

**DATES:** The meeting will be held on June 20, 2016, from 9:30 a.m. to 1 p.m.

**ADDRESSES:** FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD, 20993-0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>. For those unable to attend in person, the meeting will also be Webcast and will be available at the following link: <https://collaboration.fda.gov/bpac2016/>.

**FOR FURTHER INFORMATION CONTACT:**

Bryan Emery or Joanne Lipkind, Division of Scientific Advisors and Consultants, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6132, Silver Spring, MD 20993-0002, 240-402-8054, [bryan.emery@fda.hhs.gov](mailto:bryan.emery@fda.hhs.gov), and 240-402-8106, [joanne.lipkind@fda.hhs.gov](mailto:joanne.lipkind@fda.hhs.gov), respectively; or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

**SUPPLEMENTARY INFORMATION:**

**Agenda:** On June 20, 2016, the Committee members will participate in the meeting via teleconference. In open session, the Committee will discuss the research programs in the Laboratory of Plasma Derivatives in the Division of Hematology Research and Review, Office of Blood Research and Review, Center for Biologics Evaluation and Research, FDA.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/>

[default.htm](#). Scroll down to the appropriate advisory committee meeting link.

**Procedure:** On June 20, 2016, from 9:30 a.m. to 12:20 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before June 6, 2016. Oral presentations from the public will be scheduled between approximately 11:20 a.m. to 12:20 p.m. on June 20, 2016. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before June 3, 2016. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may 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 June 6, 2016.

**Closed Committee Deliberations:** On June 20, 2016, from 12:20 p.m. to 1 p.m., the meeting will be closed to the public to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The Committee will discuss the site visit report of the intramural research programs and make recommendations regarding personnel staffing decisions.

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 disabilities. If you require accommodations due to a disability, please contact Bryan Emery 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: May 16, 2016.

**Jill Hartzler Warner**,  
Associate Commissioner for Special Medical Programs.

[FR Doc. 2016-11854 Filed 5-19-16; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request**

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

**ACTION:** Notice.

**SUMMARY:** In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

**DATES:** Comments on this ICR should be received no later than June 20, 2016.

**ADDRESSES:** Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or by fax to 202-395-5806.

**FOR FURTHER INFORMATION CONTACT:** To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call (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 HRSA, Healthcare Systems Bureau, Office of Pharmacy Affairs (OPA) for review. OPA will review the documentation to determine if reasonable cause exists. Once the audit is complete, 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 Health and Human Services (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 should maintain written documentation as evidence of a good faith attempt to resolve the dispute. To request voluntary dispute resolution of an unresolved dispute, a party submits 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 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.

HHS has reviewed all comments submitted in response to the publication of a 60-day **Federal Register** notice requesting comments on this ICR. Comments submitted included requests for standardized reporting forms. Commenters also expressed concern that burden hours were significantly understated. HHS agrees that the burdens associated with this ICR may have been understated. Adjusted burden estimates are included in this 30-day notice. Finally, HHS appreciates the comments received regarding the development of a formal dispute resolution process. HHS is in the process of developing a regulation to establish and implement a binding administrative dispute resolution process pursuant to section 340(d)(3) of the PHS Act. Some of the comments received regarding the audit process are beyond the scope of this notice, and as such, HHS will not be addressing them in this notice.

*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 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 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. 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 ICR 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              | 60                                     | 600                |
| Audit Notification to Entity <sup>1</sup> ..... | 10                    | 1                                  | 10              | 6                                      | 60                 |

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 Workplan <sup>1</sup> ..... | 40                    | 1                                  | 18              | 12                                     | 216                |
| Audit Report <sup>1</sup> .....   | 8                     | 1                                  | 8               | 12                                     | 96                 |
| Entity Response .....             | 8                     | 1                                  | 8               | 12                                     | 96                 |
| <b>Dispute Resolution</b>         |                       |                                    |                 |  |                    |
| Dispute Request .....             | 10                    | 4                                  | 40              | 15                                     | 600                |
| Rebuttal .....                    | 10                    | 1                                  | 10              | 28                                     | 280                |
| Total .....                       | 96                    | .....                              | 104             | .....                                  | 1948               |

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

*Recordkeeping Burden:*

| Recordkeeping requirement | Number of recordkeepers | Hours of recordkeeping | Total burden |
|---------------------------|-------------------------|------------------------|--------------|
| Dispute Records .....     | 50                      | 1                      | 50           |

**Jason E. Bennett,**  
 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**

**Maternal and Child Health Collaborative Office Rounds**

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

**ACTION:** Notice of a class deviation from competition requirements for Maternal and Child Health Collaborative Office Rounds.

**SUMMARY:** HRSA announces the award of an extension in the amount of \$150,000 for the Maternal and Child Health Collaborative Office Rounds

(MCH-COR) grants. The purpose of the program is to foster joint pediatrics-child psychiatry continuing education in the psychosocial development aspects of child health, utilizing a study group approach that emphasizes the practical challenges confronted by community based practitioners. The extension will permit recipients to continue activities within the scope of the current award while the program is evaluated, during the budget period of 7/1/2016-6/30/2017.

**FOR FURTHER INFORMATION CONTACT:** Rita Maldonado, Division of Maternal Child Health Workforce Development, Maternal and Child Health Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 18W13A, Rockville, MD 20852, Phone: 301.443.3622, Email: [RMaldonado@hrsa.gov](mailto:RMaldonado@hrsa.gov).

**SUPPLEMENTARY INFORMATION:**  
*Intended Recipient of the Award:* Children’s Research Institute, Johns

Hopkins University, New York School of Medicine, Regents of the University of Minnesota, The Regents of the University of California, San Francisco. The Regents of the University of Michigan, Trustees of Dartmouth College, University of Illinois, Yale University.

*Amount of Each Non-Competitive Awards:* \$15,000.

*Period of Supplemental Funding:* 7/1/2016-6/30/2017.

CFDA Number: 93.110

**Authority:** Social Security Act, Title V, Section 502(a)(1)

*Justification:* MCHB is requesting a one-time extension to continue activities while the program is evaluated to determine future activities using the COR model. MCHB will evaluate the basic structure of the COR model, identify gaps, and propose possible enhancements to the model.

| Grant recipient/organization name                           | Grant No.  | State | Current project start date | Current project end date | Revised project end date | FY 2015 authorized funding level | FY 2016 estimated funding level |
|---|------------|-------|----------------------------|--------------------------|--------------------------|----------------------------------|---------------------------------|
| CHILDREN’S RESEARCH INSTITUTE.                              | T20MC21950 | DC    | 7/1/2011                   | 6/30/2016                | 6/30/2017                | \$15,000                         | \$15,000                        |
| Children’s Research Institute .....                         | T20MC07472 | OH    | 7/1/2011                   | 6/30/2016                | 6/30/2017                | 15,000                           | 15,000                          |
| JOHNS HOPKINS UNIVERSITY                                    | T20MC07464 | MD    | 7/1/2011                   | 6/30/2016                | 6/30/2017                | 15,000                           | 15,000                          |
| NEW YORK UNIVERSITY SCHOOL OF MEDICINE.                     | T20MC21951 | NY    | 7/1/2011                   | 6/30/2016                | 6/30/2017                | 14,999                           | 14,999                          |
| Regents of the University of Minnesota.                     | T20MC07469 | MN    | 7/1/2011                   | 6/30/2016                | 6/30/2017                | 15,000                           | 15,000                          |
| The Regents of the University of California, San Francisco. | T20MC21952 | CA    | 7/1/2011                   | 6/30/2016                | 6/30/2017                | 15,000                           | 15,000                          |
| THE REGENTS OF THE UNIVERSITY OF MICHIGAN.                  | T20MC07463 | MI    | 7/1/2011                   | 6/30/2016                | 6/30/2017                | 15,000                           | 15,000                          |
| TRUSTEES OF DARTMOUTH COLLEGE.                              | T20MC07473 | NH    | 7/1/2011                   | 6/30/2016                | 6/30/2017                | 15,000                           | 15,000                          |
| UNIVERSITY OF ILLINOIS .....                                | T20MC25634 | IL    | 7/1/2011                   | 6/30/2016                | 6/30/2017                | 14,859                           | 14,859                          |