

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval (J&A)

For

Other Than Full and Open Competition (>\$150K)

1. **Contracting Activity:** Department of Veterans Affairs, VA Pittsburgh Healthcare System; VISN 04, NC04 Acquisitions. Requirement is for the VA Clarksburg Medical Center. Purchase Request#540-15-2-072-0053.
2. **Nature and/or Description of the Action Being Processed:** Only One Responsible Source (Sole Source) Award "The Chudy Group, LLC., d.b.a, TCGRx, who is a small business. This action will awarded as a new contract.

FAR 13.5 Test Program: This procurement is for the award of an Open Market contract, in accordance with FAR Part 13.5 Test Program for Commercial Items.

3. **Description of Supplies/Services Required to Meet the Agency's Needs:**

TCGRx Inpatient Dose Packaging System, which is made up of the following items:

1. ATP-320 Narrow – 320 canisters with unit dose packaging (includes an AVF 1 cannister QC device, \$1,900 value; Replenishment Kit, value \$3,500; and 1 case of paper & ribbon. – Est. Amt. \$154,780.15
2. ULT-100 – One ULT System: Includes: ULT Docking Station, ULT Client, Scanner, Touch Screen, BioMetric, UPS and 3 ULT-64 trays. – Est. Amt. \$19,221.11
3. APS-200 – Automatic spooler, 1 Tabletop Stand, 1 Rolling Stand and 1 case of Acrylic spools. – Est. Amt. \$5,608.04
4. Interface Charges – ATP Series – Equipment interface to pharmacy information system.
5. Implementation – ATP Series – On site Implementation and Installation Training Package.
6. CP-102 – CompletePac tabletop bagging device, All in One computer with software, sealing for foot switch, countertop island workstation, spooler arm and mount, and tethered scanner. – Est. Amt. - \$35,000

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7. Implementation – CompletePac – Onsite Software and Hardware Setup, Installation and Training. – Est. Amt. - \$5,000
8. INSP24 – InspectRx24 Vision System. Est. Amt. - \$145,000
9. Implementation – InspectRx – On Site Implementation and Training. Est. Amt. - - \$5,879.40
10. SP-INS – InspectRx Support Plan, includes Software licenses per attached Service Maintenance Agreement. Est. Amt. - \$9,040.70

Total Est. Amount - \$378,529.40.

Estimated Delivery: 60 days after receipt of Contract.

4. **Statutory Authority Permitting Other than Full and Open Competition:** *41 USC §3304(a)(1), as implemented by FAR 6.302-1.*

- (X) (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;
- () (2) Unusual and Compelling Urgency per FAR 6.302-2;
- () (3) Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services per FAR 6.302-3;
- () (4) International Agreement per FAR 6.302-4
- () (5) Authorized or Required by Statute FAR 6.302-5;
- () (6) National Security per FAR 6.302-6;
- () (7) Public Interest per FAR 6.302-7;

FAR13.5 Test Program: *The authority for applying the Commercial Test Program of FAR 13.5 is (Section 4202 of the Clinger-Cohen Act of 1996) and is implemented by for restricting competition on this procurement via FAR 13.106-1(b)(2).*

5. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):**

It is essential to purchase the above TCGx Equipment brand equipment, and other Equipment, equipped with TCGRx Software and interfaces, as a total solution, since it represents the Government's minimum need, and since they have the following unique features that are not all available in another company's similar product:

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ATP (automated tablet packaging) System:

- Biometric login for all filling and replenishment activities – Proprietary software: enables a full electronic audit of the filling and replenishment activities for all medications entered into the ATP.
- Pause Batch functionality – Proprietary software – Allows a user to pause a larger batch in mid-production to accommodate a smaller or STAT order to fulfill an urgent need for medication.
- Multitasking software – Proprietary software – Allows users on the ATP to do several tasks simultaneously (i.e., Run ATP, update drug database, query reports, change medications, etc.).
- Batch Run Flexibility – Proprietary software – Allows the user to run the 'batch' in standard output or in reverse output.
- On-Site Canister Calibration – Proprietary process – Allows the user to 'self-calibrate' canisters to accommodate medication changes – other systems require a new canister be ordered specific to that new medication.
- The ATP only interfaces with the ULT system, InspectRx and CompletePac systems (below).

Neither TCGRx or the Government is aware of any other system available that has all of the functionality listed. Others have several of the features but not all in one unit.

ULT (universal lighted tray) System:

- Proprietary product specific to TCGRx (Patented product) – allows users to fill 'non-canister' medications using pick and put to light technology. Significantly reduces error potential and greatly improves efficiency.

TCGRx is the only company that offers a universal lighted tray system.

Spooling System:

- TCGRx is the only company in the industry that provides rolling floor stands and table top stands for organization. (Several other companies offer an automated spooler, as does TCGRx).

InspectRx:

- TCGRx is the sole distributor of the InspectRx in the US.
- The InspectRx only interfaces with the TCGRx ATP system.

CompletePac:

- Proprietary software allows the ATP to interface with the CompletePac device.

The InspectRx and CompletePac are only available from TCGRx. As a point of clarification, the CompletePac system utilizes a device that creates an 'overwrap' bag whereby the individually packaged medications are wrapped in a larger bag for each patient and the associated pass time (time of administration). The device itself is available through another company, however the interface, bar code reader and label manager are not commercially available from any other company and therefore would not operate independently of the TCGRx proprietary software encode in the device.

It is also essential to have TCGRx install the above items, and provide training, due their equipment containing proprietary information, and since the Government requires a turnkey requirement for the furnishing and installing of the above referenced equipment, along with the above referenced training, as a total solution to meet their minimum need. It is also essential the Government purchase all of the above items from TCGRx, since they are the Sole Seller of the following equipment: ATP[®], InspectRx[®], CompletePac[®], and ULT (universal lighted tray) system. Therefore, only TCGRx provides all components as an end-to-end solution.

Accordingly, TCGRx is the only firm capable of providing the supplies and services described in Section III above without the Veteran's Health Administration experiencing substantial duplication of cost that could not be expected to be recovered through competition and unacceptable delays in fulfilling its requirements.

6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:

This requirement along with this Justification Memorandum, will be advertised on Fedbizopps, through the posting of a Special Notice (Notice of Intent to Sole Source), for 5 days.

7. Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:

The prices for all equipment and installation and training services, listed under Number 3 above, are deemed fair and reasonable, since TCGRx is charging their FSS price for all items on the Quote that are on their FSS Contract, which include ATP; ULT; and the Spooling System, for an open market Contract, and since per FAR Part 8.404 (d), FSS prices are deemed to be fair and reasonable, and since TCGRx is also charging the same price for all needed items, including the InspectRx and CompletePac, that they charged other entities in the Open Market, as recent as 2014.

8. Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:

The Contracting Officer has verified that the items are sold by TCGRx to the general public, and therefore, considered to be commercial items.

The Contracting Officer obtained written confirmation from TCGRx, that supported that the equipment being purchased contained, or was modified to contain the unique features, stated under Number 5 above, that are not available in another company's similar product, and that they are the sole seller of these items.

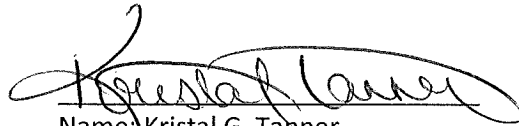
The Contracting Officer did a Google Search using the words TCGRx Dose Packaging, and only TCGRx website references were found. The Contracting Officer also did a Google Search using the words "Inpatient Pharmacy Dose Packaging System", and no related references were found.

The Contracting Officer did a search on GSA Advantage, using the words TCGRx, and only TCGRx references were found.

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The Contracting Officer was informed by the VA FSS NAC, that no Waiver is required to purchase items that are on the VA FSS, if the VA was pursuing a Sole Source Award in the Open Market.

9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** None
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** None.
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:** N/A
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.



Name: Kristal G. Tanner
Title: Chief of Pharmacy Services
Facility: Clarksburg VA Medical Center

06-02-2015
Date

- a. **Approvals in accordance with the VHAPM, Volume 6, Chapter VI: OFOC SOP. Contracting Officer's Certification (required):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

Name: Ronald Mazzei
Title: Contracting Officer
Facility: VA Pittsburgh Healthcare System, H.J. Heinz Facility

Date

- b. **Director of Contracting /Designee (Required \$150K and above):** I certify the justification meets requirements for other than full and open competition.

Name: Michael J. Lamb
NC04 Contracting – Chief of Supply Team
Facility: H.J. Heinz

Date