Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) (the PRA). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations for premarket approval applications (21 CFR part 814, OMB control number 0910–0231) and the regulations for premarket notification submissions (21 CFR part 807, OMB control number 0910–0120).

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments to *http://www.fda.gov/dockets/ecomments* 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.

Dated: November 19, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–29463 Filed 11–25–03; 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 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) 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: Data System for Organ Procurement and Transplantation Network and Associated Forms (OMB No. 0915–0157): Revision

Section 372 of the Public Health Service (PHS) Act requires that the Secretary, by contract, provide for the establishment and operation of an Organ Procurement and Transplantation Network (OPTN). The OPTN, among other responsibilities, operates and maintains a national waiting list of individuals requiring organ transplants, maintains a computerized system for matching donor organs with transplant candidates on the waiting list, and operates a 24-hour telephone service to facilitate matching organs with individuals included in the list.

Data for the OPTN data system are collected from transplant hospitals, organ procurement organizations, and tissue-typing laboratories. The information is used to match donor organs with recipients, to monitor compliance of member organizations with OPTN rules and requirements, and to report periodically on the clinical and scientific status of organ donation and transplantation in this country. Data are used in the development and revision of OPTN rules and requirements, operating procedures, and standards of quality for organ acquisition and preservation, some of which have provided the foundation for development of Federal regulations. The practical utility of the data collection is further enhanced by requirements that the OPTN data must be made available without restriction for use by OPTN members, the Scientific Registry of Transplant Recipients, the Department of Health and Human Services, and others for evaluation, research, patient information, and other important purposes.

Revisions in the 28 data collection forms and addition of 2 survey instruments are intended to clarify existing questions, to provide additional detail and categories to avoid confusion and be more inclusive, to remove obsolete data, and to comply with requests for more complete and precise data.

ESTIMATES OF ANNUALIZED HOUR BURDEN

Form	Number of respondents	Responses per respondents	Total responses	Hours per response	Total burden hours
Deceased Donor Registration	59	173	10,207	0.3	3,062.10
Death referral data	59	12	708	10	7,080.00
Living Donor Registration	692	10	6,920	0.2	1,384.00
Living Donor Followup	692	19	13,148	0.1	1,314.80
Donor Histocompatibility	152	87	13,224	0.1	1,322.40
Recipient Histocompatibility	152	163	24,776	0.1	2,477.60
Heart Candidate Registration	139	23	3,197	0.3	959.10
Lung Candidate Registration	70	28	1,960	0.3	588.00
Heart/Lung Candidate Registration	72	1	72	0.3	21.60
Thoracic Registration	139	24	3,336	0.3	1,000.80
Thoracic Followup	139	174	24,186	0.2	4,837.20
Kidney Candidate Registration	247	109	26,923	0.2	5,384.60
Kidney Registration	247	65	16,055	0.3	4,816.50
Kidney Followup *	247	493	121,771	0.2	24,354.20

ESTIMATES OF ANNUALIZED HOUR BURDEN—Continued

Form	Number of respondents	Responses per respondents	Total responses	Hours per response	Total burden hours
Liver Candidate Registration	123	82	10,086	0.2	2,017.20
Liver Registration	123	46	5,658	0.4	2,263.20
Liver Follow-up	123	299	36,777	0.3	11,033.10
Kidney/Pancreas Candidate Registration	139	12	1,668	0.2	333.60
Kidney/Pancreas Registration	139	7	973	0.4	389.20
Kidney/Pancreas Follow-up	139	64	8,896	0.3	2,668.80
Pancreas Candidate Registration	139	7	973	0.2	194.60
Pancreas Registration	139	4	0.3	166.80	556
Pancreas Follow-up	139	20	2,780	0.2	556.00
Intestine Candidate Registration	44	5	220	0.2	44.00
Intestine Registration	44	3	132	0.2	26.40
Intestine Follow-up	44	8	352	0.2	70.40
Immunosuppression Treatment	692	38	26,296	0.025	657.40
Immunosuppression Treatment Follow-up	692	281	194,452	0.025	4,861.30
Post Transplant Malignancy	692	5	3,460	0.05	173.00
Annual Unet Satisfaction Survey	750	1	750	0.03	22.50
Annual Organ Center Satisfaction Survey	750	1	750	0.03	22.50
Total	903		561,262		84,102.90

Includes an estimated 6,000 kidney transplant patients transplanted prior to the initiation of the data system

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 1445, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: November 19, 2003.

Tina M. Cheatham,

Acting Director, Division of Policy Review and Coordination.

[FR Doc. 03–29465 Filed 11–25–03; 8:45 am]

BILLING CODE 4165–15–P

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 the 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 at (301) 443–1129.

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: The Organ Procurement and Transplantation Network—New

The operation of the Organ Procurement and Transplantation Network (OPTN) necessitates certain recordkeeping and reporting requirements in order to perform the functions related to organ transplantation under contract to HHS. OMB requires review and approval of certain information collection requirements associated with the Final Rule that were not included in previous clearance requests. This is a request for approval of record keeping and reporting requirements associated with the processes for filing appeals in the case where applicants are rejected for membership or designation. To date, no appeals have been filed, and any forthcoming burden requirements for this process will be minimal. In the event of an appeal, the estimate of burden for this process consists of preparing a letter requesting reconsideration and compiling supporting documentation.

The estimated annual response burden is as follows:

Section	Number of respondents	Responses per respondent	Total responses	Burden hour per respondent	Total burden hour
42 CFR 121.3(b)(4) Appeal for OPTN membership	2	1	2	3	6
42 CFR 121.9(d) Appeal for designation	2	1	2	6	12
Total	4		4		18