

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 discount program must comply with the requirements of 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)(5)(C) to develop audit guidelines and because of the potential for disputes involving covered entities and participating drug manufacturers, the HRSA Office of Pharmacy Affairs (OPA) developed a dispute resolution process for manufacturers and covered entities as well as manufacturer guidelines for audit of 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.

The annual estimate of burden is as follows:

Reporting/Notification requirement	Number of respondents	Responses per respondent	Total responses	Hours/ response	Total burden hours
<b>AUDITS</b>					
Good Faith Resolution <sup>1</sup> .....	10	1	10	40	400
Audit Notification of Entity <sup>1</sup> .....	10	1	10	4	40
Audit Workplan <sup>1</sup> .....	8	1	8	10	80
Audit Report <sup>1</sup> .....	6	1	6	10	60
Entity Response .....	6	1	6	8	48
<b>DISPUTE RESOLUTION</b>					
Mediation Request .....	10	4	40	10	400
Rebuttal .....	10	1	10	16	160
<b>TOTAL</b> .....	<b>50</b>	<b>.....</b>	<b>80</b>	<b>.....</b>	<b>1188</b>

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

#### Recordkeeping Burden:

Recordkeeping requirement	Number of recordkeepers	Hours of recordkeeping	Total burden
Dispute Records .....	50	0.5	25

**ADDRESSES:** Submit your comments 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. Please direct all correspondence to the "attention of the desk officer for HRSA."

**Deadline:** Comments on this ICR should be received within 30 days of this notice.

Dated: February 13, 2013.

**Bahar Niakan,**

*Director, Division of Policy and Information Coordination.*

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**BILLING CODE 4165-15-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which

would constitute a clearly unwarranted invasion of personal privacy.

**Name of Committee:** National Institute of Child Health and Human Development Special Emphasis Panel; Demographic/Behavioral Population Science.

**Date:** March 12, 2013.

**Time:** 8:00 a.m. to 5:00 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** Hotel Lombardy, 2019 Pennsylvania Avenue NW., Washington, DC 20006.

**Contact Person:** Marita R. Hopmann, Ph.D., Scientific Review Officer, Division of Scientific Review, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5B01, Bethesda, MD 20892, 301-435-6911, [hopmannm@mail.nih.gov](mailto:hopmannm@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: February 14, 2013.

**Michelle Trout,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2013-03855 Filed 2-20-13; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Mental Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of an Interagency Autism Coordinating Committee (IACC) meeting.

The purpose of the IACC meeting is to discuss updates and issues related to ASD research and services activities. The meeting will be open to the public and will be accessible by webcast and conference call.

*Name of Committee:* Interagency Autism Coordinating Committee (IACC).

*Type of meeting:* Open Meeting.

*Date:* April 9, 2013.

*Time:* 9:00 a.m. to 5:30 p.m. \* Eastern Time \* Approximate end time.

*Agenda:* To discuss updates and issues related to ASD research and services activities.

*Place:* The National Institute of Mental Health, The Neuroscience Center, 6001 Executive Boulevard, Conference Rooms C and D, Rockville, MD 20852.

*Webcast Live:* <http://videocast.nih.gov/>.

*Conference Call Access:* Dial: 888-843-7184, Access code: 5279679.

*Cost:* The meeting is free and open to the public.

*Registration:* Pre-registration is recommended to expedite check-in. Seating in the meeting room is limited to room capacity and on a first come, first served basis. For more on registration please visit the IACC Web site at: [www.iacc.hhs.gov/events](http://www.iacc.hhs.gov/events).

*Deadlines:* Notification of intent to present oral comments: Tuesday, March 26, 2013 by 5:00 p.m. ET. Submission of written/electronic statement for oral comments: Tuesday, April 2, 2013 by 5:00 p.m. ET. Submission of written comments: Tuesday, April 2, 2013 by 5:00 p.m. ET.

*Access:* White Flint Metro (Red Line)—approximately ½ mile walk. On-site parking with parking validation available.

*Contact Person:* Ms. Lina Perez, Office of Autism Research Coordination, National Institute of Mental Health, NIH, 6001 Executive Boulevard, Room 6182A, Bethesda, MD 20892-9669, Phone: 301-443-6040, Email: [IACCPublicInquiries@mail.nih.gov](mailto:IACCPublicInquiries@mail.nih.gov).

**Please Note:** Any member of the public interested in presenting oral comments to the Committee must notify the Contact Person listed on this notice by 5:00 p.m. ET on Tuesday, March 26, 2013, with their request

to present oral comments at the meeting. Interested individuals and representatives of organizations must submit a written/electronic copy of the oral presentation/statement including a brief description of the organization represented by 5:00 p.m. ET on Tuesday, April 2, 2013. Statements submitted will become a part of the public record. Only one representative of an organization will be allowed to present oral comments and presentations will be limited to three to five minutes per speaker, depending on number of speakers to be accommodated within the allotted time. Speakers will be assigned a time to speak in the order of the date and time when their request to speak is received, along with the required submission of the written/electronic statement by the specified deadline.

In addition, any interested person may submit written comments to the IACC prior to the meeting by sending the comments to the Contact Person listed on this notice by 5:00 p.m. ET on Tuesday, April 2, 2013. The comments should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person. All written statements received by the deadlines for both oral and written public comments will be provided to the IACC for their consideration and will become part of the public record.

The meeting will be open to the public through a conference call phone number and webcast live on the Internet. Members of the public who participate using the conference call phone number will be able to listen to the meeting but will not be heard. If you experience any technical problems with the webcast or conference call, please send an email to [iacchelpdesk2012@gmail.com](mailto:iacchelpdesk2012@gmail.com) or by phone at (301) 339-3840.

Individuals who participate in person or by using these electronic services and who need special assistance, such as captioning of the conference call or other reasonable accommodations, should submit a request to the Contact Person listed on this notice at least 5 days prior to the meeting.

As a part of security procedures, attendees should be prepared to present a photo ID at the meeting registration desk during the check-in process. Pre-registration is recommended. Seating will be limited to the room capacity and seats will be on a first come, first served basis, with expedited check-in for those who are pre-registered.

Meeting schedule subject to change.

Information about the IACC is available on the Web site: <http://www.iacc.hhs.gov>.

Dated: February 14, 2013.

**Carolyn A. Baum,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

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**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Mental Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Interagency Autism Coordinating Committee (IACC) Subcommittee for Basic and Translational Research.

The IACC Subcommittee for Basic and Translational Research will have a conference call on Wednesday, March 6, 2013. The Subcommittee will discuss future subcommittee activities. The meeting will be accessible by conference call.

*Name of Committee:* Interagency Autism Coordinating Committee (IACC) Subcommittee for Basic and Translational Research.

*Type of meeting:* Conference Call.

*Date:* March 6, 2013.

*Time:* 2:00 p.m.–5:00 p.m. \*Eastern Time\*—Approximate end time.

*Agenda:* The subcommittee will discuss future subcommittee activities.

*Place:* Conference call only; No in-person meeting.

*Conference Call:* Dial: 888-316-9409; Access code: 4311740.

*Cost:* The conference call is free.

*Contact Person:* Ms. Lina Perez, Office of Autism Research Coordination, National Institute of Mental Health, NIH, 6001 Executive Boulevard, NSC, Room 6182A, Rockville, MD 20852, Phone: (301) 443-6040, Email: [IACCPublicInquiries@mail.nih.gov](mailto:IACCPublicInquiries@mail.nih.gov).

**Please Note:** The meeting will be open to the public and accessible via conference call. Members of the public who participate using the conference call phone number will be able to listen to the meeting but will not be heard. If you experience any technical problems with the conference call, please email [iacchelpdesk2012@gmail.com](mailto:iacchelpdesk2012@gmail.com) or call the IACC Technical Support Help Line at 301-339-3840.

*Accommodations Statement:* Individuals who participate by using the conference call and who need special assistance such as captioning or other reasonable accommodations should submit a request to the Contact Person listed on this notice at least 5 days prior to the meeting.

This meeting notice is being published less than 15 days prior to the meeting due to the urgent need for the subcommittee to discuss subcommittee upcoming activities and emerging issues in the autism community.

Schedule subject to change.

Information about the IACC is available on the Web site: <http://www.iacc.hhs.gov>.