DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval (J&A)
For
Other Than Full and Open Competition (>SAT)

Acquisition Plan Action ID: 36C257-26-AP-3660 **JOFOC:** FY26-NCO-17-1368

1. **Contracting Activity:** Department of Veterans Affairs, VISN 17, North Texas Veterans Health Care System, VA North Texas Health Care System 4500 S. Lancaster Rd., Dallas, TX 75216.
   2237: 549-26-3-081-9468

2. **Nature and/or Description of the Action Being Approved:** VISN 17 intends to issue an urgent and compelling sole-source award to Ascensia Diabetes Care US Inc. for the procurement of CONTOUR PLUS Blue Blood Glucose Test Strips and associated replacement system kits. This action is required to support an FDA-classified Class I Recall affecting glucose monitoring supplies currently in clinical circulation, necessitating immediate replacement to prevent patient harm and ensure continuity of safe diabetic care. The procurement will be executed as a Firm-Fixed Price sole-source action under the authority of RFO 6.103-1, Unusual and Compelling Urgency RFO 6.103-2, as Ascensia is the OEM and the only source capable of supplying the required FDA-cleared recall replacement materials within the time-frame necessary to mitigate risk. Items will be obtained through the mandatory NAC Contract 36F79724D0097, awarded to Ascensia Diabetes Care US Inc.

3. **Description of Supplies/Services Required to Meet the Agency's Needs:**
   VISN 17 requires the urgent procurement of CONTOUR PLUS Blue Blood Glucose Test Strips and associated replacement system kits to comply with an FDA-classified Class I Recall affecting glucose monitoring supplies. These items must be replaced immediately to mitigate significant patient safety risks.
   The required supplies include:
   • CONTOUR PLUS Blood Glucose Test Strips, 50-count (Item #00193)
   • CONTOUR PLUS System Kits, including the meter and required accessories for full recall replacement
   • Direct shipment to affected veterans, ensuring timely recall compliance and uninterrupted access to safe glucose monitoring supplies.

   This procurement will be executed under a Firm-Fixed Price arrangement with an estimated value of $[redacted] with a Period of Performance from June 3, 2026 through July 29, 2027.

These products are FDA-cleared, OEM-specific diagnostic consumables manufactured exclusively by Ascensia Diabetes Care US Inc. They are available only through the OEM's mandatory NAC Contract 36F79724D0097. No alternative products or sources can meet the technical, compatibility, or recall compliance requirements within the urgent time-frame.

4. **Statutory Authority Permitting Other than Full and Open Competition**

( ) (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per 41 USC §3304(a)(1) as implemented by RFO 6.103-1;
(X) (2) Unusual and Compelling Urgency per 41 USC §3304(a)(2) as implemented by RFO 6.103-2;
( ) (3) Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services per 41 USC §3304(a)(3) as implemented by RFO 6.103-3;
( ) (4) International Agreement per 41 USC §3304(a)(4) as implemented by RFO 6.103-4
( ) (5) Authorized or Required by Statute per 41 USC §3304(a)(5) as implemented by RFO 6.103-5;
( ) (6) National Security per 41 USC §3304(a)(6) as implemented by RFO 6.103-6;
( ) (7) Public Interest per 41 USC §3304(a)(7) as implemented by RFO 6.103-7;

5. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):** Ascensia Diabetes Care US Inc. is the OEM and sole manufacturer of the CONTOUR PLUS test strips and system kits required for replacement under the FDA Class I Recall. Items required are available on the mandatory NAC Contract, 36F79724D0097. Ascensia does not authorize third-party production, and no other vendor can supply FDA-cleared, recall-compliant items that meet the required technical and compatibility specifications. Because the recall necessitates immediate replacement of affected glucose monitoring supplies and only Ascensia can deliver the required products within the specified timeline through use of their established NAC contract, the use of the authority RFO 6.103-2 (Unusual and Compelling Urgency) is fully justified.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as possible (including whether a notice was or will be publicized as required by RFO Part 5 and, if not, which exception under RFO Part 5 applies):** Industry engagement was limited because Ascensia Diabetes Care US Inc. is the OEM and sole manufacturer of the CONTOUR PLUS test strips and system kits required for replacement under the FDA Class I Recall and all items are available on the mandatory NAC Contract , 36F79724D0097. Ascensia does not authorize third-party production, and no other vendor can supply FDA-cleared, recall-compliant items that meet the required technical and compatibility specifications. No third-party distributors, resellers, or alternative vendors exist for this test strips. All other market research results are provided in Paragraph 8. A pre-solicitation notice is not required in accordance with RFO 5.101 (b) (iv). In accordance with the JOFOC posting requirements, the approved justification will be posted within the required time frames after award, with proprietary and sensitive information redacted as appropriate.

7. **Determination by the CO that the Anticipated Cost to the Government will be Fair and Reasonable:** The anticipated cost of $[redacted] is determined to be fair and reasonable based on the pricing established under Ascensia Diabetes Care US Inc.'s NAC Contract No. 36F79724D0097. Prices awarded under the VA National Acquisition Center's FSS program are the result of negotiated, pre-determined pricing and are considered fair and reasonable.

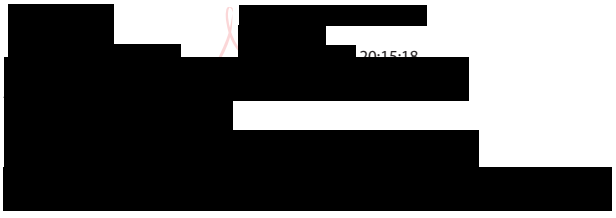
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Market research was conducted on May 28, 2026. Searches of the VA Supply Catalog, GSA Advantage, and the NAC CCST database found that only Ascensia Diabetes Care US Inc., under NAC FSS Contract 36F79724D0097, provides the required CONTOUR PLUS Blood Glucose Test Strips. An SBA search under NAICS 325413 identified no SDVOSB, VOSB, or small-business sources capable of supplying the OEM product. Ascensia confirmed they are the sole manufacturer and do not authorize third-party production. No alternative or equivalent products were identified that meet the technical requirements. Due to the urgent and compelling need to replace recalled glucose monitoring supplies without delay, Ascensia is the only source capable of meeting the requirement within the necessary timeline. Based on this information, no other vendors were identified that can meet the requirement.

9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** The requirement is driven by an urgent and compelling need to replace recalled glucose monitoring supplies. Immediate action is necessary to avoid disruption to patient care, and only the OEM can supply the required items within the needed time-frame via mandatory NAC Contract 36F79724D0097.

10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** No other sources could express interest since Ascensia is the sole manufacturer, sole intellectual-property holder, and sole authorized distributor of the Ascensia CONTOUR PLUS Blood Glucose Test Strips.

11. **A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making subsequent acquisitions for the supplies or services required**: For future requirements, the Government will continue to monitor the market to identify any new sources capable of providing compatible glucose monitoring supplies. If additional vendors or alternative solutions become available, they will be evaluated for potential competition. At this time, however, the urgent and immediate need to replace recalled items limits the opportunity for competitive sourcing.

12. **Requirements Certification:** I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.



13. Approvals in accordance with the VHAPM Part 806.3 OFOC SOP:

a. **Contracting Officer Certification (required):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

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b. **One Level Above the Contracting Officer (Required over SAT but not exceeding $900K):** I certify the justification meets requirements for other than full and open competition.

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