

facilities for construction-related activities and/or capital equipment purchases. Awarded facilities are required to provide a periodic (quarterly for construction-related projects, annually for equipment only projects) update of the status of the funded project until it is completed. The monitoring period averages about 3 years, although some projects take up to 5 years to complete. The information collected from these updates is vital to

program management staff to determine whether projects are progressing according to the established timeframes, meeting deadlines established in the Notice of Grant Award (NGA), and drawing down funds appropriately. The data collected from the updates is also shared with the Division of Grants Management Operations (DGMO) and the Division of Engineering Services (DES) for their assistance in the overall evaluation of each project's progress.

An electronic form has been developed for progress reporting for the HCOF program. This form will provide awardees access to directly input the required status update information in a timely, consistent, and uniform manner. The electronic form will minimize burden to respondents and will inform respondents when there are missing data elements prior to submission.

The estimate of burden for the form is as follows:

| Project type               | Number of respondents | Response per respondent | Total responses | Hours per response | Total burden hours |
|----------------------------|-----------------------|-------------------------|-----------------|--------------------|--------------------|
| Construction-Related ..... | 395                   | 4                       | 1,580           | .5                 | 790                |
| Equipment Only .....       | 523                   | 1                       | 523             | .5                 | 262                |
| Total .....                | 918                   | .....                   | 2,103           | .....              | 1,052              |

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

Dated: June 28, 2007.

Caroline Lewis,

Associate Administrator for Management.

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**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: 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 system 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 indicate the disease severity of transplant candidates, 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 to develop transplant, donation and allocation policies, to determine if institutional members are complying with policy, to determine member specific performance, to ensure patient safety when no alternative sources of data exist and to fulfill the requirements of the OPTN Final Rule. The practical utility of the data collection is further enhanced by requirements that the OPTN data must be made available, consistent with applicable laws, 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 26 data collection forms are intended to implement approved reduction in data collection for candidates and recipients, to provide additional information specific to pediatric patients, and to clarify existing questions.

**ESTIMATES OF ANNUALIZED HOUR BURDEN**

| Form                               | Number of respondents | Responses per respondents | Total responses | Hours per response | Total burden hours |
|------------------------------------|-----------------------|---------------------------|-----------------|--------------------|--------------------|
| Deceased Donor Registration .....  | 58                    | 215                       | 12,470          | 0.4200             | 5,237.4000         |
| Death referral data .....          | 58                    | 12                        | 696             | 10.0000            | 6,960.0000         |
| Living Donor Registration .....    | 711                   | 10                        | 7,110           | 0.4100             | 2,915.1000         |
| Living Donor Follow-up .....       | 711                   | 18                        | 12,798          | 0.3300             | 4,223.3400         |
| Donor Histocompatibility .....     | 154                   | 95                        | 14,630          | 0.0600             | 877.8000           |
| Recipient Histocompatibility ..... | 154                   | 172                       | 26,488          | 0.1100             | 2,913.6800         |
| Heart Candidate Registration ..... | 135                   | 23                        | 3,105           | 0.2800             | 869.4000           |
| Lung Candidate Registration .....  | 67                    | 27                        | 1,809           | 0.2800             | 506.5200           |

ESTIMATES OF ANNUALIZED HOUR BURDEN—Continued

| Form   | Number of respondents | Responses per respondents | Total responses | Hours per response | Total burden hours  |
|--|-----------------------|---------------------------|-----------------|--------------------|---------------------|
| Heart/Lung Candidate Registration .....      | 59                    | 1                         | 59              | 0.2800             | 16.5200             |
| Thoracic Registration .....                  | 135                   | 27                        | 3,645           | 0.4400             | 1,603.8000          |
| Thoracic Follow-up .....                     | 135                   | 229                       | 30,915          | 0.4130             | 12,767.8950         |
| Kidney Candidate Registration .....          | 250                   | 133                       | 33,250          | 0.2800             | 9,310.0000          |
| Kidney Registration .....                    | 250                   | 69                        | 17,250          | 0.4400             | 7,590.0000          |
| Kidney Follow-up .....                       | 250                   | 544                       | 136,000         | 0.3332             | 45,315.2000         |
| Liver Candidate Registration .....           | 125                   | 89                        | 11,125          | 0.2800             | 3,115.0000          |
| Liver Registration .....                     | 125                   | 54                        | 6,750           | 0.4000             | 2,700.0000          |
| Liver Follow-up .....                        | 125                   | 383                       | 47,875          | 0.3336             | 15,971.1000         |
| Kidney/Pancreas Candidate Registration ..... | 146                   | 12                        | 1,752           | 0.2800             | 490.5600            |
| Kidney/Pancreas Registration .....           | 146                   | 7                         | 1,022           | 0.5300             | 541.6600            |
| Kidney/Pancreas Follow-up .....              | 146                   | 65                        | 9,490           | 0.5027             | 4,770.6230          |
| Pancreas Candidate Registration .....        | 146                   | 7                         | 1,022           | 0.2800             | 286.1600            |
| Pancreas Registration .....                  | 146                   | 3                         | 438             | 0.4400             | 192.7200            |
| Pancreas Follow-up .....                     | 146                   | 23                        | 3,358           | 0.4133             | 1,387.8614          |
| Intestine Candidate Registration .....       | 45                    | 8                         | 360             | 0.2400             | 86.4000             |
| Intestine Registration .....                 | 45                    | 4                         | 180             | 0.5300             | 95.4000             |
| Intestine Follow-up .....                    | 45                    | 17                        | 765             | 0.5059             | 387.0135            |
| Post Transplant Malignancy .....             | 711                   | 6                         | 4,266           | 0.0800             | 341.2800            |
| <b>Total .....</b>                           | <b>923</b>            | <b>.....</b>              | <b>388,628</b>  | <b>.....</b>       | <b>131,472.4329</b> |

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

Dated: June 28, 2007.

**Caroline Lewis,**

*Associate Administrator for Management.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Notice Regarding the 340B Drug Pricing Program; Children's Hospitals**

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** Section 340B of the Public Health Service Act (section 340B) and section 1927(a) of the Social Security Act (section 1927(a)) implement a drug pricing program in which manufacturers who sell covered outpatient drugs to covered entities must agree to charge a price that will not exceed an amount determined under a statutory formula. Section 6004 of the Deficit Reduction Act of 2005 (Pub. L. 109-171) (section 6004) added children's hospitals to the list of covered entities eligible to access

340B discounted drugs. The purpose of this notice is to inform interested parties of proposed guidelines regarding the addition of children's hospitals that meet certain requirements, specifically: (1) The process for the addition of children's hospitals to the 340B Program; and (2) the obligation of manufacturers to provide the statutorily mandated discount to children's hospitals. These proposed guidelines will not take effect until final guidelines are issued.

**DATES:** The public is invited to comment on the proposed guidelines by September 7, 2007. After consideration of the submitted comments, the Health Resources and Services Administration (HRSA) will issue the final guidelines.

**ADDRESSES:** Address all comments to Mr. Bradford R. Lang, Public Health Analyst, Office of Pharmacy Affairs (OPA), Healthcare Systems Bureau (HSB), HRSA, 5600 Fishers Lane, Parklawn Building, Room 10C-03, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Mr. Jimmy Mitchell, Director, OPA, HSB, HRSA, 5600 Fishers Lane, Parklawn Building, Room 10C-03, Rockville, MD 20857, or by telephone through the Pharmacy Services Support Center at 1-800-628-6297.

**SUPPLEMENTARY INFORMATION:**

**(A) Background**

Section 602 of Public Law 102-585, the Veterans Health Care Act of 1992, enacted section 340B, Limitation on Prices of Drugs Purchased by Covered Entities and added certain

implementation provisions for the 340B Program to section 1927(a) of the Social Security Act. Section 340B contains the majority of the requirements for covered entities participating in the 340B Program, while the relevant provisions of section 1927(a) of the Social Security Act provide primarily for the requirement that manufacturers provide the statutorily mandated discount to covered entities.

Section 340B contains a list of covered entities that are eligible to receive discounts through the 340B Program. The list includes entities such as Federally Qualified Health Centers, State-operated AIDS drug purchasing assistance programs, and certain disproportionate share hospitals. Children's hospitals were not included as covered entities under section 340B in the Veterans Health Care Act of 1992 as enacted.

Section 6004 added children's hospitals as covered entities eligible to access 340B discounted drugs. To accomplish this, section 6004 did not amend section 340B (which contains many of the requirements for covered entities). Section 6004 amended section 1927(a) of the Social Security Act (which primarily contains requirements for manufacturers' participation) to add children's hospitals to the 340B Program.

To be eligible for the 340B Drug Pricing Program, section 1927(a), as amended by section 6004, requires children's hospitals to meet the requirements of clauses (i) and (iii) of section 340B(a)(4)(L) of the Public Health Service Act, which contain