

recent studies conducted by the Public Health Service and revised the guidance accordingly. FDA considered several options to address the comments in response to the revised MSM donor deferral policy. Because evidence indicates that the indefinite deferral policy for MSM may have become less effective over time, FDA has determined that a change in policy is warranted at this time. Data on the limitations of nucleic acid tests to identify antibody negative window period HIV infections suggests that donor testing alone, absent any deferral for MSM, would result in an unacceptable increased risk of transfusion-transmitted HIV. Similarly, pretesting at risk donors with a rapid HIV test prior to donation would be logistically challenging and would not necessarily identify newly HIV-infected individuals. While individual donor assessment for risk has been implemented in a few countries, the implementation of this strategy in the United States would present significant practical challenges and currently there is no validated and accepted individual risk assessment tool or questionnaire. Therefore, FDA concluded a time-based deferral for history of male-male sex is the most appropriate policy to maintain the safety of the U.S. blood supply. Scientific data regarding the effectiveness of a 1-year deferral in Australia, a country with similar HIV epidemiology to the United States, supports FDA's policy change to the blood donor deferral period for MSM from indefinite deferral to 1 year since the last sexual contact. Scientifically robust data are not available for time-based deferrals of less than 1 year. FDA also concluded that scientific data are not currently available that would support revisions to the indefinite deferral policy for commercial sex workers or intravenous drug users.

In response to comments, FDA made the following changes when finalizing the guidance: (1) Amended the recommendations regarding the inclusion of signs and symptoms associated with HIV in the donor educational materials; (2) revised the recommendation for the deferral of female donors who have had sex with MSM; (3) stated that FDA no longer recommends deferral for individuals who have had sex with an individual with hemophilia or related clotting deficiencies requiring treatment with clotting factor concentrates; and (4) revised the recommendations regarding product retrieval and consignee notification of distributed blood products collected from a donor who should have been deferred for HIV risk

factors. In addition, FDA made the following changes to clarify certain recommendations in the guidance, which are consistent with current policy: (1) Clarified that donors who have been determined to have a false-positive HIV test may be reentered according to a requalification method found acceptable to FDA; (2) noted that recipients of allogeneic blood transfusions (*i.e.*, not autologous transfusions), should be temporarily deferred; (3) provided reference to an FDA guidance on the collection of blood components from donors at risk of HIV infection; and (4) clarified the deferral by the responsible physician of a blood establishment of any donor if the donation could affect the health of the donor or the safety of the blood component. Additionally, the background section has been expanded to summarize FDA's evaluation of the available policy options under the available evidence relevant to the MSM deferral policy. Minor editorial changes have also been made to the guidance.

FDA remains committed to exploring options and engaging in public discussions regarding enhancements to donor and public education regarding safe blood donors and evaluating the effectiveness of the donor history questionnaire. Further, with the implementation of a transfusion transmitted infectious disease monitoring system, FDA will be able to monitor donor risk factors and the safety of the blood supply, as well as investigate and refine blood safety measures in the future. FDA's recommendations may evolve over time as new scientific data become available on strategies to maintain or improve blood safety.

The guidance announced in this notice finalizes the draft guidance dated May 2015 and supersedes the 1992 blood memo.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on recommendations for reducing the risk of HIV transmission by blood and blood products. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

## II. Paperwork Reduction Act of 1995

The guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and

Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 601.12 have been approved under OMB control number 0910–0338; the collections of information in 21 CFR 606.171 have been approved under OMB control number 0910–0458; and the collections of information in 21 CFR 610.46, 630.6, 640.3 and 640.63 have been approved under OMB control number 0910–0116.

## III. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: December 17, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Proposed Collection; Public Comment Request

**AGENCY:** Health Resources and Services Administration, HHS.

**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 ICR should be received no later than February 22, 2016.

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Information Collection Clearance Officer, Room 10C–16, 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](mailto: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: 340B Drug Pricing Program Reporting Requirements.

OMB No. 0915-0176—[Revision].

Abstract: 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 participates in Medicaid must sign a Pharmaceutical Pricing Agreement with the Secretary of Health and Human Services in which the manufacturer agrees to charge enrolled covered entities a price for covered outpatient drugs that will not exceed an amount determined under a statutory formula. Covered entities who 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 requesting Medicaid reimbursement from a drug that has been discounted under the 340B Program. 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.

Section 340B(a)(5)(C) of the PHS Act permits the Secretary and manufacturers of a covered outpatient drug to conduct audits of covered entities in accordance with procedures established by the Secretary related to the number, duration and scope of the audits.

Manufacturers are permitted to conduct an audit only when there is reasonable cause to believe a violation of section 340B(a)(5)(A) or (B) has occurred. The manufacturer notifies the covered entity in writing when it believes the covered entity has violated these provisions of the 340B Program. If the problem cannot be resolved, the manufacturer will then submit an audit

work plan describing the audit and evidence in support of the reasonable cause standard to the HRSA Office of Pharmacy Affairs (OPA) for review. OPA will review the documentation to determine if reasonable cause exists. Once the audit is completed, the manufacturer will submit copies of the audit report to OPA for review and resolution of the findings, as appropriate. The manufacturer will also submit an informational copy of the audit report to the HHS Office of Inspector General (OIG).

In response to the statutory mandate of section 340B(a)(5)(C) to permit the Secretary or manufacturers to conduct audits of covered entities and because of the potential for disputes involving covered entities and participating drug manufacturers, OPA developed an informal voluntary dispute resolution process for manufacturers and covered entities, who prior to filing a request for resolution of a dispute with OPA, should attempt in good faith to resolve the dispute. All parties involved in the dispute must maintain written documentation as evidence of a good faith attempt to resolve the dispute. If the dispute is not resolved and dispute resolution is desired, a party must submit a written request for a review of the dispute to OPA. A committee appointed to review the documentation will send a letter to the party alleged to have committed a violation. The party will be asked to provide a response to or a rebuttal of the allegations.

HRSA published a Notice in 1996 and a policy release in 2011 on manufacturer audit guidelines and the informal dispute resolution process. (61 FR 65406 (December 12, 1996) and “Clarification of Manufacturer Audits of 340B Covered Entities,” Release No. 2011-3).

The expected revision to this package includes additional background information on the dispute resolution process and clarifies the need and proposed use of information regarding the manufacturer audit guidelines and the informal dispute resolution process.

**Need and Proposed Use of the Information:** HRSA is proposing the collection of information related to the manufacturer audit guidelines. These

guidelines contain the following reporting/notification elements:

1. Manufacturers should notify the entity in writing when it believes a violation has occurred;

2. Manufacturers should submit documentation to OPA as evidence of good faith of attempts to resolve a dispute.

3. Manufacturers must submit an audit work plan to OPA;

4. Manufacturers should submit the audit report to the OPA and informational copies to the HHS OIG; and

5. The covered entity should provide a written response to the audit report.

This information is necessary to ensure the orderly conduct of manufacturer audits. In addition, the informal dispute resolution process requires the participating manufacturer or covered entity requesting dispute resolution to provide OPA with a written request. The party alleged to have committed a section 340B violation, may provide a response or rebuttal to OPA. This information is necessary in order to ensure that the dispute will be resolved in a fair and equitable manner.

**Likely Respondents:** Drug manufacturers and 340B covered entities.

**Burden Statement:** Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested during an audit. 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 for both covered entities and manufacturers. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

#### TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

| Form name                                       | Number of respondents | Number of responses per respondent | Total responses | Average burden per response (in hours) | Total burden hours |
|-------------------------------------------------|-----------------------|------------------------------------|-----------------|----------------------------------------|--------------------|
| <b>AUDITS:</b>                                  |                       |                                    |                 |                                        |                    |
| Good faith Resolution <sup>1</sup> .....        | 10                    | 1                                  | 10              | 40                                     | 400                |
| Audit Notification to Entity <sup>1</sup> ..... | 10                    | 1                                  | 10              | 4                                      | 40                 |
| Audit Workplan <sup>1</sup> .....               | 40                    | 1                                  | 18              | 8                                      | 144                |

## TOTAL ESTIMATED ANNUALIZED BURDEN HOURS—Continued

| Form name                       | Number of respondents | Number of responses per respondent | Total responses | Average burden per response (in hours) | Total burden hours |
|---------------------------------|-----------------------|------------------------------------|-----------------|----------------------------------------|--------------------|
| Audit Report <sup>1</sup> ..... | 8                     | 1                                  | 8               | 8                                      | 64                 |
| Entity Response .....           | 8                     | 1                                  | 8               | 8                                      | 64                 |
| DISPUTE RESOLUTION:             |                       |                                    |                 |                                        |                    |
| Dispute Request .....           | 10                    | 4                                  | 40              | 10                                     | 400                |
| Rebuttal .....                  | 10                    | 1                                  | 10              | 16                                     | 160                |
| Total .....                     | 96                    | .....                              | 104             | .....                                  | 1272               |

<sup>1</sup> Prepared by the manufacturer.

## RECORDKEEPING BURDEN

| Record-keeping requirement | Number of record-keepers | Hours of record-keeping | Total burden |
|----------------------------|--------------------------|-------------------------|--------------|
| Dispute Records .....      | 50                       | 0.5                     | 25           |

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.

**Jackie Painter,**

*Director, Division of the Executive Secretariat.*

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**BILLING CODE 4165-15-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Health Resources and Services Administration

## Agency Information Collection

## Activities: Proposed Collection: Public Comment Request

**AGENCY:** Health Resources and Services Administration, HHS.

**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 February 22, 2016.

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Information Collection Clearance Officer, Room 10-29, 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](mailto: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 National Environmental Policy Act (NEPA) Environmental Information and Documentation (EID) OMB No. 0915-0324—Extension.

*Abstract:* HRSA is requesting extension of the approval for the Environmental Information and Documentation (EID) checklist which

consists of information that the agency is required to obtain to comply with the National Environmental Policy Act of 1969 (NEPA). NEPA establishes the federal government's national policy for protection of the environment. HRSA has developed the EID for applicants of funding that would potentially impact the environment and to ensure that their decision-making processes are consistent with NEPA.

*Need and Proposed Use of the Information:* Applicants must provide information and assurance of compliance with NEPA on the EID checklist. This information is reviewed in the Pre-Award stage.

*Likely Respondents:* HRSA applicants applying for federal construction grants and cooperative agreements.

*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.

*Total Estimated Annualized burden hours:*

| Form name                | Number of respondents | Number of responses per respondent | Total responses | Average burden per response (in hours) | Total burden hours |
|--------------------------|-----------------------|------------------------------------|-----------------|----------------------------------------|--------------------|
| NEPA EID Checklist ..... | 1,350                 | 1                                  | 1,350           | 1.0                                    | 1,350              |
| Total .....              | 1,350                 | 1                                  | 1,350           | 1.0                                    | 1,350              |