MANDATORY BUSINESS RULES FOR VHA PROGRAM OFFICES

1. POLICY

a. To improve Veterans Health Administration (VHA) national policy development and the local implementation of national policies, this notice establishes mandatory business rules for VHA program offices. This includes standards and requirements for developing and recertifying national policies and implementing national policies and programs at Department of Veterans Affairs (VA) medical facilities.


2. BACKGROUND

In 2019, representatives from the Office of Regulatory and Administrative Affairs (ORAA) visited eight VA medical facilities. Representatives from these VA medical facilities proposed business rules for VA medical facilities, Veterans Integrated Services Networks (VISNs), and VHA program offices to reduce the overall policy burden on VA medical facilities and increase reliance directly on national policy documents. NOTE: See VHA Notice 2019-24, Mandatory Business Rules for Local Policy Development, dated November 1, 2019. More information about the development of these business rules is available at: https://dvagov.sharepoint.com/sites/VACOVHACOS/10B4/PIRP/10B4/SitePages/Home.aspx. This is an internal VA Web site that is not available to the public.

3. RESPONSIBILITIES AND MANDATORY BUSINESS RULES FOR THE OFFICE OF REGULATORY AND ADMINISTRATIVE AFFAIRS

a. Upon Publication. Immediately upon publication of this notice, the Senior Advisor, ORAA, is responsible for:

   (1) Maintaining a mail group to serve as a point of contact for VA employees to request: communication of barriers to implementation of national policy to responsible VHA program offices and entities, resolution of conflict between VA employees and responsible VHA program offices and entities on issues of implementation, review of proposed amendments to VHA national policy, and responses to other VHA national policy-related issues. NOTE: This mail group is designed to assist VA employees who have not reached a resolution with the responsible VHA program office or entity. VA employees should send this feedback to VHACO10B4FormsandPubs@va.gov and may request to remain anonymous.
(2) Developing and maintaining standardized definitions of national and local policy and policy-related documents. **NOTE:** See Appendix A for the list of definitions of policy and policy-related documents.

(3) Disseminating and updating, based on feedback from the field, a standardized template for VISN policies, medical center policies (MCPs), standard operating procedures (SOPs), and charters, available at: https://dvagov.sharepoint.com/sites/VACOVHACOS/10B4/PIRP/10B4/SitePages/Home.aspx. **NOTE:** This is an internal VA Web site that is not available to the public.

(4) Collaborating with responsible VHA program offices and entities on every VHA directive that begins development or recertification after publication of this notice to ensure content better suited to clinical practice guidelines are not communicated through policy documents.

b. **6 Months After Publication.** Within 6 months after publication of this notice, by May 1, 2020, the Senior Advisor, ORAA, is responsible for:

(1) Providing education and training materials for local document development. **NOTE:** Implementation guidance and additional training materials are available at: https://dvagov.sharepoint.com/sites/VACOVHACOS/10B4/PIRP/10B4/SitePages/Home.aspx. This is an internal VA Web site that is not available to the public.

(2) Creating a process to ensure collaboration with the appropriate responsible VHA program office or entity to review the need for and remove any unnecessary local policy mandates in current VHA national policy and every VHA directive that begins development or recertification after publication of this notice.

(3) Developing an internal reporting mechanism for informing senior leadership when ORAA has not received draft VHA national policies from responsible VHA program offices or entities 6 months prior to the due date for recertification.

c. **12 Months After Publication.** Within 12 months after publication of this notice, by November 1, 2020, the Senior Advisor, ORAA, is responsible for:

(1) Developing and implementing a standardized naming convention for VHA national policy and MCPs.

(2) Establishing a workgroup to improve resource planning for field implementation of VHA national policy.

4. **RESPONSIBILITIES AND MANDATORY BUSINESS RULES FOR VHA PROGRAM OFFICES**

a. **Upon Publication.** Immediately upon publication of this notice, for every VHA directive that begins development or recertification after publication of this notice, the Chief or Director of the responsible VHA program office or entity is responsible for:
(1) Providing a template with required elements when a VHA directive requires a local document and receiving reports of necessary diversions from VA medical facilities. **NOTE:** For VISN policies, MCPs, and SOPs, this template must adhere to the standardized templates, unless an exemption exists (for example, regulatory requirement or current sterile processing service templates), available at: https://dvagov.sharepoint.com/sites/VACOVHACOS/10B4/PIRP/10B4/SitePages/Home.aspx. This is an internal VA Web site that is not available to the public.

(2) Developing implementation guidance and tools, including implementation timelines, for VA medical facilities to implement VHA directives.

(3) Where applicable, referencing health care accreditation bodies’ requirements in VHA directives or contributing to a crosswalk.

(4) Serving as a point of contact for VHA national policy for which they are listed as the responsible office and responding to reports of barriers to field implementation, proposed amendments to VHA national policy, and other VHA national policy-related issues.

b. **6 Months After Publication.** Within 6 months after publication of this notice, by May 1, 2020, the Chief or Director of the responsible VHA program office or entity is responsible for:

(1) Providing a service-specific distribution Email list to ORAA for inclusion in ORAA’s weekly Email distribution of VHA directives in the ORAA informal review process.

(2) Reporting recertification action plans to ORAA for VHA national policies for which they are listed as the responsible office 12 months prior to the due date for recertification and submitting the draft document to ORAA no later than 6 months prior to the due date for recertification.

(3) Collaborating with ORAA to review the need for and remove any unnecessary local policy mandates in current VHA national policy and every VHA directive that begins development or recertification after publication of this notice.

5. All inquiries regarding this notice should be addressed to the Office of Regulatory and Administrative Affairs (10B4) at VHACO10B4FormsandPubs@va.gov.

6. This VHA notice will be archived as of November 30, 2020.
BY DIRECTION OF THE UNDER SECRETARY FOR HEALTH:

/s/ Lawrence B. Connell
VHA Chief of Staff

DISTRIBUTION: Emailed to the VHA Publications Distribution List on November 4, 2019.

NOTE: All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.
POLICY AND POLICY-RELATED DEFINITIONS

1. BACKGROUND

a. Policy documents alone establish a mandatory and definite course of action and assign responsibilities for executing that course of action to identifiable individuals or groups of individuals. Veterans Health Administration (VHA) policy documents are signed by the Under Secretary for Health, or designee, and are limited to directives and notices. **NOTE:** VHA Directive 0000, Delegation of Authority, dated January 3, 2019, delegates signature and decisional authority for controlled national policy (CNP), national practices, and procedures to VHA upper level leadership. Regional and local policy documents are limited to Veterans Integrated Service Networks (VISN) policy and medical center policy (MCP). **NOTE:** Examples of documents and a definitional grid are available at: https://dvagov.sharepoint.com/sites/VACOVHACOS/10B4/PIRP/10B4/SitePages/Home.aspx. This is an internal Department of Veterans Affairs (VA) Web site that is not available to the public.

b. All policy documents must be authorized by law, be fully resourced, establish an effective system of internal controls, and conform to the standards and practices established in VHA Directive 6330(4), Controlled National Policy/Directives Management System, dated June 24, 2016. **NOTE:** Standardized definitions for local clinical documents (for example, protocol, standard of care, etc.) are outside the scope of this document but will be included in the recertification of VHA Directive 6330(4).

2. DEFINITIONS OF NATIONAL POLICY AND POLICY-RELATED DOCUMENTS


b. **Directive.** A directive establishes standards, a mandatory and definite course of action for VHA, and assigns responsibilities for executing that course to identifiable individuals or groups within VHA. Directives are under the authority of the Under Secretary of Health, or designee, and must be recertified or rescinded within 5 years; however, directives do not expire and remain in effect until recertified or rescinded. **NOTE:** Only directives and notices are considered CNP. Handbooks, manuals, and memoranda signed by the Under Secretary for Health that were certified before June 24, 2016 will continue to serve as national policy until rescinded. VHA Handbook 1004.03, Life-Sustaining Treatment Decisions: Eliciting, Documenting, and Honoring
Patient's Value, Goals and Preferences, published January 11, 2017 is excluded from this requirement and remains CNP until its next recertification. See VHA Directive 6330(4) for more information on CNP.

c. **Guidance.** Guidance documents provide supplemental information that establish a course of action or procedures for a program from a subject matter expert or responsible VHA program office or entity. Guidance documents are not policy and must be consistent with national policy.

d. **Notice.** A notice establishes a mandatory and definite course of action for VHA and assigns responsibilities for executing that course to identifiable individuals or groups of individuals. Notices are under the authority of the Under Secretary of Health, or designee and are automatically rescinded after 1 year unless incorporated into a directive. Notices may be used as interim policy vehicles when policy needs to be communicated more immediately to the field. **NOTE:** Only directives and notices are considered CNP. Handbooks, manuals, and memoranda signed by the Under Secretary for Health that were certified before June 24, 2016 will continue to serve as national policy until rescinded. See VHA Directive 6330(4) for more information on CNP.

e. **Operational Memorandum.** An operational memorandum is supplemental guidance that establishes a course of action from a supervisor to a supervisee. An operational memorandum is not policy, and its authority is limited to that of the issuer only and must be consistent with national policy. An operational memorandum (also known as a “10N memo”) is most often disseminated to VISNs and VA medical facilities by the Deputy Under Secretary for Health for Operations and Management and is intended for a national VHA audience. **NOTE:** For more information on operational memoranda, see VHA Notice 2019-19, Maintaining VHA’s Policy-Establishing Documents, dated October 23, 2019.

f. **Regulation.** A regulation is an agency statement of general applicability and future effect, which has the force and effect of law, that is designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency, in this case, the Department of Veterans Affairs.

g. **Under Secretary for Health Memorandum.** An Under Secretary for Health memorandum establishes policy for VHA Central Office only and is not CNP. **NOTE:** See VHA Directive 6330(4) for more information on CNP.

3. DEFINITIONS OF LOCAL POLICY AND POLICY-RELATED DOCUMENTS

a. **Charter.** A charter establishes and outlines the responsibilities and function of a committee, council, board, subcommittee, or equivalent type of standing group (for example, process improvement teams or workgroups) and its reporting requirements to the appropriate governance body or position. **NOTE:** A charter, rather than an MCP, should be used for committee, council, board, subcommittee, or equivalent type of standing group establishment. It is strongly encouraged that charters are available on
the VISN or VA medical facility intranet for dissemination and communication purposes. A charter template (non-mandatory) is available at: https://dvagov.sharepoint.com/sites/VACOVHACOS/10B4/PIRP/10B4/SitePages/Home.aspx. This is an internal VA Web site that is not available to the public.

b. Director's Memorandum. A Director’s memorandum is issued from the VA medical facility Director to the VA medical facility staff. A Director’s memorandum is published to have immediate effect and can establish a course of action from the VA medical facility Director to the VA medical facility staff or is informational in nature.

c. Employee Handbook. An employee handbook describes mandatory standards and procedures for VA employees to conduct work duties and access benefits, including a VA medical facility's internal processes. An employee handbook informs VA employees of workplace rules and expectations. Requirements included in an employee handbook may include but are not limited to: dress code, leave requests, alarms, sanitation and safety, key distribution, and pay schedules.

d. Interagency Agreement. An interagency agreement (IAA) establishes an agreement between a VA medical facility and a non-VA partner. An IAA can be used when the exchange of funds is involved and results in a financial commitment or obligation. An IAA can also be used to establish an agreement that specifies the goods to be furnished or tasks to be accomplished by one of the entities. NOTE: Where information, not funds, is exchanged, a memorandum of understanding (MOU) must be used.

e. Medical Center Policy. A medical center policy (MCP) is VA medical facility policy. It creates mandatory standards, information, instructions, and responsibilities on VA medical facility-wide matters with the authority of the VA medical facility Director. MCPs are permanent in nature and remain in effect until recertified or rescinded. MCPs are not recommended and must exist only by exception. NOTE: Only VISN policies and MCPs are “local policy.” MCPs must follow these requirements:

(1) MCPs must be recertified 5 years from their date of publication and must not contradict or restate information from VA and VHA directives, notices, handbooks, regulations, or other MCPs.

(2) MCPs must be reviewed when there is a change to the governing document, including relevant national policy or health care accreditation body requirements. NOTE: MCPs may require review on a more frequent basis to comply with regulatory standards.

(3) MCPs must be formatted in accordance with the standardized template, available at: https://dvagov.sharepoint.com/sites/VACOVHACOS/10B4/PIRP/10B4/SitePages/Home.aspx. NOTE: This is an internal VA Web site that is not available to the public.
f. **Memorandum of Understanding.** A memorandum of understanding (MOU) is an agreement between a VA medical facility and an external entity, such as another VA medical facility, a non-VA partner, stakeholder, hospital service, or an outside agency. An MOU authorizes exchange of information and can be used when there is no exchange of funds, personnel, services, or property. **NOTE:** Where funds are exchanged, an MOU is not appropriate.

g. **Performance Plan.** A performance plan is written or otherwise recorded critical performance elements and standards that identify professional expectations. **NOTE:** See VA Handbook 5013.1, Performance Management Systems, dated November 18, 2003.

h. **Service Line Agreement.** A service line agreement (SLA) is an agreement between two or more services internally within the VA medical facility with the authority of the responsible service chiefs. SLAs may include but are not limited to: mutually agreed upon responsibilities and processes including targets, goals, key performance indicators, stakeholders, conflict resolution, and other guidance, as appropriate. SLAs must be recertified, at a minimum, 5 years from their date of publication. **NOTE:** Services involved in an SLA are encouraged to publish these documents in the VA medical facility intranet for dissemination and communication purposes.

i. **Standard Operating Procedure.** An SOP details all steps and activities relating to a process or procedure with the authority of the responsible service chief(s) or standing group. SOPs must follow these requirements:

   (1) SOPs must be available to all VA medical facility employees. Access to the VA medical facility’s SOPs must also be granted to “VHA Publications Access” to facilitate oversight. **NOTE:** Exceptions exist for specific services with separate SOP sites (that is, Sterile Processing and Pathology & Laboratory Medicine), for sensitive emergency response protocols, and by specific exemption by the VA medical facility Director.

   (2) SOPs must be reviewed by the responsible service chief, subject matter expert, and any other appropriate responsible entity, at minimum at issuance, recertification, and when there are changes to the governing document.

   (3) SOPs must be recertified at least 5 years from the date of their publication, when there is a change to the governing document that requires an update, or when there is a change in the process that requires an update, whichever occurs first. **NOTE:** SOPs may require review on a more frequent basis to comply with regulatory standards.

   (4) SOPs must be formatted in accordance with the standardized template, with exception for templates otherwise required by regulation or mandate, available at: https://dvagov.sharepoint.com/sites/VACOVHACOS/10B4/PIRP/10B4/SitePages/Home.aspx. **NOTE:** This is an internal VA Web site that is not available to the public.

j. **Veterans Integrated Service Network Policy.** VISN policy establishes standards and a course of action required at the VISN level with the authority of the VISN Director.
It assigns responsibilities, as needed, to individuals within the VISN (that is, VISN employees) or all individuals in VA medical facilities within that VISN. VISN policies must be formatted in accordance with the standardized template, available at: https://dvagov.sharepoint.com/sites/VACOVHACOS/10B4/PIRP/10B4/SitePages/Home.aspx. **NOTE:** This is an internal VA Web site that is not available to the public.

4. PROCESS AND OTHER DEFINITIONS

a. **Amendment.** An amendment is a non-substantive change to a policy. Examples of amendments include: changes solely to an appendix, changes to the title of a responsible office, and technical or grammatical changes that do not change the originally intended meaning of a provision. **NOTE:** Amendments are denoted by the number in parentheses following the policy number; for example, VHA Directive 6330(4) means that VHA Directive 6330 has been amended four times.

b. **Gap Analysis.** A gap analysis is a process that determines the additional information required locally to fully implement the national policy or program and address what, if any, mandatory standards, processes and responsibilities are missing from CNP, in order for the national policy or program to be fully implemented at the local level. **NOTE:** The gap analysis is used to help determine the most appropriate local document(s) for implementation. Guidance on the gap analysis is described in the local document assessment tool, available at: https://dvagov.sharepoint.com/sites/VACOVHACOS/10B4/PIRP/10B4/SitePages/Home.aspx. This is an internal VA Web site that is not available to the public.

c. **Health Care Accreditation Body.** A health care accreditation body encompasses The Joint Commission, Commission on Accreditation of Rehabilitation Facilities (CARF), and any other health care accreditation body that conducts audits on VA campuses.

d. **Recertification.** Recertification is the process by which a document is evaluated for efficacy, updated, and signed by the designated signatory authority.

e. **Review.** Review occurs when the subject matter expert or experts review a document to ensure that all the information contained is still valid and to determine if any changes are needed. **NOTE:** Where applicable, the document must be amended or recertified to incorporate necessary changes.