

PERFORMANCE WORK STATEMENT – CATARACT SURGERY

The Department of Veterans Affairs in Erie, Pennsylvania requires a Contractor for cataract surgery for patients at the Erie VA Medical Center, which is located at 135 East 38 Street, Erie, PA 16504. The Contractor shall provide the equipment, disposables, supplies, and technical support personnel needed to perform these services. Services will typically be scheduled for one (1) day each month with the possibility of increasing services to two times per month over the contract term at the Erie VAMC and not at the Contractor's site.

Under the authority of Public Law 104-262 and 38 U.S.C. 8153, the Contractor agrees to provide Health Care Resources in accordance with the terms and conditions stated herein, to furnish to and at the Department of Veterans Affairs Medical Center, the services and prices specified herein.

The Erie VAMC intends to award a five year contract, for one base year plus four one year option periods.

OBJECTIVES: An overview of this SOW will include the following goals and objectives. The Erie VAMC has a need to continuously utilize cataract equipment rental and outsourcing services for cataract procedures. The minimum day charge applies when the contractor makes timely delivery of the equipment and supplies to the VAMC's site on a schedule day. If the equipment and supplies are delivered to the VAMC's site and equipment is inoperable for 60 minutes or more with the result that the designated surgeon must postpone surgical procedures, the contractor will forego the charge for that surgical procedure.

SCOPE, TASKS, OR REQUIREMENTS:

A. The general scope of the work the contractor will be performing is to supply the government (Erie VAMC) with rentals of mobile cataract equipment and a trained surgical coordinator to operate the cataract equipment and assist with room turnover (as needed) on specific scheduled days designated by the VA. The trained surgical coordinator will bring the requested cataract equipment directly to the operating room at VAMC for use in operative procedures. It is expected that all requested cataract equipment meet the inspection criteria of the VAMC BioMed Department. In addition to monitoring cataract equipment before and during procedures, the surgical coordinator/technician shall serve as a consultant for all associated supplies and accessories.

B. The types of cataract equipment required by this VA facility will be determined by the VA Operating Room Physician to include the Zeiss Lumera I Microscope and appropriate handle covers, Phacoemulsification Unit, Cataract instrument trays, as well as all necessary disposables and IOL lenses as outlined below:

| TABLE 1 Cataract Service | Equipment, Instruments, & Disposables |
|---|--|
| | Phaco-Alcon Centurion (back-up machine) |
| | Zeiss Lumera I Microscope Unit Per Visit (1) |
| | Zeiss Lumera Microscope Handle Set per Visit (4) |
| | Stryker Surgistool (1) |
| | Utrata Forcep E2002 Per Visit (4) |

| TABLE 1 Cataract Service | Equipment, Instruments, & Disposables |
|---|---|
| | Vantage Instrument Set Per Visit (4) |
| | Vantage I/A Set Per Visit (4) |
| | Vantage Threaded Unipak Per Visit (4) |
| | CTR Injector Per Visit (1) |
| | Malyugin Ring Manipulator Per Visit (1) |
| | Gresishaber Lens Forceps 560.01 Per Visit (4) |
| | MST IOL Cutter Set DFH-0012, DFH 0019, and DFH-0028 Per Visit (4) |
| | Cataract Pack, V160 (Custom Pack) |
| | Centurion Phaco Pack FMS with 0.9mm Ultra, ABS Balanced 30 Bevel Up Pink Tip, Single Use, Curved I/A |
| | BSS Sterile Irrigating 500ML Bag |
| | BSS 15 ML |
| | Viscoelastic Duovisc- Viscoat.5- Provisc .55 |
| | Crescent Blade Angled Bevel Up Full |
| | Keratome Blade 2.4mm Intrepid Single Bevel |
| | Cartridge Lens, Monarch "D" SN60WF |
| | Cystotome, Side Cutting Irrigating |
| | Drape, Aperture Plastic with Pouch 16 X 24 |
| | Drape, Head and Neck |
| | Drape, Sheet Split 76 X 120 |
| | Drape, Occular Occluder 4 3/4 X 1 7/8 |
| | Shield, Eye Aluminum with Blue Garter |
| | Paracentesis Blade 15' x 3mm |
| | Cannula Anterior Chamber 27ga x 6mm |
| | Cannula Hydrodissection 27ga x 8mm |
| | Cautery Pencil 18ga |
| | Irrigating Cystotome 25ga Formed |
| | Drape, Aperature Paper 65 x 100 |
| | Drug Labels, Sterile |
| | Needle Counter 20/cnt |
| | Needle Retrobulbar 25ga x 1 1/2" Atkinson |
| | Lens, Alcon SN60WF |
| | Glove PROTEXIS PI Micro Polyisoprene Latex & Powder Free SZ 8.0 |

C. The cataract equipment must be mobile, and able to accommodate cataract surgery procedures.

D. A detailed document outlining the IOL lenses implanted with the patient specific information will be provided to the Erie VAMC's Prosthetic staff within 24 hours of completion of scheduled procedures.

E. The types of cataract surgical supplies required by the Erie VAMC will include all such supplies as specified by each surgeon as he/she deemed necessary to perform cataract procedures. The surgeon's specific equipment & case supplies are listed above.

The surgical coordinator/technician will bring in the requested equipment and supplies directly to the operating room at the VAMC for use in operative procedures. It is expected that all

requested equipment meet the inspection criteria of the VAMC BioMed Department. In addition to monitoring cataract equipment before and during procedures, the surgical coordinator/technical shall serve as a consultant for all associated supplies and accessories.

F. Approximately 6-8 cataract surgical procedures are anticipated to be scheduled on a monthly basis with the possibility of increasing services to two times per month during the term of the contract.

G. The Contractor may waive the five (5) case minimum per visit requirement in this contract, however, the Government will be billed for a minimum of eight (8) hours labor at the normal rate for the Surgical Technologist.

H. An orientation session between the Erie VAMC, the VA Ophthalmologist, and the awarded contracted vendor will be scheduled prior to the first scheduled procedure date for cataract surgeries at no additional charge. This orientation/start-up process will include a day of preparation to review the cataract equipment, supplies, patient flow, and individual roles to include the following members: the VAMC's Ophthalmologist, the VAMC's OR Nursing staff, the vendor's Surgical Coordinator and the vendor's Contract Representative. The orientation date should be scheduled within three weeks of the contract awarded date and the first cataract procedure date scheduled per the Ophthalmologist's first availability.

SELECTION CRITERIA:

A. The objective standard of acceptable performance that is to be provided by the contractor is to have a trained surgical coordinator on the premises, readily available, on the day when the procedure(s) is/are being performed. The duties of the Surgical Coordinator are to set up the equipment and monitor the performance of the equipment during each surgical procedure making any adjustments as directed by the physician. In addition, the Surgical Coordinator assists the Operating Room staff in staging supplies and turning the Operating Room between cases. The Surgical Coordinator will report directly to the operating physician and/or the Medical Director, Surgical Care while assisting with the surgical procedures.

B. The contractor should also acknowledge that the cataract surgery equipment is in good working condition and is regularly maintained. The contractor will be liable for damages should patient injury result due to equipment malfunction. The contractor must also indicate that sufficient insurance coverage is maintained for its contracted employees and for its equipment. The Contractor will maintain, for the term of this contract, fire and theft insurance coverage for the equipment. In addition, the Contractor will maintain, for the term of this agreement, general and professional liability insurance regarding their cataract services.

DELIVERY SCHEDULE:

A. On each scheduled surgical day, the contractor shall deliver the cataract equipment and disposable to the Erie VAMC the day before the surgical procedure is scheduled. The VAMC shall afford the contractor with advance notice of the number of procedures to be performed for the purpose of providing supplies. Such advance notified shall be provided no later than four working days prior to the scheduled visit.

B. Instrument trays and any other equipment that require sterilization at the Erie VA must arrive at a minimum 48 hours prior to surgical procedures. If cataract surgical procedures would be scheduled on a Monday, instrument trays and the equipment that require sterilization must

arrive at the Erie VA no later than Thursday before the scheduled procedure due to no weekend staffing in the Sterile Processing department.

C. The VAMC shall afford the contractor not less than 24 hours telephone notice of the time of the first procedure. In the event the VA surgeon is unable to arrive at the VA the day of scheduled procedures due to emergent situations, the contractor will be immediately notified and may remove the equipment from the Operating Room. As an alternative, the party giving notice may request that the VAMC and the contractor adopt an alternative time. Due to the Erie VAMC's patient commitments and the contractor's itinerary, the rights to cancel and to request a change may be exercised sparingly. The contractor may remove the cataract equipment at the conclusion of the last scheduled surgical procedure.

D. Contingency Plan: Because continuity of care is an essential part of the Erie VAMC's medical services, the Contractor shall have a contingency plan in place to be utilized in the event equipment or supplies are unavailable for scheduled surgical procedure dates in accordance with the terms and conditions of the resulting contract.

E. During the term of this SOW, the Erie VAMC shall utilize the contractor's equipment rental and outsourcing service for all cataract procedures.

GOVERNMENT- FURNISHED EQUIPMENT & GOVERNMENT-FURNISHED INFORMATION:

A. The VAMC certifies that each surgeon designated by the VA to operate the cataract equipment is trained and competent in the use of that equipment in his or her surgical capacity. The VAMC maintains a facility adequate and suitable for the operation of the equipment. VAMC shall perform or cause to be performed all medical services, supervision, diagnosis and patient care in accordance with all applicable professional standards. Further, each designated surgeon shall protect the cataract equipment from injury (including attempted modification) and shall be liable to the contractor for damages occasioned by improper use or handling, carelessness or neglect of the equipment.

B. The contractor will have a trained Surgical Coordinator on the premises, readily available, on the day when the procedure(s) is/are being performed. Only VAMC's employees, while in the performance of their official duties, and not the contractor's employees, are covered by the Federal Tort Claims Act, 28 U.S.C. §1346(b), 2671 through 2680. The contractor acknowledges that the cataract equipment is in good working condition and is regularly maintained. The contractor will be liable and indemnify the VAMC for damages should patient injury result due to equipment malfunction. The contracted vendor acknowledges that it maintains sufficient insurance coverage.

ERIE VAMC RESPONSIBILITIES:

B. The VAMC shall provide a qualified and credentialed ophthalmologist to perform all cataract surgeries to be performed.

C.

D. The VAMC staff in the Sterile Processing Department will be responsible for appropriate sterilization practices regarding all instrument trays and reusable medical equipment.

E. The VAMC will be responsible for providing a circulating Registered Nurse (RN) and a scrub nurse (RN) and/or OR Technician for each procedure.

F. The VAMC will be responsible for providing the following patient care components for each cataract surgical procedure:

- Preparing patients for procedure
- Transporting the patient
- Administering anesthesia and/or pharmaceuticals to include pre and post op eye drops as per ophthalmologist's orders
- Administration of life-saving emergency services
- Provide IOL lens information to the Contractor prior to cataract surgery within one week prior to surgical date

G. One service day will be scheduled per month by the VAMC. Specific days of service will occur during normal business hours and will be mutually agreed upon between the Erie VAMC and the Contractor. The Erie VAMC and the Contractor may negotiate additional days, if necessary. The Erie VAMC will supply the patient stretcher appropriate for cataract surgeries.

SECURITY: The Erie VAMC Optometry Service, the OR Nursing staff, or the designated surgeons shall assure that surgical consent forms have been received from all patients prior to the scheduled surgery.

PLACE OF PERFORMANCE: The work will be performed at a Government site, specifically in the Erie VAMC operating rooms and not at the contractor's site.

QUALIFICATIONS:

Technical Proficiency – The Contractor's Surgical Coordinator/Technician shall be technically proficient in the skills necessary to fulfill the government's requirements, including the ability to speak, understand, read and write English fluently. Contractor shall provide documents upon request of the CO/COR to verify current and ongoing competency, skills, and training related to the provision of care, treatment and/or services performed. Contractor shall provide verifiable evidence of all educational and training experiences including any gaps in educational history.

WORK HOURS:

The services covered by this contract shall be furnished by the Contractor as defined herein. The Contractor will not be required, except in case of emergency, to furnish such services during off duty hours as described below.

Work Hours: Monday – Friday, 7:30 a.m. – 4:00 p.m.

Federal Holidays Observed by the VAMC: New Year's Day, Martin Luther King's Birthday, President's Day, Memorial Day, Independence Day, Labor Day, Columbus Day, Veterans Day, Thanksgiving Day, and Christmas Day.

Off-Duty Hours: Friday at 4:30 p.m. through Monday – 7:30 a.m.
Monday - Friday, 4:30 p.m. – 7:30 a.m.

When a holiday falls on a Sunday, the following Monday shall be observed as a legal holiday by the U.S. Government agencies. When a holiday falls on a Saturday, the preceding Friday shall be observed as a legal holiday.

Also included would be any other day specifically declared by the President of the United States to be a National Holiday

PERSONNEL POLICY:

All Contractor employees providing services at the Erie VAMC are required to comply with the facility's immunization policy. As such, contract employees must submit proof of health care requirements per VA policy. No contract employees will be authorized to commence work until all health care requirements are met and cleared by the VA Employee Health.

CONTRACTOR'S RESPONSIBILITY:

- A. Contractor will hold and submit certificates of insurance for general liability and malpractice insurance, workmen's compensation and vehicle insurance. Under no circumstances are contractor's employees considered VAMC employees.

- B. Technician(s) must be trained on equipment operations, HIPAA, surgical procedures, intraocular lens, blood borne pathogens, OR fire safety, micro instruments, OR protocol, sterile technique, cultural diversity, and customer service.

- C. The contractor is responsible for keeping equipment in good working order and shall provide all maintenance, repairs and upgrades to the equipment as required, keeping it in optimal condition.

- D. Surgical Coordinator/Technician is subject to the same quality assurance standards as established by The Joint Commission (JC).

- E. The contractor will provide services in accordance with ethical, professional and technical standards of the health care industry

IDENTIFICATION, PARKING, SMOKING, AND VA REGULATIONS:

The contractor shall wear visible identification at all times while on the premises of the Erie VAMC. The VAMC will not invalidate or make reimbursement for parking violations or charges for the contractor under any conditions. Smoking is prohibited inside any buildings at the VAMC. Possession of weapons is prohibited. Enclosed containers, including tool kits, shall be subject to search. Violations of VA regulations may result in citation answerable in the United States (Federal) District Court, not a local district, state, or municipal court.

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CONTRACTOR PERSONNEL SECURITY REQUIREMENTS:

- A. Completion of mandatory annual training will be completed in the Talent Management System (TMS). Training completion will be verified through TMS records.

- B. All contractor employees and subcontractor employees requiring access to VA information and VA information systems shall complete the following before being granted access to VA information and its systems:

- Sign and acknowledge (electronically) understanding of and responsibilities for compliance with the *Contractor Rules of Behavior*, Appendix A relating to access to VA information and information systems through TMS.
- Successfully complete the VA Cyber Security Awareness and Rules of Behavior training and annually complete required security training electronically through TMS.
- Successfully complete the VA Privacy training and annually complete required privacy training electronically through TMS; and
- Successfully complete any additional cyber security or privacy training, as required for VA personnel with equivalent information system access *[to be defined by the VA program official and provided to the contracting officer for inclusion in the solicitation document – e.g., any role-based information security training required in accordance with NIST Special Publication 800-16, Information Technology Security Training Requirements.]*

C. The contractor shall provide to the Contracting Officer and/or the COR a copy of the training certificates and certification of signing the Contractor Rules of Behavior for each applicable employee within one week of the initiation of the contract and annually thereafter, as required.

D. Failure to complete the mandatory annual training and sign the Rules of Behavior annually, within the timeframe required, is grounds for suspension or termination of all physical or electronic access privileges and removal from work on the contract until such time as the training and documents are complete. Contractor will be required to provide substitution of personnel.

CONTRACTOR SECURITY REQUIREMENTS (HANDBOOK 6500.6):

A. Contractors, contractor personnel, subcontractors, and subcontractor personnel shall be subject to the same Federal laws, regulations, standards, and VA Directives and Handbooks as VA and VA personnel regarding information and information system security.

B. All General/Prime Contractor employees to include subcontractor personnel who require unsupervised/unescorted, logical and/or physical access to the Department of Veterans Affairs facilities, computer systems or have access to sensitive information shall be the subject of a background investigation. Contractor personnel performing work under any contract shall satisfy all requirements for appropriate security eligibility in dealing with access to sensitive information and information systems belonging to or being used on behalf of the Department of Veterans Affairs.

C. Risk levels and the Personal Identity Verification (PIV) program will determine what level of investigation is required. At a minimum a Special Agreement Check (SAC) will be required for all contractor personnel prior to performing services under any resulting contract requiring unsupervised/unescorted logical and/or physical access to the facility or having access to sensitive information.

Position Sensitivity - The position sensitivity has been designated as **Low Risk**.

Background Investigation - The level of background investigation commensurate with the required level of access is **NACI (low risk)**.

Non-citizen contract personnel appointed to low risk positions will be subject to a National Agency Check with Law Enforcement and Credit Check (**NACLC**).

D. The General/Prime Contractor shall submit to the Contracting Officer and Contracting Officer's Representative (COR) within five (5) business days after award of contract a list of personnel including subcontractor's personnel who will be performing work on the contract. The list will include a brief description of the work to be performed and degree of access to information management systems and if remote access will be required. The Contractor will update and submit the list anytime changes are made in the level of access or personnel performing work on the contract.

E. Contractors who have a current favorable background investigation conducted by another Federal agency may be accepted through reciprocity. Information substantiating a current favorable background installation will be submitted to the Contracting Officer and Contracting Officer's Representative (COR will submit this information to HR for submission/validation with the Security and Investigation Center (SIC)). Members of the SIC staff will coordinate verification of existing favorable background investigations. Furthermore contractor may utilize a private investigating agency if such agency possesses an OPM and Defense Security Service certification. A Cage Code number of the private investigating agency must be provided to the VA Office of Security and Law Enforcement/Security and Investigation Center staff.

F. The Department of Veterans Affairs in conjunction with Office of Personnel Management (OPM) at the request of the General/Prime Contractor may execute the required background investigation for contractor personnel employees to include subcontractor's personnel performing services under this contract. The General/Prime Contractor shall bear the expense of the background investigations initiated/scheduled regardless of the final adjudication determination. The VA facility will pay for investigations conducted by the Office of Personnel Management (OPM) in advance. In these instances, the General/Prime Contractor will reimburse the VA facility within 30 days of receiving the Bill of Collections from the VA. A Bill of Collections shall be generated by the VA after the investigation has been initiated/scheduled. It has been determined that this contract requires the following level of investigations and associated costs (per person): Tier I (NACI) \$381; Tier 2S (MBI) \$1730; and Tier 4S (BI) \$4,431.

G. The amounts stated above are estimated prices based on previous pricing and are subject to periodic price changes as established by the OPM in Federal Investigations Notices. Contractors shall be billed per OPM/SIC guidelines and should anticipate periodic increases. All fee schedule questions should be directed to the SIC at 501-257-4031 or vhalitsicontracting@va.gov.

H. Based on COR completion (in consultation with the Contractor) and submission of VA Form 2280 Position Risk and Sensitivity Level Designation (or replacement form), COR will determine level of background investigation required for all applicable personnel and will submit a background investigation request through HRM to the Security and Investigation Center and receive access to the Contractor Request Database (CRD) located at <https://vaww.letc.little-rock.med.va.gov/>. Upon receipt, the CRD will automatically generate an e-mail notification identifying the web site link that includes detailed instructions regarding completion of the application process and what level of background was requested.

I. For all contractor personnel requiring a National Agency Check with Written Inquiries (NACI) or higher background Investigations the contractor shall submit to the Security Investigations Center (SIC), the completed background investigation packet. Completed

packages must be submitted promptly and in sufficient time to meet the contract performance or delivery schedule. If a delay is due to the failure of the Contractor to provide a complete application as soon as practicable after contract award, this delay shall not excuse the Contractor from meeting the contract performance or delivery schedule and may result in termination for default.

J. The contractor is encouraged to have its employee immediately download the background investigation packet from http://www.va.gov/vabackground_investigations upon notification of contract award. Contract performance shall not commence prior to confirmation from the SIC that the investigative documents have been submitted. The SIC will notify the VA and the contractor upon receipt of the appropriate investigative documents. The investigation is not considered initiated until the contract employee submits his/her completed package to the SIC and it is accepted. The Contractors may be granted access prior to receiving final adjudication of the employee's background investigations.

K. The VA Security Investigations Center will notify the VA and Contractor after adjudicating the results of the background investigations received from OPM. Final adjudication results may take up to six months but are normally received within 90 days after submission.

L. The General/Prime Contractor will be responsible for the actions of individuals performing work for the VA under this contract. In the event that damages arise from work performed by contractor-provided personnel, under the auspices of this contract, the General/Prime Contractor will be responsible for all resources necessary to remedy the incident.

M. The Contractor, when notified of an unfavorable determination, will withdraw the employee from consideration from working under the contract.

N. Failure to comply with the Contractor Personnel Background Investigation Requirements section shall result in termination of the contract for default.

VA INFORMATION AND INFORMATION SYSTEM SECURITY/PRIVACY LANGUAGE:

A. A contractor/subcontractor shall request logical (technical) or physical access to VA information and VA information systems for their employees, subcontractors, and affiliates only to the extent necessary to perform the services specified in the contract, agreement, or task order.

B. All contractors, subcontractors, and third-party servicers and associates working with VA information are subject to the same investigative requirements as those of VA appointees or employees who have access to the same types of information. The level and process of background security investigations for contractors must be in accordance with VA Directive and Handbook 0710, *Personnel Suitability and Security Program*. The Office for Operations, Security, and Preparedness is responsible for these policies and procedures

C. The contractor or subcontractor must notify the Contracting Officer immediately when an employee working on a VA system or with access to VA information is reassigned or leaves the contractor or subcontractor's employ. The Contracting Officer must also be notified immediately by the contractor or subcontractor prior to an unfriendly termination.

D. The C&A requirements do not apply, and that a Security Accreditation Package is not required.

VA INFORMATION CUSTODIAL LANGUAGE:

A. Information made available to the contractor or subcontractor by VA for the performance or administration of this contract or information developed by the contractor/subcontractor in performance or administration of the contract shall be used only for those purposes and shall not be used in any other way without the prior written agreement of the VA. This clause expressly limits the contractor/subcontractor's rights to use data as described in Rights in Data - General, FAR 52.227-14(d) (1).

B. VA information should not be co-mingled, if possible, with any other data on the contractor/subcontractor's information systems or media storage systems in order to ensure VA requirements related to data protection and media sanitization can be met. If co-mingling must be allowed to meet the requirements of the business need, the contractor must ensure that VA's information is returned to the VA or destroyed in accordance with VA's sanitization requirements. VA reserves the right to conduct on-site inspections of contractor and subcontractor IT resources to ensure data security controls, separation of data and job duties, and destruction/media sanitization procedures are in compliance with VA directive requirements.

C. Prior to termination or completion of this contract, contractor/ subcontractor must not destroy information received from VA, or gathered/ created by the contractor in the course of performing this contract without prior written approval by the VA. Any data destruction done on behalf of VA by a contractor/subcontractor must be done in accordance with National Archives and Records Administration (NARA) requirements as outlined in VA Directive 6300, Records and Information Management and its Handbook 6300.1 Records Management Procedures, applicable VA Records Control Schedules, and VA Handbook 6500.1, Electronic Media Sanitization. Self-certification by the contractor that the data destruction requirements above have been met must be sent to the VA Contracting Officer within 30 days of termination of the contract.

D. The contractor/subcontractor must receive, gather, store, back up, maintain, use, disclose and dispose of VA information only in compliance with the terms of the contract and applicable Federal and VA information confidentiality and security laws, regulations and policies. If Federal or VA information confidentiality and security laws, regulations and policies become applicable to the VA information or information systems after execution of the contract, or if NIST issues or updates applicable FIPS or Special Publications (SP) after execution of this contract, the parties agree to negotiate in good faith to implement the information confidentiality and security laws, regulations and policies in this contract.

E. The contractor/subcontractor shall not make copies of VA information except as authorized and necessary to perform the terms of the agreement or to preserve electronic information stored on contractor/subcontractor electronic storage media for restoration in case any electronic equipment or data used by the contractor/subcontractor needs to be restored to an operating state. If copies are made for restoration purposes, after the restoration is complete, the copies must be appropriately destroyed.

F. If VA determines that the contractor has violated any of the information confidentiality, privacy, and security provisions of the contract, it shall be sufficient grounds for VA to withhold payment to the contractor or third party or terminate the contract for default or terminate for cause under Federal Acquisition Regulation (FAR) part 12.

G. Except for uses and disclosures of VA information authorized by this contract for performance of the contract, the contractor/subcontractor may use and disclose VA information

only in two other situations: (i) in response to a qualifying order of a court of competent jurisdiction, or (ii) with VA's prior written approval. The contractor/subcontractor must refer all requests for, demands for production of, or inquiries about, VA information and information systems to the VA contracting officer for response.

SECURITY INCIDENT INVESTIGATION:

A. The term "security incident" means an event that has, or could have, resulted in unauthorized access to, loss or damage to VA assets, or sensitive information, or an action that breaches VA security procedures. The contractor/ subcontractor shall immediately notify the COR and simultaneously, the designated ISO and Privacy Officer for the contract of any known or suspected security/privacy incidents, or any unauthorized disclosure of sensitive information, including that contained in system(s) to which the contractor/ subcontractor has access.

B. To the extent known by the contractor/subcontractor, the contractor/ subcontractor's notice to VA shall identify the information involved, the circumstances surrounding the incident (including to whom, how, when, and where the VA information or assets were placed at risk or compromised), and any other information that the contractor/subcontractor considers relevant.

LIQUIDATED DAMAGES FOR DATA BREACH:

A. Consistent with the requirements of 38 U.S.C. §5725, a contract may require access to sensitive personal information. If so, the contractor is liable to VA for liquidated damages in the event of a data breach or privacy incident involving any SPI the contractor/subcontractor processes or maintains under this contract. However, it is the policy of VA to forgo collection of liquidated damages in the event the contractor provides payment of actual damages in an amount determined to be adequate by the agency.

B. Based on the determinations of the independent risk analysis, the contractor shall be responsible for paying to the VA liquidated damages in the amount of \$37.50 per affected individual to cover the cost of providing credit protection services to affected individuals consisting of the following:

- 1) Notification;
- 2) One year of credit monitoring services consisting of automatic daily monitoring of at least 3 relevant credit bureau reports;
- 3) Data breach analysis;
- 4) Fraud resolution services, including writing dispute letters, initiating fraud alerts and credit freezes, to assist affected individuals to bring matters to resolution;
- 5) One year of identity theft insurance with \$20,000.00 coverage at \$0 deductible; and
- 6) Necessary legal expenses the subjects may incur to repair falsified or damaged credit records, histories, or financial affairs.

MEDICAL RECORDS:

A. Authorities: Contracted staff providing healthcare services to VA patients shall be considered as part of the Department Healthcare Activity and shall comply with the U.S.C.551a (Privacy Act), 38 U.S.C. 5701 (Confidentiality of claimants records), 5 U.S.C. 552 (FOIA), 38 U.S.C. 5705 (Confidentiality of Medical Quality Assurance Records) 38 U.S.C. 7332 (Confidentiality of certain medical records), Title 5 U.S.C. § 522a (Records Maintained on Individuals) as well as 45 C.F.R. Parts 160, 162, and 164 (HIPAA).

B. HIPAA: This contract and its requirements meet exception in 45 CFR 164.502(e), and do not require a BAA in order for Covered Entity to disclose Protected Health Information to: a health care provider for treatment. Based on this exception, a BAA is not required for this contract. Treatment and administrative patient records generated by this contract or provided to the Contractors by the VA are covered by the VA system of records entitled 'Patient Medical Records-VA' (24VA19). Contractor generated VA Patient records are the property of the VA and shall not be accessed, released, transferred, or destroyed except in accordance with applicable laws and regulations. Contractor shall ensure that all records pertaining to medical care and services are available for immediate transmission when requested by the VA. Records identified for review, audit, or evaluation by VA representatives and authorized federal and state officials, shall be accessed on-site during normal business hours or mailed by the Contractor at his expense.

C. Disclosure: Contractor staff may have access to patient information; however, Contractor shall obtain permission from the VA before disclosing any patient information. Subject to applicable federal confidentiality or privacy laws, the Contractor, or their designated representatives, and designated representatives of federal regulatory agencies having jurisdiction over Contractor, may have access to VA 's records, at VA's place of business on request during normal business hours, to inspect and review and make copies of such records. The penalties and liabilities for the unauthorized disclosure of VA patient information mandated by the statutes and regulations mentioned above, apply to the Contractor.

D. Release of Information: The VA shall maintain control of releasing any patient medical information and will follow policies and standards as defined, but not limited to Privacy Act requirements.

INVOICING/BILLING:

A. Invoice requirements and supporting documentation: Supporting documentation and a properly prepared invoice must be submitted no later than the 15th workday of the following month of services rendered. If the COR refuses an invoice due to incorrect billing, subsequent changes or corrections to the monthly invoice shall be resubmitted by the vendor with a corrected invoice. In addition to information required for submission of a "proper" invoice in accordance with FAR 52.212-4 (g), all invoices must include:

- Name and Address of Contractor
- Invoice Date and Invoice Number
- Contract Number and Purchase/Task Order Number
- Date of Service
- Contractor's physician(s)
- Hourly Rate
- Quantity of hours worked
- Total price

B. Vendor Electronic Invoice Submission Methods: Facsimile, e-mail, and scanned documents are not acceptable forms of submission for payment requests. Electronic form means an automated system transmitting information electronically according to the accepted electronic data transmission methods below:

1. VA's Electronic Invoice Presentment and Payment System – The FSC uses a third-party contractor, OB10, to transition vendors from paper to electronic invoice submission. Please go to this website: <http://ob10.com/us/en/veterans-affairs-us/> to begin submitting electronic invoices, free of charge.

2. The Contractor may contact FSC at the phone number or email address listed below with any questions about the e-invoicing program or OB10:

OB10 e-Invoice Setup Information: 1-877-489-6135

OB10 e-Invoice email: VA.Registration@ob10.com

FSC e-Invoice Contact Information: 1-877-353-9791

FSC e-invoice email: vafscshd@va.gov

C. Payments in full/no billing VA beneficiaries: The Contractor shall accept payment for services rendered under this contract as payment in full. VA beneficiaries shall not under any circumstances be charged nor their insurance companies charged for services rendered by the Contractor, even if VA does not pay for those services. This provision shall survive the termination or ending of the contract.

D. The Contractor shall not bill, charge, collect a deposit from, seek compensation, remuneration, or reimbursement from, or have any recourse against, any person or entity other than VA for services provided pursuant to this contract. It shall be considered fraudulent for the Contractor to bill other third party insurance sources (including Medicare) for services rendered to Veteran enrollees under this contract.