

**Tab 1-15**

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

provisions for State or local government affiliations and non-participation in group purchasing organizations. In addition, children's hospitals must meet the requirements of clause (ii) of such section, which contains requirements for the provision of indigent care, if such section "were applied by taking into account the percentage of care provided by the hospital to patients eligible for medical assistance" under Medicaid.

### **(B) Obligation of Manufacturers To Provide 340B Discounts to Children's Hospitals**

Section 1927(a)(5)(A) of the Social Security Act requires manufacturers to enter into agreements with the Secretary that meet the requirements of section 340B with respect to covered outpatient drugs purchased by a covered entity. Section 1927(a)(5)(B), as amended by section 6004, defines covered entities for purposes of section 1927(a)(5) as those covered entities listed in the Public Health Service Act and certain children's hospitals. As section 1927(a)(5)(A) requires manufacturers to enter into agreements "with respect to covered outpatient drugs purchased by a covered entity," and covered entity is defined as including children's hospitals for purposes of section 1927, manufacturers are required to extend 340B pricing to eligible children's hospitals.

The Pharmaceutical Pricing Agreements (PPA) between the Secretary and each manufacturer require manufacturers to provide 340B discounted covered outpatient drugs to covered entities. Given the clear congressional intent in Section 6004 to expand the category of covered entities, the PPAs currently in place effectively require manufacturers to provide 340B discounts to children's hospitals without need for further amendment to currently existing PPAs.

### **(C) Process for Admission of Children's Hospitals to the 340B Program**

#### *(1) Children's Hospitals Participation*

Children's hospitals participation in the 340B Drug Pricing Program is voluntary. Consistent with the participation of other covered entities, once a children's hospital has elected to participate in the program, it must wait to enter or withdraw from the program until the next official updating of the 340B covered entity database. OPA will update this list two weeks before the beginning of each calendar quarter. Participating children's hospitals must comply with all program guidelines for covered entities until the date they are

removed from the 340B covered entity database. OPA will accept applications from children's hospitals for entry into the 340B Program as of the date of publication of the final notice of these guidelines.

#### *(2) Certification by Children's Hospitals Prior to 340B Drug Pricing Program Entry*

As with other covered entities, prior to entry into the 340B Drug Pricing Program, children's hospitals will be required to provide OPA with a certification regarding several different program requirements.

As a threshold matter, a hospital wishing to qualify for the 340B Program as a children's hospital must demonstrate that the hospital is a "children's hospital" as defined by section 6004. Section 6004 requires that a hospital wishing to qualify as a children's hospital covered entity must (1) satisfy the definition of "children's hospital" contained in section 1886(d)(1)(B)(iii) of the Social Security Act; and (2) meet minimum requirements for the receipt of an additional payment under Medicare pursuant to section 1886(d)(5)(F)(i) of the Social Security Act (if such clause were applied by taking into account the percentage of care provided by the hospital to Medicaid patients). Given the reliance of section 6004 on Medicare payment provisions for the definition of "children's hospital," a hospital will need to demonstrate that it has been provided a Medicare provider number identifying the hospital as a "children's hospital" (i.e., a hospital with a 3300 series Medicare provider number).

Prior to entry into the 340B Program, a children's hospital must certify that it will abide by all the requirements of section 340B that all other covered entities abide by (e.g., prohibition on resale of covered outpatient drugs; prohibition on duplicate discounts or rebates). While children's hospitals are not explicitly mentioned in section 340B, it is implicit in section 1927(a) of the Social Security Act that children's hospitals abide by the requirements of section 340B. Section 1927(a) provides that manufacturers must have entered into agreements with the Secretary that meet the requirements of section 340B and several of the provisions contained in these agreements concern covered entities' compliance with provisions of section 340B. Furthermore, it is within the Secretary's authority under section 340B to create guidelines necessary for the implementation of the program. Unless children's hospitals are subject to all of the same rules as other covered entities, the inclusion of children's

hospitals in the 340B Program would be difficult, if not impossible.

Prior to entry into the 340B Program a children's hospital must certify compliance (along with the date of compliance) with clauses (i), (ii), and (iii) of section 340B(a)(4)(L) (in accordance with section 1927(a)(5)(B) of the Social Security Act). To comply with section 340B(a)(4)(L)(i), a children's hospital will have to certify (and include such supporting documentation as requested by OPA) that the children's hospital is:

(1) Owned or operated by a unit of State or local government;

(2) a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government; or

(3) A private non-profit hospital under contract with State or local government to provide health care services to low income individuals who are not eligible for Medicare or Medicaid.

To comply with section 340B(a)(4)(L)(ii), a children's hospital will have to certify (and include such supporting documentation as requested by OPA) that the children's hospital:

(1) Is located in an urban area, has 100 or more beds, and can demonstrate that its net inpatient care revenues (excluding any of such revenues attributable to Medicare), during the cost reporting period in which the discharges occur, for indigent care from State and local government sources and Medicaid exceed 30 percent of its total of such net inpatient care revenues during the period; or

(2) for the most recent cost reporting period that ended before the calendar quarter involved, had a disproportionate share adjustment percentage (as determined under section 1886(d)(5)(F) of the Social Security Act) greater than 11.75 percent.

To comply with section 340B(a)(4)(L)(iii), a children's hospital will have to certify that the children's hospital will not participate in a group purchasing organization or group purchasing arrangement for covered outpatient drugs as of the effective date in the 340B covered entity database.

Prior to entry into the 340B Program, OPA requires certification of a children's hospital's compliance with section 340B(a)(4)(L)(ii). In addition to having a 3300 series Medicare provider identification number, initially, OPA will seek verification of compliance based on the Medicare cost report submitted by the children's hospital to the Centers for Medicare and Medicaid Services (CMS). Given that children's hospitals are not eligible for the

prospective payment system, the materials submitted by any particular children's hospital may not provide the required verification. To the extent that OPA is unable to obtain independent verification, a children's hospital will be expected to verify that the children's hospital meets the requirements of section 340B(a)(4)(L)(ii) if requested by OPA.

OPA is considering whether it would be appropriate to require a statement from an independent auditor certifying that a children's hospital meets the requirements of section 340B(a)(4)(L)(ii) in those cases where there is no established method of verification analogous to that utilized to annually certify DSH eligibility in the 340B Drug Pricing Program. OPA invites comments from stakeholders on the feasibility of an independent auditor to verify eligibility of children's hospitals. OPA also seeks comments from children's hospitals as to the relative burden that an independent auditor statement may entail and welcomes alternate proposals as to how to best ensure the integrity of the 340B Drug Pricing Program while minimizing costs.

### (3) Eligibility for Retroactive Discounts

Section 6004 indicates that the amendment authorizing entry of children's hospitals into the 340B Program "shall apply to drugs purchased on or after the date of the enactment of this Act." Section 6004 was enacted on February 8, 2006. Therefore, once they are admitted to the 340B Program, children's hospitals are eligible for 340B drug pricing retroactive to February 8, 2006. However, a children's hospital will be eligible for retroactive discounts only to the extent that it has satisfied all requirements for participation in the 340B program back to the date discounts are requested.

Similar to when the 340B Program was first started, children's hospitals that participate in the program will be eligible for retroactive discounts. Until 120 days after publication of the final notice, children's hospitals which have been included in OPA's database of covered entities may request retroactive discounts (discounts, rebates, or account credit) from pharmaceutical manufacturers for covered outpatient drugs that satisfy all the following conditions:

(1) The covered outpatient drugs must have been purchased on or after February 8, 2006;

(2) The covered outpatient drugs must not have generated Medicaid rebates (the children's hospital must have appropriate documentation to demonstrate this); and

(3) The covered outpatient drugs must have been purchased on or after the date on which the children's hospital satisfied all requirements for participation in the 340B Program as outlined in section (C)(2) of this notice.

In order to satisfy the last condition listed above, a children's hospital must be able to demonstrate, at a minimum, that as required by section 340B(a)(4)(L)(iii) of the Public Health Service Act the children's hospital did not have a group purchasing agreement for covered outpatient drugs and satisfied the requirements of section 340B(a)(4)(L)(i) and 340B(a)(4)(L)(ii) at the time the covered outpatient drugs for which rebates are requested were purchased.

Dated: June 29, 2007.

**Elizabeth M. Duke,**

*Administrator.*

[FR Doc. E7-13239 Filed 7-6-07; 8:45 am]

**BILLING CODE 4165-15-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Indian Health Service

#### **American Indians Into Medicine; Notice of Competitive Grant Applications for American Indians Into Medicine Program**

*Announcement Type:* Initial.

*Funding Opportunity Number:* HHS-2007-IHS-INMED-0001.

*CFDA Number:* 93.970.

*Key Dates:*

*Application Deadline:* August 16, 2007.

*Application Review:* August 21, 2007.

*Application Notification:* August 27, 2007.

*Anticipated Award Start Date:* September 1, 2007.

#### **I. Funding Opportunity Description**

The Indian Health Service (IHS) announces that competitive grant applications are being accepted for the American Indians into Medicine Program. These grants are established under the authority of 25 U.S.C. 1616g(a) of the Indian Health Care Improvement Act, as amended by Public Law (Pub. L.) 102-573. The purpose of the Indians into Medicine program is to augment the number of American Indian/Alaska Native (AI/AN) health professionals serving AI/AN by encouraging them to enter the health professions and removing the multiple barriers to their entrance into IHS and private practice among AI/AN communities. For the purpose of maintaining and expanding the Indians

into Medicine program two grants will be funded. One grant will be funded at \$300,000 and a second grant will be funded at \$60,000. Each grant will have different criteria which will be listed separately in this announcement.

This program is described at 93.970 in the Catalog of Federal Domestic Assistance. The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of Healthy People 2010, a PHS-led activity for setting priority areas. This program announcement is related to the priority area of Educational and Community-based programs. Potential applicants may obtain a copy of Healthy People 2010, summary report in print, Stock No. 017-001-00547-9, or via CD-ROM, Stock No. 107-001-00549-5, through the Superintendent of Documents, Government Printing Office, P.O. Box 371954, Pittsburgh, PA 15250-7945, (202) 512-1800. You may access this information via the Internet at the following Web site: [www.health.gov/healthypeople](http://www.health.gov/healthypeople).

The PHS strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of the facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

#### **II. Award Information**

*Type of Awards:* Grant.

*Estimated Funds Available:* The total amount identified for Fiscal Year 2007 is \$360,000 to provide support for an estimated two awards. The awards are for 12 months in duration and the awards are approximately \$300,000 for one grant award and \$60,000 for a second grant award. Future awards issued under this announcement are subject to the availability of funds.

*Anticipated Number of Awards:* An estimated two awards will be made under the program. Applicants may apply for both grants but only one grant will be awarded per applicant.

*Project Period:* 36 months = \$300,000 grant award; 12 months = \$60,000 grant award.

*Award Amount:* \$300,000, per year for one grant award and \$60,000, per year for a second grant award.