

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

Item	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
510(k) reviews	35	4	140	10	1,400 ²

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

²Due to clerical error, the recordkeeping burden hours for 510(k) reviews that appeared in a notice issued in the FEDERAL REGISTER of August 4, 1998 (63 FR 41575), were incorrect. Table 2 of this document contains the correct estimates.

The burdens are explained as follows:

1. Reporting

a. *Requests for accreditation:* Under the agency's Third-Party Review Pilot Program, the agency received 37 applications for recognition as third-party reviewers, of which the agency recognized 7. Under this expanded program, the agency anticipates that it will not see a significant increase in the number of applicants. Therefore, the agency is estimating that it will receive 40 applications. The agency anticipates that it will accredit 35 of the applicants to conduct third-party reviews.

b. *510(k) reviews conducted by accredited third parties:* In 18 months under the Third-Party Review Pilot Program, FDA received only 22 510(k)'s that were requested and were eligible for review by third parties. Because the new program is not as limited in time, and is expanded in scope, the agency anticipates that the number of 510(k)'s submitted for third-party review will increase. The agency anticipates that it will receive approximately 140 third-party review submissions annually, i.e., approximately 4 annual reviews per each of the estimated 35 accredited reviewers.

2. Recordkeeping

Third-party reviewers are required to keep records of their review of each submission. The agency anticipates approximately 140 annual submissions of 510(k)'s for third-party review. The agency estimates that each third-party reviewer will require approximately 10 annual hours to maintain records of their reviews and reports.

Dated: October 26, 1998.

William K. Hubbard,
Associate Commissioner for Policy
Coordination.

[FR Doc. 98-29108 Filed 10-29-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources And Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443-1891.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Surveys to Assess the Outcomes of Curricular Changes at Eight Medical Schools—NEW

In July, 1998, eight medical schools were awarded federal funding under the Undergraduate Medical Education

Program for the Twenty-first Century (UME-21) initiative to develop and implement curricular change during the clinical years. This project aims to bring about change in the clinical phase of medical education so that medical students are better prepared for residency training and practice. The selected schools must institute specific changes in their clinical education programs, including the addition of content related to clinical practice in a managed care environment and the introduction of primary care based clinical experiences that cut across the generalist disciplines. UME-21 is administered by the Bureau of Health Professions of the Health Resources and Services Administration. The surveys are designed to: (1) Obtain the opinions of graduating seniors regarding their education in selected topics important for practice in the changing health care environment, and (2) determine whether the physicians who supervise the graduates during their first year of residency believe that these graduates possess appropriate knowledge, skills, and attitudes.

The surveys are being conducted as part of a broader evaluation of the overall UME-21 initiative. The study population of students will consist of 2,400 seniors at the eight medical schools, evenly distributed between the graduating classes of 1999 and 2000. The study population of residency program directors will consist of approximately 1,200 physicians in residency programs throughout the country determined by the residency locations of the graduating seniors in each year.

The estimated respondent burden is as follows:

Respondent	Number of respondents	Responses per respondent	Hours per response (minutes)	Total Burden hours
Students	2,400	1	7	280
Program Directors	1,200	2	7	280

Respondent	Number of respondents	Responses per respondent	Hours per response (minutes)	Total Burden hours
	3,600	560

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 14-33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: October 23, 1998.

Jane Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 98-29111 Filed 10-29-98; 8:45 am]

BILLING CODE 4160-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

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

Periodically, the Health Resources and Services Administration (HRSA)

publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Application for NHSC Recruitment and Retention Assistance (in Use Without Approval)

The National Health Service Corps (NHSC) of the HRSA's Bureau of Primary Health Care assists underserved communities through the development, recruitment, and retention of primary health care clinicians dedicated to serving people in health professional shortage areas.

The Application for NHSC Recruitment and Retention Assistance submitted by sites or clinicians requests information on the practice site, sponsoring agency, recruitment contact, staffing levels, service users, site's 5-year infant mortality or low birth rate averages, and next nearest site. The information on the application is used for determining eligibility of sites and to verify the need for NHSC providers. Sites must submit applications annually or when they need a provider.

Estimates of annualized reporting burden are as follows:

Type of report	Number of respondents	Responses per respondent	Hours per response	Total burden hour
Application	1,000	1	.75	750

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Wendy A. Taylor, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: October 23, 1998.

Jane Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 98-29112 Filed 10-29-98; 8:45 am]

BILLING CODE 4160-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Publication of the OIG's Provider Self-Disclosure Protocol

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice.

SUMMARY: This **Federal Register** notice sets forth the OIG's recently-issued Provider Self-Disclosure Protocol. This Self-Disclosure Protocol offers health care providers specific steps, including a detailed audit methodology, that may be undertaken if they wish to work openly and cooperatively with the OIG to efficiently quantify a particular problem and, ultimately, promote a higher level of ethical and lawful conduct throughout the health care industry.

FOR FURTHER INFORMATION CONTACT: Ted Acosta, Office of Counsel to the Inspector General, (202) 619-2078.

SUPPLEMENTARY INFORMATION: The OIG has long stressed the role of the health care industry in combating health care fraud, and believes that health care providers can play a cooperative role in identifying and voluntarily disclosing program abuses. The OIG's use of voluntary self-disclosure programs, for example, is premised on a belief that health care providers must be willing to police themselves, correct underlying problems and work with the

Government to resolve these matters. Based on insights gained from a pilot program undertaken as part of Operation Restore Trust, discussions with the provider community and the growing need for an effective disclosure mechanism, the OIG has now developed a more open-ended process, or protocol, for making a disclosure and allowing a health care provider to cooperative work with the OIG. Unlike the previous voluntary disclosure pilot programs, this self-disclosure protocol gives detailed guidance to the provider on what information is appropriate to include as part of an investigative report and how to conduct an audit of the matter, while setting no limitations on the conditions under which a health care provider may disclose information to the OIG.

A reprint of the OIG's Provider Self-Disclosure Protocol follows.

Provider Self-disclosure Protocol

I. Introduction

The Office of Inspector General (OIG) of the United States Department of