

TABLE 1.—SUMMARY OF POSTMARKETING STUDY COMMITMENTS (NUMBERS AS OF SEPTEMBER 30, 2007)—Continued

	NDA/ANDAs (% of Total)	BLAs <sup>1</sup> (% of Total)
• Terminated	1 (0.1%)	3 (1%)
• Submitted	157 (12%)	81 (20%)
Concluded studies (October 1, 2006—September 30, 2007)	133	26
• Commitment met	101 (76%)	21 (81%)
• Commitment not met	1 (<1%)	0
• Study no longer needed or feasible	31 (23%)	5 (19%)
Applications with open postmarketing commitments with annual reports due, but not submitted within 60 days of the anniversary date of U.S. approval	115 (37%) <sup>2</sup>	41 (51%)

<sup>1</sup> On October 1, 2003, FDA completed a consolidation of certain products formerly regulated by CBER into CDER. The previous association of BLA reviews only with CBER is no longer valid; BLAs are now received by both CBER and CDER. Fiscal year statistics for CDER BLA post-marketing study commitments will continue to be counted under BLA totals in this table.

<sup>2</sup> Note that this statistic counts all annual reports submitted more than 60 days after the anniversary date of U.S. approval as overdue, including reports that may have been submitted on a modified reporting schedule in accordance with prior FDA agreement. Of the applications categorized as having overdue annual reports using this definition, annual reports were subsequently submitted in FY06 for 115/115 (100 percent) of NDAs/ANDAs and 20/41 (49 percent) of BLAs.

Dated: April 15, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

[CFDA Number 93.224; HRSA-09-095, HRSA-09-096, HRSA-09-097, and HRSA-09-098]

#### Amendment to the Fiscal Year 2009 Service Area Competition—New and Competing Continuation Funding

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

**ACTION:** Change in application deadline and amendment of the available service areas.

**SUMMARY:** HRSA is announcing the reissuance of Fiscal Year 2009 Service Area Competition—New and Competing Continuation Funding (HRSA Announcement Numbers HRSA-09-095, HRSA-09-096, HRSA-09-097, and HRSA-09-098). The HRSA Electronic Handbook (EHB) application deadline for project periods beginning in November and December 2008 has been changed and the list of available service areas has been updated.

The new EHB application deadline for HRSA-09-095 is May 9, 2008. (The grants.gov application deadline of April 7, 2008 remains the same.) All other

requirements of HRSA-09-095 remain the same. Please see the chart on pages 6 and 7 of the guidance for a complete listing of all application deadlines.

In addition, corrections to two service areas listed in the Service Area Competition guidance have been made. In Appendix F of the guidance, Bismarck, ND, is *incorrectly* listed as an available service area in fiscal year (FY) 2009. The correct service area that is currently available in FY 2009 is Beulah, ND. Also, Clay, WV, is *incorrectly* listed as an available service area in FY 2009. The correct service area that is currently available in FY 2009 is Blacksville, WV. Bismarck, ND and Clay, WV, are not available service areas for the FY 2009 Service Area Competition. For a complete listing of all available service areas for the FY 2009 Service Area Competition funding opportunity, please see Appendix F of the guidance.

**DATES:** The effective date of this amended Agency guidance is April 24, 2008.

**Background:** HRSA administers the Health Center Program, which supports more than 4,000 health care delivery sites, including community health centers, migrant health centers, health care for the homeless centers, and public housing primary care centers. Health centers serve clients that are primarily low-income and minorities, and deliver comprehensive, culturally competent, quality primary health care services to patients regardless of their ability to pay. Charges for health care services are set according to income.

**FOR FURTHER INFORMATION CONTACT:** For questions regarding this notice, please contact Nicole Amado in the Office of Policy and Program Development, Bureau of Primary Health Care, HRSA, at 301-594-4300 or [Nicole.Amado@hrsa.hhs.gov](mailto:Nicole.Amado@hrsa.hhs.gov).

Dated: April 17, 2008.

**Elizabeth M. Duke,**  
*Administrator.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### National Advisory Committee on Rural Health and Human Services; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given that the following committee will convene its fifty-ninth meeting.

**Name:** National Advisory Committee on Rural Health and Human Services.

**Dates and Times:** June 2, 2008, 9 a.m.–4:30 p.m. June 3, 2008, 8:45 a.m.–5:15 p.m. June 4, 2008, 8:15 a.m.–10:30 a.m.

**Place:** Siena Hotel, 1505 East Franklin Street, Chapel Hill, NC 27514. Phone: 919-929-4000.

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

**Purpose:** The National Advisory Committee on Rural Health and Human Services provides advice and recommendations to the Secretary with respect to the delivery, research,

development and administration of health and human services in rural areas.

*Agenda:* Monday morning, at 9 a.m., the meeting will be called to order by the Chairperson of the Committee, the Honorable David Beasley. The first presentation will be an overview of rural North Carolina. The Committee will hear presentations on the three chosen Subcommittee topics. The first panel will focus on Workforce and Community Development. Erin Fraher, MPH, with the Rural Health Research and Policy Analysis Center, is a confirmed speaker. The second panel of speakers will lead a discussion on At-Risk Children. The final panel for the day is on the Medical Home Model. After the panel discussions, the Committee Chair will give an overview of the site visits. The Monday meeting will close at 4:30 p.m.

Tuesday morning, at 8:45 a.m., the Committee will break into Subcommittees and depart to the site visits. The Workforce and Community Development Subcommittee will depart to Raleigh, North Carolina, to visit the Turning Point Allied Health Regional Skills Partnership. The At-Risk Children Subcommittee will depart to Siler City, North Carolina and take a "ChildWatch" Tour where they will learn about the different services provided for children and the status of children and families. After the tour, the Subcommittee will arrive at the Chatham Family Resource Center. The Medical Home Subcommittee will depart for Community Care of Eastern Carolina in Greenville, North Carolina. Transportation to the site visits will not be provided to the public. At 4:15 p.m. the Subcommittees will arrive back at the Siena Hotel for Subcommittee meetings. The Tuesday meeting will close at 5:15 p.m.

The final session will be convened Wednesday morning, at 8:15 a.m. The Committee will break into Subcommittee format and meet for forty-five minutes. The Committee as a whole will reconvene at 9 a.m. There will be a review of the site visits and action items will be developed for the Committee members and staff. The Committee will draft the letter to the Secretary and discuss the September meeting. The meeting will be adjourned at 10:30 a.m.

*For Further Information Contact:* Anyone requiring information regarding the Committee should contact Jennifer Chang, MPH, Executive Secretary, National Advisory Committee on Rural Health and Human Services, Health Resources and Services Administration, Parklawn Building, Room 9A-55, 5600 Fishers Lane, Rockville, MD 20857, Telephone (301) 443-0835, Fax (301) 443-2803.

Persons interested in attending any portion of the meeting should contact Michele Pray-Gibson, Office of Rural Health Policy (ORHP), Telephone (301) 443-0835. The Committee meeting agenda will be posted on ORHP's Web site <http://www.ruralhealth.hrsa.gov>.

Dated: April 16, 2008.

**Alexandra Huttinger,**

*Director, Division of Policy Review and Coordination.*

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**BILLING CODE 4165-15-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[Docket No. USCG-2008-0308]

### Houston/Galveston Navigation Safety Advisory Committee; Meetings

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of meetings.

**SUMMARY:** The Houston/Galveston Navigation Safety Advisory Committee (HOGANSAC) and its working groups will meet in Houston, Texas to discuss waterway improvements, aids to navigation, area projects impacting safety on the Houston Ship Channel, and various other navigation safety matters in the Galveston Bay area. These meetings will be open to the public.

**DATES:** The Committee will meet on Thursday, May 22, 2008 at 9 a.m. The meeting of the Committee's working groups will be held on Thursday May 8, 2008 at 9 a.m. These meetings may close early if all business is finished. Written material and requests to make oral presentations should reach the Coast Guard at least five (5) working days before the meeting. Requests to have a copy of your material distributed to each member of the committee or working group should reach the Coast Guard at least ten (10) working days before the meeting.

**ADDRESSES:** The full Committee meeting and working groups meetings will be held at the Houston Pilots Association, 8150 South Loop East, Houston, Texas 77011-1747, (713) 645-9620. Send written material and requests to make oral presentations to Captain William Diehl, Designated Federal Officer (DFO) of HOGANSAC, 9640 Clinton Drive, Houston, Texas 77029. This notice may be viewed in our online docket, USCG-2008-0308 at <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** Commander Hal R. Pitts, Assistant to the DFO of HOGANSAC, telephone (713) 671-5164, e-mail [hal.r.pitts@uscg.mil](mailto:hal.r.pitts@uscg.mil) or Lieutenant Sean Hughes, telephone (713) 678-9001, e-mail [sean.p.hughes@uscg.mil](mailto:sean.p.hughes@uscg.mil).

**SUPPLEMENTARY INFORMATION:** Notice of these meetings is given pursuant to the

Federal Advisory Committee Act, 5 U.S.C. App. (Pub. L. 92-463).

### Agendas of the Meetings

*Houston/Galveston Navigation Safety Advisory Committee (HOGANSAC).* The tentative agenda is as follows:

(1) Opening remarks by the Committee Sponsor (RADM Whitehead) or the Committee Sponsor's representative, DFO (CAPT Diehl) and Chairperson (Ms. Tava Foret).

(2) Approval of the 26 February 2008 minutes.

(3) Old Business:

(a) Navigation Operations (NAVOPS)/Maritime Incident

Review subcommittee report;

(b) Deep Draft Entry Facilitation

(DDEF) subcommittee report;

(c) Dredging subcommittee report;

(d) Technology subcommittee report;

(e) Area Maritime Security Committee

(AMSC) Liaison's report;

(f) Harbor of Safe Refuge

subcommittee report;

(g) HOGANSAC Outreach report;

(h) Maritime Awareness

subcommittee report.

(4) New Business:

*Working Groups Meeting.* The tentative agenda for the working groups meeting is as follows:

(1) Presentation by each working group of its accomplishments and plans for the future;

(2) Review and discuss the work completed by each working group;

(3) Put forth any action items for consideration at the full committee meeting.

Working groups have been formed to examine the following issues: Dredging and related issues, electronic navigation systems, aids to navigation (AtoN) knockdowns, impact of passing vessels on moored ships, boater education issues, facilitating deep draft movements, mooring infrastructure, and harbor of safe refuge. Not all working groups will provide a report at this session. Further, working group reports may not necessarily include discussions on all issues within the particular working group's area of responsibility.

*Procedural:* All meetings are open to the public. Please note that the meetings may close early if all business is finished. At the Chair's discretion, members of the public may make oral presentations during the meetings. If you would like to make an oral presentation at a meeting, please notify the Assistant DFO at least five (5) working days before the meeting. Written material for distribution at a meeting should reach the Coast Guard at least ten (10) working days before the meeting. If you would like a copy of