

meeting agenda will be posted on the Committee's Web site at <http://www.hrsa.gov/advisorycommittees/rural/>.

**Jackie Painter,**

*Director, Division of the Executive Secretariat.*

[FR Doc. 2015-09080 Filed 4-20-15; 8:45 am]

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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 (NAC).

*Date and Time:* May 6, 2015 from 2:00 p.m.–3:30 p.m. (EST).

*Place:* Conference Call Format.

*Status:* The meeting will be open to the public.

*Purpose:* The NAC provides advice to the Secretary of the Department of Health and Human Services and the Administrator of the Health Resources and Services Administration (HRSA), with respect to their responsibilities for designating areas of the United States with critical health professional shortages (*i.e.*, Health Professional Shortage Area) and assigning health care personnel to improve the delivery of health services in these areas.

*Agenda:* The members of the NAC will discuss: (a) The activities and goals for fiscal year 2016 for the National Health Service Corps; (b) their vision and approaches for future NAC meetings; and (c) planning for an in-person meeting. The official agenda will be available 2 days prior to the meeting on the HRSA Web site at: <http://nhsc.hrsa.gov/corpsexperience/aboutus/nationaladvisorycouncil/>. Agenda items are subject to change as priorities dictate.

*Public Comment:* Requests to make oral comments or provide written comments to the NAC should be sent to CAPT Shari Campbell, Designated Federal Official, using the address and phone number below. Individuals who plan to participate on the conference call should notify CAPT Campbell at least 3 days prior to the meeting, using the address and phone number below. Members of the public will have the opportunity to provide comments.

Interested parties should refer to the meeting, in the subject line, as the HRSA National Advisory Council on the National Health Service Corps. The conference call-in number is: 888-566-5974. The passcode is: 4439136.

#### FOR FURTHER INFORMATION CONTACT:

Anyone requesting information regarding the NAC should contact CAPT Shari Campbell, Designated Federal Official, Bureau of Health Workforce, HRSA, in one of three ways: (1) Send a request to the following address: CAPT Shari Campbell, Designated Federal Official, Bureau of Health Workforce, HRSA, Parklawn Building, Room 8C-26, 5600 Fishers Lane, Rockville, Maryland 20857; (2) call (301) 594-4251; or (3) send an email to [scampbell@hrsa.gov](mailto:scampbell@hrsa.gov).

**Jackie Painter,**

*Director, Division of the Executive Secretariat.*

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## 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 May 21, 2015.

**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:

*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. Manufacturers rely on the information in the 340B database to determine if a 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, as well as the routine renewal of approval for the existing information collections. The previously approved collections are substantially unchanged, except that HRSA has transitioned completely to online versus hardcopy forms.

*Pricing data submission, validation and dissemination:* In order to implement Section 340B(d)(1)(B)(i)(II),

HRSA has already developed a system to calculate 340B ceiling prices prospectively from data obtained from the Centers for Medicare & Medicaid Services as well as OPA-identified commercial databases. However, in order to conduct the comparison required under the statute, manufacturers must submit the quarterly pricing data as required by section 340B(d)(1)(B)(i)(II).

HRSA is developing a mechanism for secure manufacturer submissions. This notice proposes collecting Average Manufacturer Price, Unit Rebate Amount, Package Sizes, National Drug Code (NDC), period of sale (year and quarter), and manufacturer-determined 340B ceiling price for each NDC produced by a manufacturer 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 ICR are summarized in the table below.

**TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS**

Form name	Number of respondents	Number of responses per respondent	Total responses	Hours per respondent	Total burden hours
<b>Hospital Enrollment, Additions &amp; Recertifications</b>					
340B Program Registrations & Certifications for Hospitals	194	1	194	2	388
Certifications to Enroll Hospital Outpatient Facilities .....	697	8	5,576	0.5	2,788
Hospital Annual Recertifications .....	2,134	6	12,804	0.25	3,201
<b>Registrations and Recertifications for Entities Other Than Hospitals</b>					
340B Registrations for Community Health Centers .....	427	3	1,281	1	1,281
340B Registrations for STD/TB Clinics .....	647	1	647	1	647
340B Registrations for Various Other Eligible Entity Types .....	405	1	405	1	405
Community Health Center Annual Recertifications .....	1,204	5	6,020	0.25	1,505
STD & TB Annual Recertifications .....	3,123	1	3,123	0.25	780.75
Annual Recertification for entities other than Hospitals, Community Health Centers, and STD/TB Clinics .....	4,899	1	4,899	0.25	1,224.75
<b>Contracted Pharmacy Services Registration &amp; Recertifications</b>					
Contracted Pharmacy Services Registration .....	1,758	5	8,790	1	8,790
<b>Other Information Collections</b>					
Submission of Administrative Changes for any Covered Entity .....	9,396	1	9,396	0.5	4,698
Submission of Administrative Changes for any Manufacturer .....	350	1	350	0.5	175
Manufacturer Data Required to Verify 340B Ceiling Price Calculations .....	600	4	2,400	0.5	1,200
Pharmaceutical Pricing Agreement .....	200	1	200	1	200
<b>Total .....</b>	<b>26,034</b>	<b>.....</b>	<b>.....</b>	<b>.....</b>	<b>27,283.5</b>

**Jackie Painter,**

*Director, Division of the Executive Secretariat.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Request for Comments on Deliberation and Bioethics Education

**AGENCY:** Department of Health and Human Services, Office of the Secretary, Presidential Commission for the Study of Bioethical Issues.

**ACTION:** Notice.

**SUMMARY:** The Presidential Commission for the Study of Bioethical Issues is requesting public comment on deliberation and bioethics education.

**DATES:** To ensure consideration, comments must be received by July 20, 2015. Comments received after this date will be considered only as time permits.

**ADDRESSES:** Individuals, groups, and organizations interested in commenting on this topic may submit comments by email to [info@bioethics.gov](mailto:info@bioethics.gov) or by mail to the following address: Public Commentary, Presidential Commission for the Study of Bioethical Issues, 1425 New York Ave. NW., Suite C-100, Washington, DC 20005.

**FOR FURTHER INFORMATION CONTACT:**

Hillary Wicai Viers, Communications Director, Presidential Commission for the Study of Bioethical Issues. Telephone: 202-233-3960. Email: [hillary.viers@bioethics.gov](mailto:hillary.viers@bioethics.gov). Additional information may be obtained at <http://www.bioethics.gov>.

**SUPPLEMENTARY INFORMATION:** On November 24, 2009, the President established the Presidential Commission for the Study of Bioethical Issues (Bioethics Commission) to advise him on bioethical issues generated by novel and emerging research in biomedicine and related areas of science and technology. The Commission is charged with identifying and promoting policies and practices that ensure ethically responsible conduct of scientific research and health care delivery. Undertaking these duties, the Commission seeks to identify and examine specific bioethical, legal, and social issues related to potential scientific and technological advances; examine diverse perspectives and possibilities for international collaboration on these issues; and recommend legal, regulatory, or policy actions as appropriate.

The Bioethics Commission is considering two overarching themes of its work, deliberation and education,

focusing on their symbiotic relationship as twin pillars of public bioethics. Democratic deliberation has been a guiding ethical principle in the Commission's work, informing both its processes and its recommendations. The Commission also is committed to supporting bioethics education at all levels and across disciplines, through its own pedagogical materials and its recommendations for improving and integrating ethics education in a range of settings. This new project will explore the relationship between deliberation and bioethics education and the importance of public engagement in the bioethics conversation. For example, the Commission's deliberations not only advise the U.S. federal government, but also play a vital role in civic education. Bioethics education fosters the scientific and ethical literacy that supports public deliberation about science, medicine, public health, and bioethics, and helps to prepare students for their role as citizens in understanding different perspectives on complex issues that are often the subject of public policy debates.

At its meeting on November 6, 2014, the Commission heard from scholars in education, medical ethics, and political philosophy, and began its consideration of the relationship between deliberation and bioethics education and its own role in promoting both of these to advance public understanding of and engagement with bioethical debates. For example, in its most recent report, *Ethics and Ebola: Public Health Planning and Response*, the Commission made recommendations regarding the importance of public education and deliberation in preparing for public health emergencies. The ethical challenges that emerged in the U.S. response to the ongoing Ebola epidemic in western Africa underscore the need for appropriate forums for public engagement and debate on the ethical dimensions of public health decision making.

The Commission is interested in receiving comments from individuals, groups, and professional communities regarding deliberation and education in bioethics. The Commission is particularly interested in receiving public commentary regarding:

- The role of deliberation and deliberative methods to engage the public and inform debate in bioethics;
- Approaches to integrating public dialogue into the bioethics conversation;
- Bioethics education as a forum for fostering deliberative skills and preparing students to participate in public dialogue in bioethics;

- Goals of bioethics education (*e.g.*, empirical training, normative foundations, clinical ethics), and the competencies and skills bioethics education seeks to foster;

- Methods and goals of designing bioethics education and training programs at different levels (*e.g.*, undergraduate foci, master's degree programs, terminal degree programs, and professional certification);
- Potential training in bioethics across the lifespan at different educational levels and settings (*e.g.*, primary/secondary education, community education, continuing professional education), and the role of education in laying the foundation for constructive public deliberation and debate in bioethics;

- The appropriate role of professional standards for bioethicists, including core competencies for bioethicists, and potential accreditation of bioethics training or education programs;

- Integrating bioethics education across different professional contexts, and establishing "dual competency" through reciprocal training in bioethics and a home or primary discipline (*e.g.*, engineering and bioethics, medicine and bioethics, law and bioethics).

To this end, the Commission is inviting interested parties to provide input and advice through written comments. Comments will be publicly available, including any personally identifiable or confidential business information that they contain. Trade secrets should not be submitted.

Dated: April 13, 2015.

**Lisa M. Lee,**

*Executive Director, Presidential Commission for the Study of Bioethical Issues.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Committee on Vital and Health Statistics: Meeting; Privacy, Security & Confidentiality Subcommittee

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting.

*Name:* National Committee on Vital and Health Statistics (NCVHS) Subcommittee on Privacy, Confidentiality & Security.

*Time And Date:* May 6, 2015 9:00 a.m.–5:00 p.m. EST, May 7, 2015 9:00 a.m.–12:00 p.m. EST.

*Place:* U.S. Department of Health and Human Services, Centers for Disease