

PERFORMANCE WORK STATEMENT

1. GENERAL

1.1. SERVICES REQUIRED:

The Department of Veterans Affairs, Central California Health Care System (VACCHCS) requires a pharmacy contractor to prepare and deliver to VACCHCS pharmacy IV chemotherapy and other hazardous drug (HD) products as requested by the VACCHCS pharmacy on an on-demand basis. Because of the critical need of these services to be provided in a timely manner, only vendors within a 5-mile radius of the Fresno VA Medical Center need to respond to this RFQ.

2. Procedure – Contractor will send a representative to VACCHCS every business day (defined below) at approximately 7 am. The VACCHCS pharmacist will provide the contractor representative the patient specific order labels for the orders required for the day. The labels will contain all the information required by the contractor pharmacist to prepare the sterile HD medication order(s) for the VA patient(s). VA Pharmacy will provide the contractor with HD medications and diluent bags required for each label provided. VA pharmacy will also provide some non-medications supplies required to compound the order (sterile IV tubing sets, empty sterile CADD cassettes). The contractor pharmacy will prepare the HD IV medications in a USP 797/800 certified suite following all USP 797, 800, joint commission and other regulations required for HD medication preparation. The contractor will then transport the completed order(s) to the VACCHCS pharmacy. The cutoff time for delivery of the completed orders is 11:00 AM.

- 2.1. **PLACE OF PERFORMANCE:** Services shall be performed at the Contractor's facility in an USP 797/800 certified hazardous drug sterile IV preparation suite. Contractor will follow all applicable regulations and standards for safely in preparing sterile HD IV solutions.

- 2.2. **HOURS OF OPERATION:** VACCHCS pharmacy is a 24/7 operation however this service is only required during operation of the VA ambulatory infusion clinic (AIC). Normal duty hours for the AIC are 7:30 am to 4:30 pm Monday through Friday. The Contractor shall provide services on an as needed basis as scheduled by the VA Chief, Pharmacy Services. Typical Contractor hours will be Monday through Friday from 7:00 AM till the orders for the day are completed, expected to be no later than 11am. However, there may be occasion when the Contractor will be required to work outside these hours. The contractor will not be required, except in case of emergency, to furnish such services on a national holiday. VA observes the following 10 holidays:

New Year's Day	Labor Day
Martin Luther King's Birthday	Columbus Day
Washington's Birthday	Veterans Day
Memorial Day	Thanksgiving
Independence Day	Christmas

- 2.3. **DELIVERY LOCATION:** Deliveries will be made Monday through Friday (excluding holidays which are listed above) between the hours of 07:00 AM and 11:00 AM, except in the case of an emergency.

2.3.1. Transportation of the chemotherapy and other HD medications will be done by a (Department Of Transportation) D.O.T. certified driver supplied by the contractor. The contractor is responsible for maintaining compliance with all federal, state and other regulations governing transport of the medications.

2.3.2. Delivery Commitment: Time of delivery is no later than 11:00 AM except when specified by mutual agreement of the VACCHCS and the contractor.

2.4. AUTHORITY: 38 USC 8153, Health Care Resources (HCR) Sharing Authority

2.5. POLICY AND REGULATIONS: The Contractor shall comply with all applicable OSHA, USP800, Joint Commission, federal and state laws and regulations as required for performing the type of services required, including the Center for Medicare and Medicaid Services .

2.5.1. Privacy Act of 1974 (5 U.S.C. 552a) as amended

http://www.justice.gov/oip/foia_updates/Vol_XVII_4/page2.htm

2.5.2. VHA Handbook 1907.01 Health Information Management and Health Records:

http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=27911

2.6. CONTRACT COMPLIANCE: Contract Compliance and clinical performance shall be monitored by the Contracting Officer's Representative (COR).

COR: Christopher Cervantes

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(559) 225-6100 ext 5691

3. CONTRACTOR QUALIFICATIONS

3.1. LICENSING AND ACCREDITATION: The Contractor shall maintain current licenses and certificates and provide copies of such to VA upon reasonable written request.

3.1.1. Contractor shall have all licenses, permits, accreditation and certificates required by law including USP 797/800 certification for the HD preparation area and other areas of the pharmacy and facility as required by USP 797/800.

3.1.2. Contractor/Sub-Contractor shall be accredited by Centers for Prevention and Disease Control (CDC) under CLIA if contractor is engaged in interstate commerce.

3.2. CONTRACTOR PERSONNEL: Contractor shall provide the services of a fully trained, registered and licensed Pharmacist trained and certified competent in preparing IV chemotherapy and other HD preparations.

If a technician is used by the contractor to prepare the medication documentation of competency and close supervision by a pharmacist is required.

- 3.2.1. Perform the services covered by this contract, the Contractor's personnel shall be licensed in a State, Territory, or Commonwealth of the United States or the District of Columbia. Qualifications shall be subject to the review by the VA Chief of Staff and approval by the VA facility Director.
- 3.2.2. The Contractor's personnel shall be responsible and able to show evidence of reliability, ability and experience. Verified references of ability and qualifications may be accepted by the Contracting Officer to satisfy these requirements. This includes all current external and internal IV suite testing and certification for sterility and functionality of equipment and of rooms used in the preparation of chemotherapy and other HD. The contractor will provide up to date training and certification records for those staff involved in the preparation, finished product checking (Verification of all aspects of the completed product are as required in the VA order, correct medications, strengths, diluents and volume) and transport of chemotherapy and other
- 3.2.3. HD. The contractor will provide documents indicating active and current licensure of all staff involved in the transport, preparation and checking of chemotherapy and other HD.
- 3.2.4. The Contractor Pharmacist shall work and communicate effectively while remaining courteous, tactful, and understanding when interacting with others, even in potentially difficult or volatile situations.

4. CONTRATOR TASKS:

4.1. CLINICAL DUTIES:

Contractor shall compound IV chemotherapy as ordered by VA supplied order (recipe) adhering to all relevant USP 797/800 standards (<http://www.usp.org/sites/default/files/usp/document/our-work/healthcare-quality-safety/general-chapter-800.pdf>) in a timely fashion as defined by VA patient need

- 4.1.1.. Duties involved include verifying medication(s) and diluent(s) supplied by VA are not expired and do not appear to have any defects (cracked container, leaks, precipitation or other debris, cracked stoppers/lids, inappropriate color changes), verifying the medication was transported correctly between VA and the contractor, verifying supplied medications and diluents supplied by VA against the supplied label, drawing up correct quantities from the supplied medication stock, removing an equal amount of diluent from the bag to account for the volume of medication required to compound the recipe, inspecting all drawn up and finished products for precipitation, cores or other defects, labeling each product accurately, providing a final inspection and initialing each medication label.
- 4.1.2. The contractor is responsible for ensuring the medications supplied by VA are stored under conditions as recommended by the manufacturer for each medication once received, during compounding and after completion of compounding. Contractor will return any unused medication, diluent, IV tubing and CADD cassettes to VA pharmacy in the condition they were supplied to the contractor by VA pharmacy.

4.1.3. The Contractor shall affix a label to the finished product that clearly lists all ingredients contained within the product (both active and inactive), add any recommended warning or storage requirement labels (Refrigerate/warning chemotherapy) and attach to the medication container a label that notes the item's expiration date and time. Once properly labelled, they will place the finished product in a suitable transportation container (sealed plastic box or cooler) and enclose the National Drug Code (NDC), lot numbers and expiration date for all the ingredients used in the container

4.1.4. The contractor will transport the finished product to the VA pharmacy using DOT licensed transportation and following all applicable rules and precautions required to transport hazardous materials specifically IV chemotherapy products.

4.2. ADMINISTRATIVE:

Patient Safety Compliance and Reporting: Contract provider(s) shall follow all established patient safety and infection control standards of care. Contract providers(s) shall make every effort to prevent medication errors. All events related to medication errors, and other breeches of patient safety shall be reported to the COR per VA Safety Policy. As soon as practical as (but no later than 24 hours) contractor shall notify COR of incident and submit to the COR the Patient Safety Report, following up with COR as required or requested.

5. **VA PROVIDED MATERIALS:**

The VA will provide the Contractor's employee with all labels, pharmaceutical medications, diluents, IV tubing, and empty CADD cassettes.

6. **BILLING/INVOICING**

- 6.1. Invoices rendered by the contractor to VACCHCS for services furnished under this agreement, will be invoiced in full for each month in which services were performed. All payments made under this contract will be made monthly in arrears in accordance with FAR Clause 52.212-4. No advance payments will be authorized.
- 6.2. Payment made during all periods of performance of this agreement shall constitute the total cost for services rendered by the contractor, and shall not exceed the amounts specified in the "Schedule of Supplies and Services" without written request and the written approval from the Contracting Officer.
- 6.3. All invoices applicable to this agreement must be submitted no later than thirty (30) days after the end of the contract period. Any problems regarding unpaid invoices should be directed to the Contracting Officer.
- 6.4. Invoices will be submitted for services on a monthly basis. At a minimum, each invoice must contain the following: A brief written synopsis of oversight, audit or other services provided during the month, dates services were provided, name of contract person(s) who provided services, Contract Line Item Number (CLIN), quantity, unit, unit price, and total cost of services provided, contract number, and remittance address. All invoices must include the name, title and phone number of person to be notified in the event of defective invoicing. Invoices shall be submitted in

accordance with, and at the prices specified in the continuation of SF Form 1449, Schedule of Supplies and Services of this agreement.

- 6.5. The payment for any leave, including sick leave or vacation time, is the responsibility of the contractor. Periods of any absences are not paid by the VA.

Attachment 1:

USP<797>



USP797GC.pdf