This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/ohrms/dockets/default.htm*, *http://www.fda.gov/cder/guidance/index.htm*, or *http://www.fda.gov/cber/reading.htm*.

Dated: July 9, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–13667 Filed 7–12–07; 8:45 am]

BILLING CODE 4160–01–S

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 the Office of Management and Budget (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) 443–1129.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the agency; (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: Uniform Progress Reports (OMB No. 0915–0061)—Revision

The HRSA Uniform Progress Report (UPR) is used for the preparation and submission of continuation applications for Title VII and VIII health professions and nursing education and training programs. The UPR measures grantee success in meeting (1) The objectives of the grant project, and (2) the cross-cutting outcomes developed for the Bureau of Health Professions' education and training programs. Part I of the progress report is designed to collect information to determine whether sufficient progress has been made on the approved project objectives, as grantees must demonstrate satisfactory progress to warrant continuation of funding. Part II collects information on activities specific to a given program. Part III, the Comprehensive Performance Management System (CPMS), collects data on overall project performance related to the Bureau's strategic goals, objectives, outcomes, and indicators. Progress will be measured based on the objectives of the grant project, and outcome measures and indicators developed by the Bureau to meet requirements of the Government Performance and Results Act (GPRA).

The Bureau has simplified several tables in UPR II and added the ability for grantees to provide better race and ethnicity data. In addition, to respond to the requirements of GPRA, the Bureau has revised its cross-cutting goals, expected outcomes, and indicators in UPR III CPMS that provide the framework for collection of outcome data for its Title VII and VIII programs. An outcome based performance system is critical for measuring whether program support is meeting national health workforce objectives. At the core of the performance measurement system are found cross-cutting goals with respect to workforce quality, supply, diversity, and distribution of the health professions workforce.

The estimated annual burden is as follows:

Report	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Uniform progress report	1,550	1	1,550	24	37,200
Total	1,550		1,550		37,200

Send comments to Susan G. Queen, PhD, HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: July 5, 2007.

Alexandra Huttinger,

Acting Director, Division of Policy Review and Coordination.

[FR Doc. E7–13626 Filed 7–12–07; 8:45 am]

BILLING CODE 4165–15–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 (OMB), 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: Healthcare Integrity and Protection Data Bank for Final Adverse Information on Health Care Providers, Suppliers, and Practitioners (OMB No. 0915–0239)—Extension

Section 221(a) of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 specifically directs the Secretary to establish a national health care fraud and abuse data collection program for the reporting and disclosure of certain final adverse actions taken against health care providers, suppliers, and practitioners. A final rule was published October 26, 1999, in the **Federal Register** to implement the statutory requirements of section 1128E of the Social Security Act (The Act) as added by Section 221(a) of HIPAA. The Act requires the Secretary to implement the national health care fraud and abuse data collection program. This Data Bank is known as the Healthcare Integrity and Protection Data Bank (HIPDB). It contains the following types of information: (1) Civil judgments against a health care provider, supplier, or practitioner in Federal or State court related to the delivery of a health care item or service; (2) Federal or State criminal convictions against a health care provider, supplier, or practitioner related to the delivery of a health care item or service; (3) Actions by Federal or State agencies responsible for the licensing and certification of health care providers, suppliers, or practitioners; (4) Exclusion of a health care provider, practitioner or supplier from participation in Federal or State health care programs; and (5) Any other adjudicated actions or decisions that the Secretary shall establish by regulations. Access to this Data Bank is limited to Federal and State Government agencies and health plans. The final regulations governing the HIPDB are codified at 45 CFR part 61.

The reporting forms and the request for information forms (query forms) must be accessed, completed, and submitted to the HIPDB electronically through the HIPDB Web site at *http://www.npdb-hipdb.hrsa.gov.* All reporting and querying is performed through this secure Web site. Due to overlap in requirements for the HIPDB, some of the National Practitioner Data Bank's burden has been subsumed under the HIPDB.

Estimates of burden are as follows:

Regulatory citation	Number of respondents	Frequency of responses	Total responses	Hours per response (min.)	Total burden hours
61.6(a),(b) Errors & Omissions	188	4.4	817	15	204.25
61.6 Revisions/Appeal Status	130	26.9	3,492	30	1,746
61.7 Reporting by State Licensure Boards	305	80.8	24,640	45	18,480
61.8 Reporting of State Criminal Convictions	45	56.0	2,518	45	1,888.5
61.9 Reporting of Civil Judgments	4	2.5	10	45	7.5
61.10(b) Reporting Exclusions from participating in Federal and State Health Care Programs	9	320.3	2,883	20	961
61.11 Reporting of adjudicated actions/decisions	92	17	1,562	45	1,171.5
61.12 Request for Information—State & Federal Agencies	855	279.3	238,814	5	19,901.26
61.12 Request for Information—Health Plans, etc.	1,239	532.4	659,617	5	54,968.1
61.12 Request for Information—Health Care Providers, Suppliers, Practitioners (Self-query)	50,416	1	50,416	25	21,006.7
61.12(a)(4) Request by Researchers for Aggregate Data	1	1	1	30	.5
61.15 Place Report in Dispute	300	1	300	5	25
61.15 Add a Subject Statement	669	1	669	45	501.8
61.15 Request for Secretarial Review	15	1	15	480	120
Total	54,268		985,754		120,982.11

Note: Numbers in the table may not add up exactly due to rounding.