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.

Recertification

The purposes of recertification are to request that 340B covered entities annually certify program eligibility and confirm the accuracy of all information in the covered entity's 340B database record. Recertification is an electronic process that will require the covered entity to review the current database record and submit required edits (i.e., covered entity name and address changes, changes to 340B designated contact information, billing and shipping arrangements). The recertification process will pose a minimal burden to 340B covered entities.

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
DSH & CHILDREN'S HOSPITAL ENROLLMENT, ADDITIONS & RECERTIFICATIONS					
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 Outpatient facilities to 340B Program	180	1	180	.083	14.94
DSH & Children's Hospitals' Annual Recertification	937	1	937	.5	468.5
REGISTRATION FOR ENTITIES OTHER THAN HOSPITALS & RECERTIFICATIONS					
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
CONTRACTED PHARMACY SERVICES REGISTRATION & RECERTIFICATIONS					
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.

E-mail comments to *paperwork@hrsa.gov* or mail 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: October 28, 2008.

Alexandra Huttinger,

Director, Division of Policy Review and Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Meeting of the Advisory Council on Blood Stem Cell Transplantation

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of Meeting of the Advisory Council on Blood Stem Cell Transplantation.

SUMMARY: Pursuant to Public Law 92–463, the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the third meeting of the Advisory Council on Blood Stem Cell Transplantation (ACBSCT), Department of Health and Human Services (HHS). The meeting will be held from approximately 8:30 a.m. to 5 p.m. on December 15, 2008,

and from 8:30 a.m. to 3:30 p.m. on December 16, 2008, at the Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, Maryland 20814. The meeting will be open to the public; however, seating is limited and pre-registration is encouraged (see below).

SUPPLEMENTARY INFORMATION: Pursuant to Public Law 109–129, 42 U.S.C. 274k (section 379 of the Public Health Service Act, as amended) the ACBSCT was established to advise the Secretary of HHS and the Administrator, HRSA, on matters related to the activities of the C.W. Bill Young Cell Transplantation Program (Program) and the National Cord Blood Inventory (NCBI) Program. ACBSCT is composed of up to 25 members, including the Chair, serving as Special Government Employees. The current membership includes representatives of marrow donor centers and marrow transplant centers; representatives of cord blood banks and participating birthing hospitals; recipients of a bone marrow transplant; recipients of a cord blood transplant; persons who require such transplants; family members of such a recipient or family members of a patient who has requested the assistance of the Program in searching for an unrelated donor of bone marrow or cord blood; persons with expertise in bone marrow and cord blood transplantation; persons with expertise in typing, matching, and transplant outcome data analysis; persons with expertise in the social sciences; basic scientists with expertise in the biology of adult stem cells; ethicists; hematology and transfusion medicine researchers with expertise in adult blood stem cells; persons with expertise in cord blood processing; and members of the general public.

The Council will hear reports from four of the ACBSCT Work Groups: Cord Blood Accreditation Organization and Recognition Process, Need for Public Funding for Required Data Documentation, Scientific Factors Necessary to Define a Cord Blood Unit as High Quality, and Program Confidentiality/Policies for Cord Blood Donors. The Council also will hear presentations and discussions on Product Labeling; the Blood Stem Cell Transplant Physician Shortage; CMS Evaluation of Coverage for Myelodysplastic Syndromes; Models for Cord Blood Donor Recruitment; and the Center for International Blood and Marrow Transplant Research update on several research activities.

The draft meeting agenda and a registration form will be available on November 17, 2008, on the HRSA's Program Web site at *http://bloodcell.transplant.hrsa.gov/ABOUT/Advisory_Council/index.html*. The completed registration form should be submitted by facsimile to Professional and Scientific Associates (PSA), the logistical support contractor for the meeting, at fax number (703) 234–1701 ATTN: Lilly Cho. Registration can also be completed electronically at *https://www.team-psa.com/dot/fall2008/acbsct/*. Individuals without access to the Internet who wish to register may call Lilly Cho with PSA at (703) 234–1733.

Individuals who plan to attend the meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the ACBSCT Executive Secretary, Remy Aronoff, in advance of the meeting. Mr. Aronoff may be reached by telephone at 301–443–3264, e-mail: *Remy.Aronoff@hrsa.hhs.gov* or in writing at the address provided below. Management and support services for ACBSCT functions are provided by the Division of Transplantation, Healthcare Systems Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Parklawn Building, Room 12C–06, Rockville, Maryland 20857; telephone number 301–443–7577.

After the presentations and Council discussions, members of the public will have an opportunity to provide comments. Because of the Council's full agenda and the timeframe in which to cover the agenda topics, public comment will be limited. All public comments will be included in the record of the ACBSCT meeting. Meeting summary notes will be made available on the HRSA's Program Web site at *http://bloodcell.transplant.hrsa.gov/ABOUT/Advisory_Council/index.html*.

Dated: October 28, 2008.

Elizabeth M. Duke,

Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are 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: Notification of Intent to Use Schedule III, IV, or V Opioid Drugs for the Maintenance and Detoxification Treatment of Opiate Addiction Under 21 U.S.C. 823(g)(2) (OMB No. 0930–0234)—Revision

The Drug Addiction Treatment Act of 2000 (''DATA,'' Pub. L. 106–310) amended the Controlled Substances Act (21 U.S.C. 823(g)(2)) to permit practitioners (physicians) to seek and obtain waivers to prescribe certain approved narcotic treatment drugs for the treatment of opiate addiction. The legislation sets eligibility requirements and certification requirements as well as an interagency notification review process for physicians who seek waivers. The legislation was amended in 2005 to eliminate the patient limit for physicians in group practices, and in 2006, to permit certain physicians to treat up to 100 patients.

To implement these provisions, SAMHSA developed a notification form (SMA–167) that facilitates the submission and review of notifications. The form provides the information necessary to determine whether practitioners (*i.e.*, independent physicians) meet the qualifications for waivers set forth under the new law. Use of this form will enable physicians to know they have provided all information needed to determine whether practitioners are eligible for a waiver.

However, there is no prohibition on use of other means to provide requisite information. The Secretary will convey notification information and determinations to the Drug Enforcement Administration (DEA), which will assign an identification number to