conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by July 25, 2012.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Yvette Waples at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 16, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2012–17667 Filed 7–19–12; 8:45 am]

BILLING CODE 4160–01–P

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, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Office on (301) 443–1984.

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 (OMB No. 0915–0327)—[Revision]

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 section 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) of the PHS Act 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 Drug Pricing Program. This information is entered into the 340B database by entities and verified by OPA staff according to 340B Drug Pricing Program requirements. Accurate records are critical to implementation of the 340B Drug Pricing Program legislation, especially to prevent diversion and duplicate discounts. To maintain accurate records, 340B statute also requires that entities recertify eligibility annually and that they notify the program of updates to any administrative information that they submitted when initially enrolling into the program. The burden requirement is low for recertification and for submitting change requests.

Contract Pharmacy Self-Certification

In order to ensure that drug manufacturers and drug wholesalers recognize contract pharmacy arrangements, covered entities that elect to utilize one or more contract pharmacies are also required to submit general information about the arrangements and to certify that signed agreements are in place with those contract pharmacies.

Pharmaceutical Pricing Agreement

In accordance with the guidance found in the May 7, 1993, **Federal Register**, Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible entities must sign a Pharmaceutical Pricing Agreement (the ''Agreement'') with the Secretary of Health and Human Services (the ''Secretary'') in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed the average manufacturer price (''AMP'') decreased by a rebate percentage.

The estimates of annualized burden are as follows:

Reporting requirement	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
HOSPITAL ENROLLMENT, ADDITIONS & RECERTIFICATIONS					
340B Program Registrations & Certifications for Hospitals	546	1	546	2.0	1,092.0
Certifications to Enroll Hospital Outpatient Facilities	606	1	606	0.5	303.0
Hospital Annual Recertification	4,842	1	4,842	0.5	2,421.0

Reporting requirement	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
REGISTRATIONS AND RECERTIFICATIONS FOR ENTITIES OTHER THAN HOSPITALS					
340B Registrations for Community Health Centers	253	1	253	1.0	253.0
340B Registrations for Family Planning Programs, STD/TB Clinics and Various Other Eligible Entity Types	353	1	353	1.0	353.0
Community Health Center Annual Recertification	4,507	1	4,507	0.5	2,253.5
Family Planning Annual Recertification	3,879	1	3,879	0.5	1,939.5
STD & TB Annual Recertification	2,754	1	2,754	0.5	1,377.0
Annual Recertification for entities other than Hospitals, Community Health Centers, Family Planning, STD or TB Clinics	1,174	1	1,174	0.5	587.0
CONTRACTED PHARMACY SERVICES REGISTRATIONS					
Contracted Pharmacy Services Registration	2500	1	2500	1.0	2500.0
OTHER INFORMATION COLLECTIONS					
Submission of Administrative Changes for any Covered Entity	2,500	1	2,500	0.5	1,250.0
Submission of Administrative Changes for any Manufacturer	350	1	350	0.5	175.0
Pharmaceutical Pricing Agreement	200	1	200	1.0	200.0
Total	24,464		24,464		14,704.0

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 email to *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: July 16, 2012.

Jennifer Riggle,

Deputy Director, Office of Management.

[FR Doc. 2012–17777 Filed 7–19–12; 8:45 am]

BILLING CODE 4165–15–P

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, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Office on (301) 443–1984.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Faculty Loan Repayment Program (OMB No. 0915–0150)—[Revision]

Under the Health Resources and Services Administration (HRSA) Faculty Loan Repayment Program, degree-trained health professionals from disadvantaged backgrounds may enter into a contract under which the Department of Health and Human Services will make payments on eligible educational loans in exchange for a minimum of 2 years of service as a full-time or part-time faculty member of an accredited health professions college or university. Applicants must complete an application and provide all other required documentation, including information on all eligible educational loans.

The annual estimate of burden is as follows:

Instrument	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Online Application	304	1	304	1	304
Institution/Loan Repayment Employment Form	*304	*1	304	1	304
Authorization to Release Information Form	304	1	304	.25	76
Total	912				684

*Respondent for this form is the institution for the applicant.

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 email to *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.''