

VA and the ARRA of 2009

VA's Plan for Implementing ARRA



The American Recovery and Reinvestment Act (ARRA) of 2009 provides the Department of Veterans Affairs (VA) with \$1.4 billion to improve its medical facilities and national cemeteries; provide grants to assist States in remodeling, acquiring, or constructing State nursing homes and domiciliary facilities in order to provide

Veterans with adequate living arrangements; to hire and train temporary claims processors; to pursue needed information technology initiatives; to administer one-time payments of \$250 to eligible Veterans and their survivors or dependents; and to oversee and audit programs, grants, and projects funded under ARRA. Additional information about the money that was designated to the VA under the ARRA can be seen below.

- **Veterans Health Administration - Medical Facilities Non-Recurring Maintenance (NRM) and Energy Projects (\$1 Billion)**
- **Veterans Health Administration - Grants for State Extended Care (\$150 Million)**
- **National Cemetery Administration - Monument and Memorial Repairs (\$50 Million)**
- **Veterans Benefits Administration - Hiring Temporary Claims Processors (\$150 Million)**
- **Veterans Benefits Administration - Veteran Economic Recovery Payments (estimated \$700 Million for payments plus \$7.1 Million for General Operating Expenses and \$100,000 for Information Technology to administer the payments)**
- **Office of Information and Technology - (\$50 Million)**
- **Office of Inspector General - (\$1 Million)**
 - [Overview of the VA Implementing ARRA](#)
 - [View the VA's ARRA Plans and Reports](#)
 - [View the ARRA Bill](#)

Training Topic

510(K) Clearance & Pre-Market Approval

▪ **What is 510(K) Clearance & Pre-Market Approval?**

Section 510(k) of the [Food, Drug and Cosmetic Act](#) requires device manufacturers to register and notify the Food & Drug Administration (FDA) of their intent to market a medical device at least 90 days in advance, which is known as Pre-market Notification (PMN). As a result, the FDA is able to determine whether the device is equivalent to a device already placed into one of the three classification categories (i.e. Class I, Class II, and/or Class III). Thus, "new" devices (not in commercial distribution prior to May 28, 1976) that have not been classified can be properly identified. Specifically, medical device manufacturers are required to submit a pre-market notification if they intend to introduce a device into commercial distribution for the first time or reintroduce a device that will be significantly changed or modified to the extent that its safety or effectiveness could be affected.

▪ **When is 510(k) Required?**

A 510(k) is required when:

- (1) A new device is introduced into commercial distribution (marketing) for the first time.
- (2) A firm proposes a different intended use for a device that is already in commercial distribution
- (3) There is a change/modification of a legally marketed device that could significantly affect its safety or effectiveness.

▪ **When is 510(k) NOT Required**

A 510(k) is not required if:

- (1) A firm sells unfinished devices to another firm for further processing.
- (2) A device is not being marketed or distributed commercially.
- (3) A firm distributes another firm's domestically manufactured device.
- (4) In most cases, if your firm is a re-packager and the existing labeling or condition of the device has not changed significantly.
- (5) Your firm's device was legally in commercial distribution before May 28, 1976.
- (6) The device is made outside the US and your company is an importer of the foreign made medical device.
- (7) Your device is exempted from 510(K) by regulation. A list of the Class I and II exempted devices can be found on [Medical Device Exemptions 510\(k\) and GMP Requirements](#).

- [How to Market Your Firm's Device?](#)
- [Recently 510\(K\) Approved Devices](#)
- [Determine Whether Your Firm's Product Needs 510\(K\) Approval](#)
- [Search the FDA's Medical Device Databases](#)

News You Can Use

The Veterans 1st Contracting Program

P.L. 109-461 VETERANS BENEFITS, HEALTHCARE, AND INFORMATION TECHNOLOGY ACT OF 2006 authorizes a unique "Veterans First" approach to VA contracting by changing the priorities for contracting preferences within the VA, placing Service Disabled, Veteran Owned Small Businesses (SDVOSB) and Veteran Owned Small Businesses (VOSB) first and second, respectively, in satisfying VA's acquisition requirements.

Although the sole source and set-aside procedures of this program do not apply to FSS, ordering activities are encouraged to include an evaluation factor in RFQs issued under FSS contracts that give additional consideration to quotes received from SDVOSB and VOSB concerns. An evaluation factor may also give consideration to any offeror, regardless of size status, that proposes to subcontract with SDVOSBs or VOSBs. If an offeror proposed to use a SDVOSB or VOSB subcontractor in response to such an evaluation factor, the contract specialist shall ensure that the offeror, if awarded the order or BPA, actually does use the proposed subcontractor(s).

- o [Read P.L. 109-461](#)
- o [Information Letter \(IL\) 049-07-08](#)

VA FSS Working For You

Tip of the Month

How to Market to the Federal Government.

The VA FSS wants you to be a successful contractor. As such, you need to market your firm to Government customers just as your company would market its commercial business. Your firm's marketing plan should include steps to define, promote and distribute your company's approved product/service information, and to establish/maintain a relationship with Government customers – all while complying with your firm's VA FSS contract terms and conditions. Please review the links below in order to learn how your firm's marketing efforts can identify Government customers, get their attention, and motivate them to buy from your company.

- o [Register for the "Marketing to the Federal Government Webinar"](#)
- o [How to Sell to the Government](#)
- o [Steps to Success](#)
- o [Marketing to DoD](#)
- o [Opportunities for Small Businesses](#)
- o [SBA Marketing & Advertising](#)

National News

Recent Emergency & Disaster Declarations

Under the Disaster Recovery Purchasing Program, state and local Government entities may purchase a variety of products and services from contracts awarded under FSS contracts to facilitate recovery from a major disaster, terrorism, or nuclear, biological, chemical, or radiological attack. As such, there were 7 declarations by President Obama during the month of June 2010, which can be seen below. [Frequently Asked Questions About the Disaster Recovery Purchasing Program.](#)

Major Disaster Declarations (June 2010)

Number	Date	State	Disaster Type
1918	6/24	West Virginia	Severe Storms & Flooding
1919	6/24	Puerto Rico	Severe Storms & Flooding

Fire Management Assistance Declarations (May 2010)

Number	Date	State	Incident
2843	6/02	New Mexico	Rio Fire
2844	6/09	Hawaii	Maalaea Fire
2845	6/19	Arizona	Hardy Fire
2846	6/20	Arizona	Shultz Fire

Emergency Declarations (June 2010)

Number	Date	State	Title
3313	6/29	Texas	Tropical Storm Alex

Upcoming Events

VA NAC FSS Customer Training

The Federal Supply Schedule Service of the VA National Acquisition Center (NAC) will be conducting Webinar Training Sessions on the General Overview of the FSS program, the benefits for Customers, as well as discussions on the best way to use the contract vehicle to produce the maximum benefit. This course is designed to provide contracting officers and other purchasing officials within the Government an in-depth understanding of the following:

- 1) How the Federal Supply Schedule program works
- 2) Benefits of using FSS Schedules
- 3) How to place orders against FSS contracts, including:
 - FAR 8.405-1 Ordering Procedures for Supplies, and Services Not Requiring a Statement of Work
 - FAR 8.405-2 Ordering Procedures for Services Requiring a Statement of Work
 - Compliance Check Requirements
 - Priorities of Use of Government Supply Sources
 - Open Market Waiver Request Process
 - Competition Requirements
- 4) Electronic Tools

The VA NAC FSS Customer Training is mandatory and the associated resources have been developed specifically for VHA facilities to address the training needs identified by the Office of the Inspector General Report No. 08-01519-172, which was issued on July 2, 2009. Please note that the Customer Training is **ONLY APPLICABLE TO GOVERNMENT AGENCIES**.

REGISTRATION INSTRUCTIONS

In order to register for one of the VA NAC FSS training classes, please perform the following:

- 1) Go to the [Register Online](#) link on the ARC eCMS page.
- 2) Enter your VA Network User Name (including domain) and Password and Click "OK."
- 3) On the Registration Home page, fill in your email address and organization (if not pre-populated).
- 4) From the Event Type dropdown list, select "Training."
- 5) From the Event dropdown list, select the desired VA NAC FSS Training class.

NOTE: Only register for 1 class. (The system will indicate how many spaces are available).

- 6) Click on "Submit."

MEETING/WEBINAR SCHEDULE

July 2010

- July 14th – 9:30am to 2:30pm Eastern Time
- July 21st – 8:30am to 1:30pm Pacific Time (11:30am to 4:30pm Eastern Time)
- July 28th – 9:30am to 2:30pm Eastern Time

August 2010

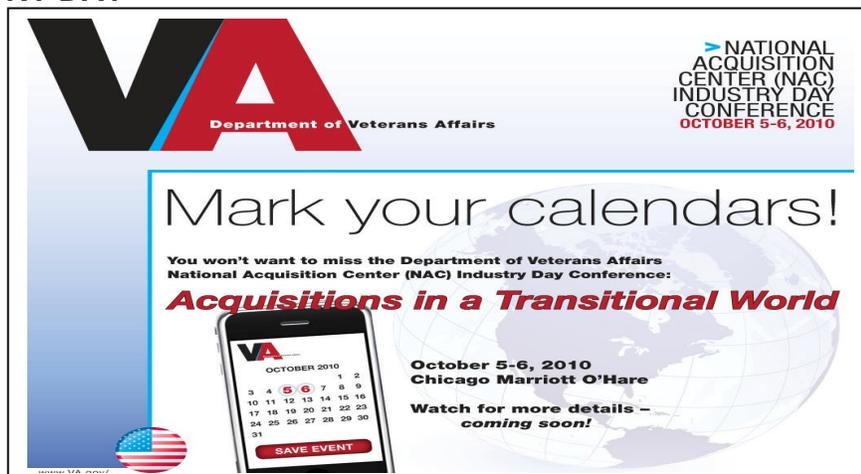
- Aug. 4th – 9:30am to 2:30pm Eastern Time
- Aug. 11th – 8:30am to 1:30pm Pacific Time (11:30am to 4:30pm Eastern Time)
- Aug 18th – 9:30am to 2:30pm Eastern Time
- Aug. 25th – 8:30am to 1:30pm Pacific Time (11:30am to 4:30pm Eastern Time)

September 2010

- Sept. 1st – 9:30am to 2:30pm Eastern Time

An e-mail containing the Web Conference Login Information will be sent to all registrants a week prior, as well a day before, their scheduled webinar. If you have any questions or problems registering, please contact Mrs. Veronica Hazen at Veronica.Hazen@va.gov.

VA NAC INDUSTRY DAY



VA
Department of Veterans Affairs

**> NATIONAL ACQUISITION CENTER (NAC) INDUSTRY DAY CONFERENCE
OCTOBER 5-6, 2010**

Mark your calendars!

You won't want to miss the Department of Veterans Affairs National Acquisition Center (NAC) Industry Day Conference:

Acquisitions in a Transitional World

October 5-6, 2010
Chicago Marriott O'Hare

Watch for more details - coming soon!

The poster features a large 'VA' logo, a calendar for October 2010 with the 5th and 6th highlighted, and a globe in the background.

Recently Awarded FSS Contracts (June 2010)

Pharmaceutical, Dental, Patient Mobility, & X-Ray:

- UniFirst First Aid DBA Medique Products: V797P-5171B (Small Pharmaceutical Business)
- Dyax Corporation: V797P-5142B (Small Pharmaceutical Business)
- Genta Incorporated: V797P-5168B (Small Pharmaceutical Business)
- Grifols Biologicals, Inc.: V797P-5159B (Large Pharmaceutical Business)
- The Brewer Company, LLC.: V797P-3206M (Small Dental Business)
- Avtec Dental, LLC.: V797P-3208M (Small, Woman Owned Dental Business)

Medical/Surgical Equipment:

- CareFusion 211, Inc.: V797P-4287B (Large Med/Surg Business)
- KNK Custom Sewing, LLC.: V797P-4296B (Small, Woman Owned Med/Surg Business)
- Jaken Medical, Inc.: V797P-4294B (Small Disadvantaged, 8(A) Med/Surg Business)
- Competitive Technologies, Inc.: V797P-4300B (Small Med/Surg Business)
- Skin & Wound Allograft Institute: V797P-4293B (Small Med/Surg Business)
- M&R Medical, LLC.: V797P-4303B (Small, Woman Owned Med/Surg Business)
- Buffalo Supply, Inc.: V797P-4299B (Small, Woman Owned Med/Surg Business)

Medical Professional & Laboratory Testing Services & Cost-Per-Test:

- Elite Nurse Staffing, Inc.: V797P-7268A (Small, Woman Owned Professional Medical Healthcare Services Business)
- Nurse Anesthesia of Maine: V797P-7269A (Small Professional Medical Healthcare Services Business)
- NorTek Medical Staffing, Inc.: V797P-7270A (Small, Woman Owned Professional Medical Healthcare Services Business)
- New Wave People, Inc.: V797P-7271A (Small Disadvantaged, Woman Owned Professional Medical Healthcare Services Business)

In order to obtain pricing information for all of the companies referenced above, please review the [NAC Contract Catalog Search Tool \(CCST\)](#) or [GSA E-Library](#). If you have any questions/concerns or would like to learn more about a specific topic and/or issue, please feel free to contact the FSS helpdesk by phone at (708)786-7737 and/or by e-mail at helpdesk.ammhinfss@va.gov.