

PERFORMANCE WORK STATEMENT (PWS)
Community Based Outpatient Clinic (CBOC) Services

1. GENERAL:

- 1.1 **SERVICES REQUIRED:** The Mann-Grandstaff Veterans Affairs Medical Center (Mann-Grandstaff VAMC) “the parent facility” requires Community Based Outpatient (CBOC) services including the provision of Primary Care (PC), Comprehensive Women’s Health care, and Mental Health (MH) services in a private hospital, office or clinic environment to Veterans, primarily residing in the Stevens County Washington. The Mann-Grandstaff VAMC has operated a rural health clinic in Stevens County, Washington for the last five years. The current contract for services will expire on June 30, 2015, and the Mann-Grandstaff VAMC has identified a need to continue receiving these services for Veterans residing within Stevens County to provide primary care to these rural Veterans.

The Mann-Grandstaff VAMC as known as “parent facility” requires CBOC services providing Primary Care, and administrative support and space for Tele-Mental Health services and Tele-Health services in a private hospital, office or clinic environment to Veterans primarily residing in Stevens County, Washington.

Unless otherwise noted, hereafter within this document, singular terms such as “CBOC”, “clinic” or “Contractor’s facility” shall refer to the Stevens county Washington CBOC. Primary Care services will provide a continuum of care from prevention to diagnosis and treatment, to appropriate referral and follow-up. Those Veteran patients needing specialty of follow-up care not included in this contract shall be referred to the VA.

- 1.2 **PLACE OF PERFORMANCE:** The Mann-Grandstaff VAMC has identified a need for the CBOC facility to be located within the city limits of Colville, Washington. Please refer to physical requirements in section 68. of this document.
- 1.3 **AUTHORITY:** Authority for entering into this contract is Public Law 104-262 and Title 38 United States Code (USC) § 8153 for healthcare services to be furnished by the Contractor on behalf of the Mann-Grandstaff VA Medical Center.
- 1.4 **POLICY AND REGULATIONS:** The Contractor is required to meet VHA performance and quality criteria and standards including, but not limited to, customer satisfaction, prevention index, chronic disease index and clinical guidelines. Performance and quality standards may change during the course of the contract. New or revised quality/performance criteria or standards will be provided to the Contractor as the Mann-Grandstaff VAMC receives them. Compliance with mandated performance is required as a condition of this contract. Contractor shall comply with all relevant VA policies and procedures, including those related to quality, patient safety and performance, including, but not limited to, the following:

- 1.4.1 The care provided by the Contractor is to be patient centered, continuous, accessible, coordinated, and consistent with VA standards, including the thirteen service standards detailed in VHA Directive 2006-041, "Veterans Health Care Service Standards," dated 6/27/06 (2006-041 expired on June 30, 2011 but will still be effective until a revision or rescission is published and/or subsequent revisions thereto.
https://www1.va.gov/vhapublications/ViewPublication.asp%3Fpub_ID%3D1443&sa=U&ei=Gsy0UKPaDYPW9QSiwIH0Dw&ved=0CBIQFjAA&usg=AFQjCNH7nlCrCNId0DKfdyOe9wxpbr1mMg
- 1.4.2 Title 21 C.F.R 900.12(c) Mammography Quality Standards
<http://www.gpo.gov/fdsys/pkg/CFR-2012-title21-vol8/pdf/CFR-2012-title21-vol8-sec900-12.pdf>
- 1.4.3 Title 21 CFR "Food and Drugs" Section 1300-end.
http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&tpl=/ecfrbrowse/Title21/21tab_02.tpl
- 1.4.4 38 USC. Section 7332, regarding a timely special consent for any medical treatment for drug abuse, alcoholism or alcohol abuse, infection with the human immunodeficiency virus (HIV), or sickle cell anemia, to a Veteran with health insurance. A special consent from the Veteran is needed to allow VA to release bills and medical records associated with the treatment.
<http://www.gpo.gov/fdsys/granule/USCODE-2011-title38/USCODE-2011-title38-partV-chap73-subchapIII-sec7332/content-detail.html>
- 1.4.5 42 CFR Part 482 Conditions of Participation
<http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr;sid=aceca18b9fbe0110ffa37c08075c2b0e;rgn=div5;view=text;node=42%3A5.0.1.1.1;idno=42;cc=ecfr>
- 1.4.6 42 CFR 493.15(b) Laboratories performing waived tests:
<http://www.gpo.gov/fdsys/pkg/CFR-2003-title42-vol3/pdf/CFR-2003-title42-vol3-sec493-17.pdf>
- 1.4.7 Clinical Laboratory Improvement Amendments (CLIA):
<http://cms.hhs.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=/clia/appendc.asp>
- 1.4.8 VA Directive 1663: Health Care Resources Contracting - Buying
http://www1.va.gov/vapubs/viewPublication.asp?Pub_ID=347
- 1.4.9 VA Directive 6371, Destruction of Temporary Paper Records
http://www.va.gov/vapubs/viewPublication.asp%3Fpub_ID%3D523%26FType%3D2&sa=U&ei=xRc1UITrNNDPqwHftIHABg&ved=0CBIQFjAA&usg=AFQjCNGoA1eWwbY4L9Fn4JHbaAuEL_CvPQ

- 1.4.10 VHA Record Control Schedule 10-1
<http://www1.va.gov/vhapublications/rcs10/rcs10-1.pdf>
- 1.4.11 "Patient Medical Records-VA" (24VA19). 24VA19
<http://vaww.vhaco.va.gov/privacy/SystemofRecords.htm>.
- 1.4.12 VHA Directive 2006-041 "Veterans' Health Care Service Standards" (expired but still in effect pending revision)
https://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=1443
- 1.4.13 VHA Directive 2007-016 Coordinated Care Policy for Traveling Veterans.
http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=1562
- 1.4.14 VHA Directive 2007-033 "Telephone Service for Clinical Care,"
http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=1605
- 1.4.15 VHA Directive 2008-015 "Public Access to Automated External Defibrillators (AEDs): Deployment, Training, and Policies for use in VHA Facilities"
http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=1665
- 1.4.16 VHA Directive 2009-019, "Ordering and Reporting Test Results,"
www.va.gov/vhapublications/ViewPublication.asp?pub_ID=1864
- 1.4.17 VHA Directive 2009-038 "VHA National Dual Care Policy"
http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=2058
- 1.4.18 VHA Directive 2010-020 "Anticoagulation Management"
http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=2234
- 1.4.19 VHA Directive 2010-027 "VHA Outpatient Scheduling Processes and Procedures"
http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=2252
- 1.4.20 VHA Directive 2010-033 "Military Sexual Trauma (MST) Programming,"
http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2272
- 1.4.21 VHA Directive 2011-012 "Medication Reconciliation"
http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2390
- 1.4.22 VHA Handbook 1003.4, "VHA Patient Advocacy Program,"
http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=1303.
- 1.4.23 VHA Handbook 1100.17: National Practitioner Data Bank Reports -
http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=2135

- 1.4.24 VHA Handbook 1100.18 Reporting And Responding To State Licensing Boards -
http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=1364
- 1.4.25 VHA Handbook 1100.19 Credentialing and Privileging -
http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2818
- 1.4.26 VHA Handbook 1101.02 Primary Care Management Module.
http://www.va.gov/vhapublications/ViewPublication.asp%3Fpub_ID%3D2017&sa=U&ei=4SQ1UOLOK4SY9QTI54CADg&ved=0CBIQFjAA&usg=AFQjCNETnxx03rTASLztFU6RQCemhujcHQ
- 1.4.27 VHA Handbook 1105.03 “Mammography Program Procedures and Standards”
http://www1.va.gov/VHAPUBLICATIONS/ViewPublication.asp?pub_ID=2411
- 1.4.28 VHA handbook 1106.1 “Pathology and Laboratory Medicine Service Procedures
http://www1.va.gov/VHAPUBLICATIONS/ViewPublication.asp%3Fpub_ID%3D1779&sa=U&ei=ix42UMHnNqLC2QWRrIDIBg&ved=0CBIQFjAA&usg=AFQjCNHHT4E2tWMUkFWxfqdfqHckMQXGiw
- 1.4.29 Handbook 1330.1, "VHA Services for Women Veterans" dated 7/16/04,
<http://www1.va.gov/VHAPUBLICATIONS/publications.cfm?Pub=2>.
- 1.4.30 Handbook 1160.01 “Uniform Mental Health Services”
http://vaww1.va.gov/vhapublications/ViewPublication.asp?pub_ID=1762
- 1.4.31 VHA Handbook 5005, Part 2, Appendix G15, Licensed Pharmacist Qualification Standards.
http://www.va.gov/vapubs/viewPublication.asp?Pub_ID=512&FType=2
- 1.4.32 Privacy Act of 1974 (5 U.S.C. 552a) as amended
http://www.justice.gov/oip/foia_updates/Vol_XVII_4/page2.htm
- 1.4.33 Mann-Grandstaff VAMC “Clinic Cancellations” Memorandum 11-11-14



11 11 14 Clinic
Cancellation Policy.doc

- 1.4.34 Mann-Grandstaff VAMC “Reporting Critical Tests and Critical Tests Results”
Memorandum 113-03-14



113 03 14 Reporting
Critical Tests and Crit

1.4.35 Mann-Grandstaff VAMC “Credentialing and Privileging Policies and Procedures
Memorandum 11MSO-01-13



Numbered
Memorandum 11MSO-

1.4.36 Numbered Memorandum 00-53-12



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Rights & Responsibilit

1.4.37 VHA Handbook 1120.2 “Health Promotion and Disease Prevision Core Program
Requirements”



VHA Handbook
1120.2 Health Promc

1.4.38 Choice Card Program Information

http://vaww.hines.med.va.gov/VACAA/VA%20Choice%20Law%20-%20QuickReferenceGuide_IB10-674_Choice_Program_Internal_508.pdf

1.4.39 The Contractor must be poised to respond quickly to VA policy and procedure
changes.

1.5 DEFINITIONS/ACRONYMS:

1.5.34 ABMS: American Board of Medical Specialties

1.5.35 ACLS: Advanced Cardiac Life Support

1.5.36 ACGME: Accreditation Council for Graduate Medical Education

1.5.37 ACPE: American Council on Pharmaceutical Education

1.5.38 ACO: Administrative Contracting Officer

1.5.39 ADE: adverse drug events

1.5.40 ADPAC: Automated Data Processing Applications Coordinator

1.5.41 AED: Automatic External Defibrillator

1.5.42 AIS: Automated Information Security

1.5.43 ANA: American Nurses Association

1.5.44 AOA: American Osteopathic Association

1.5.45 ARRT: American Registry of Radiologic Technology

1.5.46 BAA: Business Associate Agreement

- 1.5.47 BI-RADS: Breast Imaging-Reporting and Data System; a quality assurance tool designed to standardize mammography reporting
- 1.5.48 BLS: Basic Life Support
- 1.5.49 BOS: Bureau of Osteopathic Specialists
- 1.5.50 CAHEA: Committee on Allied Health Education and Accreditation
- 1.5.51 CAP: College of American Pathologists
- 1.5.52 CARF: Commission on Accreditation of Rehabilitation Facilities
- 1.5.53 CBO: VA Central Billing Office.
- 1.5.54 CDC: Centers for Disease Control and Prevention
- 1.5.55 CEU: Certified Education Unit
- 1.5.56 CLIA: Clinical Laboratory Improvement Amendments
- 1.5.57 CME: Continuing Medical Education
- 1.5.58 CMS: Center for Medicare and Medicaid Services
- 1.5.59 CO: Contracting Officer
- 1.5.60 COPD: chronic obstructive pulmonary disease
- 1.5.61 COR: Contracting Officer's Representative
- 1.5.62 COS: Chief of Staff
- 1.5.63 CPA: collaborative practice agreement
- 1.5.64 CPS : Clinical Pharmacy Specialist
- 1.5.65 CPT: Current Procedural Terminology
- 1.5.66 CRNP: Certified Registered Nurse Practitioners
- 1.5.67 CSWE: The Council on Social Work Education The CSWE website is <http://www.cswe.org/>.
- 1.5.68 CPARS: Contractor Performance Assessment Reporting System
- 1.5.69 CPRS: Computerized Patient Recordkeeping System- electronic health record system used by the VA.
- 1.5.70 CVT: Clinical video telehealth
- 1.5.71 DEA: Drug Enforcement Administration
- 1.5.72 DICOM: Digital Image and Communication in Medicine
- 1.5.73 DIGMA: Drop In Group Medical Appointment
- 1.5.74 DRG: Diagnostic Related Group
- 1.5.75 DSS: Decision Support System
- 1.5.76 ECC Extended Care Center

- 1.5.77 EPRP: External Peer Review Program
- 1.5.78 FDA: Food and Drug Administration
- 1.5.79 FSMB: Federation of State Medical Boards
- 1.5.80 FTE: Full-time equivalent
- 1.5.81 HHS: Department of Health and Human Services
- 1.5.82 HCFA: HealthCare Financing Administration
- 1.5.83 HICPAC: Healthcare Infection Control Practices Advisory Committee- a federal advisory committee made up of 14 external infection control experts who provide advice and guidance to the CDC and the Secretary of HHS regarding the practice of health care infection control, strategies for surveillance and prevention and control of health care associated infections in United States health care facilities.
- 1.5.84 HPV: Human Papillomavirus
- 1.5.85 HT: Home Telehealth
- 1.5.86 ICAVL: Intersocietal Commission for the Accreditation of Vascular Laboratories
- 1.5.87 INR: International Normalized Ratio
- 1.5.88 ISO: Information Security Officer
- 1.5.89 LIP: licensed independent practitioner
- 1.5.90 MCCR: Medical Care Cost Recovery
- 1.5.91 MQSA: Mammography Quality Standards Act
- 1.5.92 MSN: Master of Science in Nursing
- 1.5.93 NACI: National Agency Check with inquiries
- 1.5.94 NCCPA: National Commission on Certification of Physician Assistants
- 1.5.95 NLN: National League for Nursing
- 1.5.96 NSQIP/CICSP: National Surgical Quality Improvement Program/Continuing Improvement in Cardiac Surgical Program
- 1.5.97 OTC: Over the Counter
- 1.5.98 PA: Physician Assistant
- 1.5.99 PACS: Picture Archiving and Communications System
- 1.5.100 PACT: Patient Aligned Care Team Background & Introduction: VA has implemented a PCMH model at all VA Primary Care sites which is referred to as PACT. This initiative supports VHA's Universal Health Care Services Plan to redesign VHA healthcare delivery through increasing access, coordination, communication, and continuity of care. PACT provides accessible, coordinated, comprehensive, patient-centered care, in team based environment including the active involvement of other clinical and non-clinical staff. PACT allows patients to have a more active role in their health care and is associated with increased quality

improvement, patient satisfaction, and a decrease in hospital costs due to fewer hospital visits and readmissions. Actions that will assist CBOC Contractor in implementing PACT model:

- 1.5.100.1 Participation in PACT national teleconferences and educational forums.
- 1.5.100.2 Teamlet staff should attend VA sponsored Transformational Learning Centers of Excellence.
- 1.5.101 Parent Facility: VAMC responsible for performance monitoring and payment for contracted CBOC services.
- 1.5.102 PCMH: patient-centered medical home
- 1.5.103 PCMM: Primary Care Management Module- a software program used to track Primary Care Clinic Veteran rosters.
- 1.5.104 PCP: Primary Care Provider
- 1.5.105 Pharm.D: Doctor of Pharmacy
- 1.5.106 POC: Point of Care Testing
- 1.5.107 PWS: Performance Work Statement
- 1.5.108 QAPI: Quality Assessment and Performance Improvement
- 1.5.109 QASP: Quality Assurance Surveillance Plan
- 1.5.110 RME: reusable medical equipment
- 1.5.111 SIC: Security Information Center
- 1.5.112 SOP (Clinical): Scope of Practice
- 1.5.113 SELF- REFERRAL: Referring patients to Contractor's facility for follow-up care. Self-referral for outpatient services at the Contractor's facility is prohibited.
- 1.5.114 SM: Secure Messaging
- 1.5.115 SMA: Shared Medical Appointments
- 1.5.116 SPD: Sterile Processing Division
- 1.5.117 SPE: Senior Procurement Executive
- 1.5.118 TJC: The Joint Commission
- 1.5.119 TIU: Text Integration Utility
- 1.5.120 TCT: Telehealth Clinical Technicians
- 1.5.121 VA: Veterans Affairs
- 1.5.122 VAMC: Veterans Affairs Medical Center
- 1.5.123 VetPro: a federal web-based credentialing program for healthcare providers.
- 1.5.124 VHA: Veterans Health Administration
- 1.5.125 VISTA: Veterans Health Information Systems and Technology Architecture

2. CBOC PACT STAFFING AND QUALIFICATIONS:

- 2.1 The Contractor shall provide personnel, either through direct hire or through subcontracting, in numbers and qualifications capable of fulfilling the requirements of the resultant contract. The Contractor shall provide a sufficient number of primary care providers so that each primary care provider has a reasonable caseload. Current caseload ratios are based on the expectation that a fulltime physician will care for approximately 1200 patients, and a midlevel provider will care for approximately 900 patients. These numbers may be adjusted, upon approval by the Government, based on the availability of exam rooms and support staff (refer to VHA Handbook 1101.02).
- 2.2 **PACT Staffing Model:** Provision of appropriate staffing resources is an essential component of the PACT model. Teams need to be staffed adequately to fully implement a robust PACT model. Staffing for the PACT model is divided into the teamlet and expanded team. The teamlet staff is responsible for managing the care for a panel of patient(s) equivalent to a full time provider (1200). The expanded PACT staff is equally important for the roles they play in the overall care of the Veteran and deliver care to multiple teamlets.
- 2.3 **Teamlet staffing:** The recommended staffing for a “teamlet” is 4.00 FTE for a full time provider panel (approximately 1200). Members of the teamlet include a primary care provider (MD, NP, PA), a RN Care Manager, a Clinical Associate (LPN/LVN, MA, HCT) and a Clerical Associate.
- 2.4 **Discipline-specific team member:** A discipline-specific team member is a health care professional designated to a PACT position in PCMM who provides direct discipline-specific patient care to more than one panel of patients, but not to all primary care patients at the facility. Examples of discipline-specific team members are: Clinical Pharmacy Specialists, Registered Dietitians, Social Workers, Primary Care-Mental Health Integration providers.
- 2.5 **Expanded Team staffing:** Other PACT members such as pharmacists, social workers, and dieticians are critical to effective and efficient PACT delivery. Expanded team members deliver care to multiple teamlets. Recommended staffing for expanded team members per teamlet includes 0.3 FTE clinical pharmacy specialist, 0.5 FTE and 0.2 FTE registered dietician. The following are recommendations for minimal staffing ratios of select discipline-specific team members:
- 2.6 At least one CPS for every three patient panels. The PACT CPS will function in the capacity of a mid-level provider functioning with an advanced scope of practice as their primary duty is to assist teamlets with comprehensive medication management. Staffing ratio may be adjusted upward locally to provide appropriate comprehensive medication management.

- 2.7 At least one anticoagulation CPS for every five patient panels, in addition to the PACT CPS. Since the staffing for anticoagulation management depends on the facility demographics for chronic anticoagulation, this equates to one anticoagulation CPS to safely manage approximately 400-500 chronic warfarin patients. Staffing ratio may be adjusted upward locally to provide appropriate pharmacy-related care to patients.
- 2.8 At least one dietitian for every five patient panels or approximately 6000 patients per dietitian. Staffing ratio may be adjusted upward locally to provide appropriate medical nutrition therapy or education.
- 2.9 At least one social worker for every two patient panels (2400 patients).

3. MINIMUM STAFFING REQUIREMENTS:

- 3.1 Sufficient support staff to conduct daily business in an orderly manner, including such functions as patient registration, financial assessments, and medical record documentation in VISTA. "Support staff" is defined as staff present in the clinic area assisting providers in the actual delivery of primary care to patients. It consists of RNs, LPNs, Medical Assistants, Health Technicians, and Medical Clerks in the clinic.
- 3.2 Staff involved in Coumadin Anticoagulation Clinics. Anticoagulation clinic management and Telephone Care for the primary care patients are also considered support staff, even if located in a separate area. Staff time dedicated to Business Office functions (means testing, registrations or billing), phlebotomy, and file room activities, or supporting non-primary care clinics (e.g., podiatry, social work, and dietary) are not considered support staff for the purposes of this definition.
- 3.3 Support staff should be in ratios to Primary Care Providers of at least three support staff for each full time equivalent Primary Care Provider. Clinical Pharmacy Services (provided by contractor or VA) The CPS shall be provided the same support staffing given to other providers on the team when they are working in the capacity of a mid-level provider. The support staffing mix should include a registered nurse care manager for every 1200 patients served by the CBOC.
- 3.4 A physician with current licensure in any state may be designated to serve as medical director to oversee and be responsible for the proper provision of covered services to enrolled patients. It is preferred that this physician be board certified in Internal Medicine or Family Practice (see qualifications).
- 3.5 Other primary care staff: Provider staff including nurse practitioners, physician assistants, registered nurses, and support staff including licensed practical nurses, medical assistants, and health technicians as deemed necessary to support the PACT concept outlined and the caseload ratios described in the PWS.

- 3.6 Clinical Pharmacy Specialists (CPS) scheduled to sufficiently provide the needs of enrolled patients functioning in the capacity of a mid-level provider (under SOP or collaborative practice agreement) as their primary duty is to assist providers with comprehensive medication management (anticoagulation and chronic primary care disease management). VA will provide CPS services as staffing is available.
- 3.7 All personnel qualifications listed in this PWS must be met.
4. CBOC STAFFING QUALIFICATIONS: Personnel provided by the contractor (including subcontractors) shall provide the education and credentials of each clinical employee by name (C.V. and/or resume acceptable).
- 4.1 CONTRACTOR'S PHYSICIAN(S) (including subcontractors)
- 4.2 Contractor's Physicians providing primary care services under the resultant contract shall demonstrate evidence of education, training, and experience in Internal Medicine or Family Practice.
- 4.3 Contractor's Physicians shall have current DEA licensure. Contractor shall provide copies of DEA cards for staff providing services under the resultant contract.
- 4.4 Contractor's Physicians performing under this contract shall be board certified or board eligible by the ABMS in Internal Medicine and/or Family Practice or the BOS in Internal Medicine and/or Family Practice
- 4.5 If selected for contract award and physician(s) proposed by the Contractor are not board certified or not eligible for board certification to provide services under this contract, the VA Chief of Staff and Director will make a determination that these physicians are well qualified and fully capable of providing high quality care for veteran patients based on the verification of their credentials related to education, training, professional experience and competency. If VA rejects a proposed physician, the Contractor is required to propose substitute acceptable personnel within five (5) calendar days.
- 4.6 Contractor's Physicians and personnel providing services under this contract must speak and write English proficiently.
- 4.7 CONTRACTOR'S ADVANCED REGISTERED NURSE PRACTITIONERS (CRNPs) (including subcontractors) must have a MSN from a NLN accredited nursing program and have ANA Certification as a Nurse Practitioner in either Adult Health or Family Practice. Authorization for prescriptive authority is required. Three years of clinical nursing experience is required. A minimum of one (1) year clinical experience as a CRNP is required (three (3) years preferred). Experience in outpatient care in a Family Medicine or Internal Medicine environment is preferred.
- 4.8 CONTRACTOR'S PHYSICIAN ASSISTANTS(including subcontractors) must meet one of the three following educational criteria: a) A bachelor's degree from a

PA training program which is certified by the CAHEA; or b) Graduation from a PA training program of at least twelve (12) months duration, which is certified by the CAHEA and a bachelor's degree in a health care occupation or health related science; or c) graduation from a PA training program of at least twelve (12) months duration which is certified by the CAHEA and a period of progressively responsible health care experience such as independent duty medical corpsman, licensed practical nurse, registered nurse, medical technologist, or medical technician. The duration of approved academic training and health care experience must total at least five (5) years. Authorization for prescriptive authority is required. PAs must be certified by the NCCPA.

- 4.9 CONTRACTOR'S RADIOLOGIC TECHNOLOGISTS (including subcontractors) must be certified in general radiologic technology by the ARRT and possess an active, current certification. Must meet any State, Territory, or Common Wealth of the United States or District of Columbia radiological technologist requirements.
- 4.10 CONTRACTOR'S TELEHEALTH SERVICES (including subcontractors) All staff employed providing telehealth related services into the clinic must be appropriately credentialed and; where necessary, privileged. All contractor staff who support telehealth services must be working within permitted licensure and scope of practice. Where non-licensed staff is supporting telehealth services provided through the contractor they must do so under the appropriate clinical supervision.
- 4.11 TCT's will serve in a generalist role to support and manage tele-health clinical encounters from a patient and provider location as the Tele-presenter and imager for Tele-health store and forward applications. This position serves as the clinic manager for real time Tele-health events, including patient education activations, provision of equipment for the Home Tele-health program, technical and scheduling activities, training, developing and monitoring improvement process for all Tele-health activities as well as other program support duties as assigned. TCTs will perform patient screening and determine the cognitive, physical, emotional and chronological development of adult and geriatric patients effecting appropriate inter/intra facility and outpatient transportation. Ensure proper operation of equipment and products by performing routine maintenance and maintaining proper records for quality reports and workload reporting. The TCT will be required to complete training as required by the Mann-Grandstaff VAMC and at the expense of the Contractor. The training will be conducted at the Mann-Grandstaff VAMC and by Talent Management System (TMS).
- 4.12 Contractor shall provide back-up staff to maintain the normal operations of the clinic during absences of staff for vacation, sickness, etc. Back-up plan must include policy on cancellation of appointments which must be consistent with VHA regulations. Contractor shall provide VA with its plan for back-up support for approval. Policy must be consistent Mann-Grandstaff VAMC policy (located in policy section).

- 4.13 Contractor shall be responsible for assuring that all persons, whether they be employees, agents, subcontractors, providers or anyone acting for or on behalf of the Contractor, are in full compliance with all applicable licensure and/or VA national certification requirements, and shall be subject to credentialing and privileging requirements by the Mann-Grandstaff VAMC. In the event a contract employee or subcontractor employee is non-compliant with these terms, the Contractor is required to remove the employee from the contract pending full compliance with licensure and/or VA national certification requirements.
- 4.14 Contractor provided personnel shall comply with The Joint Commission requirements pertaining to patient treatment, Mann-Grandstaff VAMC Quality Assurance requirements, and existing and future VA requirements.
- 4.15 Contractor shall provide the opportunity for staff to participate in continuing education/CME.
- 4.16 Mann-Grandstaff VAMC shall provide the contractor staff orientation to VA policies and procedures required for the administrative and clinical functions of the CBOC.
- 4.17 Thirty (30) days prior to the contract expiration date, the Contractor shall certify in writing to the Contracting officer that all indexes and registrations of personnel employed under this contract are valid and current and shall be renewed as necessary during the option period. Failure to provide this certification may result in a determination not to exercise the VA's renewal option. Updated copies of all licenses and registrations shall be provided to the Contracting Officer annually no later than the contract anniversary date.
5. LICENSE AND ACCREDITATION: All licenses held by the personnel working on this contract shall be full and unrestricted licenses.
- 5.1 Technical Proficiency/Board Certification: The qualifications of such personnel shall also be subject to review and approval by the VA COS. Personnel 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.
- 5.2 The Contractor must ensure that all individuals who provide services and/or supervise services at the CBOC, including individuals furnishing services under contract are qualified to provide or supervise such services.
- 5.3 Contractor staff qualifications, licenses, certifications and facility accreditation must be maintained throughout the contract period of performance. In the event that Contractor's staff is not directly employed by the treating facility, documentation must be provided to the COR to ensure adequate certification. All actions required for maintaining certification must be kept up to date at all times. Documentation

verifying current licenses, certifications and facility accreditation must be provided by the Contractor on an annual basis.

- 5.4 The Contractor is responsible for assuring that all persons, whether they be employees, agents, subcontractors, providers or anyone acting for or on behalf of the Contractor, are properly licensed at all times under the applicable state law and/or regulations of the provider's license, and shall be subject to credentialing and privileging requirements by VA.
- 5.5 The Contractor will not permit any employee to begin work at a CBOC prior to confirmation from the VA that the individual's background investigation has been reviewed and released to the Office of Personnel Management (OPM), by the Security and Investigations Center (SIC), and that credentialing and privileging requirements have been met. A copy of licenses must be provided with offer and will be updated annually. Any changes related to the providers' licensing or credentials will be reported immediately to the VA Credentialing Office. Failure to adhere to this provision may result in one or more of the following sanctions, which shall remain in effect until such time as the deficiency is corrected:
- 5.5.1 The VA will not pay the capitation payment due on behalf of an enrolled patient if service is provided or authorized by unlicensed personnel, without regard to whether such services were medically necessary and appropriate.
- 5.5.2 The VA may refer the matter to the appropriate licensing authority for action, as well as notify the patient that he/she was seen by a provider outside the scope of the contract and may pursue further action.
- 5.6 THE GOVERNMENT RESERVES THE RIGHT TO REFUSE ACCEPTANCE of Contractor, if personal or professional conduct jeopardizes patient care or interferes with the regular and ordinary operation of the facility. Breaches of conduct include intoxication or debilitation resulting from drug use, theft, patient abuse, dereliction or negligence in performing directed tasks, or other conduct resulting in formal complaints by patient or other staff members to designated Government representatives. Standards for conduct shall mirror those prescribed by current federal personnel regulations. The CO and COR shall deal with issues raised concerning contract personnel's conduct. The final arbiter on questions of acceptability is the CO.
- 5.7 All reported complaints to the COR, regarding the Contractor relations with Government employees or patients that are unable to be resolved, will reported to the CO immediately (within 24 hours). The CO shall resolve complaints received from the COR concerning Contractor relations with the Government employees or patients. Providers and staff are familiarized with the process outlined in contractor's grievance procedures as well as patient rights. The CO is final authority on validating complaints. In the event that the Contractor is involved and named in a validated patient complaint, the Government reserves the right to refuse acceptance of the services of such personnel. This does not preclude refusal in the event of incidents involving physical or verbal abuse.

- 5.8 **CREDENTIALING AND PRIVILEGING:** Credentialing and privileging will be done in accordance with the provisions of VHA Handbook 1100.19. This VHA Handbook provides updated VHA procedures regarding credentialing and privileging, to include incorporating: VHA policy concerning VetPro; the Expedited Medical Staff Appointment Process; credentialing during activation of the facility Disaster Plan; requirements for querying the FSMB; credentialing and privileging requirements for Telemedicine and remote health care; clarifications for the Summary Suspension of Privileges process in order to ensure both patient safety and practitioner rights; and the credentialing requirements for other required providers.
- 5.9 Contractor will ensure that all Physicians, Diagnostic Radiology Technologist, and any specialist that requires licensure or accreditation under this contract participate in the Credentialing and Privileging process through VHA's electronic credentialing system, "VetPro" No services are to be provided by any contract provider requiring credentialing until the parent VA Medical Executive Board and Director have granted approval. The Contractor will be provided copies of current requirements and updates as they are published.
- 5.10 Credentials and Privileges shall require renewal annually in accordance with VA and TJC requirements. Credentialed providers assigned by the Contractor to work at the CBOC shall be required to report specific patient outcome information, such as complications, to the VA. Quality improvement data provided by the Contractor and/or collected by the VA will be used to analyze individual practice patterns. The Service Chief, Ambulatory Care Service Line will utilize the data to formulate recommendations to the Medical Executive Board when clinical privileges are being considered for renewal.
- 5.11 Contractor will ensure that all Nurse Practitioners and Physician Assistants to be employed under this contract also participate in the Credentialing process through VA's VetPro, as described above. Since Nurse Practitioners and Physician Assistants are not recognized by the VA as independent practitioners, they function under a Scope of Practice (not Clinical Privileges). The credentials and scope of practice for Nurse Practitioners and Physician Assistants are reviewed at the time of the initial appointment and at least every two years thereafter by an appropriate VA discipline-specific Professional Standards Board.
- 5.12 CME/CEU: Contractor staff registered or certified by national/medical associations shall continue to meet the minimum standards for CME to remain current. CME hours shall be reported to the credentials office for tracking. These documents are required for both privileging and re privileging. Failure to provide will result in loss of privileges.
- 5.13 **TRAINING (BLS/VA MANDATORY):** Contractor staff shall complete VA mandatory training as requested and complete BLS training and keep BLS certifications current throughout the life of the contract. Copies of current certifications shall be provided to the COR prior to expiration.

6. PATIENT INFORMATION: In performance of official duties, Contractor's provider(s) have regular access to printed and electronic files containing sensitive data, which must be protected under the provisions of the Privacy Act of 1974 (5 U.S.C. 552a), and other applicable laws, Federal Regulations, Veterans Affairs statutes and policies. Contractor's provider(s) are responsible for (1) protecting that data from unauthorized release or from loss, alteration, or unauthorized deletion and (2) following all applicable regulations and instructions regarding access to computerized files, release of access codes, etc., as set out in a computer access agreement which contract provider(s) signs.
- 6.1 Contractor staff shall complete required security training and sign a VA Computer Access Agreement prior to having access to the VA computer system. Security Training will be accomplished **annually**. Contractor staff shall select training modules for Privacy Training and Information Security Training. Upon completion of the training, please fax training certificates to the Contracting Officer at **509-434-7533**.
- 6.2 In addition, if providing medical services, Contractor staff will attend CPRS training, prior to providing any patient care services, at the Mann-Grandstaff VAMC, at the Contractor's expense. Contractor staff shall document patient care in CPRS to comply with all VA and equivalent to TJC standards.
- 6.3 Rules of Behavior for Automated Information Systems: Contractor staffs having access to VA Information Systems are required to read and sign a Rules of Behavior (ROB) statement which outlines rules of behavior related to VA Automated Information Systems. The COR will provide, through the facility ISO, the Rules of Behavior to The Contractor for the respective facility. The Contractor staff are required to fax a sign copy of the ROB statement to the COR at **509-434-7189**.
7. NATIONAL PROVIDER IDENTIFICATION (NPI): All Contractors who provide billable healthcare services to VA; VHA, shall obtain a NPI as required by the Health Insurance Portability and Accountability Act (HIPPA) National Provider Identifier Final Rule, administered by the CMS. This rule establishes assignment of a 10-digit numeric identifier for Contractor staff, intended to replace the many identifiers currently assigned by various health plans. Contractor staff needs only one NPI, valid for all employers and health plans. Contractor staff must also designate their Specialties/Subspecialties by means of Taxonomy Codes on the NPI application. The NPI may be obtained via a secure website at: <https://nppes.cms.hhs.gov/NPPES>
8. CONFLICT OF INTEREST: the Contractor is responsible for identifying and communicating to the CO and COR conflicts of interest at the time of proposal and during the entirety of contract performance. At the time of proposal, the Contractor shall provide a statement which describes, in a concise manner, all relevant facts concerning any past, present, or currently planned interest (financial, contractual, organizational, or otherwise) or actual or potential organizational conflicts of interest

relating to the services to be provided. The Contractor shall also provide statements containing the same information for any identified consultants or sub-Contractors who shall provide services. The Contractor must also provide relevant facts that show how it's organizational and/or management system or other actions would avoid or mitigate any actual or potential organizational conflicts of interest.

9. CITIZENSHIP RELATED REQUIREMENTS: While performing services for the Department of Veterans Affairs, the Contractor shall not knowingly employ, contract or subcontract with an illegal alien; foreign national non-immigrant who is in violation their status, as a result of their failure to maintain or comply with the terms and conditions of their admission into the United States. **The Contractor must return a signed certification at the time of proposal that the Contractor shall comply with any and all legal provisions contained in the Immigration and Nationality Act of 1952, As Amended; its related laws and regulations that are enforced by Homeland Security, Immigration and Customs Enforcement and the U.S Department of Labor as these may relate to non-immigrant foreign nationals working under contract or subcontract for the Contractor while providing services to the VA.** This certification concerns a matter within the jurisdiction of an agency of the United States and the making of a false, fictitious, or fraudulent certification may render the maker subject to prosecution under 18 U.S.C. 1001 and is applicable to the entire period of performance.
10. ANNUAL OFFICE OF INSPECTOR GENERAL (OIG) STATEMENT: In accordance with The Health Insurance Portability and Accountability Act (HIPAA) and the Balanced Budget Act (BBA) of 1977, the VA OIG has established a list of parties and entities excluded from Federal health care programs. Specifically, the listed parties and entities may not receive Federal Health Care program payments due to fraud and/or abuse of the Medicare and Medicaid programs.
 - 10.1 Therefore, all Contractors shall review the OIG List of Excluded Individuals/Entities on the OIG web site at www.hhs.gov/oig to ensure that the proposed Contract staff and/or firm(s) are not listed. Contractors should note that any excluded individual or entity that submits a claim for reimbursement to a Federal health care program, or causes such a claim to be submitted, may be subject to a Civil Monetary Penalty (CMP) for each item or service furnished during a period that the person or entity was excluded and may also be subject to treble damages for the amount claimed for each item or service. CMP's may also be imposed against the Contract staff and entities that employ or enter into contracts with excluded individuals or entities to provide items or services to Federal program beneficiaries.
 - 10.2 By submitting their proposal, the Contractor certifies that the OIG List of Excluded Individuals/Entities have been reviewed and that the Contractor and/or firm is/are not listed as of the date the offer/bid was signed.
11. NON-PERSONAL SERVICES: The parties agree that the Contractor, contract staff, agents and sub-Contractors shall not be considered VA employees for any purpose. All individuals who provide services under this resultant contract and are not employees of the Contractor will be regarded as subcontractors. The Contractor shall

be responsible and accountable for the quality of care delivered by any and all of its subcontractors. The Contractor shall be responsible for strict compliance of all contract terms and conditions without regard to who provides the service.

12. CONTRACT PERSONNEL: The Contractor shall be responsible for protecting all Contractor personnel furnishing services. To carry out this responsibility, the Contractor shall provide or certify that the following is provided for all contract staff providing services under the resultant contract:

- Workers' compensation
- Professional liability insurance
- Health examinations
- Income tax withholding, and
- Social security payments

12.1. CONTRACTOR AND CONTRACT STAFF SHALL NOT PERFORM INHERENTLY

GOVERNMENTAL FUNCTIONS. This includes, but is not limited to, determination of agency policy, determination of Federal program priorities for budget requests, direction and control of government employees, selection or non-selection of individuals for Federal Government employment including the interviewing of individuals for employment, approval of position descriptions and performance standards for Federal employees, approving any contractual documents, approval of Federal licensing actions and inspections, and/or determination of budget policy, guidance, and strategy.

12.2. TORT: The Federal Tort Claims Act does not cover Contract staff. When a contract staff member has been identified as a provider in a tort claim, The Contractor's staff member shall notify the Contractor's legal counsel and/or insurance carrier. Any settlement or judgment arising from a Contractor's provider's action or non-action is the responsibility of The Contractor and/or insurance carrier.

13. HOURS OF OPERATION:

13.1. BUSINESS HOURS: Services shall be available from the contractor Monday through Friday, 8:00 AM to 4:30 PM except from federal holidays and weekends. Federal holidays are outlined in the next paragraph. Each clinic may be required to provide extended hours to eliminate any wait lists, backlogs, or access problems at no additional costs to the VA.

13.1.1. The Contractor may elect to have evening and weekend hours to enhance Veterans access as appropriated but without increased costs to the VA.

13.2 FEDERAL HOLIDAYS: The following holidays are observed by the Department of Veterans Affairs:

1. New Year's Day
2. Washington's Birthday
3. Martin Luther King's Birthday
4. Memorial Day
5. Independence Day
6. Labor Day
7. Columbus Day
8. Veterans Day
9. Thanksgiving
10. Christmas
11. Any day specifically declared by the President of the United States to be a national holiday.

- 13.2.1 The Contractor shall be required to obtain approval from the COR prior to closing the CBOC for any reason during the business hours of 8:00 AM through 4:30 PM Monday through Friday that are not federal holidays. The Contractor shall be required to obtain approval from the Contracting Officer at least one week in advance prior to closing the CBOC for any reason if the closure will be for a whole day. Any clinic that is cancelled by the provider must adhere to the Mann-Grandstaff VAMC Memorandum 11-11-14 dated October 7, 2014 (or subsequent revisions).

14. CONTRACTOR RESPONSIBILITIES

- 14.1. GENERAL: Contractor performing Primary Care services shall provide a continuum of care from prevention to diagnosis and treatment, to appropriate referral and follow-up.
- 14.2. Those patients needing specialty or follow-up care shall be referred to VA.
- 14.3. Contractor's CBOC must have the necessary professional medical staff, diagnostic testing and treatment capability, and referral arrangements needed to ensure continuity of health care.
- 14.4. If requested or required by either the Government or the Contractor, the Contractor will work closely with the CO and COR to modify the contract expeditiously, in order to limit the impact on the clinic's veterans and ensure consistency with the care provided by the VA's other Primary Care Clinics.
- 14.5. Standard of Practice: Contractor shall be responsible for meeting or exceeding VA and TJC (or equivalent) standards.
- 14.6. PACT PILLARS AND FOUNDATIONS: The PACT delivery model is predicated on a foundation of delivering care that is patient centered, team based and continuously striving for improvement. A systems redesign approach has been developed to help teams focus on important components of the model including

Patient Centered Care, Access, Care Management and Coordination as well as redesigning the team and work.

14.7. ENHANCE PATIENT CENTERED CARE: Establishing a patient centered practice environment and philosophy as a core principle of PACT requires a knowledgeable staff and an engaged, activated patient and family. Contractor CBOC Clinic staff shall be required to complete the following tasks in order to begin to implement Patient Centered Care:

- 14.7.1. Engage the patient/family in self-management and personal goal setting
- 14.7.2. Provide education pertinent to care needs and document the provision of that education.
- 14.7.3. Provide support on site to enroll patients in MyHealtheVet & Secure Messaging
- 14.7.4. Ensure staff is trained in self-management techniques, motivational interviewing, shared decision making as made available by the Veterans Affairs (VA).
- 14.7.5. CBOC patients will be notified of all normal test results within 14 days.

14.8. ENHANCE ACCESS TO CARE: PACT strives for superb access to care in all venues including face to face and virtual care. Achievement of the following list of requirements will assist the Contractor's CBOC in achieving superb access for Veterans.

- 14.8.1. Face to Face Visit Access:
 - 14.8.1.1 Provide same day access for patients
 - 14.8.1.2 Increase (establish) group visits and shared medical appointments for example, diabetes group and blood pressure groups, nutrition groups, pain management groups, etc.
- 14.8.2. Virtual Access
 - 14.8.2.1. Telephones:
 - 14.8.2.1.1. Phones should be answered by a "live" person with a focus on achieving first call resolution. First call resolution is taking care of the Veteran's issue/request during that call. This approach requires thoughtful planning and strategy.
 - 14.8.2.1.2. Increase telephone care delivered to veterans by PACT members.
 - 14.8.2.2. Automated Patient Kiosks: Grandstaff VAMC is moving towards using patient check in. Contractor shall provide staff assistance and training for veterans as needed to ensure program success and to rescue angst of new technology for patients as these systems are installed and utilized. Kiosks will require network drops in the clinic waiting area

which will be at the expense of the Contractor. VA will provide the Kiosks.

14.8.2.3. MyHealtheVet (MHV):

14.8.2.3.1. Provide support to enroll into MyHealtheVet

14.8.2.3.2. Increase enrollees in MHV and Secure Messaging

14.8.2.4. Secure Messaging (SM):

14.8.2.4.1. Encourage & educate patients to use SM as a non-synchronous mode of communication

14.8.2.4.2. Establish SM as a communication method in clinic

14.8.2.4.3. Increase Veteran participation

14.8.2.5. Telemedicine & Telehealth

14.8.2.5.1. Improve access to scarce medical services via telemedicine as deemed appropriate by Mann-Grandstaff VAMC.

14.8.2.5.2. Increase Veteran enrollment in telehealth modalities available at Mann-Grandstaff VAMC.

14.9. ENHANCE CARE MANAGEMENT & COORDINATION OF CARE: Improving systems and processes associated with critical patient transitions, managing populations of patients and patients at high risk has proven to have a positive impact on quality, patient satisfaction and utilization of high cost services such as acute inpatient admissions, skilled nursing facility stays, and emergency department visits. CBOC staff shall focus on the following actions to achieve improvements.

14.9.1. Improve Critical Transitions Processes:

14.9.1.1. Inpatient to Outpatient:

14.9.1.1.1. Develop systems to identify admitted primary care patients.

14.9.1.1.2. Provide follow up care either by face to face visit or telephone visit within 2 days post discharge.

14.9.1.1.3. Document the follow up care in computerized patient Record System (CPRS) delivered and communicate among the team.

14.9.2. Enhance Primary Care to Specialty Care Interface

14.9.2.1. Participate in electronic virtual consults & SCAN ECHO as available.

14.9.2.2. Develop resource listing of specialty care points of contact for nursing and medical care.

14.9.2.3. Participate in Mann-Grandstaff VAMC sponsored medical educational activities to enhance networking with specialty staff

14.9.3. Enhance VA & Community Interfaces in Caring for Veterans

14.9.3.1. Develop a list of community points of contact

14.9.3.2. Develop mutually agreeable interface systems with community facilities and providers

- 14.9.4. Improve Systems for Managing the Care of Patient Populations
 - 14.9.4.1. Enhance Management of Patients with Chronic Illness
 - 14.9.4.2. Identify patients with suboptimal chronic disease indices from VHA databases (registries)
 - 14.9.4.3. Develop and implement plans including staff roles and responsibilities in addressing care needs. Include all team members in delivering care as license allows. Use face to face and virtual care delivery methods such as pharmacy/nurse clinics, telephone clinic etc.
- 14.9.5. Enhance Health Promotion & Disease Prevention Focus in Care Delivery
 - 14.9.5.1. Identify patients with preventive care needs from VHA databases (registries)
 - 14.9.5.2. Develop & implement plans including staff roles and responsibilities in addressing care needs. Include all team members in delivering care as license allows. Use face to face and virtual care delivery methods such as pharmacy/nurse clinics, telephone clinic etc.
- 14.9.6. Enhance Management of High Risk Veterans: frequent emergency department visits, frequent inpatient admissions for ambulatory sensitive conditions, and severely injured/disabled, frail elderly.
 - 14.9.6.1. Identify patients with preventive care needs from VHA databases (registries)
 - 14.9.6.2. Develop plans including staff roles and responsibilities in addressing care needs. Include all team members in delivering care as license allows. Use face to face and virtual care delivery methods such as pharmacy/nurse clinics, telephone clinic etc.
- 14.9.7. Improve Practice Design & Flow to Enhance Work Efficiency & Care Delivery:
 - 14.9.7.1. Maximize functioning of all team members through role and task clarification for work flow processes.
 - 14.9.7.2. Develop a plan to improve work flow process for visit or virtual care.
 - 14.9.7.3. Conduct daily teamlet huddles to focus on operational needs for that day
 - 14.9.7.4. Conduct weekly team meeting to focus on systems and process improvements, review and use data to monitor processes, etc.
- 14.9.8. See Attachment C on PACT roles.

15. DIRECT PATIENT CARE: Contractor's CBOC shall provide Primary Care services supporting a continuum of care from prevention to diagnosis and treatment, to appropriate referral and follow-up. Simple to Moderately Complex workload that can be appropriately managed in primary care and mental health are identified below:

Hypertension
Ischemic Heart Disease
Hypercholesterolemia

Depression
Anxiety
Degenerative Arthritis

Congestive Heart Failure	Respiratory Infection
Cerebral Vascular Disease	Chronic Obstructive Pulmonary Disease (COPD)
Peripheral Vascular Disease	Urinary Tract Infection
Diabetes Mellitus	Common Dermatological Conditions
Chronic Pain	Acute Wound Management
Gastric Disease	Skin Ulcers (Stasis and Dermal)
Anemia	Male Genitourinary (GU) Issues
Stable Chronic Hepatic Insufficiency	Cervical Cancer screening
Constipation	Osteoporosis
Common otic and optic conditions	Preventative Medicine Screening and Procedures
Basic diagnostic evaluation and tests for infertility	Cervical Cancer Screening
Breast Cancer Screening	Pharmacology in Pregnancy & Lactation
Evaluation & Treatment of Vaginitis	Evaluation of Abnormal Uterine Bleeding
Amenorrhea/Menstrual Disorders	Menopause Symptom Management
Diagnosis of pregnancy and initial screening tests	Crisis Intervention; Evaluate psychosocial
Evaluation and management of Acute and Chronic Pelvic Pain	well being and risks including issues regarding abuse
Recognition and management of Postpartum	Violence in women & Intimate Partner Violence Screening
Depression and Postpartum Blues	-Personal and physical abuse
Evaluation and management of Breast Symptoms	-Verbal/Psychological abuse
(Mass, Fibrocystic Breast Disease, Mastalgia,	Preconception Counseling
Nipple Discharge Mastitis, Galactorrhea,	Assessment of abnormal cervical pathology
Mastodynia)	

15.1. Contractor shall schedule initial or follow-up visits to primary care providers at the Contractor's CBOC site.

15.2. Contractor shall obtain a complete history and physical examination which must be performed on the first visit other than in exceptional circumstances. Cervical cancer screening is not required on first visit but must be accomplished within VA screening guidelines, documenting any outside results and meeting guidelines for a new patient within the guideline time limits. **This is a Vesting CPT Code visit.**

15.2.1 **Exceptional circumstances** means the Veteran is seen for his/her first visit as an emergency for a shorter duration visit. In this case, a complete history and physical examination must be completed within 72 hours.

- 15.3 The complete history and physical examination shall be performed with documentation of Veteran problems via the on-line Problem List option in VISTA/CPRS computer system which shall be updated as needed on each subsequent visit.
- 15.4 The Problem List shall be updated by the third visit and all subsequent visits, and include all significant diagnoses, procedures, drug allergies, and medications.
- 15.5 Contractor shall ensure within twelve (12) months of the last visit, the Veteran receives a visit which justifies any of the ***Vesting CPT Codes***.
- 15.6 Contractor shall schedule office, telephone and telehealth visits with other health care providers including nurses, physician extenders, CPSs, or dietitians for the purposes of monitoring or preventing disease and providing patients with information and/or skills so they can participate in decision-making and self-care.
- 15.7 Contractor shall ensure phone contacts with patients and primary care providers or their designee.
16. INPATIENT CARE:
- 16.1 Should elective inpatient care be deemed necessary by the Contractor, the Contractor shall contact the Transfer Nurse at (509) 434-7665 to schedule admission.
- 16.2 If the contract licensed individual practitioner (LIP) physically evaluates an assigned patient at the CBOC and determines the patient is in need of emergent/urgent care such that time and distance are too great to come to Spokane VA , then the contract provider needs to enter a consult for Non-VA Care Transfer Request VA to Non VA ED. In addition, a brief electronic Progress Note shall be entered immediately, and electronically signed, outlining the reason for the emergent referral for care. The LIP is to notify the transfer nurse at (509) 434-7665 of the patient.
- 16.3 All emergently dispositioned patients via telephone or in clinic (that are not physically evaluated by a licensed independent practitioner), shall be advised by the clinician/nurse he/she may be financially liable for any costs incurred based upon this disposition as the emergency referral is based upon clinical need only and does not constitute VA authorization for emergency treatment in a non-VA facility. If the clinician determines patient's condition is such that treatment at and travel to a VA facility is acceptable but is refused by the patient, the contractor must advise the patient as to the financial liability of his/her decision. All patients recommended for emergency disposition by the authorized clinician must be documented in the patient record and include statement that patient was advised of financial responsibility and advised VA may not cover emergency care at a non-VA facility. The veteran, or agent for the veteran, should be advised contact the VA

Medical Center Administrative Officer of the Day (AOD) at 509-434-7010 as soon as possible. In all cases the contractor will immediately document the occurrence in the assigned patient's medical record with a note. The documentation will include appropriate medically indicated disposition and follow-up. The contractor will notify the Medical Center's designee of such events (AOD).

17 AMBULANCE SERVICES:

17.1 If an ambulance is required to transport a patient to a local hospital for emergency care, the Contractor shall contact a local ambulance company and the LIP enter a travel consult in CPRS on behalf of the patient.

17.2 The ambulance company shall be instructed to bill the VA for these services at the following address:

Patient Transportation Office
Grand-staff VAMC
4815 N. Assembly St.
Spokane, WA 99205

If a patient is actually physically evaluated at the CBOC and the provider determines the patient is in need of emergent/urgent care such that time and distance are too great to come to Spokane VA, then the provider needs to enter a consult for Non-VA Care Transfer Request VA to Non VA emergency department (ED). This also obligates the VA for the ED care and inpatient care if deemed necessary.

The Non-VA Care Transfer Request VA to Non VA emergency department (ED) form is not to be completed unless the patient was actually evaluated by a licensed independent practitioner and deemed by that LIP to need emergent or urgent care.

If the CBOC calls an ambulance to transport a patient to the ED from the CBOC, [the provider is required to enter a travel consult on behalf of the veteran.](#)

18. LABORATORY SERVICES:

18.1 Lab Requirements: The Contractor's Lab shall meet all regulatory agency requirements and have available for review and display all required licenses and permits mandated by state accreditations.

18.1.1 Contractor shall follow the Clinical Laboratory Improvement Act (CLIA) and VHA regulations in regards to any site testing (see attachment one). Contractor shall obtain and keep current the required CLIA certification. If the Contractor's CLIA certification undergoes a conditional status or is terminated, the Contractor shall inform the Contracting Officer Representative (COR). The Contractor shall provide a report of laboratory operations at time inspections and the findings. If applicable personnel, that affected the certification status. The Contractor is expected to have

initiated or completed corrective actions needed to reestablish within 60 day period.

18.1.2 If plant or equipment defects or malfunctions will prohibit laboratory operations for more than 24 hours, the COR must be notified. The Contractor shall establish a contingency plan to meet the needs of the patients that require laboratory services during this time frame.

18.1.3 Lab work must be accomplished in a laboratory which has been approved by the College of American Pathologists (CAP) (see attachment A) or equivalent.

18.2 Contractor shall also meet or exceed VHA Handbook 1106.1, "Pathology and Laboratory Medicine Service Procedures and Standards", which can be viewed on attachment one, "Policies and Regulations", which will include proficiency testing. Contractor must be enrolled in proficiency testing surveys for each analyte reported. Survey enrollment and results shall be made available for VA review upon request.

18.3 All labs, with the exception of stat labs and on site Hemocult testing shall be analyzed by the Mann-Grandstaff VA medical Center. Contractor shall be responsible for collection and handling of lab specimens in accordance with the instructions in the "Spokane Laboratory Users Guide 2013-Updated" found on the Spokane SharePoint under Laboratory SharePoint under Laboratory Service, Shared documents and also included in attachment two. Current instructions for both routine and non-routine tests are incorporated in these guidelines. The Contractor shall process specimens for shipment to the Mann-Grandstaff VA Medical Center in accordance with Laboratory instruction to ensure integrity of the specimen is maintained. If required, frozen specimens shall be shipped on Contractor supplied dry ice. All supplies required for specimen collection, storage and packaging shall be borne by the Contractor and approved by the Mann-Grandstaff VA medical Center prior to Utilization. The VA will provide transportation of lab specimens from the contracted site to the Mann-Grandstaff VA Medical Center.

18.3.1 For any stat lab tests, the Contractor shall provide specimen processing and analysis and the quickest turn-around time for lab results. If the Stat lab services provided under this contract are not on-site, the Contractor shall be responsible for transporting lab samples to the remote site in a manner that maintains the integrity of the specimen. The costs of analytical testing fees are the responsibility of the Contractor. The Contractor shall enter lab results and any on site Hemocult test results in the patient electronic record via a Progress Notes in the VA's electronic medical record (CPRS).

18.3.2 All Critical INR (>3.9) results for Spokane Anticoagulation Clinic patients (performed out of Spokane VA Laboratory) will be immediately called to the Anticoagulation (AC) Clinic at 509-663-7615. Stat PT/INR results

will be processed and called into the VA AC Clinic before 4:00 p.m. on the same day of the drawing and testing.

19. Patients who are under VA specialty care and not enrolled in the contracted clinic shall have access to phlebotomy services and shipping of their specimens to the VA Medical Center. Blood draws shall be for individually specified patients for specialty care related to transplant, oncology, hepatitis C, or other specialty care as determined necessary and shall be coordinated on a case by case basis by treating physician and clinic involved thru the Chief of Primary Care Service. The Contractor shall obtain and prepare specimens according to available instructions to maintain the appropriate temperature and ensure safe handling of the specimen. Contractor shall label laboratory refrigerator for "Laboratory Specimens only". The following is a list of specific laboratory supplies needed for COMMUNITY PARTNERSHIPS and is at the contractor's expense to provide. The specific tubes listed are tubes that our instrumentation can easily accommodate; any deviation from this list of supplies must be approved by supervisory staff at the Mann-Grandstaff VAMC Laboratory. Requests to deviate from supply list must be submitted in writing to the Contracting Officer for review and approval.

20. Supplies Ordered/Supplied by Contractor:

- (1) BD Vacutainer Tubes:
- (2) Vacutainer Tubes:
- (3) K2 EDTA w/Hemoguard closure: 13x100 4.0 ml draw item #
367864
(lavender top tubes)
- (4) SST plus tubes 8.5 ml draw item # 367988
(16x100)* (large
(5) Marbled top tube)
- (6) SST plus tubes (13x75)* 3.5 ml draw item # 367983
(gold top tube)
- (7) PST plus tubes (13x75)* 3.0 ml draw item # 367960
(light green top tubes)
- (8) Sodium Citrate 2.7 ml draw item # 363083
(blue top tube for coags)
- (9) Clot tube (163x100) (Plain 10 ml draw item # 366430
Red – no gel tube)
- (10) Swabs: Copan LQ Stuart (double swab) item#139c
- (11) Transport Tube:
Starstedt (13x75mm) part # 55.525

(Polypropylene test tubes)

- (12) Hemocult:
Hemocult II Dispensapak, 100 kits per pack (Hemocult Sensa Dispensapak Item 64130 directly from Beckman Coulter)
- (13) Ova and parasite:
- (14) Para Pak Pink & Gray, Zn-PVA item # 301012
- (15) Specimen cups (urine, stool):
Starplex leak proof vials, 120 ml item # B1202-10
- (16) 24 hour urine containers:
Fisherbrand Amber colored container, item # 14-375-248
3000ml capacity,
- (17) Specimen Bags:
Single patient specimen, two part bag:
Fisherbrand Saf-T-Zip bags, 6x9 inches cat# 22-043196
- (18) Specimen Labels for supplied Zebra printer:
10 part 2.375 x 1 inch core item # 83987
By: Platinum Code Labels
- (19) Supplies provided by the Government:
Vacutainer Tubes: Dark Green top (heparin) tubes,
Yellow top (ACD) tubes,
Royal Blue tubes (either EDTA or no additive),
UA C&S transport tubes
- (20) Histopathology/Cytology:
10% Buffered Formalin collection vials
- (21) ThinPrep® or SurePath™ Collection vials, brushes and spatulas.

21. Community Partnership Specimen Processing: The following is an overview of specimen processing required by COMMUNITY PARTNERSHIP staff. Detailed procedures are supplied to Community Partnership staff for collection, processing and packaging specimens for transport.

- (1) All PST and SST tubes (noted with * above) are to be centrifuged at the COMMUNITY PARTNERSHIP prior to transport to VAMC. Centrifugation must occur between 15 minutes and 1 hour post collection for optimal specimen preservation. Centrifugation must be performed in a horizontal (swinging head) centrifuge. No other centrifugation method is acceptable or approved by the Government. Such centrifugation must have a speed/rotor

sufficient to achieve 1100 RCF and sufficient specimen separation after approximately 8-10 minutes of centrifugation.

- (2) All K2 EDTA blood specimens are submitted without centrifugation.
 - (3) Sodium Citrate tube for coagulation studies are to be centrifuged and submitted frozen, unless special processing instructions are noted.
 - (4) All blood specimens for single patient are to be in one zippered biohazard bag. Urine specimens for each patient are submitted in separate zippered biohazard bag.
 - (5) Surgical Pathology and/or Cytology requisitions must be submitted in the paper form with two patient identifiers and two signatures (one provider and one witness) on the request.
 - (6) Additional specimen processing (separation/freezing of plasma) may be needed for specialized testing and this is communicated to the Community Partnership staff as needed.
 - (7) An accompanying, shipping manifest is to be included with each shipment from a COMMUNITY PARTNERSHIP. The shipping manifest form is supplied by the Spokane VA laboratory.
 - (8) COMMUNITY PARTNERSHIP prior to transport to Spokane VA must perform the following: Centrifugation must occur between 15 minutes and 1 hour post collection for optimal specimen preservation. Centrifugation must be performed in a horizontal (swinging head) centrifuge. No other centrifugation method is acceptable or approved by the Government. Such centrifugation must have a speed/rotor sufficient to achieve the specification above.
22. The contractor shall notify patients regarding lab and x-ray results within time frames consistent with standards of care and provide follow-up treatment within the scope of the contract. Any waived testing provided by the contractor must be approved in advance by the VA and in compliance with VA, College of American Pathology (CAP), and The Joint Commission regulations.
- 22.1. The Contractor is responsible for entering orders for laboratory tests into VISTA utilizing the CPRS. Information concerning the laboratory tests is available in CPRS under the Tools Menu.
- 22.2. The Contractor will send laboratory tests to the VA, *except* for those specified in this PWS.
- 22.3. The Contractor is responsible for ensuring compliance with VA laboratory service requirements included in this PWS.
- 22.4. The Contractor shall be responsible for the proper collection, collection supplies, and other preservation of specimens. The Contractor is responsible for providing appropriate specimen collection containers that are compatible with the instrumentation and methodology used by the VA laboratory.

22.5. The cost of all lab work, with the exception of lab work sent to the VA or emergency lab work sent to another site which has been authorized by the Non-VA Care, shall be

23. See Attachment A Mann-Grandstaff Spokane Laboratory User Guide Specimen Collection for specific details on specimen collection.

24. **RADIOLOGY SERVICES:** Contractor is to provide general radiology procedures at their cost to include but not limited to chest x-ray, KUB, lumbar spine, thoracic spine, cervical spine, ribs, hands, wrist, forearm, shoulder, foot, ankle, os calcis, knee, hip, elbow, sinus, skull, and mandible, when ordered by a primary care provider.

24.1. Radiology services to be provided under the awarded contract by contractor or sub-contractor will be in compliance with the standards of the American College of Radiology (listed under policies).

24.2. Contract CBOC providers will document the radiology order in CPRS under patient's progress note.

24.3. Contractor shall be responsible for acquiring a copy of the official interpreted radiology report for ALL radiology studies completed under this contract, directly or through a sub-contractor within 48 hours from conclusion of the study. Contractor is to send the official interpreted radiology report to Mann-Grandstaff VAMC, Attn: Release of Information (ROI) Department Scanning via Lab Courier within same day of receipt. Release of Information will scan the radiology report into CPRS.

24.4. Contractor shall be required to obtain the RAW DICOM CD for ALL radiology studies completed under this contract, directly or through a sub-contractor within 72 hours from conclusion of the study. Contractor to send the RAW DICOM CD to Mann-Grandstaff VAMC Radiology (114) MRI, Attn: FOR SCANNING via Lab Courier within 72 hours.

25. LAB AND X-RAY RESULTS:

25.1. VHA Directive 2009-019, "Ordering and Reporting Test Results," (located in section 1.4, dated March 24, 2009 or subsequent revisions thereto), mandates that all test results, even normal results, be reported to the patient within 14 days of when the results become available.

25.2. The Contractor shall provide the Mann-Grandstaff VAMC with the name, pager/cell phone number of a LIP (physician, nurse practitioner, or physician assistant) at the CBOC to accept critical laboratory results discovered on tests done by the VA during business hours (8:00 AM – 4:30 PM, Monday – Friday excluding federal holidays). For critical laboratory results, the LIP must respond back to the Core Laboratory within forty-five (45) minutes of the initial page or telephone call.

The receiving LIP will document the results in the record and conduct a “read back” procedure to ensure accuracy of transmission and translation of all verbal results

- 25.3. VA will not be responsible for the failure of the Contractor to receive critically abnormal test results. For critical laboratory and x-ray results that represent an imminent danger to the patient, the Contractor shall notify the patient immediately. Critical results must be reported to the clinician by the radiologist by telephone. Documentation of this notification, “who, when” must appear in the radiology report.
- 25.4. For critical results that do not pose an imminent danger to the patient, the Contractor shall notify the patient within twenty-four (24) hours of receipt of the results and provide follow-up treatment within the scope of the contract.
- 25.5. Documentation of actions taken regarding critical laboratory results and serious radiology results must be made by the Contractor in an electronic Progress Note.
- 25.6. During non-business hours as annotated in 25.2, Mann-Grandstaff VAMC Numbered Memorandum 113-03-14 dated June 17, 2014 (herein subsequent revisions) “Reporting critical test and critical test results” (located in policy section) procedures will be followed.
26. ELECTROCARDIOGRAM SERVICES: The contractor must utilize MUSE-compatible EKGs which are interfaced with VistA Imaging. Contractor to utilize Government owned VA MAC 5500 EKG Machine with 12 leads, manufactured by General Electric, Inc. This is compatible with existing VA MUSE System. Contractor is required to upload EKG Machine and transmit data on a daily basis. The EKGs will be confirmed and/or read and signed by CBOC providers the same day the EKG is performed. The signed EKG copy will be sent to the Mann-Grandstaff VAMC Attn: Vascular Lab via lab courier each day.

27. PHARMACY SERVICES:

- 27.1. Contractor shall be responsible for prescribing medications as needed. Prior to prescribing any medications, the Contractor shall review medication profiles in CPRS for duplicate therapy, drug-disease complications, drug-drug, drug-food, drug-lab interferences, appropriateness of dose, frequency and route of administration, drug allergy, clinical abuse/misuse, and documentation of medications obtained outside of the VA in CPRS “Non-VA” medications list, including over-the-counter and herbal agents and known allergies.
- 27.2. Routine prescriptions will be dispensed by at the VA and mailed to the veteran. The Contractor is required to enter all prescription orders using the CPRS outpatient medication order entry option. The Contractor must include complete directions for the prescription (“PRN” alone is not acceptable), the indication for the medication use (whenever possible), and the appropriate quantity and subsequent refills for the medication.

- 27.3. Medication orders for controlled substance (Schedule II) prescriptions must be entered into CPRS (as per local policy) as well as be written (on an authorized VA Form 10-2547F or other State or Federally approved controlled substance order form) and sent to the VA Pharmacy at the end of each business day. The VA will dispense controlled substances in accordance with Federal Law CFR Title 21 1300-end.
- 27.4. The Contractor is required to utilize the VA drug formulary. The formulary is available electronically under Drug File Inquiry in the VISTA physician package. Non-formulary drugs are also marked “NF” in the CPRS drug file. Changes to the formulary effecting prescribing will be sent to the Contractor electronically. Non-formulary medications can be obtained with appropriate clinical justification by utilization of the electronic non-formulary medication order form in CPRS. The Contractor is required to follow national and local VA guidelines for the use of non-formulary or restricted medications, and to support evidence based pharmacy cost savings initiatives undertaken by the local VA. These guidelines can be accessed in CPRS through the Tools menu, Web links, Pharmacy Benefits Management website or directly through the PBM website at <http://www.pbm.va.gov/default.aspx>. The Contractor is required to adhere to the local VA Dual Care Policy.
- 27.5. All prescriptions shall be entered electronically in CPRS for transmission to the VA Pharmacy for processing and mailing (as per local policy). The VA will dispense controlled substance in accordance with Federal Law CFR Title 21 1300-end.
- 27.6. The VA Pharmacy will work closely with the Contractor in prompt mailing of medications. Should the provider determine that it would be detrimental to the patient’s health to wait 7-10 days before initiating drug therapy, the provider may write a prescription (based on a limited formulary of emergent items attached) for a bridge supply of the drug to be filled at the local contracted pharmacy vendor until the prescription can be processed and mailed from VA Pharmacy. This also includes Plan B for women veterans. The Contractor will not dispense more than a 10-day supply of emergent medications through a local contract that Mann-Grandstaff VAMC has contract with. The list of limited formulary of emergent items, which is regularly updated, will be provided during orientation.
- NOTE: The provider must enter an order for the drug in CPRS as with documentation that the medication was filled locally.**
- 27.7. Medications determined by the provider to be emergent but NOT on the emergent formulary list must be pre-approved by VA pharmacy service prior to being filled at the local contracted pharmacy vendor (Check with PBM website at <http://www.pbm.va.gov/> . Authorization must occur BEFORE sending the patient to the local pharmacy to ensure the prescription will be filled. To gain said authorization, the Contractor must contact outpatient pharmacy supervisor at 509-434-7931 or outpatient pharmacy supervisor, at 509-434-7702 PRIOR to sending the patient to the local pharmacy. The VA CBOC EMERGENT DRUG FORMULARY should NOT be used to bridge refills for the patient (i.e. used to give partials until refills are processed through the Mann-Grandstaff VAMC mail-

out program). The Contractor shall clearly make this understood to each patient receiving a prescription.

- 27.8. All medications and supplies that are stocked at the CBOC location must be approved by VA Pharmacy. All routine medications and supplies used in the treatment of outpatients on premises are required to be stored and secured to meet compliance with TJC standards, VHA policy, and OSHA guidelines. Efforts should be made to limit the number of ward stock medications and supplies stored at the CBOC. The contractor will provide, at the contractor's expense (included in the capitation rate), immunizations (not provided by the VA), routine medications and supplies used in the treatment of outpatients in clinic settings (ex. Solu-medrol, Benadryl tab/cap/inj, heparin/saline flush, etc.). All medications on premises shall be stored/secured as per TJC, VA and OSHA guidelines.
- 27.9. The Contractor is responsible to ensure all medications are subject to routine inspection, inventory as required by VA Pharmacy, proper storage (in a secure and locked location), and meet all VA policy and TJC standards for medication management.
- 27.10. Pharmacy will provide the Contractor with a limited supply of routine vaccines for administration. An order for the vaccine must be entered into CPRS by the provider. The Contractor must keep all vaccines furnished by the VA separated from all other pharmaceuticals, in a secure and locked location, refrigerated and monitor temperatures of vaccines and other refrigerated drugs on a twice daily basis per TJC and CDC guidelines for vaccines. A record of refrigerator temperature monitoring must be maintained by the contractor. If a temperature variation is identified by the contractor, the contractor should contact the VA immediately to determine the appropriate disposition for the refrigerated medications. Vaccines furnished to the Contractor by the VA are only to be used for VA patients. To monitor the use of VA provided vaccines, the Contractor must document all injection/immunizations administered to VA patient in CPRS in the Reminder Dialog Template for each VA-furnished vaccine in CPRS.
- 27.11. No paper based log books are to be maintained for any reason. When nearing depletion, the supply of vaccines provided to the Contractor will be replenished by sending an email to the designated pharmacy staff (which will be provided upon contract appointment). Influenza, pneumococcal, tetanus/diphtheria toxoid, with and without pertussis (TD/TDaP), human papilloma virus, and PPD will be stocked at the CBOCs. The more expensive, less routine vaccines will not be stocked, but must be ordered by prescription for the specific patient.
- 27.12. Expired vaccines/immunizations will be returned to the Mann-Grandstaff VAMC Pharmacy via Lab Courier to include the pharmacy count sheet form to verify returned quantity. Mann-Grandstaff VAMC Pharmacy to provide these forms to the CBOC.

27.13. Patient's new allergy information shall be entered into the patient's record via CPRS. The specifics of the patient's allergy or adverse drug reaction, if known, must be included in the documentation. VA Pharmacy is not permitted to dispense any prescriptions without documentation of a patient's allergies being listed in the chart (or documentation that no known allergies exist as appropriate).

27.14. In accordance with TJC standards, the Contractor shall conduct inspections on a monthly basis. The medication storage sites and clinic nursing station will be inspected to ensure that medications are being stored properly (i.e. under refrigeration, if required; externals separated from internals; expiration dates checked, etc.), and VA Medication Inspection Form (VA Form 10-0053) will be completed and mailed to the VA Outpatient Pharmacy Supervisor and the COR by the tenth (10th) day of each month. [Any compliance concerns shall be directed to](#) both the Assistant Chief of Pharmacy and COR. This information will be used in conjunction with the COR's quarterly evaluation of the Contractor's performance. The Mann-Grandstaff VA will provide the Contractor with a supply of VA Form 10-0053. The mailing address is:

Outpatient Pharmacy Supervisor (119)

Mann-Grandstaff VAMC
4815 North Assembly Street
Spokane, WA 99205

27.15. The Contractor shall be responsible for providing all necessary information for each provider with prescriptive authority to VA Pharmacy to include a signature documentation that includes the prescribers name, state license information, DEA number (as applicable), address, phone number and the original prescribers "wet" signature. A signature card with the prescribers "wet" signature must be provided to the VA Pharmacy prior to the prescribers start date.

27.16. New drug orders: The contractor will ensure that at least 95% of all new drug order requests follow all Mann-Grandstaff VAMC prescribing guidelines. This is including but not limited to ensuring all appropriate labs have been previously ordered and that the order is not a non-formulary drug.

27.17. The Contractor shall provide counseling to patients, family or caregivers in accordance with State and Federal laws and VHA requirements, family, including, but not limited to: Medication instructions regarding drug, dose, route, storage, what to do if dose is missed, self-monitoring drug therapy, precautions, common side effects, drug-food interactions, and medication reconciliation, and importance of maintaining an accurate and up-to-date list of all medications (including herbals and over-the-counter medications). Confirmation and documentation of patient/caregiver instruction and the of patient's/caregiver patient's understanding of the instructions including telephone contacts must be documented in the Progress Notes or by using a template provided for this purpose.

- Instructions of VA refill process (VA patient handout).
- Instructions to veterans and/or care giver on the safe and appropriate use of equipment being supplied shall be documented in the veteran's medical record.
- Instructions on VHA Directive 2007-016 “Coordinated Care Policy for Traveling Veterans”.
- Instructions on VHA Directive 2009-038 “VHA National Dual Care Policy”.

27.18. Reports of ADEs will be documented in the patients’ medical record (under the Allergy/Adverse Drug Reaction tracking option in CPRS).

27.19. All medication errors and medication related incidents shall be voluntarily reported immediately to the Patient Safety Officer by filling out the electronic Patient Safety Event Report link on the VA computer desktop.

27.20. Customer complaints regarding pharmacy services must be addressed by the VA pharmacy service. The Contractor cannot resolve a medication related issue; the Contractor shall contact the Mann-Grandstaff VAMC Pharmacy Service Administrative Officer to assist in resolution.

27.21. The Contractor must work in collaboration with Mann-Grandstaff VAMC Pharmacy when there are identified medication management needs of the CBOC patients. Examples of this include notification and management of patients that are taking medications that pose a medication safety concern or patients that are taking medications that require therapeutic substitution based on formulary or medication safety concerns. Contractor requirements will be identified by VA governing bodies and VA Pharmacy.

27.22. In accordance with TJC regulations, the Contractor shall provide the patient with an accurate, reconciled list of medication to include medications that the patient is receiving from the VA, medications that he takes from non-VA providers, and any OTC, herbal or alternative medications that the patient reports taking. The Contractor shall meet all requirements of VHA Directive 2011-012 “Medication Reconciliation” (or subsequent revisions thereto in attachment one) as well as Mann-Grandstaff VAMC policy related to medication reconciliation (included in policy list).

27.23. The Contractor shall meet all requirements for anticoagulation management outlined in VHA Directive 2010-020 “Anticoagulation Management” (or subsequent revisions thereto) as well as Mann-Grandstaff VAMC policy related to the management of patients on anticoagulation.

27.24. The contractor will provide an annual influenza vaccine and pneumovax administration (**provided by the VA**) when clinically indicated by current CDC guidelines. Documentation of all vaccines will be in accordance with VA Policy and Procedures, utilizing VA templates when applicable.

27.25.VA will provide prescriptions to patients through the VA mail out program and, in rare cases, through pick up at the VA hospital pharmacy. When clinically indicated that a patient must start a new medication without delay, contracted providers shall maintain standard of care and prescribe emergent/urgent need medications from a VAMC approved list or obtain approval from the VAMC for a medically necessary drug not on the approved list. Medications determined by the provider to be emergent but NOT on the emergent formulary list must be pre-approved by VA pharmacy service prior to being filled at the local contracted pharmacy vendor (Check with PBM website at <http://www.pbm.va.gov/>). Authorization must occur BEFORE sending the patient to the local pharmacy to ensure the prescription will be filled. To gain said authorization, the Contractor must contact outpatient pharmacy supervisor at 509-434-7931 outpatient pharmacy supervisor, at 509-434-7702 PRIOR to sending the patient to the local pharmacy. The VA CBOC EMERGENT DRUG FORMULARY should NOT be used to bridge refills for the patient (i.e. used to give partials until refills are processed through the Mann-Grandstaff VAMC mail-out program). The Contractor shall clearly make this understood to each patient receiving a prescription.

27.26.Patients will be provided a prescription by the CBOC provider that will be taken to a locally approved community pharmacy. Prescriptions for medications not on the list of approved urgent/emergent medications will be discussed with the VA RHC pharmacy liaison prior to sending the patient to the local community pharmacy. Quantities prescribed will be limited to those approved by the VA pharmacy. Contractor will be responsible for any charges incurred related to resubmission fees for illegible prescriptions, wrong drug spelling, and incorrect social security numbers, etc. In addition, contractor shall be financially responsible for medications that are non-formulary or not approved by VA RHC Pharmacy liaison.

27.27.Contractors shall be responsible for prescribing medications as needed, in compliance with VA required formulary. Prior to prescribing any medications, the contractor shall review medication profiles in VISTA for duplicate therapy and known allergies. The formulary will be provided to the contractor upon contract award. Any deviations from the VA formulary must be documented and be in accordance with VA guidelines. A revised formulary will be provided as it is updated. Schedule II narcotic prescriptions must be delivered to the VA Pharmacy the same day as the patient's visit.

27.28.The contractor shall provide to the VA a copy of procedures/policies regarding disposal of pharmaceuticals in accordance with state and federal environmental protection regulations.

27.29.As part of the professional practice, the Contractor shall:

27.30.Monitor for and document any medication related problems in the patient's record to include:

1. Therapeutic duplication
2. Drug-disease contraindication,
3. Drug-drug, drug-food, drug-lab interferences,
4. Appropriateness of dose, frequency and route of administration,
5. Drug allergy, and clinical abuse/misuse
6. Document medications obtained outside of VA in CPRS including, but not limited to, nutraceuticals, herbal agents, over-the-counter remedies and legend drugs obtained from alternate sources outside of VHA.

27.30.1. Offer all patients and/or caregivers counseling to ensure appropriate and optimal outcomes from the drug therapy. This teaching must be documented in the patient record and may include but is not limited to:

1. Name and indication for medication
2. Dose and route
3. Special directions and precautions
4. Common side effects and actions required if needed
5. Techniques for self-monitoring
6. Proper storage
7. How to obtain medication refills'
8. What do if a dose is missed

Patient education shall be provided on site by the RHC Contract staff to complete medication reconciliation at every patient visit in accordance with VHA standards.

28. TELEHEALTH SERVICES: Several telehealth medical specialty initiatives (e.g., teleretinal, teledermatology, telesurgery, etc.) are either in service or being planned for in the near future. The Contractor will be prepared to implement these services upon direction by the Mann-Grandstaff VAMC. The Mann-Grandstaff VAMC will provide all necessary equipment for the appropriate telehealth specialty. The Contractor shall provide fully furnished space for telehealth equipment to be placed within the CBOC facility. The Contractor will provide all necessary supplies to perform telehealth services. This will include nondisposable surgical supplies to perform punch biopsies, simple excisions, and shave biopsies, simple excisions, and shave biopsies for teledermatology. This space will provide privacy for patients to meet confidentially in an individual or group seating with providers at the Mann-Grandstaff or Boise VA via electronic transmissions. The space shall be a minimum of 100 square feet and furnished with a desk, chair, computer, and TV, video conferencing equipment (computer and videoconferencing equipment provided by Mann-Grandstaff VA) The Mann-Grandstaff VAMC will maintain the VA-provided telehealth equipment.

- 28.1. Telehealth involves the delivery of clinical care in situations in which patient and provider are separated by geographic distance. It is the responsibility of the contractor to ensure that in the event of a patient emergency, e.g. acute medical event, violence or threat of self-harm that explicit processes are in place that ensures a distance provider can alert the clinic and institute the appropriate actions to protect patients and/or staff from harm. These processes must be regularly checked to ensure they are operational and meet specified response times.
- 28.2. The Contractor shall provide at least one primary care provider at each location that will be privileged to perform simple surgical procedures as part of the teledermatology and telesurgery programs. The VA will provide training in dermatological and surgical procedures to selected staff as needed. All providers performing surgical procedures will be privileged prior to performing any invasive procedure in accordance with the most current version of the Mann-Grandstaff VAMC Bylaws and Rules of the Medical Staff.
- 28.3. The Contractor shall be responsible for facilitating the use of the equipment for the veterans and hiring qualified Telehealth Clinical Technician (TCT) and support staff.
- 28.4. The TCT is a Licensed Practical Nurse (LPN) or Medical Assistant/Health Technician (MA/HT) that serves in a generalist role to support Telehealth clinical programs from the patient location. The incumbent provides a wide range of clinical and technical services to the veteran under general supervision of a registered nurse, LIP, or MD.
- 28.5. If utilizing an LPN the incumbent must be a graduate of a school of practical or vocational nursing approved by the appropriate state accrediting agency and/or the National League of Nursing, and must possess a current unrestricted license to practice as a Licensed Practical Nurse.
- 28.6. MA/HTs must have the experience, skills, knowledge and abilities to perform all requirements of the position.
- 28.7. The TCT shall support all of the Telehealth/Telemental health programs, as technology becomes available and as identified and referred by the primary care provider or other providers. Contractor must be ready to expand resources dedicated to Telehealth programs to include additional staff and space as required by the VA after proper notification.
- 28.8. The TCT, guided by local policy/standing orders, will initiate consultations for patients on behalf of the primary care provider, who retains responsibility for patient care. The TCT will provide patient education regarding the imaging process.
- 28.9. Contractor is responsible for the patient site facilitation of the clinical, business, scheduling, consult management, and technical aspects for real-time Telehealth

applications, including, but not limited to, Telemental health, primary care Telehealth, Telerehabilitation, and telepatient education clinics. Scheduling and consult management will require the use of VistA.

- 28.10. Contractor Uses video-conferencing technologies, Telehealth technology and scheduling software to coordinate and connect staff, resources, patients, and providers in the manner effective to delivery of services, patient care, education, and training.
- 28.11. The TCT is responsible for any patient, staff education/ training, documentation, and assistance with workload capture that is basic for the completion of the visit and/or training.
- 28.12. The TCT assists in patient care under the direct supervision of an independent licensed healthcare provider.
- 28.13. The TCT performs a range of direct care duties that may include, collecting vital signs, clinical reminders, and other clinical components of a primary care visit as directed by policy or clinic standard.
- 28.14. The TCT conducts quality control procedures on equipment and products and maintains proper records for quality control reports and workload reporting. The TCT is responsible for the day-to-day operation of the clinical video conferencing, training, Care Coordination Home Telehealth (CCHT), Store and Forward (SF), My Health E Vet, and Telehealth clinics.
- 28.15. The TCT performs personal care, diagnostic support duties and treatments according to procedure under the direction of the professional nurse in a timely manner. The TCT also responds to patient's nursing needs, including physical comfort, and emotional needs and recognizing deviations from the normal within their scope of practice.
- 28.16. The TCT ensures all patient encounters are documented in the VA Computerized Patient Record System (CPRS) and/or VISTA.
- 28.17. Links to VA telehealth resources that detail clinical, technology and business associated processes are provided for information and to guide the contractor in configuring the telehealth services that VA requires. The contractor cannot assume that all clinical, technology, business, regulatory and legal aspects of telehealth that apply to VA and VA practitioners will automatically apply to a third party contracting for telehealth-related services with VA. It is the responsibility of the contractor to ensure that all services provided by a third party to VA using telehealth meet all such requirements.

29. CLINICAL PHARMACY SERVICES: The provision for clinical pharmacy services and expertise of a CPS should be available to all patients managed by the contractor. This service will be provided by the VA pharmacy as long as staffing permits.
- 29.1. Telepharmacy: The Contractor shall provide space for clinical pharmacy telehealth services at the CBOC location as appropriate. Clinical Pharmacy services may be provided by the VA pharmacy or through the contractor depending on the location and in some instances may be provided via telehealth capabilities.
- 29.2. The Contractor shall support for telepharmacy services provided by VA (for anticoagulation or PACT), space should provide privacy for patients to meet confidentially in an individual or group setting with providers at the VA via electronic transmissions. The space shall be large enough for a desk, chair, computer, and TV and videoconferencing equipment (provided by VA).
- 29.3. The VA will maintain the VA-provided telehealth equipment. VA will also provide the networking capability to support the telehealth equipment. The Contractor will facilitate use of the equipment for the veterans.
- 29.4. Contractor shall provide clerical support, including scheduling, and ancillary support for VA telepharmacy services as appropriate. The support services should include but not limited to intake vitals by LVN/LPN, Unlicensed Assistive Personnel (health tech or nursing assistant), teaching patients how to use BP monitors at home, calling patients for lab reminders, scheduling patient visits and contacting patients who no-show for rescheduling.
30. MENTAL HEALTH: This contract does not include providing Mental Health Service (MHS). However, the Contractor shall provide one fully furnished patient care office of approximately 100 square feet to be used for for VA provided telehealth-Mental Health. All MH services will be provided by VA clinical staff. The Contractor will work closely with the Mann-Grandstaff VAMC and Boise VAMC to develop a strong collaborative working relationship between contract primary care staff and VA Mann-Grandstaff and VA Boise staff. Contractor and VA will establish processes for referring Primary Care patients for MHS services; this may involve the use of MHS Consults in CPRS or other locally developed process. The Mann-Grandstaff VAMC will provide Telehealth-Mental Health services through Boise VAMC and/or Mann-Grandstaff VAMC.
- 30.1. The Contractor shall provide all support necessary to establish a highly effective MH Services. Support shall include providing all front desk administration, scheduling initial and follow up appointments, rescheduling patients when requested or if a clinic will be canceled due to illness or other reasons to include notifying the patients of these changes, calling patients to cancel and reschedule appointments when changes are made within 14 days or less, place reminder calls to patients no later than two days prior to their appointment, checking in/out of patients for clinic appointments, taking and documenting vital signs as necessary, process all consults

for the above clinics, and provide support for the telemental health equipment including set-up and scheduling. Taking calls and messages from patients and communicating to providers, entering clinic scheduling grid requests into the Clinic Website. Assist MHS providers in arranging transportation and assisting with care in emergent patient care situations as outlined in Section 18 of this document.

30.2. Estimated Mental Health Workload: In order to assist the Contractor in determining support staff requirements, approximately 30% of enrolled veterans will require Mental Health Services.

31. TELEDERMATOLOGY: The Contractor shall be prepared to provide medical specialty consultative services in Dermatology. VA will provide all necessary equipment and supplies, to include: specialized camera with associated memory cards, tripod, storage case, battery pack and cleaning equipment; transmission software; cleaning supplies with instructions; and rulers. The Contractor will be required to:

31.1. Identify a midlevel provider to complete surgical training for the teledermatology program at the Mann-Grandstaff VAMC modify scope of practice and collaborative practice agreements. This training will be at the expense of the Contractor.

31.2. The health technician/RN/LPN/MA to complete online teledermatology training through the Boston VA Medical Center.

31.3. As requested by a CBOC PCP, utilize the trained health technician/RN/LPN/MA to measure and photograph (using VA provided rulers and a telederm camera) potential dermatologic concerns

31.4. Using VA provided Vista Imaging software, utilize the trained mid-level provider or other staff member to transfer images from the telederm camera to an existing computer workstation at the CBOC, then transmit the images to the VA Dermatology Department for consultative analysis.

31.5. Initiate treatment, as directed by the VA Dermatology Department.

31.6. Provide for storage of one telederm camera (and associated supplies) and the ability to move the camera to various exam rooms to take photos of potential dermatologic concerns.

31.7. Clean camera, as needed, and request maintenance/repair, beyond user-level, from VA Biomedical Repair

32. MILITARY SEXUAL TRAUMA (MST) SCREENING: VHA Directive 2010-033 "Military Sexual Trauma (MST) Programming," dated July 14, 2010 (or subsequent revisions thereto) requires the expansion of the focus on sexual trauma beyond

counseling and treatment, mandates that counseling and appropriate care and services be provided, and mandates that a formal mechanism be implemented to report on outreach activities. The VA has mandated screening of every veteran, male and female, for sexual trauma while in the military. This includes asking the veteran whether they have experienced sexual harassment, sexual or physical assault, or domestic violence while on active duty. Screening must be conducted by the CBOC primary care physician and documented in the electronic medical record and in the MST software package in VISTA. If a veteran screens positive for such trauma and would like to receive evaluation or counseling services, a consult can be initiated to Behavioral Health outpatient services. The veteran may decline such services, and this should be documented as well. Immediate assistance can be obtained by calling the Mann-Grandstaff VAMC at 1-800-325-7940 and asking for the Military Sexual Trauma Coordinator.

33. SPECIALTY CONSULTATIONS, DIAGNOSTIC TESTING, AND CARE PROVIDED AT THE MANN-GRANDSTAFF VAMC AND SITES OTHER THAN THE CONTRACTOR's:

- 33.1. Due to changing legislation for non-emergent specialty evaluations, diagnostic testing and care not available at the CBOC and the Mann-Grandstaff VAMC, the VA will provide clear guidance and policies on how patients should be referred to community providers once contract is awarded.

34. WOMEN VETERANS HEALTH CARE:

34.1 Comprehensive primary care for women veterans is defined as the availability of complete primary care from one primary care provider at one site. The Contractor will offer all patients the choice of gender of their health care provider; Contractor should not wait for the patient to request a specific provider gender. The primary care provider will, in the context of a longitudinal relationship, fulfill all primary care needs, including acute and chronic illness, gender-specific, preventive and mental health care. Each clinic will be staffed with at least one primary care provider who is proficient in Women's health. The full range of primary care needs for women veterans is described below:

- Care for acute and chronic illness includes routine detection and management of disease such as acute upper respiratory illness, cardiovascular disorders, cancer of the breast, cervix, colon, and lung, diabetes mellitus, osteoporosis, thyroid disease, COPD, etc.
- Gender-specific primary care, delivered by the same provider, encompasses sexuality, contraception counseling, pharmacologic issues related to pregnancy and lactation, management of menopause-related concerns, and the initial evaluation and treatment of gender-specific conditions which might include pelvic and abdominal pain, abnormal vaginal bleeding, vaginal infections, and conducting annual exams such as breast cancer screenings and pap smears.
- Preventive care includes services such as age-appropriate cancer screening, weight management counseling, smoking cessation, immunizations, etc.
- The same primary care provider will screen and appropriately refer patients for military sexual trauma as well as evaluate and treat uncomplicated mental health disorders and substance use disorders.
- When specialty care is necessary, the primary care provider will coordinate this care and communicate with the specialty provider regarding the evaluation and treatment plan to ensure continuity of care.
- The Contractor will follow the guidelines in sections 27.24 and 27.25 of this document to manage the Plan B requirement.

34.2 Referral Process:

34.2.1. Mammograms

- 34.2.1.1. The Contractor may refer patients for mammograms to local accredited and certified mammography facilities in the CBOC's applicable county after facing the Non-VA Purchased Care Mammogram after the provider submits a requested in CPRS by completing the **mandatory** CPRS Non-VA Purchased Care Consult for mammography.

- 34.2.1.2. Normal Results: In addition to the mammography facility, the referring provider is responsible for informing the patient, in writing or by telephone, of the results, within 14 days of Mann-Grandstaff VAMC's receipt of the report. This notification must be documented in the patient's chart as mandated by Mann-Grandstaff VAMC Numbered Memorandum 113-03-14
- 34.2.1.3. Abnormal Results: In addition to the mammography facility, the referring provider is responsible for informing the patient within 5 working days of the mammogram, and documenting in the patient chart that the patient was contacted as mandated by the Mann-Grandstaff VAMC Numbered Memorandum 113-03-14.
- 34.2.2. Mann-Grandstaff VAMC is authorized to provide, through non-VA Purchased Care, comprehensive pre-natal, intra-partum and post-partum care to eligible women Veterans. Maternity benefits begin with the confirmation of pregnancy, preferably in the first trimester, and continue through the final post-partum visit, usually at 6-8 weeks after the delivery, when the Veteran is medically released from obstetric care. Maternity benefits now cover the first seven days of the infant's life as well. The VA does not provide OB Care; the Contractor shall initiate a Non-VA Purchased Care Consult for OB Care and notify the Women's Clinical Navigator at (208) 665-1705.
- 34.2.3. Mann-Grandstaff VAMC is authorized to provide, through non-VA Purchased Care, pregnancy test. The Contractor shall initiate a Non-VA Purchased Care Consult for Lab.
- 34.3. The Contractor must develop a plan to assign women to a primary care provider who is proficient in women's health ("Designated Women's Health Provider"). When the number of women Veterans in the CBOC allows, the Designated Women's Health Provider will have a panel that is 10% female, in order to maintain competency in caring for those veterans. The Contractor must provide ongoing education, and training to the Designated Women's Health Provider, to assure competency, proficiency and expertise in providing care to women veterans. VHA's "Mini-Residencies in Women's Health" is one such option. Staffing must be adequate to provide gender-appropriate chaperones for any procedures dealing with the breast or genitalia, or if the woman Veteran requests a chaperone for any reason. Equipment such as privacy curtains, adjustable exam tables with warming trays and stirrups, and appropriate lights for pelvic exams, will be on hand. As required, cervical cancer screening exams will be done in exam rooms with adjoining bathroom. If adjoining bathrooms are not available, patients that are undressed or wearing examination gowns must have proximity to women's restrooms that can be accessed without going through public hallways or waiting rooms. Disposable speculums, supplies, and equipment to perform Pap smears and pregnancy testing shall be on hand in the clinic area. At least one exam table in the

clinic will be able to accommodate bariatric patients. The clinic environment must meet VHA privacy standards for women, including exam tables not facing the door. In either a women's restroom or in a unisex restroom, there will be baby changing table and a feminine hygiene product dispenser. The Human Papillomavirus vaccine will be on hand in the clinic. A procedure for patients to obtain "Plan B" at a pharmacy proximate to the CBOC will be in place. Refer to Handbook 1330.1, "VHA Services for Women Veterans" dated 7/16/04 and subsequent updates located under the policy section of this document.

- 34.3.1. The CBOC must provide ongoing education, and training to the primary care women veteran champion to assure competency, proficiency and expertise in providing care to women veterans.
- 34.3.2. Staffing must be adequate to provide gender-appropriate chaperones as well as clinical support with availability of same-gender providers on request.

35. PATIENT SCHEDULING:

- 35.1. The Contractor clinic is not designated as an emergency or urgent care center, and as such is by appointment only. Nonetheless, the Contractor shall maintain a triage system for walk-in patients. Urgent walk-in patients are to be triaged by a qualified medical practitioner.
- 35.2. Episodic Care for Patients Not Assigned at the CBOC– At no additional cost the contractor is expected to provide approximately 5/month nurse-only visits and 5/month provider visits to Veterans who are not enrolled (assigned) for care at the CBOC. These visits occur when a Veteran not assigned to the CBOC is an otherwise eligible Veteran, comes to the clinic seeking limited episodic care that cannot be provided by the Veteran's assigned primary care provider/team at their preferred facility. The clinic shall ensure that the Veteran is triaged by a nurse and that any basic care that can be provided by the nurse and/or provider is provided. An example of this type of care would be a Veteran traveling from Texas to Virginia who is enrolled at a VAMC in Texas but needs a nursing visit for phlebotomy or a provider visit for an acute illness while visiting.
- 35.3. PACT patients expect that when they want or need to see their own Primary Care provider that day, that they will be able to so. Open Access is an important PACT concept for VHA primary care and is in part measured by the Same Day Appointment with Primary Care Provider metric of the percent of requested same day appointments (appointment date = create date for walk-ins) in PC Clinics the stop code is either 322, 323 or 350 for PC assigned patients where the patient was seen by their Primary Care and/or Associate Provider within 1 day of the desired

date. Note this metric does include walk-in appointments if entered in the appointment package.

35.4. The Contractor will schedule new patients as close to the patient's desired date as possible. Established or return appointments will be scheduled as indicated by the specific or general timeframe communicated by the provider and the actual desired date is established by the patient. The CBOC shall meet the Veterans Health Administration's (VHA's) timeliness standards as outlined in VHA Directive 2010-027 "VHA Outpatient Scheduling Processes and Procedures," dated June 9, 2010 (or subsequent revisions to VHA Performance Standards).

35.5. Contractor will adhere to Mann-Grandstaff Memorandum 11-11-14 (located in this document under policies) and subsequent revisions. Contractor will not cancel clinics less than 30 days in advance, except for emergency, sick leave or unscheduled leave due to unforeseen circumstances. When a clinic is cancelled on short notice, every effort will be made for alternate provider(s) to absorb as many patients as possible to avoid rescheduling. In the event a patient arrives before he/she can be telephonically notified, the patient will be absorbed into that day's schedule or be offered the following.

- Same day appointment with another provider
- Reschedule the appointment.
- Designee will ensure any patients affected by the cancellation have sufficient medication to last until their rescheduled appointment.

35.6. Radiology appointments are to be made within seven (7) days of order and completed within 30 days.

35.7. Critical patients (those with true emergent needs) shall not be served by the Contractor, and shall be referred to the nearest "safe harbor" medical facility capable of providing critical emergent services. Refer to section Emergencies in this document 36. for guidelines.

35.8. In most instances, patients shall be seen within 20 minutes of scheduled appointments in accordance with VHA Directive 2006-041 (expired on June 30, 2011 but will still be effective until a revision or rescission is published).

35.9. My Healthe Vet: Veterans interested in the My HealtheVet initiative will be directed to the web site www.myhealth.va.gov where they can register as a veteran seen at the VAHCS.

36. EMERGENCIES:

- 36.1 The Contractor will develop a local policy or standard operating procedure defining how emergencies are handled, including behavioral health emergencies. The CBOCs will maintain appropriate emergency response capability. CBOCs are required to have an Automatic External Defibrillators (AED) on site, which Mann-Grandstaff VAMC will provide. The Contractor is required to train all of their clinical staff in BLS and AED use. The Contractor is responsible for properly inspecting and recording monthly AED inspections in accordance with the most current version of VHA Directive 2008-015 (located under policies in this document).
- 36.2 Patients who self-refer to local emergency facilities and their associated charges for care are not the responsibility of the Contractor; and shall not be provided service under this contract, even if the designated Primary Care Provider under this contract is performing “on call” duties at the local facility. If an enrolled patient who is not actually receiving care in Contractor's facility contacts the Contractor, and the Contractor believes that the veteran needs emergency care that the Contractor cannot provide, the Contractor shall advise the patient to go to the nearest emergency care facility. The Contractor shall also advise the patient that VA may not be able to pay for emergency care at the non-VA facility and that the veteran should contact the VA as soon as possible to determine if VA will pay.
- 36.3 In addition to Medical Emergency plans, the Contractor shall also establish policies for dealing with disruptive patients. The Contractor may choose to hire private security firms to provide additional security. Prior to establishing such a program, the Contractor shall coordinate with the COR and VA Police.

36. Available Consult Services: Consult services available at Mann-Grandstaff VA via electronic request will be provided upon

Medicine:

Autopsy Request
Cardiology
Dermatology
Emergency Dept Referral
Physical Med & Rehab
General Medicine

Hematology/Oncology
Hospice (Palliative Care
Team)

Neurology

Surgery:

Anesthesia
Hand
General Surgery
ENT

Ophth/Optometry
Orthopedic

Podiatry

Other:

Anticoag
Audiology
Behavioral Health
Clinical Pharmacy
Community Based Care
Eye
Dental
Laboratory

Miscellaneous
Nutrition & Weight
Pain Management
Pastoral Care

Pulmonary
Renal
Rheumatology
Therapeutic Phlebotomy

Pressure
Ulcer/Wounds

Urology

Primary Care
Prosthetics

Recreation
Rehab Medicine
Social Work

36.1 Referral Process:

36.1.1. Contractor shall request specialty consultations electronically through CPRS and include consult service requested, urgency, diagnosis (when required), and reason for request. Any and all additional information required by some Specialty Sections must be entered by the referring CBOC Primary Care Provider via the consult template.

36.1.2. The Contractor is responsible for the coordination of the patient's primary care including referral to specialties as indicated. The VA serves as the referral center for any care or service outside the scope of this contract unless pre-authorized by the VA.

36.1.3. The VA is responsible for communicating with the Contractor results of any treatment provided by the VA for the patient. The primary communication link will be the computerized patient record system (CPRS).

37. TELEPHONE ACCESS:

37.1 The Contractor must make provisions for toll free telephone care, twenty-four (24) hours a day, seven (7) days a week, including evenings, weekends and holidays, for all enrolled patients, in accordance with VHA Directive 2007-033 "Telephone Service for Clinical Care," This directive further establishes benchmarks for telephone service, which will be used by VA to monitor CBOC performance (e.g., call volume, abandonment rate, and average speed to answer). Benchmarks include an average speed of answer by a live person within 30 seconds and a call abandonment rate of less than 5%.

37.1.1. VHA Directive 2007-033 mandates that the CBOC's telephone services will provide health care advice and information to all veterans receiving care via the CBOC and details requirements for telephone service during 8:00AM to 4:30PM, and answering staff (physicians, providers, or registered nurses with direct access to patient records).

37.1.2. This requirement is met if the Contractor makes arrangements with the parent VA facility after hours call center to provide after hours telephone access. The Contractor must establish a mechanism to provide this coverage, and it is recommended that the CBOC telephone rolls over to the after-hours number.

38. VISTA: VA will provide the Contractor access to VISTA, VA's patient record computer system, Computerized Patient Record System (CPRS) that contains: patient medical records, medication profiles, laboratory and radiology data, and other diagnostic test results. Access will be for the purpose of:

38.1 Obtaining patient specific information.

38.2 Requesting specialty consults, laboratory, radiology, or other diagnostic tests.

38.3 Communicating with VA Staff about patient care issues.

38.4 Checking formulary status of drugs.

39. MEDICAL RECORDS REQUIREMENTS:

39.1 Authorities: Contractor 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 (Health Insurance Portability and Accountability Act).

39.2 The resultant 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 Contractor 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's provider at his expense. Contractor shall deliver all final patient records, correspondence, and notes to the VA within twenty-one (21) calendar days after the contract expiration date.

39.3 Professional standards for documenting care: Care shall be appropriately documented in medical records in accordance with standard commercial practice and guidelines established by the VA.

40. CLINICAL REMINDERS: Proper documentation and completion of all clinical reminders as they appear during a patient's visit. Standard is 90% completion of all clinical reminders monthly.

- 40.1. Medical record entries shall be legible and maintained in detail consistent with good medical and professional practices so as to facilitate internal and external peer reviews, medical audits and follow-up treatments. Copies of received medical information shall be authenticated (signed) copies.
- 40.2. The quality of medical practice shall meet or exceed reasonable standards of professional practice for the required services in health care as determined by the same authority that governs VAMC medical professionals and will be audited by the Medical Center, Service Line or other processes established for that purpose.
- 40.3. The Contractor shall maintain up-to-date electronic medical records at the site where medical services are provided for each member enrolled under this contract. Records accessible by the Contractor in the course of performing this agreement are the property of the VA and shall not be accessed, released, transferred or destroyed except in accordance with applicable federal law and regulations. The treatment and administrative patient records created by, or provided to, the Contractor under this agreement are covered by the VA system of records entitled "Patient Medical Records-VA" (24VA19). 24VA19 can be viewed at <http://vaww.vhaco.va.gov/privacy/SystemofRecords.htm>. The VA shall have unrestricted access to these records.
- 40.4 The contractor will maintain electronic medical records using the computerized patient record system, CPRS, and Vista Imaging making sure they are up-to-date and will include the enrolled patient's medical records for all subcontractor providers. The electronic record shall include, at a minimum, medical information, prescription orders, diagnoses for which medications were administered or prescribed, documentation of orders for laboratory, radiological, EKG, hearing, vision, and other tests and the results of such tests and other documentation sufficient to disclose the quality, quantity, appropriateness, and timeliness of services performed or ordered under this contract. Each member's record must be electronic, which includes scanned images, well maintained in detail consistent with good medical and professional practice, which permits eDocumentation that occurs in CPRS and Vista Imaging. No documents from the electronic medical record will be printed as no shadow records are authorized. Effective internal and external peer review and/or medical audits facilitate an adequate system of follow-up treatment.
- 40.5 A summary progress note written by an appropriate clinician after a review of the external source documents may be used in lieu of scanning any external source documents. Original medical documents that require scanning, will be sent to the Mann-Grandstaff VAMC File Room/Scanning Department (136) on a daily basis utilizing the Lab Courier. No paper records shall be maintained.
41. AVAILABILITY OF RECORDS: The Contractor shall make all records available at the Contractor's expense for review, audit, or evaluation by authorized federal, state, and Comptroller or VA personnel. Access will be during normal business hours and will be either through on-site review of records or through the mail. All records to be

sent by mail will be sent via UPS Ground delivery at contractor's expense to the VA within one (1) business day of request at no expense to VA.

42. EXTERNAL PEER REVIEW PROGRAM: The Contractor shall document in the medical record preventive health case management measures and the chronic disease indicators of the enrolled patient. The medical treatment records generated by the contractor in the course of performing services under this contract shall be made available for audit by the VA's External Peer Review Program (EPRP). Medical record data must be available in CPRS and Vista Imaging and any additional records required for EPRP audit will be promptly forwarded to the VA upon request. These request will be sent out the same day as requested by utilizing the Lab Courier.
43. 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. In the case of the VA authorizing the Contractor to release patient information, the Contractor in compliance with VA regulations, and at his/her own expense, shall use VA Form 3288, Request for and Consent to Release of Information from Individual's Records, to process "Release of Information Requests." In addition, the Contractor shall be responsible for locating and forwarding records not kept at their facility. The VA's Release of Information Section shall provide the Contractor with assistance in completing forms. Additionally, the Contractor shall use VA Form 10-5345, Request for and Authorization to Release Medical Records or Health Information, when releasing records protected by 38 U.S.C. 7332. Treatment and release records shall include the patient's consent form. Completed Release of Information requests will be forwarded to the Mann-Grandstaff VAMC, 4815 N. Assembly St., Attn: ROI, Spokane, WA 99206-6107.
44. DISCLOSURE: Contractor and Contractor may have access to patient medical records: however, Contractor and Contractor must 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 VA will provide the Contractor with a copy of VHA Handbook 1907.1, Health Information management and Health Records and VHA Handbook 1605.1, Privacy and Release of Information. The penalties and liabilities for the unauthorized disclosure of VA patient information mandated by the statutes and regulations mentioned above, apply to the Contractor, Contractor and/or sub Contractors.
- 44.1. The Contractor will use VA Form 5345 (release of records to outside parties), and VA Form 5345a (release of records to veterans themselves), *Request for and Consent to Release of Medical Records Protected by 38 U.S.C.*, for veterans wishing to have their CBOC records released. The Contractor will release information in accordance with the Privacy Act of 1974, and the Health Insurance Portability and Accountability Act. The Contractor will release information in accordance with the

Privacy Act of 1974, and the Health Insurance Portability and Accountability Act. The CBOC will forward their requests for the release of patient information to the Mann-Grandstaff VAMC Release of Information office. Requests of a simple nature may be completed at the time of the clinic visit. Completed requests and release of information forms are forwarded to the Mann-Grandstaff VAMC Release of Information Office for inclusion into Decision Support System (DSS) for accounting purposes.

- 44.2. When releasing medical records to the veteran themselves, the 5345a form will clearly indicate:
 - 44.2.1. The veteran full name and last four of SSN
 - 44.2.2. The information that was released as authorized by the veteran.
 - 44.2.3. The date the information was released (inferred that date signed is date released)
 - 44.2.4. Block will be checked that the information was released in person to the veteran.
 - 44.2.5. When releasing the information to an outside third party, the 5345 form will clearly indicate:
 - 44.2.5.1. Full name of veteran and last four of SSN.
 - 44.2.5.2. Complete address of third party to who the records were released to
 - 44.2.5.3. The exact information that was released as authorized by the veteran
 - 44.2.5.4. The purpose for third party receiving the records
 - 44.2.5.5. The expiration date for authorization

45. PATIENT HANDBOOK:

- 45.1. The Contractor shall provide each patient with a copy of a patient handbook. A sample patient handbook (see attachment B) which the Contractor can edit to apply specifically to their clinic will be provided by the parent VAMC. The handbook shall include:
 - 45.1.1. Address of CBOC, names of providers, telephone number(s), and office hours;
 - 45.1.2. Description of services provided;
 - 45.1.3. Procedures for obtaining services;
 - 45.1.4. Procedures for obtaining emergency services; and
 - 45.1.5. Notice to the patient that they have the right to grieve eligibility related decisions directly to the VA.

- 46. RECORDS RETENTION: The Contractor must retain records generated in the course of services provided under this contract for the time periods required by VHA Record Control Schedule 10-1 and VA regulations (24 VA 136, *Patient Medical Records - VA, par. Retention and Disposal*). No hard copies of medical records or logbooks of any type may be maintained. If this agreement is terminated for any reason, the contractor will promptly provide the VA with any individually-identified

VA patient treatment records or information in its possession, as well as the database created pursuant to this agreement, within two (2) weeks of termination date.

47. **WORK-RELATED INCIDENT TREATMENT::** When treating the veteran for injuries sustained as a result of a work-related incident or an accident, the Contractor must complete the appropriate forms to allow the VA to assert a Federal Medical Care Recovery Act (FMCRA) or a Workers Compensation Claim.
48. The VA utilizes both a scanned and electronic medical record (EMR). The primary electronic component is the Veterans Information System and Technology Architecture (VISTA) /CPRS (Computerized Patient Record System), which consists of hardware configurations and software developed by the VA. VISTA/ CPRS, is a collection of over one hundred (100) applications that make up a comprehensive hospital information system. It includes both medical records and clinical applications or packages such as order entry, Progress Note, laboratory, radiology, scheduling/admission-discharge-transfer and discharge summary. The present VISTA/CPRS packages combined comprise an estimated 80 percent of a total electronic medical record. The scanned component of the medical record will consist only of those items not already on-line in CPRS. CPRS requires that all medical entries be done electronically, including, but not limited to, prescriptions, labs, radiology requests, Progress Notes, vital signs, problem lists, and consults.
- 48.1. Contractor personnel will utilize VA' current VISTA/CPRS technology to compile a concise and relevant account of the patient's health care with Contractor-owned workstation equipment and communication software.
49. **TRAINING:** VA will provide the necessary training to Contractor personnel on the proper use and operation of the CPRS system. VA will provide VISTA training and access appropriate to Contractor's decision to utilize clinic staff or subcontracted vendor for data entry.
50. **DOCUMENTATION AND CLINICAL RECORDS:** Documentation and clinical records shall be complete, timely, and compliant with VA policies, and current Joint Commission Standards.
- 50.1. The Contractor shall report workload (check-in, check-out) within 24 hours of the patient's visit and other important clinical data including entry into the Patient Care Encounter (PCE module) including ICD9-CM diagnostic codes as well as CPT as defined by the American Medical Association.
- 50.2. The Contractor shall provide individual patient encounters (visits) workload in accordance with established VA reporting procedures. The Progress Notes for each enrolled patient visit, whether the patient visit was with the Contractor or a subcontractor, shall be entered electronically in the patient's record through the VA CPRS system.
- 50.3. Documentation must be complete for all fields including whether or not the patient is service connected. The CPT and provider codes must match and codes must

accurately reflect complexity of visit. Complete documentation must be completed before the 18th of each month.

- 50.4. All Progress Notes, medication orders, and test results, applicable to services which the Contractor is responsible to provide and perform at its site or subcontractor's site, shall be entered into CPRS by the Contractor within 48 hours of completion of the patient's visit, with the exception of radiology reports.
- 50.5. VA Radiologist's professional interpretation of diagnostic radiology and diagnostic imaging performed by the Contractor will be entered into VISTA/CPRS by VA. Contractor shall be responsible for entering into VA's CPRS all information and requests for laboratory and radiology test requests.
- 50.6. Progress Notes will be entered into CPRS or the Progress Note portion of the TIU package. The results of laboratory tests performed at the CBOC must be included in the Progress Notes.
- 50.7. Progress Notes must meet CMS guidelines for documentation which include the 3 key components to determine the level of evaluation and management (E/M). These key components include: (1) History; (2) Exam; and (3) Medical decision making. Progress Notes associated with each clinic visit will include pertinent medical treatment, a treatment plan, teaching that was provided to the patient and/or the patient's family, the date of appointment, and the electronic signature of the treating clinician.
- 50.8. All notes must be linked to the correct visit and location. A patient problem list must be present on the patient's record by the third clinic visit and will be entered via CPRS on the Problem List tab. This list will include all diagnoses, medications and procedures and will be updated as the patient's condition changes. Laboratory reports and results will be entered into the Laboratory Package.
- 50.9. The process for entry of data may include manual entry or an automated procedure; however, it must adhere to applicable VA Automated Information Security (AIS) system regulations. Questions may be directed to the VA Information Security.
- 50.10. Encounter Forms: The Contractor will electronically complete encounter form data in the VISTA/CPRS system within two (2) working days of visit. Completed Encounter Forms will include, but are not limited to, the Problem list, appropriate CPT code(s), a primary ICD-9 Diagnosis Code(s), designation of a primary provider, and whether the treatment or care rendered was for a service connected condition or as a result of exposure to agent orange, environmental contaminants, or ionizing radiation.
51. ACCESS TO VA RECORDS: Subject to applicable federal confidentiality laws, the Contractor or its designated representatives may have access to VA records at VA's place of business on request during normal business hours where necessary to perform the duties under this resultant contract.
52. REPORTS: The Contractor is responsible for complying with all related VA reporting requirements requested by the VA.

53. EQUIPMENT AND TECHNICAL SUPPORT:

53.1. In accordance with VA and VHA directives, policies, and handbooks, all equipment attaching to a VA network will be owned by the Mann-Grandstaff VAMC and controlled by the Mann-Grandstaff VAMC. No other equipment will be connected to this network. The use of the equipment will be for the benefit of the Government in providing care to our veterans. The equipment will only be used by those expressly authorized in support of the Mann-Grandstaff VAMC. All users must comply with and adhere to VA Directives and VA Cyber Security policies.

53.2. The Mann-Grandstaff VAMC shall provide the PC workstations, printers, scanners, software, primary telecommunications lines and networking equipment required to access the VISTA system. The VA shall provide necessary antivirus software for PC workstations and ensure that data definition files are current. In addition the VA will ensure that all Microsoft critical updates and patches are current.

53.3. The Contractor shall be responsible for installation and maintenance of the network infrastructure within the facility including, but not limited to, cabling located inside the walls of the structure and a secure communications closet space to house the patch panels and networking equipment (see para. “g” below). For backup, contingency and continuity of operations, the Contractor will provide connectivity to the Internet via cable modem, DSL or T1 circuits. Backup, contingency, COOP connectivity to the VA will be established through a VPN connection utilizing Contractor provided Internet Service Provider (ISP). The Contractor will utilize VPN connectivity, primarily CITRIX, on contractor owned equipment. The Contractor shall be responsible for maintenance and on-going technical support for all data wiring within the walls and ceilings from the data closet to the endpoints of the network. The Contractor is responsible for all charges related to the backup, contingency, and COOP connectivity. The VA will provide T-1 or Metro-E connection to each site and data circuits at each facility for the VA owned network.

53.4. The Contractor shall be responsible for procurement, installation and maintenance of all copiers, fax machines, shredders, or other peripheral office equipment required to perform under this contract.

53.5. In accordance with VA and VHA directives, policies, and handbooks, all equipment attaching to a VA network will be owned by the Mann-Grandstaff VAMC and controlled by the Mann-Grandstaff VAMC. No other equipment will be connected to this network. The use of the equipment will be for the benefit of the Government in providing care to our veterans. The equipment will only be used by those expressly authorized in

support of the Mann-Grandstaff VAMC. All users must comply with and adhere to VA Directives and VA Cyber Security policies.

- 53.6. The Mann-Grandstaff VAMC shall provide the PC workstations, software, primary telecommunications lines and networking equipment required to access the VISTA system. The VA shall provide necessary antivirus software for PC workstations and ensure that data definition files are current. In addition the VA will ensure that all Microsoft critical updates and patches are current.
- 53.7. The Contractor shall be responsible for installation and maintenance of the network infrastructure within the facility including, but not limited to, cabling located inside the walls of the structure and a secure communications closet space to house the patch panels and networking equipment (see para. “g” below). For backup, contingency and continuity of operations, the Contractor will provide connectivity to the Internet via cable modem, DSL or T1 circuits to the communications closet space. The Mann-Grandstaff VA will make and manage the connection from that connectivity to the VA owned networking equipment in the closet. Backup, contingency, COOP connectivity to the VA will be established through a VA provided Site-to-Site VPN connection utilizing Contractor provided Internet Service Provider (ISP). The Mann-Grandstaff VAMC will provide and manage the necessary VPN security router hardware. The Contractor shall be responsible for maintenance and on-going technical support for all data and voice wiring within the walls and ceilings from the data closet to the endpoints of the network. The Contractor is responsible for all charges related to the backup, contingency, and COOP connectivity. The VA will provide T-1 or Metro-E connection to each site and data circuits at each facility.
- 53.8. The VA will provide all networked printers. The Contractor shall be responsible for procurement, installation and maintenance of all printers, copiers, fax machines, shredders, or other peripheral office equipment required to operate the facility.
- 53.9. The VA will provide advisory technical support to the Contractor’s technical support person for the initial CBOC set-up relative to VISTA, CPRS and VPN connectivity. The Mann-Grandstaff VAMC will provide on-going technical support for VISTA and CPRS software and any other VA software applications. Technical support will be through an escalation process. The Contractor’s employee technical representative will submit a Help Desk request by calling (509) 434-7444. Initial technical support will be provided by the VA via telephone, which will consist of a VA technical representative speaking to a Contractor employed representative to identify the problem, trouble-shoot and attempt to resolve the problem with the Contractor’s end-user. If the problem cannot be resolved the VA will provide on-site support for VA owned equipment, VISTA, CPRS software and other VA

software applications, if necessary within two business days or less depending on the nature and severity of the problem.

- 53.10. The Contractor will not allow its inability to access VISTA to prevent any patient from being seen by a provider. In the event, and for any reason, that the Contractor is not able to access the VISTA system, the Contractor will record all data manually including the completion of the Encounter Form. Upon recovery of the Contractor's ability to access the VISTA system, the Contractor will input all data recorded manually into the VISTA system within forty-eight (48) hours of the system becoming operational.
- 53.11. The Contractor shall have a contingency plan for computer downtime that defines the processes in order to ensure continuity of patient care and maintenance of the integrity of the patient's medical record during periods of loss of computer functions. The contingency plan must be reviewed and approved by the COR. In addition, a contingency plan template that designates criticality of application/system, estimate of impact, locations of equipment, and contact persons will be provided to the Contractor for completion after award.
- 53.12. The Contractor shall provide a secure, double locked communications closet to house the computer networking equipment and network patch panel to service the clinic space. This space shall be at least 10'x10' with air conditioning and fire suppression. The solid core door to the communications closet shall have no vents, windows, or other gaps. This door shall be keyed separately with a copy of the key only provided to the VA Office of Information & Technology department and the site manager. Access to this space shall be strictly controlled to ensure adequate information security.
- 53.13. VA Handbook 6500 that requires the following statement on all fax cover sheets be included: *This fax is intended only for the use of the person or office to which it is addressed and may contain information that is privileged, confidential, or protected by law. All others are hereby notified that the receipt of this fax does not waive any applicable privilege or exemption for disclosure and that any dissemination, distribution, or copying of this communication is prohibited. if you have received this fax in error, please notify this office immediately at the telephone number listed above.*"

54. CONTRACTOR PERSONNEL SECURITY REQUIREMENTS:

- 54.1. All Contractor employees who require access to the Department of Veterans Affairs' facilities and/or information systems will be the subject of a background investigation (BI) and must receive a favorable adjudication prior to contract performance. This requirement is applicable to all subcontractor personnel requiring the same access. It is the responsibility of the Contractor to ensure their staff complete all necessary requests of information and paperwork related to the staff's background investigation within the requested timeframes. The Contractor

will be responsibility of for the actions of those individuals they provide to perform work for VA. The investigation must be initiated prior to being granted access to VA facilities and/or information systems. Costs are born by the Contractor.

54.2. Position Sensitivity – The position sensitivity has been designated as Low Risk.

54.3. The level of BI commensurate with the required level of access is National Agency Check with Written Inquiries (NACI).

54.4. Contractor Responsibilities:

- 54.4.1. Contractor shall coordinate with COR to schedule all employees for fingerprinting a minimum of 7 days prior to start date to ensure adequate time for adjudication.
- 54.4.2. The Contractor shall provide the COR a copy of the fingerprint verification (FPV) memo and the OF 306 for submission of the back ground request. See Section A for FPV Form, Optional Form 306, and Contractor Sponsorship Form. COR will provide updated copies of these forms as needed within 7 days.
- 54.4.3. The Contractor, when notified of an unfavorable determination by the Government, will withdraw the employee from consideration from working under the contract.
- 54.4.4. Failure to comply with the security requirements may result in termination of the contract for default.

54.5 Government Responsibilities:

- 54.5.1. Upon receipt, the VA Office of Security and Law Enforcement will review the completed forms for accuracy and forward the forms to OPM to conduct the BI.
- 54.5.2. The CO will notify the COR when an employee is cleared to begin services under the contract after Contracting Security has adjudicated the results of the BI received from OPM.
- 54.5.3. The COR will ensure that the Contractor provides evidence that investigations have been completed or are in the process of being requested.
- 54.5.4. The VA facility will provide Personal Identity Verification (PIV) Badges to


contract personnel that require access to VA Data Systems. VA Badges cannot be issued until BI has been scheduled. All badges must be returned to the Security office or the COR upon termination of employment.

54.6. Current Process: The following explains the current process for Background Investigations (BI) that are required for Contractor personnel to have routine access to a facility and to authorize access to VA/Federally owned information systems. This process may change during the life of this contract. This applies to all Contractor personnel performing services for the facility, including Community Based Outpatient Clinics (CBOC). This must be completed prior to the start date. This is a federal law and is established under HSPD-12, FIPS Pub-201-1, EO 10450, and VA Directive 0710. The process is specific and required beyond any additional agency credentialing and vetting processes.


54.6.1. All Contractor employees must submit the appropriate forms to the Department Sponsor, to begin the background application process (OF-306, PIV Sponsorship Form #3, Contract Security Services Request Form #1A, and VA Form 0710). Facilities are switching to a paperless application system and will require additional information.

54.6.2. These forms are required to be completed and turned the day fingerprints are performed at the Mann-Grandstaff VAMC or if done manually submitted with the fingerprint card provided by the VA.

54.6.3. A Special Agency Check (SAC) is a process in which fingerprints are captured to establish the identity of an individual and determine if there are any outstanding actionable issues, as noted by the FBI. A SAC is the initial requirement for the entire BI program.



-Your sponsor can assist you with scheduling an appointment at the nearest VHA or VBA facility.



- It takes approximately 48 hours to 2 weeks for contracting to receive the results and adjudicate them.

-Fingerprints done in the local community on a VA provided card are acceptable at this time but subject to change without advance notice.

-Processing of fingerprints captured on a VA provided card can take up to a minimum of four weeks before they are processed and adjudicated.

- If the fingerprints are unidentifiable, they will need you will need to be retaken at the expense of the Contractor.

54.6.4. A National Agency Check with Inquiries (NACI) is the minimum BI that is

required to access federal information systems and sensitive information. Contractor employee(s) shall not commence working at VA facilities under contract, until the Contracting Officer receives an email notification from the VHA Security and Investigation Center (SIC) in Little Rock, Arkansas, confirming completion of the Contractor employee's documentation.


- 54.6.5. Once the documentation has processed by SIC, the Contracting Officer/COR can authorize a tentative clearance for a Contractor employee to begin work on a contract.

- A NACI will be initiated if you have cleared the adjudication process at the local level. The NACI is a position sensitivity designation of low risk.


- The Contractor Employee, the Contracting Officer/COR, and one additional email account (Contractor's Supervisor, COR, etc); will receive all correspondence from the SIC.

- Upon the NACI request, the Contractor employee will be provided an email notice of receipt within 48 hours of the entry. This is an acknowledgement that the Contractor has been adjudicated and cleared at the local level.

- The Contractor employee will receive a second email notifying of entry into OPM's e-QIP database. Once received, the Contractor employee will have 7 days to go into his or her account at www.opm.gov/e-qip and complete the background questionnaire.



- Once the questionnaire is complete, the Contractor employee must ensure the "release to agency" has been clicked and the two signature pages are printed.



- The following forms are required for the SIC to proceed with processing your BI. They can be mailed or faxed to the secure fax to the number provided in the email to the contract staff.

-2 Signature Pages

- Once this is completed, your Contracting Officer will receive notification from the SIC. If there is missing information or further information is needed, an email will be sent to the contract employee, their point of contact listed on their completed form, and the contracting officer.

Problems with the e-QIP database can be handled by contacting the SIC Help Desk @ 501-257-4490

- 54.6.6. The Contractor shall provide complete Background Investigation applications, for all Contract Employees, promptly and in time to meet the contract performance or delivery schedule (or: within 7 calendar days after contract award). If a delay in the notification from SIC to the Contractor that a complete application has been received is due to the failure of the Contractor to provide a complete application as soon as practicable (or: within 7 calendar days) after contract award, this delay shall not excuse the Contractor from meeting the contract performance or delivery schedule and may result in termination for cause.
- 54.6.7. Background Investigation and Special Agreement Checks. All Contractor employees are subject to the same level of investigation as VA employees who have access to VA sensitive information or routine access to VA Facilities. The level of background investigation commensurate with the level of access needed to perform the statement of work is: NACI. This requirement is applicable to all subcontractor personnel requiring the same access.
- 54.6.8. The Contractor shall bear the expense of obtaining background investigations. If the investigation is conducted by the office of Personnel Management (OPM) through the VA, the Contractor shall reimburse the VA in 30 days.
- 54.7. Contractor personnel performing work under this 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. The Contractor shall be responsible for the actions of those individuals they provide to perform 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 Contractor shall be responsible for all resources necessary to remedy the incident. Printed output containing sensitive VA data shall be stored in a secured area and disposed of properly, per VA Directive 6371, Destruction of Temporary Paper Records (attached in Section D), 10/29/2012 (or subsequent revision thereto). Under the provisions of the Privacy Act of 1974 as amended, personnel performing work under this contract shall have an obligation to indefinitely protect VA information. At cost to the Contractor the chosen shredder device must have a crosscutting capability which produces particles that are 1 X 5 millimeters in size or smaller that will pulverize/disintegrate paper material using disintegrator devices with a 3/32 inch security screen. (Reference NSA Disintegrator Evaluated Products List). Furthermore it is the Contractor's responsibility to notify the service line ADPAC, Office of Information and Technology (OI&T) staff, or the Information Security Officer (ISO) when access to Automated Information Systems is no longer needed by personnel performing work under this contract.

- 54.8. Contractor employees are required to complete the most current version of the online training classes entitled “VA Privacy and Information Security and Rules of Behavior” and “Privacy and HIPAA Training” prior to receiving an account on the VA network and annually thereafter. The COR will assist contract personnel in establishing an account for each Contractor employee in the Talent Management System (TMS). The link to the training web site is <http://www.tms.va.gov>. A Certificate of successful completion will be generated and maintained by the COR. These certificates shall be made available upon request to the Privacy Officer, CO, Information Security Officer or Mann-Grandstaff VAMC RH Coordinator/COR or designee.
- 54.9. In performing this contract, the Contractor shall be considered part of the Department of Veterans Affairs (VA) for purposes of 38 U.S.C. §§ 5701 and 7332 (<http://uscodebeta.house.gov/>). Its employees shall only have access to patient medical records to the extent necessary to perform this contract. Notwithstanding any other provision of this contract, the Contractor and its employees may disclose patient records and individually-identified patient information, including information and records generated by the Contractor in performance of this agreement, only pursuant to explicit disclosure authority from VA.
- 54.10. The VA may provide Contractor and subcontractor employees with access to VA automated patient records maintained on VA computer systems only to the extent and under the same conditions and requirements as VA provides access to these records to its own employees.
- 54.11. All Contractor personnel and any subcontracted employees, if applicable, accessing the VISTA system will be required to sign and abide by all VA security policies, and applicable VA confidentiality statutes, 38 U.S.C. §5701, 38 U.S.C. §7332, and the Privacy Act, 5 U.S.C. §552a (<http://uscodebeta.house.gov/>). The VA will provide access applications and security agreements. All access request forms will be submitted to the ISO with required signatures. Contractor shall ensure the confidentiality of all patient information and shall be held liable in the event of the breach of confidentiality. Due to the confidential nature of medical reports, all transcription will be completed in areas that provide reasonable security and maintain the highest degree of auditory privacy. All documents are confidential and are protected under the Privacy Act of 1974, as amended. All vendor personnel shall be required to observe the requirements imposed on sensitive data by law, federal regulations, VA statutes and policy, DM&S policy and the associated requirements to insure appropriate screening of personnel.
- 54.12. The database utilized by the Contractor under this agreement, the adverse drug event reports provided to the Contractor by VA, and documents created from analyzing this database, the adverse drug event reports, and patient medical records are medical quality assurance records protected by 38 U.S.C. § 5705, its implementing regulations at 38 U.S.C. §§ 17.500-.511 and VHA Directive 2008-077, Quality Management (QM) And Patient Safety Activities That Can Generate

- Confidential Documents (attached in Section D), dated 11/7/2008 (or subsequent revisions thereto). These records may be disclosed only as authorized by § 5705 and the VA regulations. Disclosure of these records in violation of § 5705 is a criminal offense under 38 U.S.C. § 5705(e).
- 54.13. The treatment and administrative patient records created by, or provided to, the Contractor under this agreement are covered by the VA system of records entitled "Patient Medical Records - VA (24VA10P2).
- 54.14. Records created by the Contractor in the course of treating VA patients under this agreement is the property of the VA and shall not be accessed, released, transferred or destroyed except in accordance with applicable federal law and regulations and VA policies. Upon expiration of this contract or termination of the contract, the Contractor shall promptly provide the VA with any individually identified VA patient treatment records.
- 54.15. Portable media (including but not limited to thumb-drives, CD-ROMs, etc.): No portable media will be allowed on VA networked systems without express consent of the Mann-Grandstaff VA.
- 54.16. No VA data is permitted to be stored on a desktop or laptop computer hard drive. Any portable computer used under this contract must have the hard drive encrypted in accordance with FIPS 140-2 (<http://csrc.nist.gov/publications/fips/fips140-2/fips1402.pdf>).
- 54.17. No records containing Individually Identifiable Information or Protected Health Information, as defined by Federal law and regulation, shall be sent, maintained, stored or accessed by the Contractor (or any subcontractor(s) outside of the United States.
- 54.18. Privacy and Security incidents shall be reported immediately to the Mann-Grandstaff VAMC Privacy Officers for entry into the Privacy Violation and Tracking Software.
- 54.19. Poster containing the names and contact information for the Mann-Grandstaff VAMC Privacy and Security Officers will be prominently displayed in an area where all Veterans can easily view.
- 54.20. The VA's Notice of Privacy Practices must be prominently displayed and copies available upon request.
- 54.21. Liquidated Damages for Data Breach
- 54.21.1. Consistent with the requirements of 38 U.S.C. §5725 (<http://uscodebeta.house.gov/>), 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 Sensitive Personal Information (SPI) the Contractor/subcontractor processes or maintains under this contract.

54.21.2. The Contractor/subcontractor shall provide notice to VA of a security incident as set forth in the Contractor Personnel Security Requirements section above. Upon such notification, VA must secure from a non-Department entity or the VA Office of Inspector General an independent risk analysis of the data breach to determine the level of risk associated with the data breach for the potential misuse of any sensitive personal information involved in the data breach. The term “data breach” means the loss, theft, or other unauthorized access, or any access other than that incidental to the scope of employment, to data containing sensitive personal information, in electronic or printed form, that results in the potential compromise of the confidentiality or integrity of the data. Contractor shall fully cooperate with the entity performing the risk analysis. Failure to cooperate may be deemed a material breach and grounds for contract termination.

54.21.3. Each risk analysis will address all relevant information concerning the data breach, including the following:

54.21.3.1. Nature of the event (loss, theft, unauthorized access);

54.21.3.2. Description of the event, including:

- date of occurrence;
- data elements involved, including any Personally Identifiable Information (PII), such as full name, social security number, date of birth, home address, account number, disability code;
- Number of individuals affected or potentially affected;
- Names of individuals or groups affected or potentially affected;
- Ease of logical data access to the lost, stolen or improperly accessed data in light of the degree of protection for the data, e.g., unencrypted, plain text;
- Amount of time the data has been out of VA control;
- The likelihood that the sensitive personal information will or has been compromised (made accessible to and usable by unauthorized persons);
- Known misuses of data containing sensitive personal information, if any;
- Assessment of the potential harm to the affected individuals;

- Data breach analysis as outlined in 6500.2 Handbook, Management of Security and Privacy Incidents (<http://www1.va.gov/vapubs/>), as appropriate; and
- Whether credit protection services may assist record subjects in avoiding or mitigating the results of identity theft based on the sensitive personal information that may have been compromised.

54.21.3.3. 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 or the current rate established by VA Central Office of General Counsel to cover the cost of providing credit protection services to affected individuals consisting of the following:

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

55. **PATIENT RIGHTS AND RESPONSIBILITIES:** Contractor shall conform to all patients' rights issues addressed in the Mann-Grandstaff VAMC Medical Center Numbered Memorandum 00-53-12 Patient Rights and Responsibilities and all recessions (Attachment located under policy section of this document).

56. **VETERAN ELIGIBILITY AND BENEFITS:**

56.1. All veterans applying for care at the CBOC will have an application processed in VISTA by the Mann-Grandstaff VAMC to determine priority enrollment category for benefits. The Contractor shall adhere to the processes and guidelines established by the Supervisor, Eligibility office in regard to all issues concerning patient enrollment and registration. No Veteran will receive clinical care by a CBOC without the Contractor confirming enrollment within the Mann-Grandstaff VA with the exception of those veteran patients that meet the criteria stated under section 35.2 of this document. Persons not verified eligible who present to a CBOC in need

of urgent or emergent care will be treated on a Humanitarian basis until stable and discharged from CBOC, or referred to the proper level of care in the community. If the patient is determined to have no authorization for services, and has received care at the Contractor's CBOC, the patient will be billed directly by the Mann-Grandstaff VAMC and will be informed by staff at the CBOC that he is not eligible to continue receiving services at this site.

- 56.2. Registration and Enrollment: Contractor is expected to maintain a supply of 10-10EZs (Application for Health Benefits) (<https://www.1010ez.med.va.gov/sec/vha/1010ez/Form/1010EZ-fillable.pdf>) in the clinic for use by veterans to apply for health care benefits. The Contractor will offer to courier or fax (509-434-7122) all completed 10-10EZs and DD Form 214s to the Eligibility office for processing. Veterans may mail the forms themselves in which case the Contractor will provide the proper mailing address. Any questions related to registrations, enrollment, and dispositions can be referred to the Mann-Grandstaff VAMC Eligibility office at (509) 434-7009.
- 56.3. Financial Assessments (Means Tests and Copayment Exams): For some veterans, an annual assessment of household income (and sometimes assets) will be completed by the veteran prior to being seen by the Contractor's provider. The Contractor will provide a blank VA Form 10-10EZR (Renewal Application for Health Benefits) (<http://www.va.gov/vaforms/medical/pdf/vha-10-10ezr-fill.pdf>) to the veteran; and the veteran will fill it out completely, including the financial information on side two of the form. The completed forms will be sent or faxed to the Eligibility office for processing.
- 56.4. Co-Payment: A co-payment may be assessed for in-patient and outpatient services, as well as pharmaceuticals, to veterans. This co-payment is determined by priority group status and the law. All VA co-payments will be billed and collected by the Mann-Grandstaff VAMC and are not the responsibility of the Contractor. The Contractor will notify the patient that, depending on the priority group determination, there may be a co-payment. All disputes for VA co-payments will be referred to the Mann-Grandstaff VAMAC Business Office.

57. PATIENT SAFETY:

- 57.1. The Mann-Grandstaff VAMC will inform the Contractor of all pertinent TJC Sentinel Event Alerts, Patient Safety Alerts/Advisories and any other patient safety notices that are applicable. For every applicable alert from either the VA or TJC, the Contractor will take the necessary steps to redesign processes, if necessary, to prevent further occurrences, and shall provide written feedback to the Patient Safety Office and the COS/CBOCs describing prevention actions taken within the time frames as outlined in the alerts.
- 57.2. Adverse events at the CBOC will be reported promptly to the VA RHC Manager and the VA Patient Safety Manager or designee at 509-434-7302. In addition, an electronic Patient Safety Event Report will be completed, which is located on the

desktop of each VA computer workstation. Adverse events will be scored utilizing the Safety Assessment Code for determination of the need for conducting a Root Cause Analysis (RCA).

58. PATIENT COMPLAINTS:

58.1. The VA Patient Advocacy Program was established to ensure that all veterans and their families, who are served in VHA facilities and clinics, have their complaints addressed in a convenient and timely manner in accordance with VHA Handbook 1003.4, "VHA Patient Advocacy Program," dated 9/2/05 (or subsequent revision thereto) available at the following hyperlink: http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=1303. Response to complaints will occur as soon as possible, but no longer than seven (7) days after the complaint is made. All patient complaints will be entered in the National Patient Complaint database. Information concerning the Patient Advocacy Program must be prominent and available to CBOC patients. The Mann-Grandstaff VA will provide the Contractor with informational handouts describing the program and how to contact the VA Patient Advocate.

59. GRIEVANCE SYSTEM REQUIREMENTS:

59.1. The enrolled patients have the right to grieve actions taken by the Contractor, including disenrollment recommendations, directly to the Contractor. The Contractor shall provide readable materials reviewed and approved by Mann-Grandstaff VAMC, informing enrolled patients of their grievance rights. The Contractor shall develop internal grievance procedures and obtain Mann-Grandstaff VA approval of the procedures prior to implementation. The grievance procedures shall be governed by the guidelines in VHA Handbook 1003.4 as cited in 60.1 of this document.

59.2. PERFORMANCE STANDARDS, QUALITY ASSURANCE AND QUALITY IMPROVEMENT: Services and documentation of care provided under the resultant contract shall be subject to quality management and safety standards as established by VA, consistent with the standards published by TJC or equivalent. The contractor shall develop and maintain Quality Improvement/ Quality Assurance Programs and provision of care equal to or exceeding VA Standards. The results of all Quality Improvement activities performed by the contractor involving VA patients will be shared with VA Quality Management Office. Documentation by the Contractor provided to the VA includes, but is not be limited to the following:

59.2.1. Quality improvement plans: Staff meetings minutes (or summary minutes) where quality improvement has been discussed and which include practitioner-specific findings, conclusions, recommendations and written plans for actions taken in response to such conclusion and recommendations, and evaluation of those actions taken.

59.2.2. Contractor must be accredited by the TJC or maintain a level of service that is in compliance with all current TJC standards. If the Contractor is TJC accredited, he/she will be required to furnish a copy of the accreditation letter(s) upon request by the Contracting Officer prior to award.

59.2.3. Listed below is the current outline of topics covered in The TJC manual of standards that must be met by the Contractor:

59.2.3.1. Patient-Focused Functions

- Ethics, Rights, and Responsibilities
- Provision of Care, Treatment, and Services
- Medication Management
- Surveillance, Prevention, and Control of Infections

59.2.3.2. Organization Functions

- Improving Organization Performance
- Leadership
- Management of the Environment of Care
- Management of Human Resources
- Management of Information

59.2.3.3. Structure with Function

- Medical Staff
- Nursing
- Medication Management

59.2.4. The Contractor shall notify the Chief of Staff in writing whenever a malpractice claim involving a VA patient has been filed against the Contractor. The Contractor shall forward a copy of the malpractice claim within three (3) workdays after receiving notification that a claim has been filed. The Contractor shall also notify the Chief of Staff when any provider furnishing services under this contract is reported to the National Practitioner Data Bank. This notification shall include the name, title, and specialty of the provider. All written notifications will be sent to the following address with a courtesy copy to the COR:

Mann-Grandstaff VAMC
Office of Chief of Staff (11)
4815 N. Assembly St.
Spokane, WA 99205-6197

The COR will notify the CO of any notification received from the Contractor.

- 59.2.5. The Contractor shall permit on-site visits by VA personnel and TJC surveyors accompanied by VA personnel and/or other accrediting agencies to assess contracted services, e.g., adequacy, compliance with contract requirements, record-keeping, etc.
- 59.2.6. The Contractor will comply with all current Mann-Grandstaff VAMC Policies. The Contractor shall participate in all quality improvement activities. The Contractor is required to meet VHA performance and quality criteria and standards including, but not limited to, customer satisfaction, prevention index, chronic disease index and clinical guidelines. The prevention index and chronic disease index are found in Handbook 1120.2, entitled, "Health Promotion and Disease Prevention Core Program Requirements" or subsequent revisions (located under policies in this document), dated 10/30/2006 (or subsequent revisions thereto). The Contractor shall comply with Handbook 1330.01, "VHA Services for Women Veterans" (located in the policy section on this document), dated 5/21/2010 (or subsequent revisions thereto). Performance and quality standards may change during the course of the contract. New or revised quality/performance criteria or standards will be provided to the Contractor before their implementation date. Compliance with mandated performance is required as a condition of this contract.
- 59.2.7. The Mann-Grandstaff VA is committed to providing high quality primary care. The Mann-Grandstaff VA measures quality in primary care through its performance measurement system. Several process and outcome measures are extracted by external reviewers from random samples of records of veterans who visited VA primary care providers at CBOCs. These measures change from year to year. The current performance measures and method of extraction are available at <http://vaww.oqp.med.va.gov>. The Contractor is responsible for achieving levels of performance on these measures that meet or exceed the annual expectations for performance of VISN 20 as outlined in the PACT performance measures and Network Performance Plan. Revisions/updates to the PACT reporting measures and Network Performance Plan will be provided as needed by the COR. The Contractor is required to utilize the CPRS clinical reminder system as a means of both ensuring high performance on these measures and to facilitate monitoring of performance at the site independent of external reviewers. Clinical reminders are required to be addressed at the time of the visit and positive screens must be addressed by the provider. Levels of performance on the quality measures in primary care and mental health will be used as a factor in decisions about renewal of the contract.

59.2.8. The Contractor shall document in writing on appropriate orientation programs for all employees involved in the delivery of patient care, e.g., infection control procedures, patient confidentiality, handling emergencies, patient safety, etc., and provide a copy to the Mann-Grandstaff VA COR. Contractor shall be required to furnish method/guidelines by which he/she intends to meet above requirement.

59.2.9. The Contractor will have a quality monitoring/performance improvement program. This program will be available to Mann-Grandstaff VA staff and TJC. The Mann-Grandstaff VA will provide regular feedback on clinic performance measures, including but not limited to the following: licensure verification, workload, consults, drug and lab utilization, formulary compliance, prescription writing patterns, Prevention and Performance measures, patient satisfaction, and medical record completeness. The Contractor shall conduct audits pertaining to access, quality improvement, documentation, and safety and performance measures. These reports shall be submitted to the COR on a monthly basis and sent via secured email using PKI or utilizing the Lab Courier.

60. STANDARDS:

60.1. The Contractor shall meet all Federal, State, and Local fire and Life Safety Codes.

60.2. The Contractor shall be responsible for meeting national quality standards and shall comply with mandated policies established by VA Central Office (VACO) Patient Care Services (PCS). Each fiscal year new quality standards are developed by PCS and forwarded to each VISN for implementing at each primary care site to include CBOCs. Those standards are found at the VA website as indicated in section 61.1.7. of this document.

60.3. The Contractor shall be responsible for meeting quality standards and shall comply with the policies of Mann-Grandstaff VAMC.

61. REQUIRED REGISTRATION WITH CONTRACTOR PREFORMANCE ASSESSMENT REPORTING SYSTEM (CPARS):

As prescribed in Federal Acquisition Regulation (FAR) Part 42.15, the Department of Veterans Affairs (VA) evaluates Contractor past performance on all contracts that exceed \$150,000, and shares those evaluations with other Federal Government contract specialists and procurement officials. The FAR requires that the Contractor be provided an opportunity to comment on past performance evaluations prior to each report closing. To fulfill this requirement VA uses an online database, CPARS, which is maintained by the Naval Seal Logistics Center in Portsmouth, New Hampshire. CPARS has connectivity with the Past Performance Information Retrieval System (PPIRS) database, which is available to all Federal agencies. PPIRS

is the system used to collect and retrieve performance assessment reports used in source selection determinations and completed CPARS report cards transferred to PPIRS. CPARS also includes access to the federal awardee performance and integrity information system (FAPIS). FAPIS is a web-enabled application accessed via CPARS for Contractor responsibility determination information. Each Contractor whose contract award is estimated to exceed \$150,000 is required to register with CPARS database at the following web address:

www.cpars.csd.disa.mil. Help in registering can be obtained by contacting Customer Support Desk @ DSN: 684-1690 or COMM: 207-438-1690. Registration should occur no later than thirty days after contract award, and must be kept current should there be any change to the Contractor's registered representative.

For contracts with a period of one year or less, the contracting officer will perform a single evaluation when the contract is complete. For contracts exceeding one year, the contracting officer will evaluate the Contractor's performance annually. Interim reports will be filed each year until the last year of the contract, when the final report will be completed. The report shall be assigned in CPARS to the Contractor's designated representative for comment. The Contractor representative will have thirty days to submit any comments and re-assign the report to the VA contracting officer. Failure to have a current registration with the CPARS database, or to re-assign the report to the VA contracting officer within those thirty days, will result in the Government's evaluation being placed on file in the database with a statement that the Contractor failed to respond.

62. GOVERNMENT RESPONSIBILITIES:

62.1.OVERSIGHT OF SERVICE/PERFORMANCE MONITORING:

62.1.1. CO Responsibilities:

- 62.1.1.1. The CO is the only person authorized to approve changes or modify any of the requirements of this contract. The Contractor shall communicate with the CO on all matters pertaining to contract administration. Only the CO is authorized to make commitments or issue any modification to include (but not limited to) terms affecting price, quantity or quality of performance of this contract.
- 62.1.1.2. The CO shall resolve complaints concerning Contractor's provider relations with the Government employees or patients. The CO is final authority on validating complaints. In the event the Contractor effects any such change at the direction of any person other than the CO without authority, no adjustment shall be made in the contract price to cover an increase in costs incurred as a result thereof.
- 62.1.1.3. In the event that contracted services do not meet quality and/or safety expectations, the best remedy will be implemented, to include but not limited to a targeted and time limited performance improvement plan;

increased monitoring of the contracted services; consultation or training for the contract staff to be provided by the VA; replacement of the contract staff and/or renegotiation of the contract terms or termination of the contract.

62.1.2. The COR:

62.1.2.1. The COR shall be the VA official responsible for verifying contract compliance. After contract award, any incidents of Contractor or Contractor's provider noncompliance as evidenced by the monitoring procedures shall be forwarded immediately to the Contracting Officer.

62.1.2.2. The COR will be responsible for monitoring the Contractor staff performance to ensure all specifications and requirements are fulfilled. Quality Improvement data that will be collected for ongoing monitoring is outlined in the QASP.

62.1.2.3. The COR will maintain a record-keeping system of services by reviewing the QASP and invoices submitted by the Contractor. The COR will review this data monthly when invoices are received and certify all invoices for payment. Any evidence of the Contractor's non-compliance shall be forwarded immediately to the Contracting Officer.

62.1.2.4. The COR will review and certify monthly invoices for payment. If in the event the Contractor fails to provide the services in this contract, payments will be adjusted to compensate the Government for the difference.

62.1.3. All contract administration functions will be retained by the VA.

62.1.3.1. **Contract Administration:** After award of contract, all inquiries and correspondence relative to the administration of the contract shall be addressed to:

Contraction Officier (CO)
Mark Mitchell
509-321-1907
Spokane, WA 99205
Mark.Mitchell14@va.gov

The Contracting Officer's Representative (COR) for this contract is:
Kim Waller
509-434-7533
4815 N. Assembly Street
Spokane, WA 99205
Kimberly.Waller@va.gov

62.1.3.2. **Liaison Persons:** The VA has designated the following liaison personnel for this resultant contract –

Title	Role	Phone Number
Primary Care Service Line	Chief of Ambulatory Care	509-434-7635
CBOC Manager/Coordinator	COR and Admin Contact	509-434-7533
Administrative Officer of the Day	Contact for any administrative and clinical problems that arise after normal working hours of 8:00 AM-4:30 P.M., Monday - Friday, weekends and holidays	509-434-7010
IT "Help Desk"	Assistance with VISTA	509-434-7444
HIMS ADPAC	Assistance with Patient Information Management System (PIMS)	509-434-7516
Patient Registration Office	Assistance with Patient Eligibility	509-434-7009
Patient Billing	Assistance with Financial Assessments	509-
Outpatient Pharmacy	Outpatient Pharmacy Supervisor	509-434-7931
Health Information Management Service	Assistance with CPRS and Medical Records	509-828-9216
VA Patient Advocate	Assistance with patient complaints, etc.	509-434-7504
Ancillary Testing	Questions involving lab work, x-rays, and other ancillary testing	509-434-7563
Pathology and Laboratory Medicine	Chief Medical Technologist for pathology and laboratory medicine	509-434-7565
Women Veterans Health Services	Program Manager for women veterans health issues	509-434-7608
Radiology Service	Chief Technologist for radiology imaging related questions	509-434-7356

- 62.1.3.3. While the liaison persons identified and other VA staff may be contacted for questions/information and/or may visit the CBOCs to oversee policy compliance, **only the CO is authorized to make commitments or issue changes which will affect the price, quantity, quality, or delivery terms of this contract.** Any guidance provided, which the Contractor feels is beyond the scope of this contract, must be communicated to the CO, via the COR, for possible contract modification.
- 62.1.3.4. The Contractor shall identify a contact person(s), who shall serve as liaison between the Contractor and the COR. This individual shall also ensure the functionality of the clinic according to contract specifications. The contact person(s) shall be readily available during the administrative tour of duty from 8:00 AM - 4:30 PM Monday through Friday, and

accessible in case of after hour emergencies. Furthermore the Contractor shall have a defined chain of command for the CBOC with a designated Clinic Manager who has responsibility for daily activates of the clinic.

63. CONTRACTOR REQUIREMENTS

- 63.1. The Contractor's start-up requirements must be completed prior to the commencement of the Contractor's treatment of VA enrolled patients. Upon approval by the VA of the Contractor's completion of the start-up requirements, the VA will issue a written Notice to Proceed to the Contractor.
- 63.2. The Contractor shall have ninety (90) days from contract award to commencement of the provision of medical care to local veterans. However, the Contractor must have all start-up requirements in place and ready to commence operation no later than (NLT) eighty-three (83) calendar days from contract award. The final seven (7) days will be used for training and resolution of any last minute or unexpected technical or personnel related challenges.
- 63.3. The Contractor will hire, train, and ensure licensure of all necessary personnel prior to the commencement of clinical operations.
- 63.4. The Contractor shall furnish evidence of insurability of the offeror and/or of all health-care providers, who will perform under this contract (see VAAR 852.237-7, *Indemnification and Medical Liability Insurance*, OCT 1996).
- 63.5. All Contractor-provided health care services shall be available:
- Preventive Health Services.
 - Primary Care Services.
 - Physician Services.
 - Telehealth Services.
- 63.6. The Contractor's case management program with primary care providers as case managers for all health care services provided to enrolled patients shall be operational.
- 63.7. The Contractor's VA approved performance improvement program shall be operational.
- 63.8. The Contractor's facility shall be in compliance with the requirements of this contract.
- 63.9. The VA will provide training to the Contractor at the Mann-Grandstaff VA relative to data reporting needs, computer system access to VISTA, CPRS, eligibility issues, billing procedures and medical referral procedures within eighty-nine (89) calendar

days of contract award. The Contractor is responsible to provide future training to his/her personnel after the initial ninety (90) calendar days of the contract award. The Contractor must provide documentation of training prior to Pathology and Laboratory Medicine providing access to VISTA laboratory software options. The Contractor will be responsible for attendance and performance regarding training sessions. Training will be coordinated by the COR and the Contractor's designee. After contract performance begins, VA staff is readily available by telephone, e-mail, and Lync to answer questions and provide guidance.

- 63.10. Upon receipt of Notice of Award, Contractor will **immediately** commence the credentialing and privileging process for all physicians, LIP's, and registered nurses through the VA. A minimum of eight (8) calendar weeks is required for VA credentialing after the package has been completed and received from the provider.

64. PATIENT TRANSPORTATION: Each patient will be responsible for his/her own transportation to appointments.

65. CONTRACTOR'S PHYSICAL FACILITY:

- 65.1. Signage: The Contractor shall furnish and install clearly visible signage on the exterior of the building, in the front window, or on the door which displays the VA logo and reads at a minimum:



VA COMMUNITY BASED OUTPATIENT CLINIC

- 65.2. The Contractor shall provide the COR with a diagram of the proposed sign which specifies dimensions and identifies the installation location for approval by the COR prior to fabrication of the sign. The VA has named Community Based Outpatient Clinics to reflect the county in which they are located.

- 65.3. The Contractor's facility must be in compliance with National Fire Protection Association (NFPA) Life/Safety requirements and the Americans with Disabilities Act. It must also assure privacy for women during examinations and with restroom facilities. Restrooms must also provide at least one changing table for infants. Mann-Grandstaff VAMC shall inspect the Contractor's facility. Contractor must be in compliance with these requirements prior to contract start date. Any inspection shall be conducted during normal Mann-Grandstaff VAMC business hours of 8:00 AM – 4:30 PM, Monday through Friday by the VA Safety Specialist or designee. A

list of any deficiencies identified during an inspection will be provided to the Contractor along with a required date for correction of the deficiencies. Any planned changes in the physical environment at the CBOC must be reviewed and approved by the Mann-Grandstaff VAMC to ensure that all life safety codes are met. Parking should be adequate enough to accommodate veteran patients, and shall include at least two (2) handicapped parking spaces.

65.4. Privacy Standards:

- 65.4.1.1. Veterans must be provided adequate visual and auditory privacy at check-in. Patient names are not posted or called out loudly in hallways or clinic areas.
- 65.4.2. Veterans must be provided adequate visual and auditory privacy in the interview area.
- 65.4.3. Patient-identified information must not be visible in the hall including charts where names are visible. Every effort should be made to restrict unnecessary access to hallways by patients and staff who do not work in that clinic area.
- 65.4.4. Patient dignity and privacy must be maintained at all times during the course of a physical examination.
- 65.4.5. The examination rooms must be located in a space where they do not open into a public waiting room or a high-traffic public corridor. Appropriate locks (either electronic or manual) for examination room doors are required (allowing staff to have key or code access in the case of emergency). When doors are closed, all healthcare personnel must knock, WAIT and enter only after invited in.
- 65.4.6. Privacy curtains must be present and functional in examination rooms. Privacy curtains must encompass adequate space for the healthcare provider to perform the examination unencumbered by the curtain. A changing area must be provided behind a privacy curtain. Curtains will be cleaned annually or when soiled.
- 65.4.7. Examination tables must be placed with the foot facing away from the door. If this is not possible, tables must be fully shielded by privacy curtains.
- 65.4.8. Female patients who are undressed or wearing examination gowns must have proximity to women's restrooms that can be accessed without going through public hallways or waiting rooms.
- 65.4.9. If toilet facilities cannot be located in close proximity to the examination

room, the woman must be discreetly offered the use of a toilet facility before she disrobes for the exam.

65.4.10. Sanitary napkin and tampon dispensers and disposal bins must be available in women's public restrooms. Tampons and sanitary pads should also be available in examination rooms where pelvic examinations are performed and in bathrooms within close proximity.

65.4.11. Restrooms must also provide at least one changing table for infants.

65.4.12. Contractor will comply with future revisions to Privacy Standards as may be issued by VHA or Mann-Grandstaff VAMC.

66. **BILLING-CPT CODES:** The Contractor shall adhere to the most current procedural terminology (CPT) coding standards used for primary care and mental health services – examples listed of CPT and Health Care Common Procedural Coding System (HCPCs) – this list is not all inclusive as it is subject to conformance to the Centers for Medicare and Medicaid Services (CMS) regulations. The contractor will submit applicable codes should changes be required based on CMS updates. As such, the contractor is responsible for identifying applicable CPT, HCPCs and any additional coding each year as CMS regulations are updated.

<u>CPT CODES</u>	<u>SERVICES</u>
99201-99215	Office or Other Outpatient Services (Primary Care)
99354-99355	Prolonged Services Face to Face
99441-99443	Telephone Calls to Patient or Other Health Care Professionals
99381-99397	Preventive Medicine Service
99401-99429	Counseling and or Risk Factor Reduction Intervention
36410, 36415	Venipuncture for collection of specimens

<p>Included in CPT codes listed elsewhere in this table.</p>	<p>Female: Women's health services, including but not limited to, pelvic/breast exams; contraception counseling and management; management of osteoporosis, menopause, pelvic pain, abnormal uterine bleeding, and sexually transmitted diseases; in addition to screening for breast and cervical cancer or, a history of sexual trauma. Referral for pregnancy, mammography and recognition of ectopic pregnancy. GYN abnormalities should be referred through a Gynecology consult to the Parent facility.</p>
<p>65205</p>	<p>Eye: Superficial removal of foreign bodies.</p>
<p>69000-69200</p>	<p>Ear: Simple procedures</p>

69210	(e.g., drainage ext. ear abscess, removal foreign body).
81002, 81025, 82272QW, 82075, 82948, 83036QW, 85610QW	Laboratory Services as follows: Urinalysis (non-automated w/o microscopic), pregnancy testing (visual color comparison), occult blood feces 1-3 tests, breath alcohol, whole blood glucose, glycated Hemoglobin (A1C), and prothrombin time/INR. Optional Provider Performed Tests are as follows: Gastrocult and crystals. <i>Note: These (waived) laboratory tests can be typically done in physicians' offices. All other laboratory services should be referred to VA.</i>
90700-90749	Immunization Injections as recommended by CDC, or other recognized medical groups/academies.
93000, 93005, 93010, 93040, 93041, 93042	Cardiography Services are limited to ECG performance and interpretation. <i>Note: The Contractor must utilize MUSE-compatible EKGs – FILLIN – VA provided EKGs and Holter Monitor (as applicable to your facility).</i>
94010, 94060, 94640, 94760	Performance and interpretation of spirometry and pulse oximetry for oxygen saturation. Other pulmonary procedures are excluded.

10060, 10061, 10080, 10081, 10120, 11200, 11730, 11770, 12001, 12002, 12004, 12005, 12006	Minor Surgery. Procedures are limited to minor surgeries that only require local anesthesia.
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67. BILLABLE ROSTER:

67.1. Additions to Billable Roster

67.1.1. Mann-Grandstaff VAMC has the sole authority to assign Veterans who are treated by the Contractor into the Primary Care Management Module (PCMM) software program used to track Primary Care Clinic Veteran rosters. Eligibility determination and enrollment of VA eligible enrolled Veterans in the Contractor's plan will be the responsibility of the Mann-Grandstaff VAMC. The Contractor is responsible for notifying the Mann-Grandstaff VAMC through electronic shared-drive spreadsheets of newly seen Veterans at the Contractor's site that are not already assigned in the PCMM software program. The Mann-Grandstaff VAMC will then verify that the Veteran was seen through VISTA documentation and enter the Veteran into the PCMM software as credited to the Contractor's site and associated clinic roster. Contract PACT teams will be set up in PCMM.

67.1.2. If the Contractor seeks to place on the billable roster a Veteran at the Contractor's site who is already assigned to another primary care team or provider in the VHA, the Mann-Grandstaff VAMC will have final authority to designate the primary care site for the Veteran. The main basis for this decision will be Veteran preference. Veterans will not be allowed to be assigned to more than one Mann-Grandstaff VAMC CBOC. In addition, Veterans will not be allowed to be assigned simultaneously at the Contractor's site and in any of the primary care teams at Mann-Grandstaff VAMC. A Veteran's checked out visit to a particular CBOC will be deemed to be an expression of that Veteran's preference as to a particular primary care site.

67.1.3. For Veterans newly assigned to the CBOC, the Contractor will be paid the monthly capitation rate for the full month in which the first visit occurs where medical care is provided to the Veteran at the Contractor's facility by a Primary Care Provider (PCP) completing and properly documenting an appropriate vesting visit and using the proper vesting CPT Codes. (nurses, social workers, psychologists, etc., are **not** considered appropriate PCPs by Mann-Grandstaff VAMC.). Acceptable ***Vesting CPT Codes*** for

this purpose are: 99203-99205; 99213-99215; 99243-99245; 99385-99387; or 99395-99397. All payments will be monthly in arrears.

67.2. Removal from Billable Roster

67.2.1. The Contractor is responsible for confirming with the Mann-Grandstaff VAMC Veterans who are no longer included on the billable roster at the Contractor's site. This includes Veterans who have died, moved to other areas, decided to receive their primary care elsewhere or whom the Contractor or Mann-Grandstaff VAMC has determined have **not** received a proper Vesting Exam Visit by the Contractor provider in the previous 12 months, i.e., do not have a visit with one Primary Care Provider which merited at least one of the ***Vesting CPT Codes*** noted in para. 70.1.3. of this document. Delayed notification that a Veteran has been removed from the billable roster for reasons documented in sections 70.2.6.9. – 70.2.6.12. below, will result in offsets being taken against subsequent invoices. Delayed notification includes circumstances in which the Contractor or Mann-Grandstaff VAMC, through no fault of their own, do not receive such information until after the fact.

67.2.2. In the event that a Veteran has a legitimate complaint and demands disenrollment for cause, payment will be discontinued as of the month the patient is dis-enrolled and the Contractor is notified. If arbitration is necessary, clinical issues will be referred to the Medical Director of the contracted facility and the Associate Director of Ambulatory Care Services for Mann-Grandstaff VAMC. In the event that a decision cannot be reached at the clinical level, referral shall be made to the Contracting Officer for final determination. This decision shall be binding.

67.2.3. Contractor, with approval of the COR, may disenroll a Veteran (remove from billable roster) for legitimate cause that may include:

67.2.3.1. Repeated disruptive behavior in clinic;

67.2.3.2. Threatening behavior towards CBOC personnel;

67.2.3.3. The Contractor shall contact the COR, or the designated representative, to discuss any issues, including possible removal from the billable roster, due to disruptive Veteran behavior. Mann-Grandstaff VAMC has a disruptive behavior review board that will be consulted with when making these decisions.

67.2.4. The Mann-Grandstaff VAMC has ultimate authority to remove from the billable roster, at any time, an enrolled Veteran from the responsibility of the Contractor. The Mann-Grandstaff VAMC will notify the Veteran (with the exception of sections 70.2.6.9. – 70.2.6.12. below) and the

Contractor of the effective date of removal from the billable roster. Removal of Veterans from the Contractor's responsibility may occur, but not be limited to, the following reasons:

- 67.2.4.1. The Veteran loses eligibility for VA care.
- 67.2.4.2. The VA decides that removal from the billable roster is in the best interest of the Veteran.
- 67.2.4.3. The Veteran was found to have falsified the application for VA services, and approval was based on false information.
- 67.2.4.4. When it is determined that a Veteran has abused the VA system by allowing an ineligible person to utilize the Veteran's identification card to obtain services.
- 67.2.4.5. When it is determined that the Veteran has willfully and repeatedly refused to comply with the Contractor's requirements or VA requirements, subject to federal laws and regulations.
- 67.2.4.6. When it is determined that the Veteran has abused the VA program by using VA identification card to seek or obtain drugs or supplies illegally or for resale, subject to state and federal laws and regulations.
- 67.2.4.7. The Contractor gives written notification to the VA that the Contractor cannot provide the necessary services to the Veteran or establish an appropriate provider Veteran relationship.
- 67.2.4.8. If the Veteran fails to show up for two consecutive appointments, Contractor shall notify the Veteran by letter after second no show, advising of potential disenrollment from the CBOC (and removal from the billable roster) if Veteran does not contact provider within two (2) weeks of notification. The Contractor shall notify the VA of any Veteran that does not respond to disenrollment notification, immediately after the lapse of the two (2) week period from notification of the Veteran.
- 67.2.4.9. Death of the Veteran.
- 67.2.4.10. When a Veteran moves to another area.
- 67.2.4.11. When a Veteran receives his/her primary care elsewhere.
- 67.2.4.12. The Veteran receives no document encounter from their Primary Care Manager within 12 months of the last vesting visit as defined in section 67.1.3 of this document.

NOTE: These circumstances may become known after the fact. Upon discovery of these situations, the Contractor shall credit or reimburse the Mann-Grandstaff VAMC back to the original date of the removal criteria being met for reasons 67.2.4.9.-67.2.4.12. above. In addition should patients be discovered that legitimately should be enrolled to the Contractor in VISTA, the VA will ensure reimbursement is included in the next billing cycle after discovery.

67.2.5. For Veterans removed from the billable roster under the per Veteran per month (PMPM) capitation payment method, the Contractor will be paid the monthly capitation rate for the full month in which the date of removal occurred.

67.2.6. If the Contractor disagrees with a removal from the billable roster, the issue will be referred to the Mann-Grandstaff VAMC Contracting Officer (CO) for resolution. Provided that such resolution is consistent with the other terms of the contract, the final decision of the CO is binding. Invoicing will not be delayed unnecessarily due to minor discrepancies. Invoices for the non-disputed portion will be generated while the Contractor and CO reconcile disputed patients.

67.3. Monthly Billable Roster and Invoice Reconciliation:

67.3.1. Monthly billable roster and invoice reconciliation shall take place as follows:

67.3.1.1. The VA shall present to the Contractor the VA billable roster for the applicable month to be invoiced.

67.3.1.2. The Contractor shall reconcile the VA billable roster with its records, negotiate any differences between its records and the VA billable roster, and invoice the VA.

67.3.1.3. The VA shall certify the Contractor's invoice.

67.3.2. No later than the **seventh** (7th) workday of each month, the VA CBOC Coordinator or the COR (or their designee) will submit to the contractor a list of Veteran names who properly meet the billing criteria. This list is the VA billable roster for the applicable month to be invoiced. This list will represent the Veterans for whom the VA is willing to provide payment for the previous month. This list will include the names of all Veterans who have received a vesting exam from a PCP within the previous 12 calendar months using one or more of the Vesting CPT codes listed earlier in this solicitation / contract. (Example: A list sent to the Contractor on October 7, 2009 will cover the time frame of October 1, 2008 through September 30, 2009.) These vesting exams must be completed by an appropriate provider employed by the Contractor and working in that particular CBOC. An appropriate provider can only be a physician trained in Internal Medicine or

Family Practice, or a Certified Registered Nurse Practitioner, or a Physician Assistant, or a Psychiatrist (if the psychiatrist actually completes and documents a proper vesting exam and uses a proper vesting CPT code). **The list of proper vesting CPT codes is: 99203-99205; 99213-99215; 99243-99245; 99385-99387; or 99395-99397.** This billable roster represents all Veterans seen in a “vesting” appointment in the previous 12 months minus any Veterans who may have been seen in that timeframe but have, in the meantime, died, moved to another location and do not plan to receive care at the particular CBOC, or have transferred their care to either another CBOC, a VA Medical Center, or to a private medical practitioner, or who meet any of the remaining disenrollment categories.

67.3.3. The VA will also provide the Contractor with alphabetically arranged lists of names of Veterans who were removed that month from the billable roster due to death, relocation, transfer of care, failure to be seen in a vesting visit for the previous 12 months and/or any one of the reasons listed above. The list shall also include which disenrollment reason is applicable to the particular disenrolled Veteran.

67.3.4. Veteran names that come to either the VA or the Contractor’s attention after the fact will not only be removed from the current list of invoiced names, but the Contractor will also credit or reimburse the VA for any previous months that may have passed during which time the VA and/or the Contractor were unaware of the Veteran’s demise, relocation, receipt of health care at a different location or any other reason listed in above, for which the VA was paying the Contractor for perceived care.

67.3.5. The Contractor shall reconcile the VA billable roster with its records. Any perceived discrepancies identified by the Contractor, regarding the VA provided billable roster, will be required to be negotiated between the Contractor and the CBOC Coordinator/COR or the CO or their designee. The final Arbitrator to any disagreements between the Contractor and the VA regarding this billable roster is CO. CO decisions in this regard are final, provided that such decision is consistent with the other terms of the contract.

67.3.6. Upon receipt of an electronic invoice from the Contractor, based on the billable roster agreed upon and including supporting data, the VA will certify the invoice for payment. The Contractor shall have 30 calendar days from the date of invoice to justify any additions to the billable roster for the applicable month of invoice. After 30 calendar days, no further changes will be authorized for the applicable month’s invoice.

68. INVOICING AND PAYMENT:

68.1. Payments will be made monthly, in arrears. The Contractor will be reimbursed at the capitation rate specified in the *Price Schedule* on page one of this document.

The Contractor will be reimbursed upon receipt of a proper invoice. Invoices will contain the following information:

68.2. Invoices will include the following three separate categories:

- 68.2.1. Total number of listed Veterans from the previous month's invoice.
- 68.2.2. New Veterans added to the billable roster since the previous month's invoice.
- 68.2.3. Veterans removed from the billable roster since the previous month's invoice.
- 68.2.4. Number of Veterans (if any) whose disenrollment generate a credit, the amount of the credit, and the calculation(s) used to arrive at the credit.
- 68.2.5. The newly enrolled and disenrolled categories will list, alphabetically: each listed Veteran Patient's name followed with his/her social security number and date of first visit and/or date of removal, as appropriate. Invoices will also reference the following:

Contract Number
Month Being Invoiced
Number of Patients Being Invoiced
Capitation Rate
Total Amount Due

- 68.2.6. Invoices will be submitted to: See VAAR clause 852.232.72, Electronic Submission of Payment Requests, <http://farsite.hill.af.mil/vfvara.htm> .

68.3. Veteran Patients determined to be ineligible for VA medical care will be billed by Mann-Grandstaff VAMC for the care rendered in accordance with VA regulations. Mann-Grandstaff VAMC will reimburse the Contractor for one visit for patient or Veteran subsequently deemed ineligible by Mann-Grandstaff VAMC. Reimbursement will be at the capitated rate if the visit meets Vesting criteria.

68.4. The Contractor shall accept payment for services rendered under this contract as payment in full. The Mann-Grandstaff VAMC beneficiaries shall not under any circumstances be charged nor their insurance companies be charged for services rendered by the Contractor, even if Mann-Grandstaff VAMC does not pay for those services. This provision will survive the termination or ending of the contract. To the extent that the Veteran desires services which are not a Mann-Grandstaff VAMC benefit or covered under the terms of this contract, the Contractor will notify the Veteran that there will be a charge for such service and that the Mann-Grandstaff VAMC will not be responsible for payment. 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 Mann-Grandstaff VAMC 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.

- 68.5. The Mann-Grandstaff VAMC may deny payment for emergency medical services performed locally outside the Contractor's facility if the Mann-Grandstaff VAMC physician reviewing the Veteran's medical record determines that no emergency existed. The Contractor can appeal this determination in writing to the Contracting Officer by submitting supporting documentation. If a dispute still exists after Contractor's documentation is reviewed; the Contractor may file a claim under the *Disputes* clause of the contract, FAR 52.212-4(d).
- 68.6. The VA agrees to reimburse the Contractor according to the terms of the contract for resources furnished in this contract.
- 68.7. Sums due to the Contractor will be paid within 30 days of receipt of a properly prepared claim submitted by the Contractor.
- 68.8. Refer to Title 42 Code of Federal Regulations (CFR) Sections 412.4, 415.170, 415.172, 415.178, 415.180 and 415.190 as conditions of payment.
69. ELECTRONIC FUNDS TRANSFER PAYMENT METHOD: Payments under this contract will be made by the Electronic Funds Transfer Payment Method. The Contractor must be registered in the System for Award Management (SAM). (SAM includes the functionality of the previous Central Contractor Registration [CCR] and Online Representations and Certifications Application [ORCA]). No contract will be entered into with an unregistered Contractor. Internet access allows registration by completing an electronic on-line registration application at <https://www.sam.gov/>.
70. PROCEDURE REGARDING THIRD PARTY RESOURCES: The Mann-Grandstaff VAMC will be entitled to, and will exercise full subrogation rights and will be responsible for making every reasonable effort to determine the legal liability of third parties to pay for services rendered to enrolled Veterans under this contract and recover any such liability from the third party.
- 70.1. If the Contractor has determined that third party liability exists for part or all of the services provided directly by the Contractor to an enrolled patient, the Contractor shall make reasonable efforts to notify Mann-Grandstaff VAMC for recovery from third party liable sources the value of services rendered. All such cases will be referred to the West Consolidated Patient Account Center (West CPAC).
- 70.2. Mann-Grandstaff VAMC has the authority to bill insurance carriers for treatment provided to Veterans for non-service related conditions. Veterans presenting for care will be asked by the Contractor's staff to provide their insurance and/or

Medicare card(s). Per the national mandate, the Contractor's staff will **then scan** the insurance cards (front and back) into the VistA Buffer File Update Management system for processing. In the event the card is not able to be scanned, a photocopy of the front and back should be made and faxed to the Mann-Grandstaff Eligibility Section at (509-434-7122) no later than the end of the business day the Veteran is seen. The system automatically requires update of this data every six months (180 days) unless the Veteran identifies a change in his insurance status. Contractor is not liable for data older than 6 months if Veteran has not visited. The Contractor shall review the health insurance information at the time of each clinic visit. Insurance Card Buffer (ICB) data is collected monthly the contract will maintain an exception rate of less than 3%.

70.3. The Contractor shall obtain, as required by 38 U.S.C. 7332, a timely special consent for any medical treatment for drug abuse, alcoholism or alcohol abuse, infection with the human immunodeficiency virus (HIV), or sickle cell anemia, to a Veteran with health insurance. A special consent from the Veteran is needed to allow VA to release bills and medical records associated with the treatment. This release of Information Form (VA# 10-5345 <http://www.va.gov/vaforms/medical/pdf/vha-10-5345-fill.pdf?sa=U&ei=mw41UM3oLgbI2AWch4HwBw&ved=0CBIOFjAA&usg=AQjCNHAqetaMIvcgLUkzUyfyRSOz0Dmnw>) also should be sent to the Mann-Grandstaff Release of Information Department for scanning via the Lab Courier. If the Veteran refuses to consent, the Contractor shall document the refusal and notify the Supervisor, West Consolidated Patient Account Center at (509-484-7918).

71. “VETERANS ONLY” CLINIC REQUIREMENTS FOR CO-LOCATED FACILITIES:

71.1. To meet VA's requirements for a “Veterans Only” clinic in a co-located facility, the CBOC must have separate signage, a separate waiting room, and dedicated staff for the CBOC. The clerical/administrative personnel who check patients into and out of the clinic, respond to questions, and resolve issues for veterans must be working with veterans only. Contractor CBOC employees must be working with one computer system only (VA's VISTA and CPRS system). The system used by the Contractor for tracking veteran patients for billing purposes must be separate from the system used to track and bill non-veterans treated in the co-located clinic. The exam room/treatment area must be separate. Clinical staff providing care to veteran patients must be dedicated solely to the task of serving the veteran patients associated with this clinic. There must be a separate telephone number associated with the veterans' clinic.

72. CONTRACTOR SECURITY REQUIREMENTS (HANDBOOK 6500.6)-

72.1. VA INFORMATION AND INFORMATION SYSTEM SECURITY/PRIVACY
GENERAL: 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.

72.2.ACCESS TO VA INFORMATION AND VA INFORMATION SYSTEMS

- 72.2.1. 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.
- 72.2.2. 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.
- 72.2.3. Contract personnel who require access to national security programs must have a valid security clearance. National Industrial Security Program (NISP) was established by Executive Order 12829 to ensure that cleared U.S. defense industry contract personnel safeguard the classified information in their possession while performing work on contracts, programs, bids, or research and development efforts. The Department of Veterans Affairs does not have a Memorandum of Agreement with Defense Security Service (DSS). Verification of a Security Clearance must be processed through the Special Security Officer located in the Planning and National Security Service within the Office of Operations, Security, and Preparedness.
- 72.2.4. Custom software development and outsourced operations must be located in the U.S. to the maximum extent practical. If such services are proposed to be performed abroad and are not disallowed by other VA policy or mandates, the contractor/subcontractor must state where all non-U.S. services are provided and detail a security plan, deemed to be acceptable by VA, specifically to address mitigation of the resulting problems of communication, control, data protection, and so forth. Location within the U.S. may be an evaluation factor.
- 72.2.5. 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.

72.3. VA INFORMATION CUSTODIAL LANGUAGE

- 72.3.1. 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).
- 72.3.2. VA information should not be co-mingled, if possible, with any other data on the contractors/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.
- 72.3.3. 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.
- 72.3.4. 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.
- 72.3.5. 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.

- 72.3.6. 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.
- 72.3.7. If a VHA contract is terminated for cause, the associated BAA must also be terminated and appropriate actions taken in accordance with VHA Handbook 1600.01, Business Associate Agreements. Absent an agreement to use or disclose protected health information, there is no business associate relationship.
- 72.3.8. The contractor/subcontractor must store, transport, or transmit VA sensitive information in an encrypted form, using VA-approved encryption tools that are, at a minimum, FIPS 140-2 validated.
- 72.3.9. The contractor/subcontractor's firewall and Web services security controls, if applicable, shall meet or exceed VA's minimum requirements. VA Configuration Guidelines are available upon request.
- 72.3.10. 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.
- 72.3.11. Notwithstanding the provision above, the contractor/subcontractor shall not release VA records protected by Title 38 U.S.C. 5705, confidentiality of medical quality assurance records and/or Title 38 U.S.C. 7332, confidentiality of certain health records pertaining to drug addiction, sickle cell anemia, alcoholism or alcohol abuse, or infection with human immunodeficiency virus. If the contractor/subcontractor is in receipt of a court order or other requests for the above mentioned information, that contractor/subcontractor shall immediately refer such court orders or other requests to the VA contracting officer for response.
- 72.3.12. For service that involves the storage, generating, transmitting, or

exchanging of VA sensitive information but does not require C&A or an MOU-ISA for system interconnection, the contractor/subcontractor must complete a Contractor Security Control Assessment (CSCA) on a yearly basis and provide it to the COR.

72.4.INFORMATION SYSTEM DESIGN AND DEVELOPMENT

- 72.4.1. Information systems that are designed or developed for or on behalf of VA at non-VA facilities shall comply with all VA directives developed in accordance with FISMA, HIPAA, NIST, and related VA security and privacy control requirements for Federal information systems. This includes standards for the protection of electronic PHI, outlined in 45 C.F.R. Part 164, Subpart C, information and system security categorization level designations in accordance with FIPS 199 and FIPS 200 with implementation of all baseline security controls commensurate with the FIPS 199 system security categorization (reference Appendix D of VA Handbook 6500, VA Information Security Program). During the development cycle a Privacy Impact Assessment (PIA) must be completed, provided to the COR, and approved by the VA Privacy Service in accordance with Directive 6507, VA Privacy Impact Assessment.
- 72.4.2. The contractor/subcontractor shall certify to the COR that applications are fully functional and operate correctly as intended on systems using the VA Federal Desktop Core Configuration (FDCC), and the common security configuration guidelines provided by NIST or the VA. This includes Internet Explorer 7 configured to operate on Windows XP and Vista (in Protected Mode on Vista) and future versions, as required.
- 72.4.3. The standard installation, operation, maintenance, updating, and patching of
- 72.4.4. software shall not alter the configuration settings from the VA approved and FDCC configuration. Information technology staff must also use the Windows Installer Service for installation to the default "program files" directory and silently install and uninstall.
- 72.4.5. Applications designed for normal end users shall run in the standard user context without elevated system administration privileges.
- 72.4.6. The security controls must be designed, developed, approved by VA, and implemented in accordance with the provisions of VA security system development life cycle as outlined in NIST Special Publication 800-37, Guide for Applying the Risk Management Framework to Federal Information Systems, VA Handbook 6500, Information Security Program and VA Handbook 6500.5, Incorporating Security and Privacy in System Development Lifecycle.

72.4.7. The contractor/subcontractor is required to design, develop, or operate a System of Records Notice (SOR) on individuals to accomplish an agency function subject to the Privacy Act of 1974, (as amended), Public Law 93-579, December 31, 1974 (5 U.S.C. 552a) and applicable agency regulations. Violation of the Privacy Act may involve the imposition of criminal and civil penalties.

72.4.8. The contractor/subcontractor agrees to:

72.4.8.1 Comply with the Privacy Act of 1974 (the Act) and the agency rules and regulations issued under the Act in the design, development, or operation of any system of records on individuals to accomplish an agency function when the contract specifically identifies:

- The Systems of Records (SOR); and
- The design, development, or operation work that the contractor/subcontractor is to perform;

72.4.8.2. Include the Privacy Act notification contained in this contract in every solicitation and resulting subcontract and in every subcontract awarded without a solicitation, when the work statement in the proposed subcontract requires the redesign, development, or operation of a SOR on individuals that is subject to the Privacy Act; and

72.4.8.3. Include this Privacy Act clause, including this subparagraph (3), in all subcontracts awarded under this contract which requires the design, development, or operation of such a SOR.

72.4.8.4. In the event of violations of the Act, a civil action may be brought against the agency involved when the violation concerns the design, development, or operation of a SOR on individuals to accomplish an agency function, and criminal penalties may be imposed upon the officers or employees of the agency when the violation concerns the operation of a SOR on individuals to accomplish an agency function. For purposes of the Act, when the contract is for the operation of a SOR on individuals to accomplish an agency function, the contractor/subcontractor is considered to be an employee of the agency.

72.4.9. "Operation of a System of Records" means performance of any of the activities associated with maintaining the SOR, including the collection, use, maintenance, and dissemination of records.

72.4.10. "Record" means any item, collection, or grouping of information about an individual that is maintained by an agency, including, but not limited to, education, financial transactions, medical history, and criminal or employment history and contains the person's name, or identifying

number, symbol, or any other identifying particular assigned to the individual, such as a fingerprint or voiceprint, or a photograph.

- 72.4.11. "System of Records" means a group of any records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual.
- 72.4.12. The vendor shall ensure the security of all procured or developed systems and technologies, including their subcomponents (hereinafter referred to as "Systems"), throughout the life of this contract and any extension, warranty, or maintenance periods. This includes, but is not limited to workarounds, patches, hotfixes, upgrades, and any physical components (hereafter referred to as Security Fixes) which may be necessary to fix all security vulnerabilities published or known to the vendor anywhere in the Systems, including Operating Systems and firmware. The vendor shall ensure that Security Fixes shall not negatively impact the Systems.
- 72.4.13. The vendor shall notify VA within 24 hours of the discovery or disclosure of successful exploits of the vulnerability which can compromise the security of the Systems (including the confidentiality or integrity of its data and operations, or the availability of the system). Such issues shall be remediated as quickly as is practical, but in no event longer than 3 days.
- 72.4.14. When the Security Fixes involve installing third party patches (such as Microsoft OS patches or Adobe Acrobat), the vendor will provide written notice to the VA that the patch has been validated as not affecting the Systems within 10 working days. When the vendor is responsible for operations or maintenance of the Systems, they shall apply the Security Fixes within 3 days.
- 72.4.15. All other vulnerabilities shall be remediated as specified in this paragraph in a timely manner based on risk, but within 60 days of discovery or disclosure. Exceptions to this paragraph (e.g. for the convenience of VA) shall only be granted with approval of the contracting officer and the VA Assistant Secretary for Office of Information and Technology.

72.5. INFORMATION SYSTEM HOSTING, OPERATION, MAINTENANCE, OR USE

for information systems that are hosted, operated, maintained, or used on behalf of VA at non-VA facilities, contractors/subcontractors are fully responsible and accountable for ensuring compliance with all HIPAA, Privacy Act, FISMA, NIST, FIPS, and VA security and privacy directives and handbooks. This includes conducting compliant risk assessments, routine vulnerability scanning, system patching and change management procedures, and the completion of an

acceptable contingency plan for each system. The contractor's security control procedures must be equivalent, to those procedures used to secure VA systems. A Privacy Impact Assessment (PIA) must also be provided to the COR and approved by VA Privacy Service prior to operational approval. All external Internet connections to VA's network involving VA information must be reviewed and approved by VA prior to implementation.

- 72.5.1. Adequate security controls for collecting, processing, transmitting, and storing of Personally Identifiable Information (PII), as determined by the VA Privacy Service, must be in place, tested, and approved by VA prior to hosting, operation, maintenance, or use of the information system, or systems by or on behalf of VA. These security controls are to be assessed and stated within the PIA and if these controls are determined not to be in place, or inadequate, a Plan of Action and Milestones (POA&M) must be submitted and approved prior to the collection of PII.
- 72.5.2. Outsourcing (contractor facility, contractor equipment or contractor staff) of systems or network operations, telecommunications services, or other managed services requires certification and accreditation (authorization) (C&A) of the contractor's systems in accordance with VA Handbook 6500.3, Certification and Accreditation and/or the VA OCS Certification Program Office. Government-owned (government facility or government equipment) contractor-operated systems, third party or business partner networks require memorandums of understanding and interconnection agreements (MOU-ISA) which detail what data types are shared, who has access, and the appropriate level of security controls for all systems connected to VA networks.
- 72.5.3. The contractor/subcontractor's system must adhere to all FISMA, FIPS, and NIST standards related to the annual FISMA security controls assessment and review and update the PIA. Any deficiencies noted during this assessment must be provided to the VA contracting officer and the ISO for entry into VA's POA&M management process. The contractor/subcontractor must use VA's POA&M process to document planned remedial actions to address any deficiencies in information security policies, procedures, and practices, and the completion of those activities. Security deficiencies must be corrected within the timeframes approved by the government. Contractor/subcontractor procedures are subject to periodic, unannounced assessments by VA officials, including the VA Office of Inspector General. The physical security aspects associated with contractor/ subcontractor activities must also be subject to such assessments. If major changes to the system occur that may affect the privacy or security of the data or the system, the C&A of the system may need to be reviewed, retested and re- authorized per VA Handbook 6500.3. This may require reviewing and updating all of the documentation (PIA, System Security Plan, and Contingency Plan). The Certification Program Office can provide guidance on whether a new C&A would be necessary.

- 72.5.4. The contractor/subcontractor must conduct an annual self-assessment on all systems and outsourced services as required. Both hard copy and electronic copies of the assessment must be provided to the COR. The government reserves the right to conduct such an assessment using government personnel or another contractor/subcontractor. The contractor/subcontractor must take appropriate and timely action (this can be specified in the contract) to correct or mitigate any weaknesses discovered during such testing, generally at no additional cost.
- 72.5.5. VA prohibits the installation and use of personally-owned or contractor/subcontractor-owned equipment or software on VA's network. If non-VA owned equipment must be used to fulfill the requirements of a contract, it must be stated in the service agreement, SOW or contract. All of the security controls required for government furnished equipment (GFE) must be utilized in approved other equipment (OE) and must be funded by the owner of the equipment. All remote systems must be equipped with, and use, a VA-approved antivirus (AV) software and a personal (host-based or enclave based) firewall that is configured with a VA-approved configuration. Software must be kept current, including all critical updates and patches. Owners of approved OE are responsible for providing and maintaining the anti-viral software and the firewall on the non-VA owned OE.
- 72.5.6. All electronic storage media used on non-VA leased or non-VA owned IT equipment that is used to store, process, or access VA information must be handled in adherence with VA Handbook 6500.1, Electronic Media Sanitization upon: (i) completion or termination of the contract or (ii) disposal or return of the IT equipment by the contractor/subcontractor or any person acting on behalf of the contractor/subcontractor, whichever is earlier. Media (hard drives, optical disks, CDs, back-up tapes, etc.) used by the contractors/ subcontractors that contain VA information must be returned to the VA for sanitization or destruction or the contractor/subcontractor must self-certify that the media has been disposed of per 6500.1 requirements. This must be completed within 30 days of termination of the contract.
- 72.5.7. Bio-Medical devices and other equipment or systems containing media (hard drives, optical disks, etc.) with VA sensitive information must not be returned to the vendor at the end of lease, for trade-in, or other purposes. The options are:
- 72.5.7.1. Vendor must accept the system without the drive;
 - 72.5.7.2. VA's initial medical device purchase includes a spare drive which must be installed in place of the original drive at time of turn-in; or
 - 72.5.7.3. VA must reimburse the company for media at a reasonable open market replacement cost at time of purchase.
 - 72.5.7.4. Due to the highly specialized and sometimes proprietary hardware and

software associated with medical equipment/systems, if it is not possible for the VA to retain the hard drive, then;

- 72.5.7.4.1. The equipment vendor must have an existing BAA if the device being traded in has sensitive information stored on it and hard drive(s) from the system are being returned physically intact; and
- 72.5.7.4.2. Any fixed hard drive on the device must be non-destructively sanitized to the greatest extent possible without negatively impacting system operation. Selective clearing down to patient data folder level is recommended using VA approved and validated overwriting technologies/methods/tools. Applicable media sanitization specifications need to be pre-approved and described in the purchase order or contract.
- 72.5.7.4.3. A statement needs to be signed by the Director (System Owner) that states that the drive could not be removed and that (a) and (b) controls above are in place and completed. The ISO needs to maintain the documentation.

72.6. SECURITY INCIDENT INVESTIGATION

- 72.6.1. 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 Contracting Office Representative (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.
- 72.6.2. 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.
- 72.6.3. With respect to unsecured protected health information, the business associate is deemed to have discovered a data breach when the business associate knew or should have known of a breach of such information. Upon discovery, the business associate must notify the covered entity of the breach. Notifications need to be made in accordance with the executed business associate agreement.
- 72.6.4. In instances of theft or break-in or other criminal activity, the

contractor/subcontractor must concurrently report the incident to the appropriate law enforcement entity (or entities) of jurisdiction, including the VA OIG and Security and Law Enforcement. The contractor, its employees, and its subcontractors and their employees shall cooperate with VA and any law enforcement authority responsible for the investigation and prosecution of any possible criminal law violation(s) associated with any incident. The contractor/subcontractor shall cooperate with VA in any civil litigation to recover VA information, obtain monetary or other compensation from a third party for damages arising from any incident, or obtain injunctive relief against any third party arising from, or related to, the incident.

72.7. LIQUIDATED DAMAGES FOR DATA BREACH

- 72.7.1. 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. In addition, the Contractor may be liable for any actual damages VA incurs associated with a data breach.
- 72.7.2. The contractor/subcontractor shall provide notice to VA of a "security incident" as set forth in the Security Incident Investigation section above. Upon such notification, VA must secure from a non-Department entity or the VA Office of Inspector General an independent risk analysis of the data breach to determine the level of risk associated with the data breach for the potential misuse of any sensitive personal information involved in the data breach. The term 'data breach' means the loss, theft, or other unauthorized access, or any access other than that incidental to the scope of employment, to data containing sensitive personal information, in electronic or printed form, that results in the potential compromise of the confidentiality or integrity of the data. Contractor shall fully cooperate with the entity performing the risk analysis. Failure to cooperate may be deemed a material breach and grounds for contract termination.
- 72.7.3. Each risk analysis shall address all relevant information concerning the data breach, including the following:
 - 72.7.3.1. Nature of the event (loss, theft, unauthorized access);
 - 72.7.3.2. Description of the event, including:
 - 72.7.3.2.1. date of occurrence;
 - 72.7.3.2.2. data elements involved, including any PII, such as full name, social

security number, date of birth, home address, account number, disability code;

72.7.3.2.3. Number of individuals affected or potentially affected;

72.7.3.2.4. Names of individuals or groups affected or potentially affected;

72.7.3.2.5. Ease of logical data access to the lost, stolen or improperly accessed data in light of the degree of protection for the data, e.g., unencrypted, plain text;

72.7.3.2.6. Amount of time the data has been out of VA control;

72.7.3.2.7. The likelihood that the sensitive personal information will or has been compromised (made accessible to and usable by unauthorized persons);

72.7.3.2.8. Known misuses of data containing sensitive personal information, if any;

72.7.3.2.9. Assessment of the potential harm to the affected individuals;

72.7.3.2.10. Data breach analysis as outlined in 6500.2 Handbook, Management of Security and Privacy Incidents, as appropriate; and

72.7.3.2.11. Whether credit protection services may assist record subjects in avoiding or mitigating the results of identity theft based on the sensitive personal information that may have been compromised.

72.7.3.3. 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:

72.7.3.3.1. Notification;

72.7.3.3.2. One year of credit monitoring services consisting of automatic daily monitoring of at least 3 relevant credit bureau reports;

72.7.3.3.3. Data breach analysis

72.7.3.3.4. Fraud resolution services, including writing dispute letters, initiating fraud alerts and credit freezes, to assist affected individuals to bring matters to resolution;

72.7.3.3.5. One year of identity theft insurance with \$20,000.00 coverage at \$0 deductible; and

72.7.3.3.6. Necessary legal expenses the subjects may incur to repair falsified or damaged credit records, histories, or financial affairs.

72.8. SECURITY CONTROLS COMPLIANCE TESTING

72.8.1 On a periodic basis, VA, including the Office of Inspector General, reserves the right to evaluate any or all of the security controls and privacy practices implemented by the contractor under the clauses contained within the contract. With 10 working-days' notice, at the request of the government, the contractor must fully cooperate and assist in a government-sponsored security controls assessment at each location wherein VA information is processed or stored, or information systems are developed, operated, maintained, or used on behalf of VA, including those initiated by the Office of Inspector General. The government may conduct a security control assessment on shorter notice (to include unannounced assessments) as determined by VA in the event of a security incident or at any other time.

72.9. TRAINING

- 72.9.1. 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:
 - 72.9.1.1. Sign and acknowledge (either manually or electronically) understanding of and responsibilities for compliance with the Contractor Rules of Behavior, Appendix E relating to access to VA information and information systems;
 - 72.9.1.2. Successfully complete the VA Cyber Security Awareness and Rules of Behavior training and annually complete required security training;
 - 72.9.1.3. Successfully complete the appropriate VA privacy training and annually complete required privacy training; and
 - 72.9.1.4. 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.]
- 72.9.2. 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 1 week of the initiation of the contract and annually thereafter, as required.
 - 72.9.2.1. 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.

Attachement A

Spokane Laboratory Users Guide 2013-Updated

Spokane VA Medical Center
4815 N Assembly Street
Spokane, WA 99205

USERS GUIDE

SPECIMEN COLLECTION

ACTING CHIEF OF STAFF: Scott Nye, MD, FACS

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ACCREDITATION/LICENSURE
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FOREWORD

The Pathology & Laboratory Medicine Service Reference Manual has been compiled to provide information for proper submission of specimens and laboratory request forms to the Laboratory.

All changes to the specimen collection manual must be reviewed and approved by the director or designee before implementation.

A current list of test methods, including performance specifications, is available for review upon request.

APPROVED:

Scott Nye, MD, FACS
Acting Chief of Staff

DATE:

Roger Graham, MD
Laboratory Director/
Consulting Pathologist

DATE:

Reviewed: _____
Laboratory Manager

DATE: _____

Reviewed: _____

DATE: _____

Reviewed: _____

DATE: _____

Reviewed: _____

DATE: _____

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GENERAL INFORMATION

- ✓ In the average adult male there are approximately 5 quarts (4.75 liters) of blood, composed of about 3 quarts (2.8) liters) of plasma and 2 quarts (1.9) of cells. The cells are suspended in plasma, which is made up of water and dissolved materials, including hormones, antibodies, and enzymes that are being carried to the tissues, and cellular waste products that are being carried to the lungs and kidneys.
- ✓ The major blood cells are classified as red cells (rbc, erythrocytes), white cells (wbc, leukocytes), and platelets (thrombocytes). The red cells are delicate, round, concave bodies that contain hemoglobin, the complex chemical that transports oxygen and carbon dioxide. If the thin protective membrane that encases the fragile red cell is ruptured by rough handling of a blood specimen, dilution, exposure to contaminants, or extremes in temperature, hemoglobin escapes into the plasma in the process called hemolysis.
- ✓ The primary purpose of the white cells is to fight infection. In a healthy person, the white cells respond to minor infections by increasing in number and destroying bacteria. Platelets are small fragments of special cells that aid in blood clotting.
- ✓ Either plasma or serum may be separated from the blood cells by centrifugation. The essential difference between plasma and serum is that plasma retains fibrinogen (the clotting component) that is removed from serum.
- ✓ Serum is obtained from clotted blood that has not been mixed with an anticoagulant (a chemical that prevents the clotting of blood). This clotted blood is centrifuged, yielding serum, which contains two types of protein, albumin and globulin. Serum is collected in RED TOP tubes, GOLD TOP tubes, and MARBLE TOP tubes.

- ✓ Plasma is obtained from blood that has been mixed with an anticoagulant in the collection tube and has therefore not clotted. This mixed blood is centrifuged, yielding plasma, which contains albumin, globulin, and fibrinogen.
- ✓ There are many coagulation factors involved in clotting of blood. Several different types of anticoagulants interfere with the activity of these factors to prevent clotting. Both anticoagulants and preservatives may be required for plasma specimens. The specified anticoagulant or preservative must be used for the test procedure ordered. Blood collected with one anticoagulant is suitable for the test described, but may not be for others.
- ✓ Many of the common errors in specimen collection are due to inadequate patient instructions.
- ✓ During specimen collection, preparation, and submission, (pre-Analytical) there is a much greater possibility of CRITICAL error than during actual testing or examination of the specimen.
- ✓ One of the MOST COMMON and EXPENSIVE errors in specimen collection is an INSUFFICIENT SAMPLE for testing.

COMMON ERRORS:

1. Failure to separate serum from cells within 30-45 minutes.
2. Failure to mix sample and anticoagulant thoroughly.
3. Failure to collect a clean-catch, midstream urine sample.
4. Failure to add proper preservative to 24hr urine container.
5. Insufficient quantity

All tubes containing anticoagulant/preservatives MUST BE allowed to FILL COMPLETELY.

The patient's response and cooperation is partly determined by your attitude and by the degree of self-confidence you show. If you appear to be organized, skilled, and attentive, the patient is more likely to cooperate, especially when an uncomfortable collection procedure is necessary.

Patients and specimens MUST be properly identified and labeled in the presence of the patient. Identify patient with two patient identifiers (Full name & Date of Birth or Full SSN), or if patient is unconscious ask the patient's physician, nurse, relative or friend to identify the patient.

Lab tests contribute important and often vital information about a patient's health. Correct diagnostic and therapeutic decisions depend, in part, on the accuracy of test results. Proper patient preparation, specimen collection, and handling are essential prerequisites for accurate testing.

REMEMBER to look up collection requirements before drawing sample. MAKE THIS PART OF YOUR DAILY ROUTINE!!! Use Specimen Processing Instruction in VISTA.

NEVER!!! Draw from ABOVE an I.V. site.

Draw blood in the amount of 2.5 times the required serum amount. 10 ml RED TOP yields approximately 4 ml of serum.

DO NOT have patient clench and unclench fist. This will cause hemoconcentration (local increase of red blood cells).

You should always ask patient if he/she has eaten or drank, before you collect the blood specimen for collection of tests requiring fasting.

Lab personnel shall accept for testing only those specimens that are properly labeled with two patient identifiers (full name, and social security number, or date of birth).

SOME CAUSES FOR HEMATOMA:

1. Needle goes through vein.
2. Leaking around needle – caused by not having your hand secure – wiggling needle.
3. Leaving tourniquet on too long.
4. If pressure is not applied after removing needle.

When you see a hematoma forming IMMEDIATELY release the tourniquet, remove the needle and apply pressure.

COMMON REASONS FOR HEMOLYSIS:

1. Tubes filled too slowly.
2. Difficult veins
3. Collection problems
4. Too much pressure on syringe plunger.
5. Too small of needle.
6. Injecting blood forcefully through needle into tube.

Hemolysis occurs when the red cells are disrupted, and hemoglobin and other intracellular components spill into the serum.

Hemolysis serum is pink or red

Normal serum is a clear, light yellow, straw color.

Turbid or Lipid serum is cloudy or milky.

Lipemic serum may NOT be a true indicator of the patient's basal physical state.

BASAL state means after a 12 to 14 hour fast.

Normal values are most frequently based on basal state collections.

Even moderate exercise can cause an increase in blood glucose, lactic acid, serum proteins, and some enzymes such as CPK.

Many commonly prescribed medications interfere with chemical determinations or alter levels.

If a patient cannot be taken off of all medications, its presence should be noted on test request form or in COMMENT SECTION of VISTA.

Tranquilizers should be discontinued 48-72 hours before and during collection of urine for steroid studies.

Drug effects usually cause False High values rather than False Low values.

PATIENT/SPECIMEN LOGIN & RECEIPT

1. Identification of the patient is the most important pre-analytical process that must adhere to the Patient Identification hospital policy.
2. Outpatients are to checking into Laboratory Blood Draw approximately 1 hour before the appointment time.
3. Patients must have at least their VA Identification Card, other picture ID, or an Armband (Inpatient only)
4. Identify the patient name to their identification. Ask DOB as secondary identifier.
5. Look up patient orders:
 - a. General Use Menu
 - b. Lookup orders for a patient: This option pulls +30days/-100days
 - c. Patient Name:
 - d. Write each order# on the manual log sheet that have not been accessioned (Only accession Oncology and Anti-Coagulation orders on date of or day before patient's appointment)
 - i. Check patient appointment schedules by "Patient Inquiry" or CPRS coversheet.
 - e. If no orders are listed under LKUP, use "Order/Test status" option to search for orders. Begin with T+120 and go back 80 days from today's date.
6. Generate Labels
 - a. Accessioning Menu
 - b. Accessioning tests ordered (ACT)
 - c. Select Order number: Enter the order number at the prompt
 - d. Is this the correct order? Yes// Verify name and order number
 - e. Collection date & time: // N for now or enter date and time

- f. Do you have the entire order? Verify you have all specimen types
- g. Print labels on: B101 main lab or BD L phlebotomy
- h. Compare patient information to what is printed on the label/s.

IDENTIFICATION OF SPECIMENS

Order the tests in the computer that the health care provider has selected. Each test will be assigned an accession number that is printed on the barcode label and is a **unique** number for each specimen.

1. Specimens that are brought to the lab (i.e. pre-collected) will be processed first so that specimens can be immediately labeled negating the possibility of specimen mix-up or lost specimens.
2. When Outpatients arrive at the lab for testing, they will usually have their tests ordered in the computer. Labels are then generated by the login method on page 7. As the specimens are collected they are immediately labeled for positive identification.

REQUESTS FOR ADD-ON TESTS

Oral/telephone requests for add-on tests are to be handled in the following manner:

1. Physicians must have written order for tests prior to asking for the add-on. When they call they will provide the order number.
2. When an order for add-on test(s) is requested check the VISTA Order/Test Status to see what tests have already been ordered and then check to see if there is an adequate amount of specimen for the add-on.
3. Accession the order, making sure to enter the correct collection time.
4. Include the comment code ADDON which expands to Added to Specimen Originally Drawn at: and include the original draw time.

SPECIMEN COLLECTION

POLICY:

1. Blood drawing procedures shall be written and adhered to, to assure accurate and efficient collections of specimens from patients whether venous or arterial.
2. Phlebotomy practices will be reviewed annually to minimize blood volume. Minimum volume is noted in Laboratory Test Information Section.
3. Properly fitting gloves will be worn for touching blood and body fluids, non-intact skin of all patients, for handling items or surfaces soiled with blood and body fluids and for performing venipunctures.
4. Blood Draw Order is as follows:
 - a. Blood Culture Bottles

- b. Coagulation tubes (light blue)
 - c. Non-additive tubes (red, glass)
 - d. Gel Separated tubes (SST, tiger/marble top, Yellow)
 - e. Additive tube: Heparin (green)
 - f. Additive tube: EDTA (lavender)
 - g. Additive tube: Oxalate fluoride (grey)
5. Charts for Draw Order have been posted in all Phlebotomy locations.

REGULATIONS:

1. Identify the patient with two patient identifiers (Full name, SSN or DOB). Have him/her tell you their name and last four numbers of their social security number or date of birth. Compare information to name and picture on VA or other identification card (Driver's License or Armband attached to the patient). Compare printed labels to patient information.
2. Label tubes in the presence of the patient immediately after collection of the specimen. Confirm the name on the tubes with the patient. Never leave the outpatient bench with unlabeled tubes. When computer labels are not available, write full name, SSN, order number, Phlebotomist initials and draw times.
3. It is a standing regulation that any time a technologists or phlebotomist fails to successfully obtain a specimen after two or three attempts, that person shall call for another technologists or phlebotomist to obtain the specimen.
4. Know and follow patient isolation requirements.
5. Never lose your temper at the doctors, nurses, or patients NO MATTER how justifiable it might seem. If a misunderstanding should occur, or you feel unduly harassed, then report the incident in full to the Lab Manager.
6. Do not discuss with the patient the test results of the tests the physician has ordered.
7. **STAT** means immediately, although it is important to develop good speed in your collections, do NOT sacrifice good technique and accurate labeling for speed.
8. Try to be organized. Have everything organized and easily reachable. This saves time.
9. Be cheerful and talk to the patients as you perform your duties as expeditiously as possible. Be patient with them.
10. When unable to obtain blood from a patient, take immediate action. Notify nurse in charge of patient that the Lab is unable to obtain the blood, and the physician in charge will have to determine the next course of action.
11. If a patient has a tendency to faint while having blood drawn. **INSIST** that they lie down before phlebotomy is performed.
12. Wash hands before and after blood collecting procedure.
13. Tourniquets are to be used once, discard after use.
14. Clean exposed chair surfaces between patients.

VACUTAINER PHLEBOTOMY

Vacutainer phlebotomy is the aseptic method of collecting and transporting a blood specimen. It works on the principle of a vacuum tube for drawing blood. A standard vacutainer multiple sample needle is used for venipuncture.

PROCEDURE:

1. Ask patient to extend and straighten arm. Patients may rest arm on table of the drawing chair. If patient has a history of fainting, lay patient down in the drawing chair.
2. Apply tourniquet using a knot that can be released easily with one hand. Using your fingertips palpitate antecubital areas of the arm, feeling for the spongy area of a filled vein.
 - a. If you are still unable to locate a suitable vein stroke arm from wrist toward elbow.
 - b. Slight hitting (gently - don't beat them) antecubital area to make veins stand out. **DO NOT HAVE PATIENT CLENCH AND UNCLENCH FIST.** This will cause hemoconcentration (a local increase in red blood cells).
 - c. A warm pack or towel may be applied to the antecubital area to allow for increased blood flow to the area to increase vein visibility.
3. After your selection of the best vein, swab site with alcohol swab (70%) except when drawing blood cultures or blood alcohol levels; blood cultures require cleaning with chloraprep, and blood alcohol levels require cleaning with soap towlettes.
4. "Fix" the vein in position. Place thumb about an inch below where the needle is to enter and press down on arm, pulling the skin towards the hand. This stretches the skin and holds the vein taut.
5. With needle at an acute angle of 30-40%, quickly penetrate the skin about ½ inch below the point where you intend to enter vein. **NEVER** enter the skin and vein with the needle vertical or perpendicular to the skin surface. Venipuncture discomfort is mainly due to slow skin penetration: rapid entry is less painful.
6. Immediately upon vein entry, complete puncture of tube stopper by pushing tube forward. This initiates vacuum suction. Careful to hold vacutainer hub stationary to remain in vein.
 - a. If multiple specimens are being drawn, remove first tube from holder after blood flow ceases and gently insert second tube and puncture stopper to initiate vacuum suction.
7. When blood flow ceases pull tube off diaphragm. When all samples have been drawn remove tourniquet, apply gauze/cotton ball to needle area and remove entire assembly from arm. **IMMEDIATELY** apply pressure to puncture site for approximately 2 minutes.
8. After ensuring patient has stopped bleeding, apply COBAN over gauze/cotton ball.

SYRINGE VENIPUNCTURE

1. Assemble syringe with needle.
2. Place tourniquet around patient's arm
3. By inspection and palpation locate desired vein.
4. Cleanse skin over vein with alcohol swab, in a circular motion moving outwards.

5. “Fix” the vein in position. Place thumb about an inch below where the needle is to enter and press down on arm, pulling the skin towards the hand. This stretches the skin and holds the vein taut.
6. Holding the syringe at approximately 30° angle insert needle through skin immediately adjacent to site to be punctured. Lower syringe and move needle parallel to vein for distance of about 1 inch. Move needle toward blood vessel and directly into lumen.
7. Withdraw plunger slightly to make certain needle is in the vein. Collect blood holding syringe secure to ensure a steady pull of the plunger for an even blood draw. Pulling too fast may result in hemolysis of the red blood cells.
8. Release tourniquet. Then place a gauze/cotton ball over venipuncture site, withdraw the needle. Immediately after withdrawing apply pressure to site for approximately 2 minutes.
9. Engage safety device over needle until the needle is completely covered.
10. Remove the needle and attach the Blood Transport device to the end of the syringe.
11. Place Vacutainer tubes one at a time in the transport device. Vacutainer tubes will fill by puncturing the stopper and allowing the tube to fill. Otherwise, remove stopper from top of tube and needle from syringe (after engaging safety device) and fill tube by running blood down the side of the tube to the fill mark on the label. Do not over fill tube.
12. Discard in the “Sharp’s” container available in phlebotomy areas and on portable collection trays.

CAPILLARY PUNCTURE

1. Identify the patient by using two patient identifiers.
2. When possible, apply hot compresses or massage area to be punctured, since cold and cyanotic skin is a source of error.
3. The puncture site is rubbed well with an alcohol swab to remove dirt and epithelial debris and increase the blood flow at the site.
4. After the site is dry, make a firm quick puncture 3-4mm deep with a lancet. A deep puncture is not more painful than a superficial puncture and makes it unnecessary to repeat the procedure, so do not hesitate when making the puncture.
5. Do not squeeze the site tightly, because the liberated tissue juices dilute the blood.
6. Wipe away the first drop of blood to avoid tissue juice contamination and apply gentle pressure in a “milking” fashion to obtain a free flow of blood. Free flow of blood is essential to obtain reproducible results comparable to those of venous blood.
7. After needed blood is obtained, pressure is applied until bleeding has stopped and a band-aid is placed over the site.
8. Label capillary tube with computer label or place label on transfer tube with capillary tube inside.

BLOOD COLLECTION FROM IV LINE

1. The Laboratory personnel will not collect specimens from an IV line unless patients Physician or nurse is consulted.

2. Never shut off or interrupt any solution to obtain specimen without assistance from patients Nurse.
3. Inform Nurse of specimen needed from IV, central IV line or PIC line ask for assistance in flush after procedure.
4. Cleanse end of IV line connector with isopropyl alcohol.
5. Do not allow cleansed connector to come in touch with anything before connecting leur-lock syringe.
6. Connect 10 ml syringe to connector remove three to five (3-5) ml of blood and fluid for discard. This clears the IV line of contaminating substances (medication, or fluids).
7. Remove discard syringe, discard in sharps container. Connect new syringe for specimen.
8. Withdraw appropriate amount for specimen processing.
9. Using vacutainer syringe adapter or butterfly adapter to transfer blood into vacutainer tubes for processing. Label tubes with patient information using accession labels.
10. Notify Nurse of completion of collection so they may flush or otherwise attend to the IV line.
11. Discard all syringes in sharps container.

CRITERIA FOR SPECIMEN REJECTION

SPECIMENS COLLECTED BY THE LAB:

1. UNLABELED specimen will NOT be accepted. (All blood and urine specimens are to be labeled immediately after collection.)
2. HEMOLYZED specimen will NOT be accepted for:
 - a. Hemolysis will be noted on final report along with which analytes are affected.
 - b. Coagulation studies.
3. HEPARIN specimen will NOT be accepted for:
 - a. Lithium, B12, Folate and PreAlbumin.
 - b. Coagulation Studies.
3. CLOTTED EDTA, CITRATE or HEPARINIZED specimens for testing in Hematology and Coagulation will NOT be accepted.
4. Blue Topped Tubes (Citrate) that are under filled will not be accepted.

SPECIMENS SUBMITTED BY HOSPITAL OR PHYSICIAN'S OFFICE.

1. Each specimen must be accompanied with a request and all pertinent patient information.
2. Specimens must be labeled with patient's name, social security number or birth date, and date/time collected. Unlabeled specimens must be rejected or the submitting personnel must be called to identify the specimen and assume the responsibility of proper identification. Correction of labels is not allowed.
3. Urine specimens submitted with incorrect preservatives are to be checked by Laboratory personnel and rejected if so advised.
 - a. Urines must be processed within 1 hour of collection. If the specimen is not processed within an hour after collection, store at 2-8° C. Refrigeration stability

of 4 hours. If processing is delayed transfer specimens to appropriate preservative tube.

- i. C&S – Boric Acid Tubes (Stable for 48 hours w/o refrigeration)
4. Specimens dated prior to date of receipt shall be checked further. Some examples: enzymes (on cells), CBC, glucose (on cells without NaFI) will be rejected.
5. Specimens incorrectly stored will not be accepted, e.g., frozen or not frozen.
6. Fecal stool older than 30 minutes for culture will be rejected unless submitted refrigerated.
7. Tissue for culture submitted in formalin or other preservatives will be rejected.
8. Sputum for culture collected in tissue paper will not be accepted. Sputum that resembles spit will be rejected.

REJECTION PROCESS:

SPECIMEN COLLECTED BY LAB PERSONNEL:

1. Recollect specimen, if possible.
2. Notify section supervisor for instructions.
3. Notify nurse, or requesting physician depending on severity of situation.
4. Enter in VISTA reason for cancellation of testing, who was notified and time.

SPECIMEN NOT COLLECTED BY LAB PERSONNEL:

1. Notify section supervisor for instructions.
2. Notify submitting nurse, or requesting physician.
3. Generate cancellation requisition or note in COMMENT section of VISTA, clearly defining problem and who was notified and date and time of notification.

Discarding or rejection of sub-optimal/unsuitable specimens will only occur after notification of the requesting physician and discussing whether testing is still appropriate after considering the condition and appropriateness of the specimen. If the physician feels that some benefit can still be derived from results obtained, a notation of the specimen condition and limitation in test results will be noted at the time of test result verification.

Laboratory will note in VISTA the reasons for rejection. Log rejection and reason on the Specimen Rejection Log located in each laboratory section. A new specimen and order must be submitted.

SPECIMEN ANALYSIS

After the specimens are accessioned they are taken to the appropriate department for analysis.

All aliquots and dilutions will be identified with a specimen label.

SEND OUT TESTING

When requisition and specimen are brought to processing area, look up requirements for specimen - specimen requirement, whether to refrigerate or freeze, etc., listed in the specimen processing or Test Description menu in the VISTA system.

Follow the reference labs guidelines for properly filling out the request form, correct labeling of specimens, proper packaging and storage.

TRANSPORT SPECIMENS TO THE LAB

Specimens collected outside of the laboratory and delivered to the lab must meet the following requirements:

1. All specimens must be placed in a tight, leak proof container.
2. The leak proof container must be properly labeled with the patients name and birth date or SSN, specimen source, health care provider, date and time of collection and collection location.
3. Each specimen must be accompanied by an approved requisition that has the following information:
 - a. Patient's Name
 - b. Date of Birth
 - c. Sex
 - d. Ward or location of facility sending specimen
 - e. ID Number
 - f. Physician
4. The container must be in an approved labeled **BIOHAZARD** plastic, sealable bag, with a separate pocket for the requisition.
5. Specimens must meet the requirements in Lab's "**Spec C&P 003.02 – 014.00**" procedures.
6. Specimens that require special handling procedures may require notification of the laboratory and/or rapid transport to the lab to obtain valid results.
7. Inpatient specimens may be transported to the lab by whatever means is convenient (volunteer, etc.) provided the specimen has the approved container, bag, label, and requisition.
8. Outpatient specimens are transported to the lab via contracted courier services.
 - a. Community Based Outreach Clinics pick up
 1. Wenatchee: Mon-Fri between 3 and 4pm
 2. Coeur d'Alene: Mon-Fri 3pm
 - b. Rural Health Clinics pick up
 1. Libby: Mon-Fri 3pm
 2. Sandpoint: Tue and Thru 3pm
 3. Colville: Mon-Fri 4pm
 4. Republic: Mon-Fri 4pm
 5. Tonasket: Mon-Fri 4pm

GUIDELINES FOR OBTAINING SPECIMENS

Principle: The quality of the results produced by the Laboratory can be no better than the quality of the specimen received. In order to collect optimal specimens, it is necessary that collection procedures be tailored to the type of specimen being collected. A brief resume of specimen collection techniques follows:

1. **Nasopharyngeal** - A sterile flexible swab should be inserted through the anterior nares all the way to the posterior pharynx, rotated and withdrawn. Alternatively, a swab may be bent at right angles close to the bud and inserted into the nasopharynx through the oral cheeks. Place the swab in a suitable transport media and send to the laboratory.
2. **Throat** - Have the patient rinse their mouth with water before collection. Using a sterile swab and sterile tongue depressor if necessary, swab the posterior pharyngeal wall, tonsils (if present) and any reddened or exudative areas adjacent thereto. Avoid touching the tongue or cheeks with the swab. Collect the specimen before the patient has eaten or used antiseptic mouthwash or gargle. Place the swab in suitable transport media and send to the laboratory.
3. **Sputum** - Have patient rinse mouth with water prior to collection. Advise the patient of desired specimen requirements: the product of a deep cough, not saliva, phlegm, or nasal discharge. Most patients have generally more production of sputum when first arising. Do not collect the specimen after the use of an antiseptic mouthwash or gargle. In some cases where a patient is repeatedly unproductive in sputum, inhalation of sterile nebulized normal or 0.5N saline may be effective in enabling the patient to produce a suitable sputum specimen. Following inhalation treatments may also increase sputum production.
4. **Urine** - All urine specimens for routine Urinalysis shall be collected using "Midstream" method.
 - a. **Midstream (not clean-catch):** Advise male patients to retract foreskin, if present, and female patients to part the labia. Instruct the patient to void a stream of urine and to collect the middle portion of that stream into a clean (not necessarily sterile) container. These routine specimens will be screened for appropriateness of culture and Lab personnel will order culture if needed.
 - b. **Clean-catch, Midstream:** Advise male patients to retract foreskin, if present, and female patients to part the labia. Instruct the patient to use the cleansing betadine or other wipes two times. Instruct the patient to void a stream of urine and to collect the middle portion of that stream into a sterile container. If the patient is unable to collect the midstream portion of the urine it may be acceptable to collect the whole specimen in a sterile container. If the urine is collected in a sterile bedpan or urinal it is acceptable if the above requirements are met. However, a notation to this effect should be made on the specimen requisition and container.

Note: The method of collection of urine must always be indicated on the microbiology or cytology requisition. If the urine was obtained by cystoscopy it should be noted whether the urine came from the left or right ureter. All urine specimens should be sent to the lab immediately within one (1) hour but if there is delay they may be refrigerated for up to four (4) hours. Alternative method for stabilization of urine for culture if delay is known, collect urine in **Urine C&S Transport kits** supplied by the laboratory and refrigerate. Urine

collected in transport tubes is appropriate for testing for 48 hours from collection for culture and 72 hours for routine urinalysis.

- c. **Catheterized Urine:** Acceptable catheterization technique should be used. Urine after collection should be placed in a sterile container or a capped syringe. Remove urine from port nearest patient body not the collection bag. Note whether the specimen is indwelling or straight catheter on requisition.
 - d. **Other urine specimens:** may be collected through the use of a suprapubic tap or by a cystoscopy.
 - e. **Patient Instructions:** How to collect a “24-hour Urine Specimen”
Your physician has asked you to provide a 24-hour urine specimen. Testing is to be performed on the specimen you provide, and your help can insure the accuracy of the tests by following these instructions:
 - 1. Avoid alcohol beverages, vitamins and other medication (if possible) for at least 24 hours before you start collecting the specimen and during the collection period.
 - 2. Your specimen container may have a preservative in it. Be sure that the urine is well mixed with the preservative. Do not dispose of the preservative and be sure to keep the container out of the reach of children.
 - 3. Do not exceed your normal intake of liquids during the day before and the day of collection unless your physician gives you specific directions to do otherwise.
 - 4. The 24-hour collection period begins when you get up in the morning to empty your bladder. Do NOT COLLECT THIS URINE: But do record the time and date of this Voiding on the specimen container label.
 - 5. Be sure to collect all urine – day and night for the next 24 hours. Do not throw out sample during this time. Make your final collection when you empty your bladder the next morning, approximately 24 hours from the time marked on your specimen container.
 - 6. Keep specimen collection container cool, refrigerate or keep on ice.
 - 7. Please call your physician for instructions if specific problems arise.
 - 8. Return the specimen as soon as possible to the VA Medical Center Laboratory.
 - f. **Urine Drug Screens:** Collected for medical purposes only. A random urine specimen (20 ml) collected in a plastic container free from preservative is adequate. Employee drug testing (legal) requires a special procedure. Contact Laboratory for arrangements.
5. **Wounds Effusions Abscesses, and Exudates, Joint Fluids ECT.** - Whenever possible, if an abscess is present, a portion of its wall, as well as a syringe full of the pus should be collected for culture. If the amount of pus is minimal, the area or abscess cavity can be irrigated with bacteriostat-free saline and the fluid aspirated with a syringe. The material may be sent in a capped syringe.
6. **Fecal material, Stool and rectal swabs** - Stool specimens for culture must be obtained directly from the patient and not collected out of the toilet bowl. Stool must be placed in a sterile container and delivered to the lab immediately. Collection for

culture and susceptibility may include a series of specimens up to 3 and may be collected at daily intervals if no pathogen is isolated on the first specimen. Specimens that cannot be delivered within one hour are to be submitted refrigerated. It is recommended that stool specimens be tested for *C. difficile* toxin for all patients with clinically significant diarrhea and a history of antibiotic exposure. Submit the specimen in a clean sterile container within 8 hours or 24 hours if refrigerated. Stool specimens for **occult blood** should be submitted on Hemoccult Sensa II Fecal Occult Blood cards. A kit is available from SPD with mailer for outpatients. For other stool specimens please see instructions in VISTA system or contact the laboratory.

7. **Stool for Ova and Parasite** - Stool for Ova and Parasite will be sent to Specialty Laboratories for processing. Collection for Ova and Parasite (O&P) detection may include a series of three or more specimens that must be collected at least daily or every other day collection. Stool for O&P may not be collected after Barium studies until the barium is cleared from the system (3-4 days), and while the patient is taking anti-diarrheal medication such as Kayopectate.
If the specimen cannot be delivered to the laboratory immediately specimens are to be placed in an Ova and Parasitology transport media.
8. **Eye** - Eye cultures must be taken before ophthalmic antimicrobials are used. A sterile swab should be touched carefully to the inflamed area or exudate. The swab is then placed in appropriate transport media. Deliver to the lab immediately.
9. **Genital- Urethra – Vaginal** - Urethral discharge may occur in both males and females. Females infected may have discharge that is less profuse and may be masked by vaginal secretions. A urogenital swab designed expressly for collection of such specimens is available in the laboratory. It includes a small rayon swab and Amies charcoal transport media. When profuse Urethral discharge is present (particularly in males) discharge may be collected without inserting the sampling device into the urethra. Separate specimens are required for Chlamydia and viral cultures and bacterial cultures. Special swabs and transport media are required and available in the laboratory.
 - a. Males: The swab is inserted approximately 2 cm in to the urethra and rotated gently before withdrawal. The swab is placed in the transport media and sent to the lab immediately or directly inoculated on to the appropriate media.
 - b. Female: The same urogenital swab as above is used. Cervical specimens are obtained after the cervix has been exposed by insertion of a speculum. The swab is inserted into the cervical canal and rotated and moved side to side for 30 seconds before removal. Care must be taken to minimize contamination of these specimens with vaginal secretions that contain great quantities of bacteria. Additional slide may be made for gram stain. Swabs should then be placed into suitable transport media and delivered to the lab immediately. Another method of vaginal culture specimen collection is by inserting the swab 2-cm into the vagina and gently rotating it before its withdrawal. Swabs should then be placed in suitable transport media and delivered to the lab immediately. Specimens collected for the identification of yeast or *Trichomonas vaginalis* should be collected using a swab as described. The swab should be placed in a tube containing 0.5 ml of sterile physiological saline. Direct wet mounts and cultures

may be obtained from this specimen. Deliver these specimens to the lab immediately.

10. Blood Cultures

- a. Blood Cultures specimens are collected by the laboratory personnel unless they are unavailable, then physicians and nurses may collect blood cultures.
- b. Blood Cultures should be a minimum of two separate collections (2 sets) 30-45 minutes apart in a 24-hr period. More than 3 sets in a 24-hour period are rarely needed and will be collected only on consultation with the Laboratory.
- c. Blood Cultures should be obtained prior to initiating antibiotic therapy. If this is not possible it may be helpful to draw blood immediately before administering the next dose.
- d. Open the chloraprep pad or iodine solution using aseptic technique. Start from the location directly at the insertion point, and move the pad in concentric circles moving away from the central point.
- e. Do not touch the pad with your glove.
- f. Allow to air dry 1 minute.
- g. **DO NOT** touch or palpate the area after cleansing.
- h. **Disinfecting Blood Culture Vials**
 1. Remove the flip-off caps from BACTEC culture vials.
 2. Wipe top of each vial with a separate 70% isopropyl alcohol pad and allow to dry.
 3. **Do not use iodine or chloraprep to disinfect tops of vial.**
- i. **Venipuncture of Blood Cultures**
 1. Avoid touching the venipuncture site. If it is necessary to touch the site after it has been cleaned, wipe your fingers with chloraprep before touching the site.
 2. When using the Blood Collection Set (“butterfly”) the phlebotomist **MUST** carefully monitor the volume collected by using the 5 mL graduation marks on the vial label. If the volume is not monitored, the stated maximum amount collected may be exceeded. This condition may adversely create a ‘false’ positive result, due to high blood background.
 3. If using a needle and syringe, typically a 20 mL syringe is used for adults. Draw 16 to 20 mL of blood for one blood culture set (aerobic and anaerobic). Aseptically inject 8 to 10 mL of specimen into each vial.
 4. Continue to care for the venipuncture site following guidelines recommended in the venipuncture procedure.
 5. The inoculated **BacT** vials should be transported as quickly as possible to the laboratory.
- j. **Volume of Blood Cultures**
 1. The volume of blood cultured is critical because the number of organisms per mL of blood in most cases of bacteremia is low, especially if the patient is on antimicrobial therapy.
Adult: 16 to 20 mL of blood per venipuncture. If it is impossible to draw the required amount, aliquot as follows:

<u>Amount per Venipuncture</u>	<u>Amount in <i>BacT</i> Plus Aerobic Vial</u>	<u>Amount in <i>BacT</i> Plus Anaerobic Vial</u>
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16-20 mL	Split equally between aerobic and anaerobic vials	
13-16 mL	8 mL	5 - 8 mL
10-12 mL	5 - 7 mL	5 mL
5-9 mL	entire blood amount	0

NOTE: Optimum recovery of isolates will be achieved by adding 8 to 10 mL of blood. The use of lower or higher volumes may adversely affect recovery and/or detection times.

11. Pathology/Cytology Specimens

Pathology

Tissue Specimens are collected and labeled at the time of collection (not before) with patient full name, full social security and date of birth, type of tissue and anatomical location.

Submission of specimens and tissue examination forms:

- All tissue removed for diagnostic or therapeutic purposes must be labeled and sent to the laboratory with a completed Tissue Examination Form (SF 515) (two signatures are required to document proper patient identification has been completed: physician performing the procedure and the assistant present for identification).
- Container label requirements include: Complete name of patient, complete social security number/Date of Birth, specimen type and location.
- Tissue examination forms are required to include: Complete name of patient, complete social security number, date of birth, specimen type and location must match labels on specimen containers, date of collection, name of provider, clinical history, pre & post op diagnoses, and clinic location.
- Specimens are brought directly to the Laboratory room A200.
- Small specimens are submitted in closed and labeled leak proof containers in 10% formalin unless special handling is required. See chart for special handling instructions.

Rejection of specimens:

Unacceptable specimens/requisitions include:

- Unlabeled or incompletely labeled specimen containers.
- Specimens received with incomplete SF 515.
- Requisitions are required to contain the following legible information:
 - The signatures of the physician performing the procedure and the assistant present during the procedure.
 - Patients full name, full social security number and date of birth
 - Name of provider submitting specimen
 - All specimens listed by the number on the specimen container and including the type of specimen and the area from which the specimen was removed.
 - Clinical history and pre- & post-op diagnoses.
 - Corrections must be made by the provider or nursing staff.

- Specimen containers must have the lid secured.

Containers and fixative:

Specimen containers and fixative are supplied by the Anatomic Pathology Section. The container lid must be secure. 10% zinc formalin is the routine fixative.

Specimen handling guidelines:

Small biopsies for light microscopy, small routine specimens, and hardware	10% zinc buffered formalin
All specimens removed outside regular working hours (weekday 8 a.m. to 4:30 p.m.)	10% zinc buffered formalin
Stones (kidney, bladder, gall if separate from gallbladder)	No fixative

Cytology

Specimen identification and forms:

All specimens use SF 515. Forms are required to include: Complete name of patient, complete social security number, date of birth, specimen type and location must match labels on specimen containers (labels with the patient's full name and the full Social Security number), name of provider, clinical history, pre & post op diagnoses, and clinic location.

All slides must be labeled in pencil on the frosted end with the patient's last name and the last four digits of the Social Security number.

Please note when submitting a specimen for both a Pap Smear and a Wet Prep two specimens should be submitted. One specimen will be sent to DMC for process and the other should be submitted to lab personnel to complete the Wet Prep.

Rejection criteria:

- Unlabeled or incompletely labeled specimens
- Specimens received without properly completed SF 515
- Improper fixation
- Delayed delivery to laboratory, with specimen deterioration

Specimen Handling and Preservation

Specimens Requiring Fixation:

The only specimens requiring fixation prior to submission to the laboratory are:

- Direct smears made by the clinicians, i.e., cervical-vaginal, endometrial material. These must be fixed immediately to avoid any drying artifact which severely limits interpretation.
- Breast Expressions - Milk breast solution into slide, fix sample to slide with Cytology spray fixative or submit slide in 95% alcohol in leak proof container. Note the color and how many drops were collected on SF 515 Non-Gyn Cytology form.

Specimens To Be Submitted Fresh:

Unfixed material must be brought to the laboratory immediately. Any delay in processing causes specimen deterioration.

Specimens must be submitted in a sterile container with a secure lid.

Respiratory tract specimen collection**OUTPATIENT SPUTUM:**

Technique: Instruct the patient in producing deep cough sputum. This should be expectorated into a sterile container. If the sample cannot be submitted to the laboratory within an hour, the container should be stored in the refrigerator. The sputum should be thoroughly mixed with Cytology liquid fixative (50% alcohol and 20% Poly ethyl alcohol) by a swirling motion once received in the lab. 20 ml of sputum is an appropriate volume.

Effusions - Specimen collection

Submit aliquots of fluid in 120 cc sterile specimen container with a secure lid. Do not submit the large vacuum bottle. The amount and appearance of the fluid withdrawn should be indicated on the request form.

Urine tract specimens**URINE:**

Do not submit first morning urine! Approximately 50-60 ml of fresh random urine should be placed in approximately 50-60 ml of cytology fixative. Specimens obtained by catheterization and/or cystoscopy should be marked accordingly.

BLADDER WASHINGS:

Vigorously irrigate the bladder five times with the same 50 ml of saline. Place the resulting solution immediately in an equal amount of cytology fixative.

Female specimens**VAGINAL POOL OF SECRETION:**

Examination of smears made of this material is helpful as an aid to detection of possible endometrial lesions.

SCRAPINGS OF VAGINAL WALL:

A smear made of scrapings from the upper lateral vaginal wall is the material needed for estimating hormone effect.

**INSTRUCTIONS FOR SPECIMEN COLLECTION AND
TRANSPORT FOR BACTERIOLOGIC CULTURE**

Container or

Specimen	Transport Device	Volume (ML)	Other
Blood			
Bacteria separate	Vacuum blood culture bottle that contain a liquid medium with	Adults: 10ml/100ml bottle	A minimum of 2 & 3 collections per 24 hr. period are required.
4 are collected	SPS		rarely needed and will be only following consultation with laboratory consultant.
Catheters	Sterile, screw-capped or anaerobe tube	-	Disinfect surrounding entry site, remove catheter, and aseptically clip off tip into tube.
Exudates			
Transudate, drainages, ulcers	Swab or sterile, screwcapped tube	-	Such specimens are rarely suitable for anaerobic culture.
Eye	Swab	-	With corneal lesions swab material and scrapings should be applied directly to slides for smears and to media for culture. Call laboratory.
Fecal material	Sterile container	-	Freshly passed or collected material recommended. Transport medium should be used when delay anticipated. (Cary Blair)
Other (e.g. synovial, pleural, peritoneal)	Syringe or transport anaerobic bottle		needle and syringe; expel air bubbles before injection into bottle; or cap syringe and send to laboratory.

1-5

INSTRUCTIONS FOR SPECIMEN COLLECTION AND
TRANSPORT FOR BACTERIOLOGIC CULTURE

(2)

Specimen	Transport Device	Volume (ML)	Other Consideration
Genitourinary For <i>Neisseria</i> gonorrhoeae	DNA Probe: Use provided swab and transport media for GC and/or Chlamydia approx		Women: Cervix—moisten speculum with water before inserting into vagina: insert swab into cervical canal. Anal canal- insert swab 2 cm and move from side to To sample crypts. Urethra or vagina-- indicated when cervical not possible. Men: Urethra—swab may be used when a discharge is present; otherwise, a sterile bacteriologic loop is inserted to obtain scrapings for smear and culture. Anal canal—as for women.
Cervix, vagina for other bacteria	Swab		unsuitable for anaerobic culture.
Urine Midstream or catheterized	Sterile, screw- capped container	1-10	Specimen should be delivered to the laboratory immediately or, if delayed (>1 h) is anticipated, refrigerate up to 4 hr during transport. If delay more than 4 hours use Urine Transport tube.

Urine Suprapubic Aspirate	Anaerobe tube or syringe	1-10	Collect with sterile needle and syringe; Expel air bubbles before injection into tube. Anaerobic transport container or CAD syringe and send to laboratory. This is the only type of urine specimen that is acceptable for anaerobic culture.
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INSTRUCTIONS FOR SPECIMEN COLLECTION AND
TRANSPORT FOR BACTERIOLOGIC CULTURE

(3)

Specimen	Transport Device	Volume (ML)	Other Consideration
Abscess, wound	Anaerobe transport container	-	Collect with sterile needle and syringe; expel air bubbles before injection into container.
Respiratory tract Nasopharynx	Flexible wire calcium alginate- tipped swab	-	Useful for detecting carrier states of Neisseria meningitidis, Corynebacterium diph- theriae, and Bordetella pertussis, although nasopharyngeal aspirate with soft rubber cathe- ter is better for detecting B. pertussis.
Throat	Swab	-	Tonsillar areas, pharynx and areas of purulence, ulceration, inflammation, or capsule formation must be swabbed with minimal oral contamination. Ordinarily, cultures for group A strep- tococci suffice; however

the laboratory must be notified when Diphtheria, pertussis, or Gonococcal infection is suspected clinically so that appropriate selective media can be inoculated.

Respiratory tract Sputum	Sterile, Screw capped Container	Submit fresh specimen resulting from deep cough as soon after collection as possible.
Transtracheal Aspirate	Anaerobe Transport Container	Collect with sterile needle and syringe or in trap; expel air bubbles before injection into container or cap syringe and send to laboratory.
Bronchial Washings	Sterile, screw capped container	Collected during Bronch procedure. These specimens are unsuitable for anaerobic culture.

INSTRUCTIONS FOR SPECIMEN COLLETION AND
TRANSPORT FOR BACTERIOLGIC CULTURE

(4)

Specimen Consideration	Container or Transport Device	Volume (ML)	Other
Tissue representative	Sterile, screw capped container Or anaerobe transport container		Samples of disease process must be submitted.
Viral Isolates	Viral Transport media		Use special Dacron swabs and transport media. Include source, type of infection and/or suspected virus on requisition.
Chlamydia	Chlamydia Transport media		Use Special Dacron swabs

and Transport media.
Include source, type of
infection.

SPECIMEN PROCESSING

Specimens are to sit upright for approximately 15 minutes after being drawn then centrifuged for approximately 10 minutes. Tubes with anticoagulant may be spun immediately.

Occasionally a specimen will need to be aliquoted into a transfer tube. Label a transfer tube with a sample label. Before aliquoting the specimen into the transfer tube **CAREFULLY EXAM BOTH TUBES - MAKING SURE THAT BOTH TUBES HAVE THE SAME SAMPLE NUMBER AND PATIENT NAME.**

NOTIFICATION OF TESTING DELAYS

The following procedure is to be followed if the Laboratory cannot report patient test results within its established time frame. The laboratory will determine (based on the urgency of the patient test(s) required) the need to notify the requesting physician of the delay. ACTION: Notify the requesting physician or responsible nursing staff personnel of the delay and what action is being taken to remedy the situation

CRITERIA FOR NOTIFICATION OF PHYSICIAN

The laboratory should take the following action when **critical** values are identified.

1. Verify the result(s) by repeat testing. If result(s) is/are reported from a Reference Laboratory (send out test), double check result(s) with reference laboratory before the notification of patient's physician.
2. Immediately notify patient's physician. If the provider is unavailable by phone overhead page. If there is no response from attending physician after 15 minutes, the result should be called to the MOD. **NOTE: Direct communication consists of face-to-face or telephone conversation.** A read back of results by the receiving practitioner is required to determine accuracy.
3. Enter the following in the "COMMENTS" section of the hospital (VISTA) computer system **after** notification has been completed.

Include the following:

- a. **CVRV** on the first line. this will expand to "Critical Value Repeated and Verified"

- b. **Test name abbreviation** and **PV** on the second line. This will expand to read: “XXX Critical values called and read back by provider.”
- c. On the third comment line enter the **name of the person contacted** (First name and last initial) and the date and time notified(0924@1435), then verifier initials. If a RN is notified, the phone extension must be listed.

			Panic Values	
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This will expand to read: Test Name: Critical value called and read back to tech by provider.
 Dr XX 09/24@1435.”

4. Note on bottom of printout verification and who notified, initial, date and time.
5. Chronic Critical Test Results may not require direct Telephone notification for repeat chronic tests; Technologists will use the comment code PVPR (Critical Value Previously Reported to Provider).

PVPRs are not to exceed 5 days. After this time, any new panic values must be called to the provider.

Chart of Critical Values

a.

PVPR should **never** be used on the following analytes: Calcium, Carbamazepine, Dilantin, Phenobarbital, Potassium, Sodium, Glucose or Troponin.

6. See following page(s) and attachments for a list of established Critical values or check the Test Description in VISTA for individual critical test value(s).

Test Name	Normal Values	Units	Less Than	Greater Than	PVPR
aPTT	23.8-42.3	seconds		75.0	
Acetaminophen	10-30	µg/ml		150.0	
Alcohol	0-99	mg/dL		300.0	
Amylase	30-100	U/L		500	
Calcium	8.4-10.3	mg/dL	6.0	14.0	No
Carbamazepine	4.0-12.0	µg/ml		15.0	No
CPK	55-170	IU/L		400	
Creatinine	0.7-1.5	mg/dL		6.0	
D-Dimer (Quantitative)	0-0.49	µg/ml		0.5	
D-Dimer Triage	0-400	ng/ml		400	
Digoxin	1.1-2.1	ng/ml		2.1	
Dilantin	10-20	µg/ml		20	No
Gentamicin Peak	5-10	µg/ml		10.1	
Gentamicin Trough	0.3-2.0	µg/ml		2.1	
Glucose	75-100	mg/dL	50	400	
Hct Female	34-47	%	20.0	60.0	
Hct Male	40-53	%	20.0	60.0	
Hgb Female	11.5-16.0	g/dl	6.5	20.0	
Hgb Male	13.5-18.0	g/dl	6.5	20.0	
INR	0.8-1.14	units		5.0	
Lithium	0.8-1.4	mmol/L		1.4	
Magnesium	2.0-2.6	mg/dL	1.5	2.7	
Phenobarbital	10-20	µg/ml		41	No
Platelet	150-400	x10 ³ /µl	50	1000	
Potassium	3.6-5.4	mmol/L	3.0	6.0	No
Protime	12.0-14.9	seconds		45.0	
Sodium	138-148	mmol/L	120	160	No
Theophylline	10-20	µg/ml		21.0	
Troponin T	0-0.04	ng/ml		0.10	No
Urea Nitrogen	7-23	mg/dL		100	
Valproic Acid	56-125	µg/ml		125	
Vancomycin Peak	25-40	µg/ml		45	
WBC	4.5-10.0	x10 ³ /µl	1.0	20.0	

*age dependent

CRITICAL LIMITS (PANIC VALUES)

The following stain and culture results are viewed as critical results and need to be called to the attending physician immediately.

1. Positive malaria or other parasite identification from the blood.

2. Positive fecal parasite identification.
3. Positive stool culture for Salmonella, Shigella, E. coli H0157, Vibrio, Yersinia or Campylobacter.
4. Positive Pseudomonas culture from the eye.
5. Positive stool specimen for Staphylococcal enteritis; pure growth of Staphylococcus aureus.
6. Positive throat culture for Beta Streptococcus pyogenes group A.
7. Positive Methicillin Resistant Staphylococcus aureus (MRSA)*
8. Positive Vancomycin-Resistant Enterococcus (VRE)*
9. Positive Clostridium Difficile (C-Diff)*
10. Positive for Extended-spectrum beta-lactamase gram negative bacteria (ESBL)*
11. Positive for any Multi-drug resistant organism (MRDO)*
12. Positive Wound Culture
13. Positive Pertussis*
14. Positive HIV*

*** Call Infection Control at x7301 or 7306**

Evaluation of Specimen Containers for Analytic Interference

Purpose:

To ensure that blood collection containers and specimen contacting transfer devices/aliquot tubes do not contribute to erroneous test results with medical consequences the following system of evaluating containers has been established.

Policies:

1. Only collection containers, which are approved by the manufacture of analytical testing instrumentation, will be used.
References: #6 ,#7 & #9
2. Collection containers, which contain anticoagulation additives, must be filled to the appropriate volume to avoid erroneous results caused by over filling or under filling collection tubes.
References: #1, #3, #4, #5 & #8
3. Collection containers which contain Serum/Plasma separators, will not be used for tests which "Instrument Manufactures" have determined can interfere with certain analytical assays.
References: #1, #6 & #7
4. All transfer/aliquot containers used within the laboratory will be made of an "Inert" material which will not affect the analytical properties of the sample it comes in contact with. This generally means using approved sample cups obtained from the Instrument Manufactures.
5. Specimens collected for referral testing will always follow the "Collection Guidelines" stated by the laboratory performing testing.

References:

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- 4) PEWARCHUK W, ET AL. PSEUDOPOLYCYTHEMIA, PSEUDOTHROMBOCYTOPENIA, AND PSEUDOLEUKOPENIA DUE TO OVERFILLING OF BLOOD COLLECTION TUBES. ARCH PATHOL LAB MED. 1992;116:90-92;
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- 8) 8) SAMPSON M, ET AL. POSITIVE INTERFERENCE IN LITHIUM DETERMINATIONS FROM CLOT ACTIVATOR IN COLLECTION CONTAINER. CLIN CHEM. 1997;43:675-679.
- 9) ANAND VD, ET AL. SOME ASPECTS OF SPECIMEN COLLECTION AND STABILITY IN TRACE ELEMENT ANALYSIS OF BODY FLUIDS. CLIN CHEM. 1975;21:595-602;

Attachment B

Patient Handbook Sample

[..\..\Republic\Republic brochure 2013.pub](#)

Attachement C

[..\..\PACT\PACT Team Roles.pptx](#)