

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/ucm310416.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.

Dated: September 25, 2012.

**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.

*Project Period:* September 1, 2012, through August 31, 2013.

*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:

Meseret Bezuneh, Project Officer, Health Resources and Services Administration, Division of Public Health and Interdisciplinary Education, 5600 Fishers Lane, Room 9C-05, Rockville, Maryland 20857, Phone: (301) 594-4149, Email: [mbezuneh@hrsa.gov](mailto:mbezuneh@hrsa.gov).

Dated: September 25, 2012.

**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).

*Amount of Award:* \$178,374.

**Authority:** Section 831 and 831a under Title VIII of the Public Health Service Act (42 U.S.C. 296p and 42 U.S.C. 296 p-1), as amended by Sec.5309 of the Patient Protection and Affordable Care Act, Public Law 111-148.

*CFDA Number:* 93.359.

*Project Period:* September 1, 2012, through August 31, 2013.

*Justification:* In FY 2010, HRSA competitively funded the eLine Military (ELM) program at TAMUCC-CONHS, an online nursing education program offered to residents of Texas who are members of the military or veterans with previous medical experience. One of the critical challenges the ELM program faced concerned granting college credit for health care training and experiences provided in training command programs. This training lacked the structure and rigor foundational to academic courses, creating a significant impediment to granting academic credit for these experiences. In FY 2011, TAMUCC-CONHS received a supplemental award to develop strategies to surmount the barriers to gaining nursing academic credit for military training and to develop recommendations for their implementation. This supplement will build upon the feasibility study and undertake a dissemination program to advance the goal of aligning enlisted health care training with civilian nursing program requirements. This supplement directly supports the scope of the ELM program/parent grant and has significant implications for returning veterans seeking academic credit for enlisted health care training at CONHS and nursing schools across the country. Identifying the barriers to efficient enrollment and pursuit of nursing education by veterans and developing a plan for surmounting these barriers will provide schools of nursing with the tools needed to develop effective academic pathways for veterans, bring nursing education opportunities to a new and largely untapped cohort of persons with interest in and training in health care occupations, open up campuses to veterans in engaging and supporting ways, spur interest in and enrollment in nursing programs by veterans, and increase diversity in the nursing workforce. A stakeholders meeting and dissemination plan will be designed to bring the study findings to the broadest possible audience.

**FOR FURTHER INFORMATION CONTACT:** Julie Sochalski, Health Resources and

Services Administration, Division of Nursing, 5600 Fishers Lane, Room 9-61, Rockville, Maryland 20857, or email at [jsochalski@hrsa.gov](mailto:jsochalski@hrsa.gov).

Dated: September 25, 2012.

**Mary K. Wakefield,**  
Administrator.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Single Source Award; Exception to Competition

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

**ACTION:** Notice of Exception to Competition—Single Source Award to Texas Area Health Education Centers (AHEC) East—University of Texas Medical Branch.

**SUMMARY:** The Health Resources and Services Administration (HRSA)'s Bureau of Health Professions is issuing a non-competitive single source award to the Texas AHEC East—University of Texas Medical Branch, an AHEC program grantee, to add a Behavioral Health component to a Community Health Worker (CHW) curriculum, pilot and evaluate it in primary care settings, and disseminate the curriculum. This project shall be titled: Community Health Worker (CHW) Behavioral Health Primary Care Integration Project. In fiscal year (FY) 2012, \$486,394 will be available to fully fund this cooperative agreement with a single project/budget period of four years. The Texas AHEC East is uniquely qualified and has the capacity, capability, expertise, experience, and infrastructure to expeditiously, effectively, and efficiently implement the CHW Behavioral Health Primary Care Integration Project within their existing educational programming, and disseminate the tested model nationally. CHWs play an important role in increasing access to services for vulnerable populations, and increasing support for direct service workers, including community health workers, which is a priority for the Department of Health and Human Services as well as the Health Resources and Services Administration.

**SUPPLEMENTARY INFORMATION:** *Intended Recipient of the Award:* Texas AHEC East—University of Texas Medical Branch.

*Amount of Award:* \$486,394.

*Authority:* Section 751 of the Public Health Service Act (42 USC 294a), as amended by Section 5403 of the Patient Protection and Affordable Care Act, Public Law 111-148.

*CFDA Number:* 93.107.

*Project Period:* September 30, 2012, through September 29, 2016.

*Justification:* The Texas AHEC East is uniquely qualified to carry out the CHW Behavioral Health Primary Care Integration Project because of their demonstrated expertise in the training of CHWs and CHW instructors for certification, and because of their proven track record as pioneers of the CHW apprenticeship model.

The Texas AHEC East has an existing infrastructure with staff expertise, and a proven track record in curriculum design and training to develop a behavioral health curriculum that can augment the existing CHW training program, as well as strong partnerships with community-based primary care providers to implement, pilot, and evaluate the curriculum in primary care settings.

Furthermore, the proposed Project Director is recognized for her work and expertise in CHW training, serves as the Chair of the National AHEC Organization's Community Health Worker workgroup, and is a member of the American Public Health Association's Community Health Worker section. She has presented at national meetings and at several states' CHW meetings on designing CHW training curriculum, as well as the CHW apprenticeship-training model. As a result of these collaborations and recognitions, significant opportunities exist for national dissemination and replication of this project. Providing the additional funding to an existing grantee (Texas AHEC East—University of Texas Medical Branch) also has benefits for program evaluation purposes, since AHEC grantees have existing evaluation requirements with which they comply. This award aligns with the current AHEC budget period cycle, resulting in administrative savings over a competitive grant making process.

**FOR FURTHER INFORMATION CONTACT:** Meseret Bezuneh, Project Officer, Health Resources and Services Administration, Division of Public Health and Interdisciplinary Education, 5600 Fishers Lane, Room 9C-05, Rockville, Maryland 20857; Phone: (301) 594-4149, Email: [mbezuneh@hrsa.gov](mailto:mbezuneh@hrsa.gov).

Dated: September 25, 2012.

**Mary K. Wakefield,**  
Administrator.

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