

Army Pharmaceutical Returns Contract

1. This is a Non-Personal Services Contract to furnish all necessary labor, materials and equipment to process pharmaceutical products in accordance with the requirements of the attached Statement of Work (SOW).
2. Personnel rendering services are not subject, either by the contract's terms nor by the manner of its administration, to the supervision and control by the Government and its employees. Likewise, no contractor personnel shall supervise or exercise control over Government employees.
3. The contract will be administered by the U.S. Army Medical Command (MEDCOM) Central Contracting Office, Ft Sam Houston, Texas and the Delivery Orders will be issued by the applicable MEDCOM Regional Contracting Office (RCO), or approved DOD, VA and/or other Federal Agency as identified in writing by the Contracting Officer, or incorporated in this contract at a later date.
4. The RCO, DOD, VA and/or other Federal Agency will determine if an onsite or an offsite service is required, furnish the contractor any applicable Prime Vendor information and determine which invoicing procedure to use, for the MTFs in the Continental United States. MTFs outside the Continental United States, (excluding Hawaii), can only obtain an offsite service, and will be required to ship all products to the U.S. via government means for processing.
5. All percentage fees referenced in CLINs 0001AA through 0005AD are inclusive of the following:
 - All class 2-5 controlled substance disposal
 - All class 2-5 controlled substance documentation
 - All non-returnable disposal
 - All hazardous material disposal
 - All shipping costs
6. Upon request, the contractor shall provide the MEDCOM Central Contracting Office with a list of all delivery orders placed during a specific time period. The list shall not be requested more frequently than semi-annually.
7. This is a UNIQUE INDEFINITE DELIVERY/INDEFINITE QUANTITY contract, pursuant to FAR 52.216-22, INDEFINITE QUANTITY, the following minimum and maximum quantities apply:

MINIMUM (Guaranteed Quantity in Base Year Only):

One (1) Military Treatment Facility

MAXIMUM QUANTITY:

Estimated \$5,000,000.00 in fees

STATEMENT OF WORK FOR RETURN OF PHARMACEUTICAL PRODUCTS

1. GENERAL. The Contractor shall provide all facilities, supplies, equipment and labor to process for credit return and/or proper disposal of designated pharmaceuticals, including scheduled drugs 2,3,4 and 5 in accordance with the EPA Code of Federal Regulation (CFR) 40 (Protection of the Environment) and Code of Federal Regulation 49 (Department of Transportation), Occupational Safety and Health Administration (OSHA), Department of Defense (DOD), Department of the Army (DOA), Federal Drug Administration (FDA), and Drug Enforcement Agency (DEA) regulations.
2. The Contractor shall be responsible for obtaining and maintaining throughout the period of performance all required permits, certifications and/or licenses required by federal, state and local authorities (EPA, FDA and DEA). This includes any required permits and licenses to be a small and/or large hazardous waste generator and for interstate transport, storage and disposal of both hazardous and non-hazardous unserviceable items or returns (i.e. miscellaneous drugs, pharmaceuticals, schedule 2,3,4 and 5 pharmaceuticals, chemicals and chemotherapeutic drugs).
3. The contractor shall ship all designated items from the Military Treatment Facility (MTF) to the contractors facility for processing. The Government will notify the contractor and schedule a date and time when items will be available for packing/pickup as applicable.
 - 3.a. The contractor shall process all designated items by sorting and returning items which qualify for a manufacturer's credit program, for item replacement, or for destruction in accordance with applicable regulations listed in paragraph 1.
 - 3.b. The Government and the Contractor shall ensure shipments of controlled substances are covered by separate shipping documents and packing lists indicating quantities shipped. All shipping will be arranged by the contractor.
4. For items which qualify for manufacturer's return, the contractor shall:
 - 4.a. Provide a return detail report. This report shall indicate the manufacturer, contract number and applicable call number, National Drug Code (NDC), product name, lot or batch number, expiration date, quantity, weight (lbs), estimated acquisition cost and Estimated Return Value (ERV).
 - 4.b. Provide a computer generated audit trail sufficient to track items from point of origin to point of disposal.
 - 4.c. Select an appropriate courier service for transportation of returns to manufacturer and be responsible for any and all freight charges incurred.
 - 4.d. Obtain and complete all manufacturer's return authorization forms.
 - 4.e. The contractor shall base the Estimated Return Value (ERV) on the Government's purchase price using per unit of measure, e.g. bt, tu, ea, etc, as listed in the most current "Federal Supply Schedule" or "Red Book" for open market items.
5. For items which do not qualify for return to manufacturer, the Contractor shall:
 - 5.a. Assume ownership of each item as the legal EPA licensed operator and be responsible for proper storage, transportation and disposal of each item in accordance with the EPA and State Resource Conservation and Recovery Act (RCRA) guidelines.

5.b. Separately list all items for disposal on a destruction manifest. The destruction manifest shall indicate the manufacturer, contract number, product name, National Drug Code (NDC) or catalog number, quantity, weight (lbs), estimated acquisition cost, disposal date, method of destruction, location of destruction, and name of disposal facility.

5.c. Provide a separate disposal manifest for disposal of scheduled (controlled) drugs.

5.d. Provide a separate uniform hazardous waste manifest when disposing of hazardous waste items as defined by the EPA under the RCRA guidelines. The manifest shall indicate manifest tracking number, addresses and EPA identification numbers for the generator, transporter and the disposal facility, item description, quantity, weight(lbs)/volume(gls), EPA and applicable state waste codes, and signatures by the generator, transporter and the disposal facility.

5.e. Destroy all non-returnable items at an EPA licensed disposal facility.

5.f. Select an appropriate licensed courier service for transportation of non-returnable hazardous and non-hazardous items to the contractor's disposal facility and be responsible for any and all freight charges incurred.

5.g. Witness destruction of scheduled/non-scheduled drugs.

5.h. Provide copies of certificates of destruction (e.g., DEA Form 41) with the invoices for payment.

5.i. Destroy item(s) in accordance with applicable federal and state (EPA, FDA and DEA) laws and regulations. Provide disposal for scheduled CII-CV's, hazardous and non-hazardous items at no additional cost to the government.

5.j. The Contractor shall forward all copies of certificates of destruction, manifests, and reports to the COR, at the medical treatment facility turning in the pharmaceuticals.

5.k. The Contractor shall arrange payment for all services through the applicable Prime Vendor unless otherwise approved by the Contracting Officer issuing the Delivery Order. Payment terms will then be identified on the Delivery Order.

6. Special Requirements:

6.a. All Estimated Return Value credits shall be received by the facility within six(6) months of the date of service and receive 100% of the aggregate, estimated return value, on credit worthy pharmaceuticals, or the contractor shall reimburse the facility the amount they were overcharged.

6.b. Contractor shall provide the government proof of current certification by FDA and maintain certification throughout the contract performance period.

6.c. Contractor shall provide the government proof of current registration with the DEA.

6.d. Contractor shall be licensed to provide services in the Continental United States and/or Overseas areas as applicable.

6.e. Contractor shall be certified a large hazardous waste generator and provide the government copies of the EPA Hazardous Waste Generator, Transporter, and Disposal Permits.

6.f. Contractor shall be licensed and capable of complete verification of destruction of unserviceable items, including DEA schedules with inventories, manifests of incineration or other appropriate documentation.

6.g. Contractor shall comply with all Federal, State and Local laws and regulations and be completely knowledgeable of manufacturer's return policies and procedures.

6.h. Contractor shall provide all required forms, authorizations, and maintain liaison with manufacturer representatives.

Listed Below are the Army Regional Medical Commands with Military Treatment Facilities. Regional Contracting Offices (RCO), as identified by an (*) below, are only authorized to issue and administer delivery orders against this contract. Additional authorized Commands, e.g., DOD, VA and/or other Federal Agencies, if required, will be approved in accordance with paragraph 3 on page 9.

MEDICAL MATERIAL AGENCY

* Ft. Detrick, Md (USAMMA)

NORTH ATLANTIC REGIONAL MEDICAL COMMAND

* Washington D.C. (Walter Reed Army Medical Center) RCO
Ft. Benjamin Harrison, In (Hawley Army Community Hospital)
Ft. Devens, Ma (Cutler Army Community Hospital)
West Point, NY (Keller Army Community Hospital)
Ft. Monmouth, NJ (Patterson Army Community Hospital)
Ft. Dix, NJ (Walson Army Community Hospital)
Ft. George G. Meade, MD (Kimbrough Army Community Hospital)
Ft. Knox, KY (Ireland Army Community Hospital)
Ft. Bragg, NC (Womack Army Community Hospital)
Ft. Belvoir, Va (Dewitt Army Community Hospital)
Ft. Eustis, Va (Mcdonald Army Community Hospital)
Ft. Lee, Va (Kenner Army Community Hospital)
Ft. Drum, NY (Guthrie Army Community Hospital)

SOUTHEAST REGIONAL MEDICAL COMMAND

* Ft. Gordon, Ga (Dwight D. Eisenhower Army Medical Center) RCO
Ft. McClellan, Al (Noble Army Community Hospital)
Ft. Campbell, KY (Col Florence A. Blanchfield Army Community Hospital)
Ft. Jackson, SC (Moncrief Army Community Hospital)
Ft. Benning, Ga (Martin Army Community Hospital)
Ft. Stewart, Ga (BG Dean F. Winn Army Community Hospital)
Ft. Rucker, Al (Lyster Army Community Hospital)
Redstone Arsenal, Al (Fox Army Community Hospital)

GREAT PLAINS REGIONAL MEDICAL COMMAND

* Ft. Sam Houston, Tx (Brooke Army Medical Center) RCO
Aurora, Co (Fitzsimons Army Medical Center)
Ft. Hood, Tx (Darnall Army Community Hospital)
Ft. Polk, La (Bayne Jones Army community Hospital)
Ft. Sill, OK (Reynolds Army Community Hospital)
Ft. Carson, CO (US Army Community Hospital)
Ft. Riley, KS (Irwin Army Community Hospital)
Ft. Leavenworth, KS (Munson Army Community Hospital)
Ft. Leonard Wood, MO (Gen Leonard Wood Army Community Hospital)
Ft. Bliss, TX (William Beaumont Army Medical Center)

PANAMA (INCLUDED IN GREAT PLAINS RMC)

Ft. Clayton, Panama (Gorgas Army Community Hospital)

NORTHWEST REGIONAL MEDICAL COMMAND

- * Ft. Lewis, Wa (Madigan Army Medical Center), RCO
- Ft. Wainwright, Alaska (Bassett Army Community Hospital)
- Ft. Huachuca, Az (Raymond W. Bliss Army Community Hospital)
- Ft. Irwin, Ca (Weed Army Community Hospital)

PACIFIC REGIONAL MEDICAL COMMAND

- * Honolulu, Hi (Tripler Regional Medical Center) RCO
- Japan, Zama

EUROPE REGIONAL MEDICAL COMMAND

- * Landstuhl (RCO)
- Wuerzburg
- Heidelberg

<u>ITEM</u>	<u>DESCRIPTION</u>	<u>QUANTITY</u>	<u>U/I</u>	<u>U/P</u>	<u>AMOUNT</u>
01	Furnish necessary labor, materials and equipment to process pharmaceutical products in accordance with the requirements of the Statement of Work. Base Year: 1 July 1997 – 30 June 1998				
0001AA	Process On-Site at Military Facility, expired pharmaceutical products to the manufacturer for credit. Fee: 4.49% This percentage is on the estimated value of all products processed when invoicing is done direct to the Government.	1.00	LT	0.000000	0.00
0001AB	Process Off-Site at Contractors Facility, expired pharmaceutical products to the manufacturer for credit. Fee: 4.49% This percentage is on the estimated value of all products processed when invoicing is done direct to the Government.	1.00	LT	0.000000	0.00
0001AC	Process On-Site at Military Facility, expired pharmaceutical products to the manufacturer for credit. Fee: 4.88% This percentage is on the estimated value of all products processed when invoicing is done through the Prime Vendor.	1.00	LT	0.000000	0.00
0001AD	Process Off-Site at Contractors Facility, expired pharmaceutical products to the manufacturer for credit. Fee: 4.88% This percentage is on the estimated value of all products processed when invoicing is done through the Prime Vendor.	1.00	LT	0.000000	0.00
0002	Furnish necessary labor, materials and equipment to process pharmaceutical products in accordance with the requirements of the Statement of Work. 1 st Option Year: 1 July 1998 – 30 June 1999				
0002AA	Process On-Site at Military Facility, expired pharmaceutical products to the manufacturer for credit. Fee: 4.49% This percentage is on the estimated value of all products processed when invoicing is done direct to the Government.	1.00	LT	0.000000	0.00
0002AB	Process Off-Site at Contractors Facility, expired pharmaceutical products to the manufacturer for credit. Fee: 4.49% This percentage is on the estimated value of all products processed when invoicing is done direct to the Government.	1.00	LT	0.000000	0.00
0002AC	Process On-Site at Military Facility expired pharmaceutical products to the manufacturer for credit. Fee: 4.88% This percentage is on the estimated value of all products processed when invoicing is done through the Prime Vendor.	1.00	LT	0.000000	0.00

<u>ITEM</u>	<u>DESCRIPTION</u>	<u>QUANTITY</u>	<u>U/I</u>	<u>U/P</u>	<u>AMOUNT</u>
0002AD	Process Off-Site at Contractors Facility, expired pharmaceutical products to the manufacturer for credit. Fee: 4.88% This percentage is on the estimated value of all products processed when invoicing is done through the Prime Vendor.	1.00	LT	0.000000	0.00
0003	Furnish necessary labor, materials and equipment to process pharmaceutical products in accordance with the requirements of the Statement of Work. 2d Option Year: 1 July 1999 – 30 June 2000				
0003AA	Process On-Site at Military Facility expired pharmaceutical products to the manufacturer for credit. Fee: 4.49% This percentage is on the estimated value of all products processed when invoicing is done direct to the Government.	1.00	LT	0.000000	0.00
0003AB	Process Off-Site at Contractors Facility, expired pharmaceutical products to the manufacturer for credit. Fee: 4.49% This percentage is on the estimated value of all products processed when invoicing is done direct to the Government.	1.00	LT	0.000000	0.00
0003AC	Process On-Site at Military Facility, expired pharmaceutical products to the manufacturer for credit. Fee: 4.88% This percentage is on the estimated value of all products processed when invoicing is done through the Prime Vendor.	1.00	LT	0.000000	0.00