

notifications to consignees of subsequent test results. It is estimated that transfusion services not subject to HCFA's regulations will need to notify physicians, or in some cases recipients, an average of 16 times per year resulting in a total number of 2,880 notifications. FDA estimates an average of 10 minutes per notification of consignees, physicians, and recipients. The estimate of one-half hour for § 610.47(b) is based on the minimum requirement of three attempts to notify recipients by

transfusion services. In Table 2 of this document, the estimate of 154 recordkeepers and 160 records is based on the estimate that the requirement is already implemented voluntarily by more than 95 percent of the facilities, which collect 98 percent of the Nation's blood supply. FDA estimates that it takes approximately 5 minutes to document and maintain the records to relate the donor with the unit number of each previous donation. The establishment of SOP's under

§ 606.100(b)(19) is a one-time burden. The maintenance of the SOP's is considered usual and customary business practice, therefore no burden is calculated for the preparation and updating of the SOP.

In the **Federal Register** of August 3, 1999 (64 FR 42132), the agency requested comments on the proposed collections of information. No significant comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
610.46(a)	3,076	60	184,560	0.17	31,375
610.46(b)	3,076	60	184,560	0.17	31,375
610.47(b)	180	16	2,880	0.5	1,440
Total					64,190

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
606.160(b)(1)(vii)	154	160	24,640	12.8	1,971
606.160(b)(1)(viii)	3,076	60	184,560	4.8	14,765
Total					16,736

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: October 27, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy,
Planning, and Legislation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-276]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and

utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection

Request: Revision of a currently approved collection;

Title of Information Collection:

Prepaid Health Plan Cost Report;
Form No.: HCFA-276 (OMB# 0938-0165);

Use: These forms are needed to establish the reasonable cost providing covered services to the enrolled Medicare population of Health Maintenance Organizations and Competitive Medical Plans (HMO/CMP) in accordance with Section 1876 of the Social Security Act and Health Care Prepayment Plans (HCPP) in accordance with Section 1833 of the Social Security Act;

Frequency: Quarterly, Annually;
Affected Public: Business or other for-profit;

Number of Respondents: 62;

Total Annual Responses: 327;

Total Annual Hours: 11,600.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access

HCFA's WEB SITE ADDRESS at

<http://www.hcfa.gov/regs/prdact95.htm>,

or E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326.

Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: October 20, 1999.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA,
Office of Information Services, Security and
Standards Group, Division of HCFA
Enterprise Standards.

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