Adding Non-TAA Covered Drugs to Schedule

May 3, 2016

Webinar 1:00 p.m.

Overview

- Welcome
- Authority
- Non-TAA Covered Drug Timeline
- “The Process” – Start to Finish
- Q & A

Welcome!

- VA has made the determination to add non-TAA covered drugs to Schedule. 65IB Solicitation has been amended, and all 65IB contracts are being mass modified. The amendment and modifications will now require covered drug manufacturers to place their covered drug NDC 11s on a Schedule contract vehicle, regardless of country of origin.
- Previously, covered drugs that were substantially transformed in a non-designated country under the Trade Agreements Act (TAA) were not allowed on Schedule.
- Now, we will be taking the following needed actions:
  - Mass modifying **all** 65IB contracts;
  - Incorporating 42-2A product addition modifications into existing contracts or (pending) interim agreements;

Authority

- Section 603 of the Veterans Healthcare Act of 1992, 38 U.S.C. Section 8126 (P.L. 102-585).
- The Trade Agreements Act (TAA), 19 U.S.C. 2501 et seq.
- Federal Acquisition Regulation Part 25.4
- GSA Procurement Information Bulletin (PIB) 05-5, May 27, 2005 – Trade Agreements and the GSA Schedules Program FAR Part 25.

Authority (cont.)

- VA's Nonavailability Determination

Non-TAA Covered Drug Timeline

- 4/20/16 – Solicitation Amended / Mass Modifications Made Available
- 4/21/16 – constant contact notice sent to all 65IB 42-2A contract holders
- 4/26/16 – covered drug manufacturers had to submit any missing NFAMP data to PBM to establish FCPs for covered drug items not already reported
- 5/6/16 – deadline for 65IB contractors to sign and return Mass Modification 0004
- 5/6/16 – deadline for RFM submittal
- 6/6/16 – date by which non-TAA covered drug NDC 11s must be on Schedule (either contract or IA):
  - Exceptions only for legitimate business reasons

The Process (cont. 2)

- By 5/6/16, 65IB contractors / IA Holders with non-TAA covered drugs must submit a “signed by contractor” copy of Mass Modification 0004 to VA FSS.
  - Make sure to CC your CO when sending these mass mods into the FSS Help Desk! These mods need to be bilaterally executed.
  - FSS Help Desk Email Subject Line needs to be “RFM – Contract # - 65IB – Mass Modification.” (e.g. RFM-V797P-5555X – 65IB – Mass Modification)

The Process (cont. 3)

- In addition to requiring the inclusion of non-TAA covered drugs on Schedule, the Solicitation Amendment / Mass Modifications require contractors to update their record in the System for Award Management (SAM.GOV):
  - These non-TAA covered drug product items being added to Schedule now need to be listed as other end products as required by 52.212-3(g)(5)(ii).

The Process (cont. 4)

- By 5/6/16 contractors and IA holders must submit their properly-completed 65IB 42-2A product addition Request For Modification (RFM) package:
  - RFM;
  - price proposal spreadsheet;
  - Any associated documentation.
- Your assigned CO must be copied on the email submittal.
- Note that we are using a DIFFERENT email address for these submittals. Send these requests into ammhin.pl102585@va.gov. Email naming convention will be as follows – "RFM- Contract # - PL2016" (e.g. RFM-V797P-5555X-PL2016).

The Process (cont. 5)

- Revisions to the RFM Form:
  - TAA Section on bottom of Page 9. If company indicates that it is offering non-TAA covered drugs, then company has to …
    - Sign the TAA Non-Availability Determination Request Letter included in the RFM package; AND
    - List the applicable covered drugs as other end products in the company's SAM record; AND
    - Visit our FSS TAA website, and become made aware of all of the requirements, deadlines, and submission procedure.
  - TAA Non-Availability Determination Request Letter – Page 10 of RFM. Needs to be completed and signed by an authorized company representative.
  - Make sure that, on the RFM verification page 11 of the RFM, the third box is NOT checked.

The Process (cont. 6)

- By 6/6/16, the product addition modification(s) need to be completed in full:
  - In addition to the usual requirements for proper completion of a 42-2A product addition modification (FDA approvals, etc.), the assigned CO must ensure that the company's SAM.GOV record has been revised in accordance with prior instructions.
  - Additional modification verbiage included in Block 14 of the SF 30 (or the continuation pages thereof). See the next slide.

The Process

- Non-TAA Covered Drug Addition Verbiage:
  - Although this modification has established [“Big 4 and OGA” or “FSS”] pricing for the NDCs included herein, the parties both agree that purchases of these NDCs under the FSS contract referenced in Block 10A above must be restricted to VA ONLY ordering activities at this time. This is due to the fact that these NDCs are from non-designated countries under the Trade Agreements Act, and VA’s head of contracting activity has made the determination under FAR 25.103(b)(2) that this particular article, material, or supply is not mined, produced, or manufactured in the U.S. or a designated country in sufficient and reasonably available commercial quantities of a satisfactory quality. If another agency’s head of contracting activity makes a similar determination, VA shall notify the contractor. However, a separate contract modification will need to be bilaterally executed in order to allow for the purchases of these NDCs under this FSS contract by any non-VA ordering activities.

Questions?