

successful home visiting programs. It is anticipated that between four and eight Development Grants will be awarded. The total grant award may range between \$1 million to \$3 million

annually. Applicants may apply for a ceiling amount of up to \$3 million per year. The project period is 2 years.

The annual estimate of burden associated with the FY2012 competitive

Development Grant Funding Opportunity Announcement is as follows:

| Instrument | Number of respondents | Responses per respondent | Total responses | Hours per response | Total burden hours |
|---|-----------------------|--------------------------|-----------------|--------------------|--------------------|
| Introduction | 20 | 1 | 20 | 10 | 200 |
| Needs Assessment | 20 | 1 | 20 | 14 | 280 |
| Methodology | 20 | 1 | 20 | 31 | 620 |
| Work Plan | 20 | 1 | 20 | 31 | 620 |
| Resolution of Challenges | 20 | 1 | 20 | 14 | 280 |
| Evaluation and Technical Support Capacity | 20 | 1 | 20 | 48 | 960 |
| Organizational Information | 20 | 1 | 20 | 10 | 200 |
| Additional Attachments | 20 | 1 | 20 | 13 | 260 |
| Total | 160 | | 160 | 171 | 3,420 |

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: May 29, 2012.

Reva Harris,

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: 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, etc.), 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, OPA 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 for these processes is low for recertification and minimal 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 certifications that signed agreements are in place with those contract pharmacies.

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 | 2.00 | 1092.0 |
| Certifications to Enroll Hospital Outpatient Facilities | 606 | 1 | 606 | 0.50 | 303.0 |
| Hospital Annual Re-Certifications | 4842 | 1 | 4842 | 0.50 | 2421.0 |
| REGISTRATIONS AND RECERTIFICATIONS FOR ENTITIES OTHER THAN HOSPITALS | | | | | |
| 340B Registrations for Community Health Centers | 253 | 1 | 253 | 1.00 | 253.0 |
| 340B Registrations for Family Planning Programs, STD/TB Clinics and Various Other Eligible Entity Types | 353 | 1 | 353 | 1.00 | 353.0 |
| Community Health Center Annual Re-Certifications | 4507 | 1 | 4507 | 0.50 | 2253.5 |
| Family Planning Annual Re-Certifications | 3879 | 1 | 3879 | 0.50 | 1939.5 |
| STD & TB Annual Re-Certifications | 2754 | 1 | 2754 | 0.50 | 1377.0 |
| Annual Re-Certification for Entities Other Than Hospitals, Community Health Centers, Family Planning, STD or TB Clinics | 1174 | 1 | 1174 | 0.50 | 587.0 |
| OTHER INFORMATION COLLECTIONS | | | | | |
| Submission of Administrative Changes for Any Covered Entity | 2500 | 1 | 2500 | 0.50 | 1250.0 |
| Submission of Administrative Changes for Any Manufacturer | 350 | 1 | 350 | 0.50 | 175.0 |
| CONTRACTED PHARMACY SERVICES REGISTRATION & RECERTIFICATIONS | | | | | |
| Contracted Pharmacy Services Registration | 2500 | 1 | 2500 | 1.00 | 2500.0 |
| TOTAL | 24,264 | | 24,264 | | 14,504.0 |

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: May 29, 2012.

Reva Harris,

Acting Director, Division of Policy and Information Coordination.

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DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS-2011-0069]

Assessment Questionnaire—IP Sector Specific Agency Risk Self Assessment Tool (IP-SSARSAT)

AGENCY: National Protection and Programs Directorate, DHS.

ACTION: 30-day Notice and request for comments; New Information Collection Request, 1670-NEW.

SUMMARY: The Department of Homeland Security (DHS), National Protection and Programs Directorate (NPPD), Office of

Infrastructure Protection (IP), Sector Outreach and Programs Division (SOPD), previously named the Sector Specific Agency Executive Management Office, will submit the following information collection request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104-13, 44 U.S.C. chapter 35). NPPD is soliciting comments concerning new Information Collection Request—Assessment Questionnaire—IP Sector Specific Agency Risk Self Assessment Tool (IP-SSARSAT). DHS previously published this ICR in the **Federal Register** on December 29, 2011, for a 60-day public comment period. DHS received no comments. The purpose of this notice is to allow an additional 30 days for public comments.

DATES: Comments are encouraged and will be accepted until July 5, 2012. This process is conducted in accordance with 5 CFR 1320.10.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, OMB. Comments should be addressed to OMB Desk Officer, DHS, Office of Civil Rights and Civil Liberties. Comments must be identified by DHS-

2011-0069 and may be submitted by one of the following methods:

- **Federal e-Rulemaking Portal:** <http://www.regulations.gov>.

- **Email:** oir_submission@omb.eop.gov. Include the docket number in the subject line of the message.

- **Fax:** (202) 395-5806.

Instructions: All submissions received must include the words "Department of Homeland Security" and the docket number for this action. Comments received will be posted without alteration at <http://www.regulations.gov>, including any personal information provided.

OMB is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the