to exceed 12 weeks. For donors tested before the effective date of the final rule, if issued, the hospital must make at least three attempts to give notification and has one year from the date the hospital received notice from the blood bank to complete notification.

6. **Content of Notification:** The notification must include: (i) a basic explanation of the need for HCV testing and counseling; (ii) enough information for the transfusion recipient to make an informed decision about HCV testing and counseling; and (iii) a list of programs or places to obtain testing and counseling, including any requirements or restrictions imposed by such programs.

7. **Recordkeeping:** Hospitals must maintain records of the source and disposition of all blood and blood products for at least 10 years from the date of disposition. Hospitals must ensure that such records can be promptly retrieved and must have a fully funded plan in place to transfer the records to another entity if the hospital ceases operation.

8. **Policies and Procedures:** Hospitals must establish notification and documentation policies and procedures that comply with law, including confidentiality of medical records rules.

Second, the proposed rule requires hospitals to comply with FDA regulations regarding testing and quarantine of blood and blood products and notification and counseling of transfusion recipients who may have received infectious blood and blood products.

**FDA’s Proposed Rule**

The FDA’s Proposed Rule is part of the FDA’s “Blood Initiative” to comprehensively review and revise regulations, policies, guidelines and procedures related to the licensing and regulation of blood products. The proposed rule mirrors HCFA’s rule in many respects. It requires a blood establishment to notify a hospital if it supplied the hospital with potentially HCV infectious blood. In addition, the FDA also requires HCV “lookback”—searching historical testing records of prior donations from donors who test repeatedly reactive on HCV screening tests, extending back indefinitely for computerized electronic records and to January 1, 1998 for other retrievable records. The FDA’s Proposed Rule is more technical than HCFA’s rule and is not discussed in detail here.

**Effect on Medicaid**

Medicaid regulations governing laboratory services provide that state plans must pay for laboratory services furnished by a hospital-based laboratory meeting the requirements for Medicare participation as set forth in 42 CFR 482.27. As such, hospitals wishing to participate in Medicaid must meet the requirements set forth in the proposed rules. The Medicaid program is also
expected to absorb some of the cost of compliance with the proposed rules.¹⁴


² Comments on the information collection provisions of the FDA’s Proposed Rule must be received by December 18, 2000. 65 FR 69377.

³ The cost of conducting the “lookback” program is estimated at $52,653,004. The Medicare and Medicaid programs may absorb some of this cost, although the impact of the outpatient prospective payment system on Medicare’s financial obligations is unclear. 65 FR 69421. The preamble to the proposed rule discusses some alternative approaches to the “lookback” program considered, and rejected, by HCFA. 65 FR 69422.

⁴ HCFA and FDA also coordinate inspections to minimize duplication and reduce the burdens on health care facilities.

⁵ 42 CFR part 482. Laboratories are also subject to regulation under the Clinical Laboratory Improvement Amendments of 1988. 42 CFR part 493.

⁶ 21 CFR parts 211, 600,601, 606, 610, and 640.

⁷ See HCFA’s Proposed Rule, 42 CFR 482.27.

⁸ HCFA’s Proposed Rule cross-references provisions of the FDA’s Proposed Rule that require hospitals to perform a “lookback” of blood or blood products collected from a donor extending back indefinitely for computerized electronic records and to January 1, 1998 for other retrievable records, or the date 12 months before the donor’s most recent negative multiantigen screening test for the antibody to HCV, whichever is the later date. See FDAs Proposed Rule, 21 CFR 610.48(h)(3)(i) and (ii) and (j)(3)(1) and (ii).


¹⁰ HCFA’s Proposed Rule provides definitions of who and when legal representatives and relatives may be notified. See HCFA’s Proposed Rule, 21 CFR 482.27(b)(10).

¹¹ Id.

¹² Clinical records currently must be maintained for five years. Lengthening the time period to ten years increases the opportunities for disease prevention or treatment years after a transfusion recipient has been exposed to a donor later determined to be at risk. See 65 FR 69418.

¹³ See HCFA’s Proposed Rule, 42 CFR 482.27(c).

¹⁴ 65 FR 69419, 69421