

This meeting will include updates from NIOSH leadership on NORA as well as updates from approximately half of the NORA Sector Councils on their progress, priorities, and implementation plans to date, likely including the NORA Construction, Manufacturing, Public Safety, Services, and Wholesale and Retail Trade Sector Councils. Updates will also be given on at least one NIOSH Program that is working on several NORA priorities, e.g., the NIOSH Global Collaborations Program. After each update, there will be time to discuss partnership opportunities.

*Status:* The meeting is open to the public, limited only by the capacities of the conference call and conference room facilities. There is limited space available in the meeting room (capacity 34). Therefore, information to allow participation in the meeting through the Internet (to see the slides) and a teleconference call (capacity 50) will be provided to registered participants. Participants are encouraged to consider attending by this method. Each participant is requested to register for the free meeting by sending an email to [noracoordinator@cdc.gov](mailto:noracoordinator@cdc.gov) containing the participant's name, organization name, contact telephone number on the day of the meeting, and preference for participation in-person or by Web meeting (requirements include: computer, Internet connection, and telephone, preferably with 'mute' capability). An email confirming registration will include the details needed to participate in the Web meeting. Non-U.S. citizens are encouraged to participate in the Web meeting. Non-U.S. citizens who do not register to attend in person on or before June 5, 2012, will not be granted access to the meeting site and will not be able to attend the meeting in-person due to mandatory security clearance procedures at the Patriots Plaza facility.

*Background:* NORA is a partnership program to stimulate innovative research in occupational safety and health leading to improved workplace practices. Unveiled in 1996, NORA has become a research framework for the nation. Diverse parties collaborate to identify the most critical issues in workplace safety and health. Partners then work together to develop goals and objectives for addressing those needs and to move the research results into practice. The NIOSH role is facilitator of the process. For more information about NORA, see <http://www.cdc.gov/niosh/nora/about.html>.

Since 2006, NORA has been structured according to industrial sectors. Ten major sector groups have been defined using the North American

Industrial Classification System (NAICS). After receiving public input through the Web and town hall meetings, ten NORA Sector Councils defined sector-specific strategic plans for conducting research and moving the results into widespread practice. To view the National Sector Agendas, see <http://www.cdc.gov/niosh/nora/>.

**FOR FURTHER INFORMATION CONTACT:** Sidney C. Soderholm, Ph.D., NORA Coordinator, Email [noracoordinator@cdc.gov](mailto:noracoordinator@cdc.gov), telephone (202) 245-0665.

Dated: March 2, 2012.

**John Howard,**

*Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.*

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**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-5052-N]

#### Medicare Program; Solicitation for Proposals for the Medicare Graduate Nurse Education Demonstration Program

**AGENCY:** Centers for Medicare & Medicaid Services (CMS).

**ACTION:** Notice.

**SUMMARY:** This notice informs interested parties of an opportunity to apply to participate in the Medicare Graduate Nurse Education (GNE) Demonstration. The primary goal of the GNE Demonstration is to increase the number of advanced practice registered nurses (APRNs) in order to meet the health care needs of the growing Medicare population.

**DATES:** Proposals will be considered timely if they are received on or before 5 p.m., Eastern Standard Time (E.S.T.) on May 21, 2012.

**ADDRESSES:** Proposals should be mailed to the following address: Centers for Medicare & Medicaid Services, Center for Medicare & Medicaid Innovation, Attention: Alexandre Laberge, Mail Stop: WB-06-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

**FOR FURTHER INFORMATION CONTACT:** Alexandre Laberge (410) 786-8625 or by email at [GNE@cms.hhs.gov](mailto:GNE@cms.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

*General Information:* Please refer to file code (CMS-5052-N) on the

application. Proposals (an unbound original and 10 electronic copies on CD-ROM) must be typed for clarity and should not exceed 50 double-spaced pages, exclusive of cover letter, the executive summary, resumes, forms, and no more than 15 pages supporting documentation. Because of staffing and resource limitations, we cannot accept proposals by facsimile (Fax) transmission. Applicants may, but are not required to, submit a total of 10 copies to assure that each reviewer receive a proposal in the manner intended by the applicant (for example, collated, tabulated color copies). Hard copies and electronic copies must be identical.

*Eligible Organizations:* As set forth in section 5509 of the Affordable Care Act (ACA) (Pub. L. 111-148, as amended by Pub. L. 111-152), an "eligible hospital" may apply to perform the responsibilities specified. Section 5509(e)(5) of the ACA defines an "eligible hospital" to mean a hospital (as defined in section 1861(e) of the Social Security Act (the Act) (42 U.S.C. 1395x)) or a critical access hospital (as defined in section 1861(mm)(1) of the Act) that has a written agreement in place with—(A) 1 or more applicable schools of nursing; and (B) 2 or more applicable non-hospital community-based care settings. The written agreement must meet specific requirements set forth in section 5509 of the ACA including—(1) the obligations of the eligible partners with respect to the provision of qualified training; and (2) the obligation of the eligible hospital to reimburse such eligible partners applicable (in a timely manner) for the costs of such qualified training attributable to partner. The demonstration will include up to five eligible hospitals.

#### I. Provisions of This Notice

We are seeking eligible hospital applicants, which includes critical access hospitals, to partner with one or more applicable schools of nursing (SONs) and two or more applicable nonhospital community-based care settings (CCSs) to provide advanced practice registered nurse (APRN) students with qualified training. See section 5509(e) of the ACA for the definitions of the terms used in the preceding sentence. At least half of the clinical training must be provided in non-hospital CCSs which may include federally qualified health centers (FQHCs), rural health clinics (RHCs), and other nonhospital settings as determined appropriate by the Secretary. However, the Secretary may waive the requirement under section

5509(e)(7)(A)(ii) of the ACA with respect to eligible hospitals located in rural or medically underserved areas.

In general terms, the demonstration provides a source of Medicare funding for the reasonable costs for clinical training attributable to the incremental increase in the number of APRN students enrolled in participating SONs during the demonstration relative to an established baseline. Section 5509 of the ACA sets forth limitations on the reasonable costs reimbursable under the demonstration. We will make interim payments to selected hospitals with a cost settlement process using Medicare reasonable cost principles. Participating eligible hospitals must establish written agreements with one or more applicable SONs and two or more applicable non-hospital CCSs that define the obligations of each partner with respect to the provision of qualified training and the corresponding eligible hospital's obligation to reimburse eligible partners applicable (in a timely manner) for the costs of such qualified training attributable to the partner and the mechanism for partner reimbursement. As outlined in the GNE Solicitation, applicant hospitals may partner with other hospitals in the demonstration and we will support an expanded configuration of hospital relationships under certain circumstances.

The GNE Demonstration will run for 4 years. Applicants must identify how they propose to significantly increase the APRN student enrollment and graduation rates for clinical nurse specialist, nurse practitioner, certified registered nurse anesthetist, and certified nurse midwife specialty programs. The proposal must present evidence that the applicant hospital and partner organizations are not only capable of successfully recruiting students but also providing relevant clinical training programs responsive to our changing health care system due to the growing number of insured by 2014. Applicants will be required to provide a detailed budget and narrative describing the rationale for the proposed GNE payment rate and why this would be an efficient investment for CMS.

A competitive process will be used to select eligible organizations. We will accept proposal applications in the standard format outlined in the GNE solicitation in order to be considered for review by an internal technical panel. Applications that are not received in this format will not be considered for review.

For more specific details regarding the GNE demonstration, please refer to the informational materials on our Web site

at <http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/>.

## II. Information Collection Requirements

In accordance with section 5509(a)(4) of the ACA, this information collection requirement is not subject to the Paperwork Reduction Act of 1995. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

**Authority:** Section 5509 of the ACA (Pub. L. 111–148, as amended by Pub. L. 111–152) (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: January 19, 2012.

**Marilyn Tavenner,**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

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**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2007–D–0369]

#### Draft and Revised Draft Guidances for Industry Describing Product-Specific Bioequivalence Recommendations; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of additional draft and revised draft product-specific bioequivalence (BE) recommendations. The recommendations provide product-specific guidance on the design of BE studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA announced the availability of a guidance for industry entitled “Bioequivalence Recommendations for Specific Products,” which explained the process that would be used to make product-specific BE recommendations available to the public on FDA’s Web site. The BE recommendations identified in this notice were developed using the process described in that guidance.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on these draft and revised draft guidances before it

begins work on the final versions of the guidances, submit either electronic or written comments on the draft and revised draft product-specific BE recommendations listed in this notice by May 21, 2012.

**ADDRESSES:** Submit written requests for single copies of the individual BE guidances to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance recommendations.

Submit electronic comments on the draft product-specific BE recommendations to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

#### FOR FURTHER INFORMATION CONTACT:

Doan T. Nguyen, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, (240) 276–8608.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled “Bioequivalence Recommendations for Specific Products,” which explained the process that would be used to make product-specific BE recommendations available to the public on FDA’s Web site at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>. As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific BE recommendations and provide a meaningful opportunity for the public to consider and comment on those recommendations. Under that process, draft recommendations are posted on FDA’s Web site and announced periodically in the **Federal Register**. The public is encouraged to submit comments on those recommendations within 60 days of their announcement in the **Federal Register**. FDA considers any comments received and either publishes final recommendations, or publishes revised draft recommendations for comment. Recommendations were last announced in the **Federal Register** of January 25,