

**VHA ENTERPRISE FRAMEWORK FOR QUALITY, SAFETY, AND VALUE**

**1. REASON FOR ISSUE.** This Veterans Health Administration (VHA) Directive establishes authority and policy to design and implement the deployment of an enterprise-wide, integrated framework for VHA to become the most trusted choice of Veterans for high quality, safe and reliable care.

**2. SUMMARY OF CHANGES.** This VHA Directive outlines redefined leadership roles at the national, network, and facility levels for oversight of the quality and safety of patient care within VHA. Designated leaders are directly accountable for program integration and communication within their level of responsibility.

**3. RELATED ISSUES.** None

**4. RESPONSIBLE OFFICE.** Office of the Assistant Deputy Under Secretary for Health for Quality, Safety, and Value (10A4) is responsible for the contents of this Directive. Questions may be addressed at 202-461-1994

**5. RESCISSIONS.** VHA Directive 2009-043, dated September 11, 2009, is rescinded.

**6. RECERTIFICATION.** This VHA Directive is scheduled for recertification on or before the last working day of August 2018.

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## VHA ENTERPRISE FRAMEWORK FOR QUALITY, SAFETY AND VALUE

**1. PURPOSE:** This Veterans Health Administration (VHA) Directive establishes policy to design and implement the deployment of an enterprise-wide, integrated framework for VHA to become the most trusted choice of Veterans for high quality, safe, and reliable care.

**AUTHORITY:** Public Law 111-163, Title V, Sec. 505.

### 2. BACKGROUND

a. The Caregivers and Veterans Omnibus Health Services Act of 2010, Public Law 111-163, Title V, Section 505, enacted in May 2010, designates leadership roles at the national, network, and facility levels for oversight of the quality and safety of patient care within VHA. Designated leaders are directly accountable for program integration and communication within their level of responsibility. Specific requirements of Section 505 of Public Law 111-163 are not addressed in this Directive.

b. Even prior to the passage of this legislation, VHA recognized an imperative to create new models of care to meet the evolving expectations of today's Veterans. VHA set the goal of serving as the Nation's leader in delivering high quality, safe and reliable care, centered on the Veteran, while promoting population health throughout the coordinated care continuum.

c. To meet this goal, VHA must foster a culture that acts with integrity to achieve accountability, a culture that is vigilant and mindful, proactively risk aware, highly reliable, predictable, and a culture that seeks to continuously improve. Such a culture allows staff to serve as positive change agents on behalf of Veterans, families, and co-workers.

d. VHA's culture must employ recognized principles, practices, and behaviors of successful organizations to create an enterprise-wide framework focused on delivering high quality, safe and reliable care centered on the Veteran. High Reliability Organizations, Learning Organizations, Enterprise Risk Management concepts, and the Baldrige Framework for Excellence® represent industry-standard approaches that VHA can utilize to facilitate the implementation of an integrated enterprise-wide program of quality, safety, and value.

e. Lessons from health care and other industries demonstrate that the achievement of high-quality outcomes requires strategic alignment and both horizontal and vertical integration within the organization. Critical to optimal outcomes is an engaged leadership that supports high-functioning teams and ensures an atmosphere of trust in which stakeholders are encouraged and feel the psychological safety to bring their essential concerns to management. Effective leaders assess performance gaps, set priorities, make changes, create a transparent environment, and a just culture that encourages employees to be individually and collectively aware of their responsibilities to ensure successful outcomes.

f. In March 2011, VHA underwent a critical realignment to transform its services to Veterans, and drive implementation of its vision for healthcare excellence and patient-centric, value-driven care. The realignment connects and integrates quality, safety, systems redesign and engineering, risk management, compliance, and consultative functions to support an enterprise

framework for high reliability and a culture of safety, robust information systems, evidence-based practice, and continuous measurement and improvement.

g. Effective leaders in VHA must ensure that Veterans are provided with high-quality health care that is safe, effective, patient-centered, timely, efficient, and equitable. Successful leadership is reflected in accountability structures, attention to early warning signals, and the flow of critical information within the organization. Leadership includes the identification, prioritization, and coordination of improvement, and re-engineering activities to promote value, safety, quality, and efficiency. VHA's leaders must be visible at all levels throughout the organization.

**3. POLICY:** It is VHA policy that an enterprise-wide framework be established for each organizational level that: integrates the functions of quality, safety, and high reliability to achieve value for Veterans; recognizes current and emerging Veteran needs; is aligned with VHA strategic guidance and resource allocation; and is consistent with Department of Veterans Affairs (VA) Core Values of Integrity, Commitment, Advocacy, Respect, and Excellence.

#### 4. ACTION

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for:

(1) Establishing the organizational leadership expectation of a transparent environment and a just culture within VHA that promotes quality, safety, high reliability, and value;

(2) Establishing the overall strategic priorities for VHA;

(3) Ensuring alignment of quality priorities with those of the organization as a whole; and

(4) Aligning resources required to implement and maintain the enterprise-wide framework.

b. **Principal Deputy Under Secretary for Health.** The Principal Deputy Under Secretary for Health is responsible for:

(1) Supporting the Under Secretary for Health in establishing both a transparent environment and a just culture that promotes quality, safety, high reliability, and value for VHA; and

(2) Ensuring that VHA Program Offices reporting to the Principal Deputy Under Secretary for Health address the quality, safety, and improvement priorities, in an integrated manner across the enterprise to achieve greatest impact and value to stakeholders.

c. **Assistant Deputy Under Secretary for Health for Quality, Safety and Value.** The Assistant Deputy Under Secretary for Health for Quality, Safety, and Value is responsible for:

(1) Integrating and providing oversight in establishing and implementing programs under the Office of Quality, Safety and Value by planning, directing, coordinating and evaluating VHA's national quality, safety, and value-producing programs and approaches;

- (2) Setting priorities for quality and safety initiatives that produce value; create safe, effective, patient-centered, timely, efficient, and equitable care; reduce risk and harm, and create a just culture;
- (3) Creating an integrated approach to compliance with applicable laws, regulations and standards that prompts accountability by building integrity in systems and internal controls;
- (4) Creating an enterprise-wide approach that mitigates and proactively prevents organizational risk through enterprise risk management;
- (5) Creating the organization-wide capacity to progress continuously toward the goal of high reliability and predictability with the identification of standard work and common delivery platforms and the instillation of quality management disciplined practices and principles;
- (6) Creating an integrated strategy to provide a broad-based glimpse of the organization's value-producing performance;
- (7) Working collaboratively with the Principal Deputy Under Secretary for Health, Deputy Under Secretaries for Health, Assistant Deputy Under Secretaries for Health, VHA Chief Officers and Program Directors, Veterans Integrated Services Network (VISN) Directors, and clinical leaders, as appropriate, to support the identified priorities of quality, safety, and value; and
- (8) Chairing the National VHA Health Care Quality and Value Committee of the National Leadership Council (HCQVC).

d. **Deputy Under Secretary for Health for Operations and Management.** The Deputy Under Secretary for Health for Operations and Management is responsible for:

- (1) Providing operational direction, support, and oversight of resource management to the network necessary to implement the enterprise-wide framework for quality, safety, high reliability, and value;
- (2) Ensuring that health care operations within VHA support evolving patient-centered delivery platforms, continuous improvement in operational performance, safe practices, and population health in a coordinated continuum;
- (3) Communicating appropriate operational priorities supporting quality and patient safety throughout VHA in coordination with the Principal Deputy Under Secretary for Health, Deputy Under Secretary for Health for Policy and Services, the Office of the Assistant Deputy Under Secretary for Health for Quality, Safety, and Value, and other program offices, as appropriate;
- (4) Collaborating with the Office of Quality, Safety, and Value to leverage risk intelligence to pinpoint high- risk areas and in identifying expert consultants for customized intervention and improvement, as needed; and

(5) Integrating key functions and processes within their program scope and across the Office of Quality, Safety, and Value to minimize duplication and overlap, and ensure oversight and assistance activities to provide the best value to VISNs.

e. **Deputy Under Secretary for Health for Policy and Services.** The Deputy Under Secretary for Health for Policy and Services is responsible for:

(1) Directing, developing, and disseminating policies, programs, and processes that are aligned with the priorities of the organization as a whole; and

(2) Ensuring that policies, programs, and processes contribute effectively to the Enterprise Framework for Quality, Safety, and Value, maximize high reliability, and optimize health outcomes.

f. **VHA Chief Officers and Program Directors.** Each VHA Chief Officer and Program Director is responsible for:

(1) Ensuring the program office's contribute effectively to the Enterprise Framework for Quality, Safety, and Value, maximizes high reliability, and optimizes health outcomes;

(2) Developing and disseminating policies, programs, and processes that are aligned with the priorities of the organization as a whole;

(3) Assessing population needs and variability within the scope of their responsibility or program;

(4) Identifying evidence-based practices, initiatives, and measures that support improvements in health in collaboration with appropriate program offices;

(5) Providing leadership in the ongoing monitoring and oversight of safety and quality within their scope of programmatic responsibility;

(6) Communicating appropriate policy supporting quality and patient safety throughout VHA in coordination with the Principal Deputy Under Secretary for Health, Deputy Under Secretary for Health for Operations and Management, Deputy Under Secretary for Health for Policy and Services, the Assistant Deputy Under Secretary for Health for Quality, Safety, and Value, and other VHA Chief Officers and Program Directors, as appropriate;

(7) Collaborating with the Office of Quality, Safety and Value in identifying expert consultants, in applying an Enterprise Framework for Quality, Safety, and Value to programs within their scope of responsibility, as needed; and,

(8) Integrating key functions and processes within their program scope and across the Office of Quality, Safety, and Value to minimize duplication and overlap to ensure oversight and assistance activities provide the best value to VISNs.

g. **VHA Health Care Quality and Value Committee of the National Leadership Council (HCQVC)**. The HCQVC serves as the key governance element within VHA that makes recommendations through the National Leadership Council to the Under Secretary for Health related to Health Care Quality and Value. The HCQVC must:

- (1) Be chaired by the Assistant Deputy Under Secretary for Health for Quality, Safety, and Value and a VISN Director;
- (2) Coordinate its recommendations with other VHA Governance Committees;
- (3) Establish measures of success for strategic quality outcomes and breakthrough goals to achieve safe, effective, patient-centered, timely, efficient, and equitable care;
- (4) Ensure that data concerning quality are robust, accurate and usable in decision making by all levels of the organization;
- (5) Examine the results of external and internal reviews of quality and safety for performance gaps and then guide continuous improvement efforts;
- (6) Develop recommendations for actions to improve quality, safety and healthcare value within VHA; and
- (7) Address matters related to areas that:
  - (a) Define and set strategic directions for quality, safety, and reliability.
  - (b) Leverage appropriate quality analytics and risk intelligence.
  - (c) Create transparency in operations and stakeholder communications.
  - (d) Oversee quality data development, management, and reporting.
  - (e) Create safe practices and high functioning teams to reduce the risk of harm.
  - (f) Produce balanced measurement to gauge progress toward organizational goals and results.

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

- (1) Ensuring that the functions of the Enterprise Framework for Quality, Safety, and Value are in compliance with VHA standards, regulations, and policies, and are integrated under an organizational structure that promotes the exchange and flow of quality information, and guards against organizational silos.
- (2) Facilitating an environment in which staff act with integrity to achieve accountability while remaining mindful and proactively risk aware, with processes that are highly reliable and predictable.

(3) Promoting a just culture in which staff can experience the psychological safety necessary to bring issues forward.

(4) Designating an official of appropriate background and skill to provide leadership for an integrated team that ensures thorough and uniform discharge of the key functions of the Enterprise Framework for Quality, Safety, and Value in alignment with policies and mandates. This designated official must report to the VISN Director. This official must function as a liaison for needed collaboration with the Assistant Deputy Under Secretary for Health for Quality, Safety, and Value.

(5) Implementing the Office of Assistant Deputy Under Secretary for Health for Quality, Safety, and Value priorities at the VISN level, and coordinating with VHA Program Offices to ensure strategic alignment.

(6) Ensuring adequate resources for planning and implementing the VISN framework.

(7) Establishing a standing committee under an enterprise framework to review data, information, and risk intelligence and to ensure that key quality, safety, and value functions are discussed and integrated on a regular basis. The committee is comprised of a multidisciplinary group working towards understanding the complex environment that results in adverse events, and loss of value and efficiency. The committee must develop prioritized recommendations to aid VISN leadership. VISN leadership must charter improvement teams or initiate strategies to make changes to improve outcomes for Veterans. The standing committee must:

(a) Meet at least quarterly, and as warranted;

(b) Be chaired or co-chaired by the VISN Director;

(c) Ensure documents generated by an Enterprise Framework for Quality, Safety, and Value activity, including meeting minutes of the standing committee, are produced in the process of conducting systematic health care reviews for the purpose of improving the quality of health care or the utilization of health care resources in VA health care facilities. Meeting minutes must record attendance and track issues to resolution;

(d) Ensure the quality assurance (QA) criteria is met, enterprise framework documents are protected as QA documents under 38 U.S.C. 5705 and its implementing regulations at 38 CFR 17.500-511;

(e) Ensure documents generated as a result of enterprise framework activity generally fall within the class of health care QA review identified as “monitoring and evaluation reviews conducted by a facility” in accordance with 38 CFR 17.501(a)(1) and must involve primarily service and program monitoring activity;

(f) Ensure that if a facility engages in any other type of QA review that is associated with enterprise framework activity, such as a focused review that requires designation as QA at the

outset of the review, the facility needs to follow its standard practice in ensuring that the review is appropriately covered as QA; and

(g) Ensure aggregated data collected for the Enterprise Framework for Quality, Safety, and Value functions are analyzed and reviewed at meetings of the standing committee. *NOTE: Use of comparison data and triggering thresholds is encouraged.*

i. **Medical Facility Director.** Each medical facility Director is responsible for:

(1) Ensuring that the functions of the Enterprise Framework for Quality, Safety, and Value are in compliance with VHA standards, regulations, and policies, and are integrated under an organizational structure that promotes the exchange and flow of quality information, and guards against organizational silos.

(2) Facilitating an environment in which staff act with integrity to achieve accountability while remaining mindful, proactively risk aware, with processes that are highly reliable, and predictable.

(3) Promoting a just culture in which staff can experience the psychological safety necessary to bring issues forward.

(4) Designating an official of appropriate background and skill to provide leadership for an integrated team that ensures thorough and uniform discharge of the key functions of the Enterprise Framework for Quality, Safety and Value in alignment with policies and mandates. This designated official must report to the medical facility Director. This official must function as a liaison for needed collaboration with the Network counterpart.

(5) Ensuring adequate resources for planning and implementing the facility Enterprise Framework for Quality, Safety and Value.

(6) Establishing a standing committee under an enterprise framework to review data, information, and risk intelligence and ensure that key quality, safety, and value functions are discussed and integrated on a regular basis. The committee is comprised of a multidisciplinary group working towards understanding the complex environment that results in adverse events, and loss of value and efficiency. The committee must develop prioritized recommendations to aid facility leadership. Medical facility leadership must charter improvement teams or initiate strategies to make changes to improve outcomes for Veterans. This standing committee must:

(a) Meet at least quarterly, and as warranted.

(b) Be chaired or co-chaired by the Medical Facility Director.

(c) Ensure documents generated by an Enterprise Framework for Quality, Safety, and Value activity, including meeting minutes of the standing committee, are produced in the process of conducting systematic health care reviews for the purpose of improving the quality of health care or the utilization of health care resources in VA health care facilities. Meeting minutes must record attendance and track issues to resolution.

(d) Ensure the quality assurance (QA) criteria is met, enterprise framework documents are protected as QA documents under 38 U.S.C. 5705 and its implementing regulations at 38 CFR 17.500-511.

(e) Ensure documents generated as a result of enterprise framework activity generally fall within the class of health care QA review identified as “monitoring and evaluation reviews conducted by a facility” in accordance with 38 CFR 17.501(a)(1) and must involve primarily service and program monitoring activity.

(f) Ensure that if a facility engages in any other type of QA review that is associated with enterprise framework activity, such as a focused review that requires designation as QA at the outset of the review, the facility needs to follow its standard practice in ensuring that the review is appropriately covered as QA.

(g) Ensure aggregated data collected for the Enterprise Framework for Quality, Safety, and Value functions are analyzed and reviewed at meetings of the standing committee. *NOTE: Use of comparison data and triggering thresholds is encouraged.*

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## 6. DEFINITIONS

a. **Enterprise Risk Management (ERM).** Risks are inherent in health care and cannot be totally eliminated. The Enterprise Framework for Quality, Safety, and Value will provide a comprehensive understanding of the factors underlying risk and improve their management and control. ERM broadly examines multiple-risk categories and anticipates how the likelihood and potential impact of interrelated risks might have implications for the entire healthcare organization. ERM fundamentally recognizes that risks do not occur in isolation but rather exist synergistically, and when managed proactively, can result in the strategic leveraging of positive opportunity and risk prevention. The goal of ERM is to prioritize and act in a deliberative and

measured manner to address the greatest risks to the entire enterprise, whether those risks are regularly found within a medical facility, or had up until now never been considered. Once the greatest risks are identified and prioritized, the medical facility needs to be able to develop an appropriate, integrated response, including prevention, mitigation, management, and financing the response.

b. **Baldrige Framework For Excellence®**. The Baldrige Framework for Excellence® is a roadmap to excellence and high reliability through implementation of interrelated concepts and values that serve as the foundation for integrating key business requirements within a results-oriented environment that continually creates a basis for action, feedback, and learning.

c. **Quality Assurance Documents**. Quality Assurance Documents are defined as documents or parts of documents produced by, or for, the Department of Veterans Affairs (VA) in the process of conducting systematic health care reviews for the purpose of improving the quality of health care and improving the utilization of health care resources, and which are protected by 38 U.S.C. and its implementing regulations.

d. **High Reliability Organization (HRO)**. An HRO is an organization that has succeeded in avoiding catastrophes in an environment where normal accidents can be expected due to risk factors and complexity. The success of HROs is attributed to their determined efforts to act mindfully. Mindfulness is a psychological quality that involves bringing one's complete attention to the present experience on a moment-to-moment basis. As an individual or as a team member, this means noticing an unexpected event in the making and taking the needed steps to halt its development. If the event cannot be halted, it is contained. If the event cannot be contained, focus is shifted to resilience and restoration.

e. **Just Culture**. A just culture learns and improves by openly identifying and examining its own weaknesses. In such a culture, employees feel safe and emotionally comfortable in the work environment. Employees will be able, and expected, to perform at peak capacity. They must also be able to admit weakness, concern, or inability and to seek assistance when the quality and safety of care may be threatened. Individuals feel as accountable for maintaining this environment as they do for delivering outstanding care. They know that they are accountable for their actions, but will not be blamed for system faults beyond their control. They accept accountability for developing and maintaining an environment that feels psychologically safe.

f. **Learning Organization**. A learning organization empowers individuals to continually exercise their ability to create desired results. It nurtures new and expansive patterns of thinking in which people are integrated and together continually learn to visualize systems as a "whole." People in a learning organization are agents, able to act upon the structures and systems of which they are a part. Key tools critical to sustaining learning organizations are: systems thinking, personal mastery, mental models, building shared vision, and team learning.

g. **Value**. Value is the generation of both population health and increasing levels of patient satisfaction, health literacy, and engagement in seamless, efficient systems throughout a patient centered experience of coordinated care at the lowest per capita cost.

h. **Enterprise Framework for Quality, Safety and Value.** Enterprise Framework for Quality, Safety and Value require the following four elements for its functionality, they are:

(1) **Sustainable Results and Breakthrough Innovations.** The Enterprise Framework for Quality, Safety and Value serves as a critical driver to deliver sustainable results and breakthrough innovations for the VA health care system. The framework requires visible and accountable leadership that is clearly focused and fully engaged in processes serving as the foundation for excellence.

(2) **Leadership Responsibility.** It is incumbent upon leadership to create and nurture an environment of transparency, and a just culture in which employees are mindful of inherent risks within their surroundings, and are empowered to bring concerns forth to leadership, confident that they will be addressed without fear of reprisal. Organizational leaders must ensure that the functions of the enterprise framework are integrated under an organizational structure that promotes unity of purpose in quality, safety, and value, and guards against organizational silos while promoting integrated joint management of quality safety and value.

(3) **Integration and Coordination.** The enterprise framework provides a mechanism for integrating and coordinating interrelated activities to achieve optimal patient value. This framework unites the efforts of many experts and organizational functions to best serve Veterans. Unity of purpose toward achieving value needs to be reflected at VA central office, Veterans Integrated Service Network (VISN), and the facility level. Staff alignment and reporting structures at the VISN and facility level will be at the discretion of the respective directors.

(4) **Key Functions.** Organizational leaders must incorporate key functions in their activities to ensure successful implementation of the enterprise framework. The framework includes environmental scanning, strategic planning, patient-centered design of delivery platforms, a focus on workforce development and learning, and efficient integrated operations. Measurement, analysis, and knowledge management are critical to risk awareness, performance gaps appraisal process improvement and sustained quality in support of fact-based, knowledge-driven management of operational systems. Key functions include:

(a) Quality Management Systems and Internal Control; **NOTE:** *This includes quality assurance, regulatory compliance, and quality control.*

(b) Continuous improvement, redesign, systems engineering, and efficiency management;

(c) Patient Safety;

(d) Internal and External Reviews;

(e) Utilization Management;

(f) Risk Management; **NOTE:** *This includes peer review, tort claim processing, and institutional disclosure monitoring.*

(g) Performance measurement and evaluation;

- (h) Veteran and family engagement, activation, satisfaction and transparency innovations;
- (i) Credentialing and Privileging; and
- (j) Environment of Care Safety and Engineering.