

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: Advanced Education Nursing Traineeship (AENT) and Nurse Anesthetist Traineeship (NAT) (OMB No. 0915-0305): Revision**

The Health Resources and Services Administration (HRSA) provides training grants to educational institutions to increase the numbers of advanced education nurses through the Advanced Education Nursing Traineeship (AENT) program and the Nurse Anesthetist Traineeship (NAT) program.

HRSA developed the AENT and NAT tables for the application guidances and

the Nurse Traineeship Database for the two nursing traineeship programs. The AENT and NAT tables are used annually by grant applicants that are applying for AENT and NAT funding. The funds appropriated for the AENT and NAT programs are distributed among eligible institutions based on a formula. Award amounts are based on enrollment and graduate data reported on the tables and two funding factors (Statutory Funding Preference and Statutory Special Consideration).

The AENT and NAT tables include information on program participants such as the number of enrollees, projected data on enrollees and graduates for the following academic year, number of trainees supported, number of graduates, number of graduates supported and the types of programs they are enrolling into and/or from which they are graduating. AENT and NAT applicants will have a single

access point to submit their grant applications including the tables. Applications are submitted in two phases: Grants.gov (Phase 1) and the HRSA Electronic Handbooks (Phase 2). These tables will be available electronically through the HRSA Electronic Handbooks (Phase 2) for applicants to submit their AENT and/or NAT grant application(s). The tables are also used in the Nurse Traineeship Database which is used by Division of Nursing staff and not the applicants.

Data from the tables will be used in the award determination and validation process. Additionally, the data will be used to ensure programmatic compliance, report to Congress and policymakers on the program accomplishments, and formulate and justify future budgets for these activities submitted to OMB and Congress.

The burden estimate for this project is as follows:

Instrument	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
AENT .....	500	1	500	1.5	750
NAT .....	100	1	100	1	100
Total .....	600	.....	600	.....	850

E-mail comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail to the 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: August 5, 2009.

**Alexandra Huttinger,**  
Director, Division of Policy Review and Coordination.

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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, e-mail [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or 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: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program [NEW]**

Section 602 of Public Law 102-585, the Veterans Health Care Act of 1992, enacted section 340B of the Public Health Service Act (PHS Act) "Limitation on Prices of Drugs Purchased by Covered Entities." Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible entities must sign a pharmaceutical pricing agreement with the Secretary of Health and Human Services in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed an amount determined under a statutory formula.

Covered entities which choose to participate in the section 340B Drug Pricing Program must comply with the requirements of 340B(a)(5) of the PHS Act. Section 340B(a)(5)(A) prohibits a covered entity from accepting a discount for a drug that would also

generate a Medicaid rebate. Further, section 340B(a)(5)(B) prohibits a covered entity from reselling or otherwise transferring a discounted drug to a person who is not a patient of the entity.

In response to the statutory mandate of section 340B(a)(9) to notify manufacturers of the identities of covered entities and the mandate of section 340B(a)(5)(A)(ii) to establish a mechanism to ensure against duplicate discounts and the ongoing responsibility to administer the 340B Drug Pricing Program while maintaining efficiency, transparency and integrity, the HRSA Office of Pharmacy Affairs (OPA) developed a process of registration of covered entities to enable it to address those mandates.

**Enrollment/Registration**

To enroll and certify the eligible federally funded grantees and other safety net health care providers, OPA requires entities to submit administrative information (e.g., shipping and billing arrangements, Medicaid participation), certifying information and signatures from appropriate grantee level or entity level authorizing officials and State/local government representatives. The purpose of this registration information

is to determine eligibility for the 340B program. This information is received and verified according to 340B requirements and entered into the 340B database. Accurate records are critical to implementation of the 340B legislation especially to prevent diversion and duplicate discounts. To maintain accurate records, the OPA requests

entities to submit modifications to any administrative information that they submitted when initially enrolling into the program. The burden requirement for these processes is minimal.

#### Contract Pharmacy Self-Certification

In order to ensure that drug manufacturers and drug wholesalers recognize contract pharmacy

arrangements, covered entities that elect to utilize a contract pharmacy are required to submit to OPA a self-certification form similar to the registration form that they have signed an agreement with the contract pharmacy.

The Estimates of annualized burden are as follows:

Reporting requirement	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
<b>DSH &amp; Children's Hospital Enrollment, Additions &amp; Recertifications</b>					
340B Program Registrations & Certifications for Disproportionate Share Hospitals .....	70	1	70	.25	17.5
340B Program Registrations & Certifications for Children's Hospitals .....	80	1	80	.25	20
Certifications to Enroll DSH & Children's Hospitals Out-patient facilities to 340B Program .....	180	1	180	.083	14.94
DSH & Children's Hospitals' Annual Recertification .....	937	1	937	.5	468.5
<b>Registration for Entities Other Than Hospitals &amp; Recertifications</b>					
340B Registration Form (Family Planning, STD, TB, and others) .....	170	1	170	.083	14.11
Family Planning Annual Recertification .....	85	47	3995	.083	331.59
STD & TB Annual Recertification .....	111	11	1221	.083	101.34
Other Entity Annual Recertification for entities other than DSHs, FP, STD or TB entities .....	400	10	4000	.083	332
Submission of Administrative Changes for any entity .....	460	1	460	.083	38.18
<b>Contracted Pharmacy Services Registration &amp; Recertifications</b>					
Contracted Pharmacy Services Registration .....	2000	1	2000	.083	166
Total .....	* 4493	.....	13,313	.....	1504.16

\* The total number of respondents may be overestimated since we are unable to avoid duplication of respondents who submit information to the OPA over the course of participation in the 340B Drug Pricing Program, via the initial registration process to any updates/modifications and enrolling contract pharmacies, if applicable, to the recertification process.

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by e-mail to [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or by fax to 202-395-6974. Please direct all correspondence to the "attention of the desk officer for HRSA."

Dated: August 5, 2009.

**Alexandra Huttinger,**

*Director, Division of Policy Review and Coordination.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Health Promotion and Disease Prevention Research Centers, Special Interest Project Competitive Supplements (SIPS) (U48 Panels N, O and P), RFA-DP09-101SUPP09, Initial Review

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting.

#### Time and Dates:

9 a.m.-5 p.m., August 5, 2009 (closed).

9 a.m.-5 p.m., August 6, 2009 (closed).

9 a.m.-5 p.m., August 7, 2009 (closed).

*Place:* Westin Hotel, 3377 Peachtree Road, NE., Atlanta, GA, 30326, Telephone (678) 500-3100.

*Status:* The meeting will be closed to the public in accordance with provisions set

forth in section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92-463.

*Matters To Be Discussed:* The meeting will include the review, discussion, and evaluation of the application received in response to "Health Promotion and Disease Prevention Research Centers, Special Interest Project Competitive Supplements (SIPS) (U48 Panels N, O and P), RFA-DP09-101SUPP09, initial review."

*Contact Person for More Information:* Brenda Colley-Gilbert, Ph.D., Director, Extramural Research Program Office, CCH, 47770 Buford Highway, MS K-92, Atlanta, GA 30341, Telephone (770) 488-8390.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

**Elaine L. Baker,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

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