Department of Veterans Affairs

FY26 Recompete of the Electro-Therapeutic Modalities for Pain Management & Transcutaneous Electrical Nerve Stimulation Procurement Program

Purpose: The purpose of this document is to formally issue the Consolidated Request for Information (RFI) Frequently Asked Questions (FAQs), along with the Government's official responses. This FAQ supports the Department of Veterans Affairs (VA) FY26 Recompete of the Electro-Therapeutic Modalities for Pain Management (ETMPM) and Transcutaneous Electrical Nerve Stimulation (TENS) Procurement Program by ensuring uniform, transparent, and acquisition-compliant clarification to all prospective industry partners.

Executive Summary: This FAQ document consolidates and standardizes all questions submitted by Industry Respondents to the VA's RFIs issued on January 20, 2026, and June 25, 2026 for the FY26 Recompete ETMPM–TENS Procurement Program. Each question appears once, even where multiple Respondents asked similar or identical questions, in order to maintain clarity and avoid redundancy. The Government's responses provide high-level clarification intended solely to support market research and requirement refinement. In accordance with FAR 15.201(e), these exchanges:

- Do not constitute Government direction,
- Do not establish proposal evaluation criteria,
- Do not represent a binding Government commitment, and
- Do not provide any competitive advantage or procurement-sensitive insight.

Final, binding requirements will be published exclusively in the formal solicitation on SAM.gov.

SECTION 1 - GENERAL PROCUREMENT QUESTIONS:

Q1. Will the VA set aside this procurement for SDVOSB/VOSB under 38 U.S.C. 8127 (VA Rule of Two)?

Government Response: Based on the results of market research, the VA did not identify two (2) or more VetCert SDVOSBs or VOSBs capable of delivering successful contract performance against all CLINs/SLINs as OEM manufacturers and/or capable of meeting all the Minimum Technical Requirements (MTRs) of all CLINs/SLINs across the full ETMPM/TENS portfolio. Therefore, the VA anticipates issuing the resultant solicitation under Full and Open Competition. A small business set aside is not anticipated at this time.

Q2. May SDVOSB authorized distributors respond to the solicitation even if they are not the OEM manufacturer?

Government Response: Yes. SDVOSBs and other small businesses may participate as authorized distributors under the SBA Nonmanufacturer Rule waiver for NAICS Code 334510.

Q3. Will OEM–distributor teaming arrangements be allowed?

Government Response: Yes. Teaming arrangements are permissible. Prime Offerors must meet all responsibility requirements under FAR 9.104 and ensure proposed products comply with the CLIN/SLIN level MTRs.

Q4. Will the VA provide individualized feedback or technical guidance before release of the RFP?

Government Response: No. All clarifications and any updates to MTRs will be released exclusively via presolicitation notices posted on SAM.gov to ensure equal access and avoid unequal information exchanges.

Q5. Are Vendors disadvantaged if they missed the June 26, 2026 RFI due-in date?

Government Response: No. RFI participation is voluntary and does not affect competitive standing. All Vendors will have full and equal opportunity to compete once the solicitation is released.

Q6. Will NAICS 339113 be used?

Government Response: No. The VA will use NAICS Code 334510, which correctly corresponds to electromedical and electrotherapeutic device manufacturing. NAICS Code 339113 does not apply to this acquisition.

Q7. Will Vendors be required to submit product samples?

Government Response: Yes. Product samples for each proposed CLIN/SLIN must be shipped to the VA's Denver Logistics Services (DLS) facility by the proposal submission deadline specified in the solicitation.

SECTION 2 - TECHNICAL SPECIFICATION QUESTIONS:

Q8. May offered devices rely on subscriptions, leases, user accounts, or smart-device applications?

Government Response: No. All devices must be fully operational at time of delivery, independent of any subscription, rental, lease, pay-per-use model, or smart-device app dependency.

Q9. Are refurbished, remanufactured, or gray-market items acceptable?

Government Response: No. Only new, OEM-manufactured items are acceptable. Gray-market items are prohibited.

Q10. Will the VA accept garment-based electrodes or alternate pad configurations?

Government Response: Yes. Alternate electrode designs may be offered where allowed under "Alternate Options" SLINs and must meet all SLIN-level MTRs.

Q11. Must devices include digital displays, adjustable parameters, dual-channel output, compliance monitors, and rechargeable power?

Government Response: Yes. These features are mandatory under the applicable CLIN/SLIN level MTRs.

Q12. Must neuromodulation devices include sensitive-skin or hypoallergenic electrode options?

Government Response: Yes, where applicable and as stated in the CLIN/SLIN level MTRs.

Q13. Is FDA 510(k) clearance required?

Government Response: Yes. All devices must hold FDA 510(k) market clearance or valid predicate at proposal submission.

SECTION 3 - BAA/TAA COMPLIANCE QUESTIONS:

Q14. Will TAA-designated country devices be accepted?

Government Response: Yes. End-products manufactured in Trade Agreements Act (TAA)-designated countries will be accepted for evaluation under FAR Subpart 25.4 and FAR Clause 52.225-5, with required certification under FAR 52.225-6. The VA intends to be consistent with the Buy American Act (BAA) and procure domestic end-products to the maximum extent practicable under FAR Subpart 25.1, FAR Clause 52.225-1, and FAR 52.225-2. Because the estimated procurement program's anticipated dollar value exceeds all TAA thresholds, the TAA applies in full to this acquisition, and the VA will follow FAR Part 25 evaluation procedures whenever domestic end-products and TAA-designated country end-products compete.

Domestic End-Products (BAA):

- Must be manufactured in the United States.
- Non-COTS commercial items (e.g., CLIN X005) must meet BAA domestic-content requirements unless waived.
- For COTS items (e.g., CLINs/SLINs X001–X004), the domestic-content test is waived, but U.S. manufacturing is still required for BAA compliance.

TAA-Designated Country Items:

Eligible products may include sources from WTO GPA designated countries, USMCA partners, various bilateral Free Trade Agreements, and least-developed designated countries.

Non-Designated Countries (Not Acceptable):

Examples include Taiwan, China, Malaysia, Thailand, Vietnam, Philippines, Pakistan, Indonesia. Products from these countries cannot be accepted unless the VA completes a BAA Nonavailability Waiver in accordance with FAR 25.103(b).

Evaluation Under FAR Part 25:

- Eligible domestic end-products and TAA end-products receive equal consideration.
- BAA price-preference rules apply where relevant.
- Non-designated country items are prohibited absent a BAA non-availability waiver.

BAA Nonavailability Waiver Criteria: A waiver may be considered only when:

1. No domestic end-product is offered;
2. No TAA-designated end-product is offered; and
3. VA cannot meet mission requirements without a non-designated source.

If any domestic end-product or TAA-designated end-product is offered for a CLIN/SLIN, no BAA nonavailability waiver is required.

Final Position: The VA will procure domestic end-products whenever practicable. Where domestic end-products are unavailable, TAA-designated country end-products will be evaluated and may be selected for award. End-products from non-designated countries are prohibited unless a BAA nonavailability waiver is submitted and approved.

SECTION 4 - LOGISTICS, DISTRIBUTION & DELIVERY QUESTIONS:

Q15. What is the required product delivery timeframe?

Government Response: No. Delivery must be made to the VA's DLS facility unless otherwise directed in an additional awarded Delivery Order.

Q16. May Vendors ship devices directly to Veterans?

Government Response: No. The delivery of all ordered products must be to the VA's DLS facility unless otherwise specified in an additional awarded Delivery Order executed by an EPO AS4D Contracting Officer.

Q17. Must shipping containers include serial numbers and scannable barcodes?

Government Response: Yes. Serial numbers must appear on both the device and shipping container, and scannable barcodes must be included.

Q18. What are the requirements for reporting product recalls?

Government Response: Performing Contractors must notify the VA within one (1) business day of any recall or safety action.

SECTION 5 - CUSTOMER SERVICE, TRAINING & VETERAN PATIENT CONTACT QUESTIONS:

Q19. May performing Contractors collect Veteran PII, PHI, therapy data, or require device registration?

Government Response: No. Contractors may not request, collect, or retain Veteran PII, PHI, or medical treatment data. Customer service registration requirements are prohibited.

Q20. May performing Contractors initiate contact with Veteran patients?

Government Response: No. All contact must be Veteran-initiated. Outbound contractor-initiated contact is prohibited.

Q21. Must performing Contractors provide web-based and telephone technical support/customer service platforms?

Government Response: Yes. Contractors must maintain U.S.-based toll-free telephone support and compliant web-based customer service and training platforms (e.g., no ads, no login, no social media links).

SECTION 6 - PRICING, OPTIONS, SUBSTITUTIONS & ANNUAL PRODUCT TECHNICAL REFRESH MECHANISM:

Q22. Will the VA allow an annual technical refresh?

Government Response: Yes. One technical-refresh window is available per period of performance. Approval is at the CO's discretion, requires no-cost product samples for DLS testing, and may result in negotiated unit pricing. Approval is not guaranteed.

Q23. Can performing Contractors request price changes during contract performance?

Government Response: No. The procurement will not include an Economic Price Adjustment (EPA) clause. All CLIN/SLIN unit prices are Firm-Fixed Price (FFP) and established at award for the Base Year and all Option Years. Unit prices:

- Are fixed for all quantities ordered,
- Cannot increase or decrease under any circumstance post-award, and
- Apply uniformly for the entire contract life.

This structure ensures pricing stability, cost integrity, and predictability across all periods of performance.

Q24. May contractors propose product substitutions if OEM models are discontinued?

Government Response: Yes. Substitutions require formal CO approval, documentation of MTR compliance, no-cost product samples for testing at DLS, and negotiated unit pricing. Approval is not guaranteed.

SECTION 7 - CONTRACT STRUCTURE & SOURCE SELECTION QUESTIONS:

Q25. Will the VA make multiple awards?

Government Response: Yes. Multiple single-award Base IDIQ contracts may be issued on a per-CLIN/SLIN basis, immediately followed by award of a funded FFP/IDIQ Delivery Order.

Q26. What source selection methods will be used?

Government Response:

- CLINs/SLINs X001–X004 (TENS/IFC/SWD – COTS items): The VA anticipates utilizing an LPTA source selection procedure; and
- CLIN X005 (Neuromodulation – Commercial item): The VA anticipates utilizing a Best-Value Continuum (Tradeoffs Permitted) source selection procedure.

Q27. Can more than one Offeror receive award for the same CLIN?

Government Response: Yes. Any CLIN/SLIN may be awarded to more than one (1) responsible Offeror.

CONSOLIDATED GOVERNMENT CLOSING STATEMENT: The VA extends its sincere appreciation to all industry participants who responded to the FY26 Recompete ETMPM-TENS RFIs. The depth and quality of feedback provided across technical capabilities, clinical functionality, delivery logistics, regulatory compliance, and emerging technology have proven invaluable to the Government's comprehensive market research effort. Industry input directly informed refinement of the Minimum Technical Requirements (MTRs), CLIN/SLIN structure, product categorization between COTS and commercial items, technical evaluation criteria, delivery lead-time assumptions, and the acquisition strategy necessary to support a national enterprise-wide Firm-Fixed-Price (FFP) Indefinite-Delivery/Indefinite-Quantity (IDIQ) procurement. These contributions strengthened the VA's understanding of commercial market conditions under NAICS Code 334510, validated the applicability of full TAA coverage at this procurement's anticipated dollar value, confirmed the availability of domestic end-products and TAA-designated country end-products, and further ensured that the Government's requirements remain commercially practicable, technically sound, and aligned with the clinical needs of Veterans. As this requirement moves from market research phase into the presolicitation phase, all finalized solicitation documents, including the RFP, CLIN/SLIN schedules, MTRs, pricing matrices, Offeror certifications, and all other solicitation attachments will be published exclusively on SAM.gov, the Governmentwide Point of Entry (GPE) website. This ensures full transparency, equal access for all prospective offerors, and strict adherence to FAR, VAAR, and VAAM procurement integrity standards.

No additional or individualized guidance will be provided outside of the issuance of the official solicitation or the posting of an additional presolicitation notice on the GPE website. The VA remains committed to conducting a fair, open, and competitive procurement that secures FDA-cleared, high-quality electro-therapeutic devices and accessories at advantageous pricing, ensures uninterrupted supply-chain support to VA Denver Logistics Services (DLS), and strengthens the VA's nationwide delivery of safe, effective, non-opioid pain-management modalities for America's Veterans.

Prepared By:

JOHN OVERSTAKE Digitally signed by JOHN OVERSTAKE Date: 2026.08.11 20:47:56 -05'00'

John Overstake
Contract Specialist