Department of Veterans Affairs **VHA DIRECTIVE 2009-001**
Veterans Health Administration
Washington, DC 20420 **January 5, 2009**

RESTRUCTURING OF VHA CLINICAL PROGRAMS

1. PURPOSE: This Veterans Health Administration (VHA) Directive provides policy implementing the restructuring of, addition to, or decrease in major clinical programs that may change or impact the delivery of care provided to veterans.

2. BACKGROUND

a. Since 1995, VHA facilities have undergone extensive restructuring and realignment in order to improve the delivery of health care services and administrative operations. Department of Veterans Affairs (VA) Central Office is responsible for working with Veterans Integrated Service Networks (VISNs) in the oversight and approval of bed changes, program restructuring and changes in clinical services to coordinate and ensure that a full continuum of safe quality care is available to enrollees in each VISN.

b. Concerns have been raised regarding advanced surgical procedures conducted without sufficient clinical support to provide a safe environment and quality outcome. One of the reasons for this is a phenomenon known as "mission creep,' where a facility progressively advances in the complexity of the procedures offered, both surgical and interventional, to its patients without sufficient evaluation of the equipment, services, practitioner competencies, and number of staff available to appropriately treat these cases.

c. When a facility or VISN plans major augmentation to services or programs, a thorough clinical evaluation needs to be conducted, to ensure competencies and skills of all clinical staff as well as necessary ancillary services needed. This applies for pre-procedural and post-procedural care and for an increase in non-procedural services, e.g., a higher level Intensive Care Unit (ICU) or an intensive mental health inpatient unit including bed numbers, space, equipment, supplies, and the requirements of support services. These support services include, but are not limited to: laboratory, imaging, respiratory therapy, etc.

d. Some examples of major restructuring of clinical programs or services include:

(1) Initiation of a new clinical program or service that has not been previously provided at the facility that involves a significant increase in complexity or volume of clinical workload.

(2) Initiation of inpatient surgery at a facility previously performing only ambulatory procedures.

(3) Expansion of an existing surgery program to include thoracic or vascular surgery services, transplant surgery, cardiac surgery, bariatric surgery, neurosurgery, or total joint replacement.

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(4) Initiation of interventional cardiology services at a site previously performing only diagnostic cardiology procedures, or initiating a new interventional radiology program.

(5) Expansion of advanced technology applications to already approved procedures, i.e., radiofrequency ablation, cryotherapy, robotic surgery, and sentinel node evaluations (pathology and nuclear medicine).

(6) Expansion of medical services including establishment of new dialysis units and infusion centers.

(7) Establishment or change in the level of complexity of an ICU or emergency department.

(8) Initiation or expansion of a clinical program that requires certification by an external organization, such as the initiation of radiation oncology or nuclear medicine services not previously performed at a facility.

(9). Significant increase in the volume of existing procedures (i.e., more than (>) 50 percent increase in baseline workload) expected to require additional equipment, space, staffing, and training.

(10) Elimination of a major clinical program, such as the provision of on-site dialysis, open heart surgery, or residential community care.

3. POLICY: It is VHA policy that all proposals requiring restructuring, reduction, or augmentation of major clinical programs or services from the VISN Director for non-mandated VHA programs, must be approved by the Under Secretary for Health, or designee, through the Deputy Under Secretary for Health for Operations and Management and the Chief Officer, Patient Care Services. ***NOTE:*** *This Directive is to be used by VISNs in the development and approval of major programmatic changes to clinical programs or services, including, but not limited to, new service requests or major augmentations or the decrease in existing programs within the VISN.*

4. ACTION

a. **The Under Secretary for Health.** The Under Secretary for Health, or designee, is the approving official for major changes to any clinical programs or restructuring of services within the VISNs.

b. **The Principal Deputy Under Secretary for Health.** The Principal Deputy Under Secretary for Health is responsible for reviewing and concurring on all requests and business plans for major changes in any clinical programs or restructuring of services with the VISNs to ensure there are appropriate clinical indications for change and appropriate program support.

c. **Deputy Under Secretary for Health for Operations and Management.** The Deputy Under Secretary for Health for Operations and Management (10N) is responsible for:

(1) Reviewing the requests and business plans for the restructuring, reduction, or augmentation of all major clinical programs or services at VA facilities to ensure there is adequate administration of resources, and that needs are being addressed.

(2) Providing a copy of the request to Patient Care Services for review.

d. **Office of Patient Care Services.** The Office of Patient Care Services (11) is responsible for:

(1) Reviewing the requests and business plans for restructuring, reduction, or augmentation of all major clinical programs or services at VA facilities to ensure there are adequate clinical resources, and that standards of care and adherence to clinical policies are being addressed.

(2) Determining the need for on-site review prior to approval. ***NOTE:*** *Site reviews may also be requested by VISN Directors.*

(3) Assembling an appropriate clinical team to conduct the on-site visit to review the facility requesting the new or expanded clinical program.

e. **Office of Nursing Services.** The Office of Nursing Services (108) is responsible for providing comments and recommendations to the Deputy Under Secretary for Health for Operations and Management (10N) on proposals from VISN Directors for changes to major clinical programs or services which impact Nursing.

f. **VISN Director.** Each VISN Director is responsible for:

(1) Ensuring appropriate facilities within the VISN prepare a Business Plan using the required format (see Att. A).

(2) Reviewing and evaluating the proposal, and submitting each approved proposal with the associated Business Plan to the Deputy Under Secretary for Health for Operations and Management (10N), who provides a copy to the Office of Patient Care Services (11) for review.

(3) Initiating a request for a site review from the Office of Patient Care Services to ensure appropriateness of implementation of new or expanded clinical program.

(4) Reviewing and ensuring that facility requests for any major reduction in clinical programs does not adversely affect the delivery of patient care and that alternate provisions for care have been identified, as needed.

(5) Forwarding the request, after review and approval, to the Deputy Under Secretary for Health for Operations and Management (10N).

g. **VISN Chief Medical Officer (CMO).** Each VISN CMO is responsible for ensuring:

(1) A thorough clinical evaluation has been conducted that ensures the competencies and skills of all clinicians and ancillary service staff required for any requested major clinical programs or services, meet the standard of care.

(2) Processes are in place for ensuring providers have the appropriate privileges to perform all procedures required for the requested major clinical programs or services.

(3) All facilities within the VISN have a process in place to evaluate the privilege-specific competence of any practitioner who does not have documented evidence of competently performing a requested privilege (see VHA Handbook 1100.19). This must be a time-limited period during which the medical staff leadership evaluates and determines the practitioner's professional performance. This process includes all new providers to a facility, and privileges for a provider who is known to the facility.

(4) A clinical evaluation is conducted to assess beds, space, equipment, supplies and the requirements of support services to include, but are not limited to laboratory, imaging, etc.

(5) A clinical evaluation is conducted to assess related processes of care, including patient selection criteria, clinical optimization, and the coordination and management of patients.

(6) A site visit is performed through the responsible clinical program office, as applicable, by an expert panel from the appropriate surgical work group when initiating new programs in robotic, bariatric, transplant, cardiac, or neurosurgery.

(7) A final clinical review and evaluation for the proposed Business Plans (see Att. A) is provided to the Deputy Under Secretary for Health for Operations and Management, who provides a copy to the Office of Patient Care Services.

(8) Proposals for major reduction in clinical programs are reviewed to ensure the provision of clinical care for these services are no longer required, or are adequately provided for by fee basis, contract services, or agreements with another VA facility.

h. **Facility Director.** The facility Director is responsible for ensuring that:

(1) The proposal request for restructuring clinical programs includes the required completed business plan (see Att. A), and

(2) This proposal request is submitted to the VISN Director for review and approval.

(3) Proposals for major reduction in clinical programs are reviewed to ensure the provision of clinical care for these services are no longer required, or are adequately provided for by fee basis, contract services, or agreements with another VA facility.

i. **Facility Chief of Staff.** The facility Chief of Staff is responsible for:

(1) Making sure a thorough clinical evaluation has been conducted to ensure that the competencies and skills of clinicians and staff of ancillary services required for any requested major clinical programs or services meet the standard of care. This clinical evaluation needs to include an assessment of:

(a) Beds,

(b) Space,

(c) Equipment,

(d) Supplies,

(e) The requirements of support services to include, but not limited to: laboratory, imaging, etc.

(f) Related processes of care, including patient selection criteria, clinical optimization, and the coordination and management of patients.

(2) Ensuring that a site visit is conducted by the responsible clinical program office as applicable, (specifically to include an expert panel from the appropriate surgical work group when initiating new programs in robotic, bariatric, transplant, cardiac, or neurosurgery).

(3) Providing a clinical review and evaluation for the proposed business plans (see Att. A).

(4) Ensuring there is a process in place to evaluate the privilege-specific competence of any practitioner who does not have documented evidence of competently performing a requested privilege (Focused Professional Practice Evaluation). ***NOTE:*** *This is a time-limited period during which the medical staff leadership evaluates and determines the practitioner's professional performance and that of all new providers to a facility. This process includes: privileges for a provider who is known to the facility, and privileges for any new providers to a facility.*

(5) Ensuring processes are in place to provide on-going review and evaluation of the quality of care provided for all clinical services.

(6) Proposals for major reduction in clinical programs are reviewed to ensure the provision of clinical care for these services are no longer required, or are adequately provided for by fee basis, contract services, or agreements with another VA facility.

5. REFERENCES

a. Deputy Under Secretary for Health for Operations and Management Memo: Advancement of Facility Mission Without Sufficient Clinical Support, January 24, 2008

b. VHA Directive 1000.1, Restructuring and Inpatient Bed Change Policy.

c. VHA Handbook 1000.1, Restructuring and Inpatient Bed Change Procedures.

d. VHA Handbook 1102.3, Criteria and Standards for Cardiac Surgery Programs.

e. VHA Handbook 1102.4, Criteria and Standards for Neurologic Surgery Programs.

6. FOLLOW-UP RESPONSIBILITY: The Deputy Under Secretary for Health for Operations and Management (10N) is responsible for the contents of this Directive. Questions may be referred the Office of the Deputy Under Secretary for Health for Operations and Management at 202-461-7042.

7. RESCISSIONS: None. This VHA Directive expires January 31, 2014.

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Under Secretary for Health

Attachment

DISTRIBUTION: CO: E-mailed 1/06/09
FLD: VISN, MA, DO, OC, OCRO, and 200 – E-mailed 1/06/09

ATTACHMENT A

REQUIRED BUSINESS PLAN FORMAT FOR
PROPOSED RESTRUCTURING OF CLINICAL PROGRAMS OR SERVICES
REQUIRING UNDER SECRETARY FOR HEALTH APPROVAL

1. VETERANS INTEGRATED SERVICE NETWORK (VISN) # _____

2. FOR FURTHER INFORMATION CONTACT: Name, address, telephone and fax number of person(s) to contact for additional information. The designated person(s) must be able to answer specific questions about the proposal**.**

3. LOCATION FOR PROPOSED PROGRAM OR SERVICE: Identify the Department of Veterans Affairs (VA) Health Care Facility, the clinical service(s) or programs involved, and whether inpatient or outpatient. ***NOTE:*** *If a proposal addresses more than one site, each site must be specifically identified.*

4. PROPOSED EXPANSION OF MAJOR CLINICAL PROGRAM OR SERVICE MEETS THE FOLLOWING CRITERIA: *(Check all that apply)*

_____ a. Initiation of a new clinical program or service that had not been previously provided at the facility that involves a significant increase in complexity or volume of clinical workload. Examples include the:

(1) Initiation of inpatient surgery at a facility previously performing only ambulatory procedures.

(2) Expansion of an existing surgery program to include: thoracic or vascular surgery services, transplant surgery, cardiac surgery, bariatric surgery, cardiac surgery, neurosurgery, or total joint replacement.

(3) Initiation of interventional radiology including cardiology services at a site previously performing only diagnostic cardiology services.

(4) Initiation or expansion of advanced technology applications to already approved procedures, i.e., radiofrequency ablation, cryotherapy, robotic surgery, and sentinel node evaluations (pathology and nuclear medicine).

(5) Initiation of additional technologies, such as Magnetic Resonance Imaging (MRI).

(6) Expansion of medical services including dialysis unit and infusion centers; or establishing, increasing, or decreasing the level of complexity of and ICU or emergency department.

_____ b. Initiation or expansion of a clinical program that requires certification by an external organization, such as the initiation of radiation oncology or nuclear medicine services not previously performed at a facility.

_____ c. Significant increase in the volume of existing procedures (i.e., more than (>) 50 percent increase in baseline workload) expected to require additional equipment, space, staffing and training.

5. DESCRIPTION OF PROPOSED CLINICAL PROGRAM OR SERVICE RESTRUCTURE:

6. JUSTIFICATION FOR REQUEST

a. General description of the proposed program or service expansion.

b. Rationale for this expansion of programs or services.

c. Resources currently available for provision of this program or service.

d. Impact of proposal on current patient care programs or services.

7. EXPECTED OUTCOME(S) FOR EXPANDED PROGRAM OR SERVICE: Describe how the addition of this clinical program or service will improve the quality of care provided to the veterans served by this facility or within this VISN.

8. DISCUSSION AND ANALYSIS OF ALTERNATIVE APPROACHES TO PROVIDING NEEDED SERVICES:

9. DEMOGRAPHIC ANALYSIS OR PROJECTED WORKLOAD: Discuss target market analysis of capacity and proposed workload projections related to the proposed program or service change. Include the veteran population served, as well as start-up, 1 and 3-year projections for workload by the priority group. How will this impact bed days of care (BDOC) in Medicine, Surgery, and Psychiatry acute beds? ***NOTE:*** The *source is the Enrollee Health Care Projection Model (EHCPM).*

VETERANS	# Treated Previous Fiscal Year (FY)	1-Year Projection	3-Year Projection
# Veterans receiving this program or service. # Veterans referred out for this program or service. # Veterans receiving this program or service at another VA medical facility.			

10. EVALUATION AND ANALYSIS OF INFRASTRUCTURE TO SUPPORT: Every new or expanded clinical program or service needs to be evaluated to ensure sufficient infrastructure is in place to support quality care. At a minimum, this includes evaluation of staffing, space, ancillary support, and equipment.

Staff or Full-time Equivalent (FTE) Employee (# staff with adequate credentials or training to provide coverage 24 hours a day, 7 days a week, or as needed for requested clinical service or program requested.)	**# Needed for Proposed Program or Service**	**Current Number**	**Difference**
a. Providers (Physician (MD or DO), Nurse Practitioner (NP), Physician Assistant (PA)). b. Nursing. c. Laboratory. d. Pharmacy. e. Respiratory Therapy. f. Radiology. g. Supply, Processing, and Distribution (SPD). h. Biomedical Engineering. i. Other.			
CLINICAL SPACE EQUIPMENT Items specific to providing the additional clinical program or service for this request. Examples:	**# Needed for Proposed Program or Service**	**Current**	**Difference**
a. # Operating Rooms of correct size or configuration. b. # Recovery Beds. c. # Inpatient Beds. d. # ICU Beds. e. # Outpatient Clinic Space.			

EQUIPMENT Items specific to providing the additional clinical program or service for this request.	**# Needed for Proposed Program or Service**	**Current**	**Difference**
a. Surgery. b. Laboratory. c. Radiology. d. Respiratory Therapy. e. Pharmacy. f. SPD. g. Other.			

11. PROCESSES OF CARE

a. Criteria for Patient inclusion in new services: This needs to include patient factors as well as facility factors (an example of "facility factors" might be the anticipated need for dialysis post procedure in a facility that did not have this available on-site).

b. Process for coordination of care throughout the continuum of care and identified processes for coverage and handoffs, as appropriate.

12. INTERIM PLAN FOR PROVISION OF CARE

a. Planned date for Implementation of Proposed Clinical Program or Service.

b. Describe how patients are currently being cared for or treated that require the clinical service or program requested in this proposal.

13. STAKEHOLDER INVOLVEMENT REPORT: Describe the involvement and/or the support of any affected stakeholder groups, as applicable. Include a description of internal "clinical stakeholders," such as: surgeons; nursing staff from the Operating Room, Post Anesthesia Care Unit (PACU), or Intensive Care Unit (ICU); intensivists; hospitalists; resident and intern training or continuing Medical Education (CME) issues; primary care for pre-op optimization; and long-term follow up in some cases (i.e., bariatric surgery).

14. ORGANIZATIONAL CHART: Provide a copy the VA medical facility organizational chart, as well as a copy of a modified chart showing the organization if the requested clinical program or services expansion alters it.

15. EVALUATION PLAN: Describe how the planned expansion of this clinical program or service will be evaluated for quality, cost, patient satisfaction, and program effectiveness.

16. CLINICAL PROGRAM SITE REVIEW REPORT: The findings and recommendations from the clinical site review conducted by the Office of Patient Care Services are forwarded to the requesting VISN Director.

Submitted by:

_____ _____

(Signature and Title of the Medical Facility Director) (Date)