4. Study duration, overall study design, and analysis of clinical trials needed to demonstrate a treatment effect on disease modification for peripheral neuropathy.

FDA will post the agenda and additional workshop background material approximately 5 days before the workshop at http://www.fda.gov/Drugs/NewsEvents/cdrh201416.htm.

II. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at http://www.regulations.gov. It may be viewed at the Division of Dockets Management (see Comments). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.


Leslie Kux,
Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Single Source Program Expansion Supplement Award to Area Health Education Centers (AHEC) Program Grantee; Exception to Competition

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Notice of Exception to Competition—Single Source Program Expansion Supplement Award to Area Health Education Centers (AHEC) Program Grantee—University of Guam School of Nursing.

SUMMARY: The Health Resources and Services Administration (HRSA)’s Bureau of Health Professions is issuing a non-competitive single source program expansion supplement award to the University of Guam School of Nursing, an Area Health Education Center (AHEC) Program grantee, to coordinate the U.S. Affiliated Pacific Islands (USAPI) Nursing Program Capacity Strengthening and Quality Improvement Initiative. In fiscal year (FY) 2012, $203,703 will be available to fund this award. The Guam/Micronesia AHEC is uniquely qualified and has the capacity, capability, expertise, experience, and infrastructure to expeditiously, effectively, and efficiently implement the project within their existing educational programming.

The University of Guam School of Nursing is the only nationally accredited baccalaureate nursing education program in the Pacific. Its focus is on health careers training and development, as well as improving the health careers pipeline in the region.

Supplementary information: Intended recipient of the award: Guam/Micronesia AHEC—University of Guam School of Nursing.

Amount of Award: $203,703.

Authority: Section 751 of the Public Health Service Act (42 U.S.C. 294a), as amended by Sec. 5403 of the Patient Protection and Affordable Care Act, Public Law 111–148.

CFDA Number: 93.824.


Justification: The Guam/Micronesia AHEC—University of Guam School of Nursing is uniquely qualified to carry out the USAPI Nursing Program Capacity Strengthening and Quality Improvement Initiative Project because of their significant role in improving the public health capacity and infrastructure in the region.

The University of Guam School of Nursing is the only nationally accredited baccalaureate nursing education program in the Pacific. The Guam/Micronesia AHEC grantee is the University of Guam School of Nursing, whose focus is health career training and development, as well as improving the health careers pipeline in the region. The activities that will be carried out through this initiative will serve as building blocks in a more comprehensive strategic effort to strengthen nursing education, and, thus the nursing workforce in the USAPI jurisdictions. Funding this supplemental award in FY 2012 will enable the grantee to implement the activities identified in this initiative, targeted on nursing program director development, student assessment and preparation, program resource purchases, and faculty development.

FOR FURTHER INFORMATION CONTACT: Meseirat Bezenneh, Project Officer, Health Resources and Services Administration, Division of Public Health and Interdisciplinary Education, 5600 Fishers Lane, Room 3C–05, Rockville, Maryland 20857, Phone: (301) 594–4149, Email: mbezenneh@hrsa.gov.


Mary K. Wakefield, Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Single Source Program Expansion Supplement Award to Nurse Education, Practice, Quality and Retention (NEPQR) Program Grantee; Exception to Competition

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice of Exception to Competition—Single Source Program Expansion Supplement Award to Nurse Education, Practice, Quality and Retention (NEPQR) Program Grantee—Texas A&M University Corpus Christi (TAMUCC), College of Nursing and Health Science (CONHS).

SUMMARY: The Health Resources and Services Administration (HRSA)’s Bureau of Health Professions is issuing a non-competitive single source program expansion supplement award to the NEPQR Program grantee TAMUCC–CONHS to build upon their feasibility study, Transitioning Enlisted Health Care Training into Academic Credit for Nursing Education Programs, and undertake a dissemination program to advance the goal of aligning enlisted health care training with civilian nursing program requirements. In fiscal year (FY) 2012, $178,374 will be available to fund this award. TAMUCC–CONHS is uniquely qualified and has the capacity, capability, expertise, experience, and infrastructure to expeditiously, effectively, and efficiently implement the project within their existing educational programming.

During the previous year, TAMUCC–CONHS has gained in-depth insight into the full range academic, financial, and socio-economic barriers that interfere with successful transition from military to civilian careers, and how these barriers are compounded by the burden of navigating the military-academic labyrinth. Thus they are well-positioned to bridge the gap between health care training command programs and academic programs in schools of nursing work.

Supplementary information: Intended recipient of the award: Texas A&M University Corpus Christi (TAMUCC), College of Nursing and Health Science (CONHS).