

the data collection plans and draft instruments, email paperwork@hrsa.gov or call the HRSA Information Collection Clearance Officer at (301) 443-1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: HRSA OFAM Grantee Customer Satisfaction Survey. OMB No. 0915-xxxx—NEW.

Abstract: The Office of Federal Assistance Management (OFAM) within HRSA plans to survey HRSA grant recipients to better understand their opinions about HRSA's grants processes and to improve the way HRSA conducts business with them. This survey will focus on grantee customer satisfaction areas related to the grants life cycle, grantee relationships with HRSA staff (e.g., Project Officers, Grants Management Officers), technical assistance received from HRSA bureaus and offices, availability of grant resources, and grantee access to guidance and instructional documents, etc. The seven (7) grants management areas, which are directly related to the grants life cycle, are: Customer Service/

Cooperation; Policies and Procedures; Pre-Award Phase; Award Phase; Reporting/Post-Award Administration; Technical Assistance; and Priorities for Improvement. The ability to receive this information from external customers will provide OFAM with a repository of information which will be incorporated into the OFAM's strategic efforts to improve grants management services and customer service overall.

Need and Proposed Use of the Information: The HRSA OFAM Grantee Customer Satisfaction Survey will provide meaningful and relevant results to agency decision makers about various customer satisfaction domains (e.g., efficiency, timeliness, usefulness, responsiveness, quality and overall satisfaction with HRSA project officers, products, and services). The information collected will assist HRSA in its efforts to gauge, understand and effectively respond to the needs and concerns of its customers, especially as they relate to the aforementioned areas. The survey results will provide HRSA with concrete indicators regarding the best areas in which to dedicate time, energy, and resources to improve customer service. This information will be used to support agency-wide continuous quality improvement (CQI) efforts. It will also

be used by HRSA to improve the efficiency, quality, and timeliness of its grants business processes, as well as to strengthen its partnership with its external customers.

Likely Respondents: HRSA Grantees, specifically individuals who hold positions as a grantee's Grant Administrator, Business Officer, or Project Director/Principal Investigators, etc.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
HRSA OFAM Grants Management Customer Satisfaction Survey	3,000	1	1,500	0.25 (15/60)	375

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Dated: September 23, 2014.

Jackie Painter,

Acting Director, Division of Policy and Information Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden

estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received no later than December 1, 2014.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 10C-03, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call the HRSA Information Collection Clearance Officer at (301) 443-1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Enrollment and Re-Certification of

Entities in the 340B Drug Pricing Program and collection of Manufacturer Data to Verify 340B Drug Pricing Program Ceiling Price Calculations.

OMB No. 0915-0327—[Revision].

Abstract: Section 602 of Public Law 102-585, the Veterans Health Care Act of 1992, enacted as Section 340B of the Public Health Service Act (PHS Act; “Limitation on Prices of Drugs Purchased by Covered Entities”), provides that a manufacturer who sells covered outpatient drugs to eligible entities must sign a Pharmaceutical Pricing Agreement (PPA) 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 (“ceiling price”).

A manufacturer subject to a PPA must offer all covered outpatient drugs at no more than the ceiling price to a covered entity listed in the 340B Program database. The manufacturer shall rely on the information in the 340B database to determine if the covered entity is participating in the 340B Program or for any notifications of changes to eligibility that may occur within a quarter. By signing the PPA, the manufacturer agrees to comply with all applicable statutory and regulatory requirements, including any changes that occur after execution of the PPA.

Covered entities which choose to participate in the 340B 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.

Need and Proposed Use of the Information: Section 340B(d)(1)(B)(i) of

the PHS Act requires the development of a system to enable the Secretary to verify the accuracy of ceiling prices calculated by manufacturers under subsection (a)(1) and charged to covered entities, which shall include the following:

(I) Developing and publishing through an appropriate policy or regulatory issuance, precisely defined standards and methodology for the calculation of ceiling prices under such subsection.

(II) Comparing regularly the ceiling prices calculated by the Secretary with the quarterly pricing data that is reported by manufacturers to the Secretary.

(III) Performing spot checks of sales transactions by covered entities.

(IV) Inquiring into the cause of any pricing discrepancies that may be identified and either taking, or requiring manufacturers to take, such corrective action as is appropriate in response to such price discrepancies.

HRSA’s Office of Pharmacy Affairs (OPA) has previously obtained approval for information collections in support of 340B covered entity recertification and registration, as well as registration of contract pharmacy arrangements and the PPA itself. OPA is requesting comments on an additional information collection in response to the above pricing verification requirements.

Pricing data submission, validation and dissemination:

In order to implement Section 340B(d)(1)(B)(i)(II), HRSA has already developed a system to prospectively calculate 340B ceiling prices from data obtained from the Centers for Medicare and Medicaid Services as well as OPA-identified commercial databases. However, in order to conduct the comparison, HRSA must require manufacturers to submit the quarterly pricing data as referenced.

HRSA has developed a mechanism for secure manufacturer submissions; the Agency currently proposes collecting

Average Manufacturer Price, Unit Rebate Amount, Package Sizes, National Drug Code and manufacturer-determined 340B ceiling price for each product subject to a PPA. Once any discrepancies between the manufacturer and OPA-calculated prices have been resolved, the validated prices will be made available to registered covered entities via a secure Internet-accessible platform as required by Section 340B(d)(1)(B)(iii).

Accurate and timely pricing data submissions are critical to successful implementation of the 340B Program, ensuring that covered entities have confidence that the amounts being charged are in accordance with statutorily-defined ceiling prices. The burden imposed on manufacturers by this requirement is low because the information requested is readily available.

Likely Respondents: Drug Manufacturers.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

The annual estimate of burden is 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	2.00	1092
Certifications to Enroll Hospital Outpatient Facilities	606	1	606	.50	303
Hospital Annual Recertifications	4842	1	4842	.50	2421
Registrations and Recertifications for Entities Other Than Hospitals					
340B Registrations for Community Health Centers	253	1	253	1.0	253
340B Registrations for Family Planning Programs, STD/TB Clinics and Various Other Eligible Entity Types	353	1	353	1.0	353
Community Health Center Annual Recertifications	4507	1	4507	.50	2253.5
Family Planning Annual Recertifications	3879	1	3879	.50	1939.5
STD & TB Annual Recertifications	2754	1	2754	.50	1377

Reporting requirement	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Annual Recertification for entities other than Hospitals, Community Health Centers, Family Planning, STD or TB Clinics	1174	1	1174	.50	587
Other Information Collections					
Submission of Administrative Changes for any Covered Entity	2500	1	2500	.50	1250
Submission of Administrative Changes for any Manufacturer	350	1	350	.50	175
Manufacturer Data Required to Verify 340B Ceiling Price Calculations	600	4	2400	.50	1200
Contracted Pharmacy Services Registration & Recertifications					
Contracted Pharmacy Services Registration	2500	1	2500	1.0	2500
Total	24,664		26,464		15,704

HRSA specifically requests comments on: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Dated: September 23, 2014.

Jackie Painter,

Acting Director, Division of Policy and Information Coordination.

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specified above using the following information: Dial-in number: 1-800-619-8528; Passcode: 2240736.

Public Comment: There will be an opportunity for the public to comment towards the end of the call.

For Further Information Contact: Ed Mekeel, Bureau of Health Workforce, Health Resources and Services Administration, Parklawn Building, Room 13-64, 5600 Fishers Lane, Rockville, Maryland 20857, email: emekeel@hrsa.gov, or telephone: 301-443-6156.

Dated: September 23, 2014.

Jackie Painter,

Acting Director, Division of Policy and Information Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Council on the National Health Service Corps; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of the following meeting:

Name: National Advisory Council on the National Health Service Corps (NHSC).

Date And Time: October 23, 2014 from 1:00 p.m.-2:30 p.m. EST.

Place: The meeting will be via audio conference call.

Status: The meeting will be open to the public.

Agenda: The Council is holding a meeting via conference call to discuss the accomplishments of the NHSC in fiscal year (FY) 2014 and activities and goals for FY 2015. The public can join the meeting via audio conference call on the date and time

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG-2014-0107; OMB Control Number 1625-0011]

Collection of Information Under Review by Office of Management and Budget

AGENCY: Coast Guard, DHS.

ACTION: Thirty-Day Notice Requesting Comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding Information Collection Requests (ICRs), abstracted below, to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting approval of a Reinstatement, with change, of a previously approved collection for which approval has expired for the following collection of information:

1625-0011, Applications for Private Aids to Navigation and for Class I Private Aids to Navigation on Artificial Islands and Fixed Structures. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

DATES: Comments must reach the Coast Guard and OIRA on or before October 30, 2014.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG-2014-0107] to the Docket Management Facility (DMF) at the U.S. Department of Transportation (DOT) and/or to OIRA. To avoid duplicate submissions, please use only one of the following means:

(1) *Online:* (a) To Coast Guard docket at <http://www.regulations.gov>. (b) To OIRA by email via: OIRA-submission@omb.eop.gov.

(2) *Mail:* (a) DMF (M-30), DOT, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590-0001. (b) To OIRA, 725 17th Street NW., Washington, DC 20503, attention Desk Officer for the Coast Guard.

(3) *Hand Delivery:* To DMF address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202-366-9329.

(4) *Fax:* (a) To DMF, 202-493-2251. (b) To OIRA at 202-395-6566. To ensure your comments are received in a timely manner, mark the fax, attention Desk Officer for the Coast Guard.

The DMF maintains the public docket for this Notice. Comments and material received from the public, as well as documents mentioned in this Notice as being available in the docket, will become part of the docket and will be