

November 1, 2019

MANDATORY BUSINESS RULES FOR LOCAL POLICY DEVELOPMENT

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 that each Department of Veterans Affairs (VA) medical facility and Veterans Integrated Services Network (VISN) must implement throughout their local policy development process. These business rules increase the integrity of VHA standards, reduce variability in processes, improve the consistency in national policy implementation, and significantly reduce the burden of developing and maintaining policies at every VA medical facility. **NOTE:** *While VA has authority over which national policies must be implemented, VISNs and VA medical facilities retain autonomy regarding how local policy documents are produced and maintained.*

b. This VHA notice is effective January 2, 2020. This notice establishes policy, pending the recertification of VHA Directive 6330(4), Controlled National Policy/Directives Management System, dated June 24, 2016.

2. BACKGROUND

a. In December 2017, the Office of Regulatory and Administrative Affairs (ORAA) conducted a census of the number of local policies at VA medical facilities and found there were at least 55,000 local policies (that is, medical center policies (MCPs) or equivalent) across the VHA system. **NOTE:** *The census was limited to local policies. All other local documents (including, among others, standard operating procedures (SOPs), protocols, service line agreements, Director's memoranda) are not considered policy. See Appendix A for the list of definitions of policy and policy-related documents.* On average, each VA medical facility maintains a local policy burden of about 400 MCPs, in addition to the roughly 900 VA and VHA national policies.

b. In 2019, representatives from ORAA visited eight VA medical facilities. Representatives from these VA medical facilities proposed business rules for VA medical facilities, VISNs, and VHA program offices to reduce the number of local policies developed at VA medical facilities by ensuring VHA program offices develop policies that can be directly relied upon by VA medical facilities. **NOTE:** *See VHA Notice 2019-23, Mandatory Business Rules for VHA Program Offices, dated November 1, 2019. More information about the development of these business rules is available at:* <https://dva.gov.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

a. **Senior Advisor, Office of Regulatory and Administrative Affairs.** The Senior Advisor, ORAA, is responsible for:

(1) Monitoring compliance of VA medical facilities and VISNs with the requirements of this notice.

(2) Approving VA medical facility and VISN level action plans for policy reduction.

(3) Serving as or designating a point of contact for questions related to the requirements in this notice. **NOTE:** *All inquiries regarding this notice should be addressed to ORAA at VHACO10B4FormsandPubs@va.gov.*

(4) 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.*

b. **Veterans Integrated Services Network Director.** The VISN Director is responsible for:

(1) Ensuring that the requirements of this notice are communicated and adhered to by all VISN staff.

(2) Ensuring that each VA medical facility Director within the VISN has the sufficient resources to implement this notice by no later than January 2, 2020.

(3) Submitting a VISN level action plan to ORAA for approval within 1 month after the effective date of this notice, by February 2, 2020, 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.* The action plan must include:

(a) Total number of current VISN policies. **NOTE:** *The number of current VISN policies includes VISN policies that are overdue for recertification.*

(b) Estimated total number of VISN policies 3 years after the effective date of this notice, by January 2, 2023.

(c) A policy point of contact at the VISN.

(4) Updating the VISN level action plan to record VISN implementation of the requirements set forth in paragraph 4 and recording the number of VISN policies every 6 months.

(5) Reviewing VA medical facility level action plans within the VISN and reporting progress on VA medical facility and VISN level action plans at least every 6 months to ORAA, including identifying patterns of non-compliance.

c. **VA Medical Facility Director.** The VA medical facility Director is responsible for:

(1) Ensuring that the requirements of this notice are communicated and adhered to by all VA medical facility staff by no later than January 2, 2020.

(2) Submitting a VA medical facility level action plan to ORAA for approval within 1 month after the effective date of this notice, by February 2, 2020, 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.* The action plan must include:

(a) Total number of current MCPs. **NOTE:** *The number of current MCPs includes MCPs that are overdue for recertification.*

(b) Estimated total number of MCPs 3 years after the effective date of this notice, by January 2, 2023.

(c) A policy point of contact at the VA medical facility.

(3) Updating the VA medical facility level action plan with the following information:

(a) Within 2 months after the effective date of this notice, by March 2, 2020, the number of MCPs that will be rescinded within 2 months because:

1. The MCP restates national policy, regulations, or national clinical practice guidelines.

2. The MCP is inconsistent with national policy, regulations, national clinical practice guidelines, or another MCP (for example, contradict or are in direct conflict with another MCP).

3. More than one MCP addresses the same subject matter and will be consolidated. **NOTE:** *Substantive content must not be changed during consolidation. If content changes, the policy or policies must go through the local policy process.*

4. The MCP establishes a committee, council, board, subcommittee, or equivalent type of standing group. **NOTE:** *Where appropriate, these documents must be converted to charters. See Appendix A for the full definition of a charter.*

(b) Within 12 months after the effective date of this notice, by January 2, 2021, the number of MCPs that will be rescinded within 12 months because:

1. The MCP conveys process or procedural information that is more appropriate as an SOP. **NOTE:** *Where appropriate, these documents must be converted to SOPs. See Appendix A for the full definition of an SOP.*

2. The MCP contains information that is more appropriate in an employee handbook. **NOTE:** *Where appropriate, these documents must be converted to employee handbooks. See Appendix A for the full definition of an employee handbook.*

(4) Recording the number of MCPs at the VA medical facility every 6 months in the VA medical facility action plan.

4. MANDATORY BUSINESS RULES

a. **Effective Date.** On the effective date of this notice, January 2, 2020, the following requirements apply:

(1) All new or recertified VISN policies, MCPs, and SOPs must be formatted using the standardized templates and meet the elements of the standardized definitions, as listed in Appendix A. **NOTE:** *The standardized template applies to VISN policies, MCPs, and SOPs that begin development or recertification after publication of this notice and must be used unless a service-specific template is otherwise required (for example, by regulation). The standardized templates are 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.**

(2) All new or recertified local documents developing or implementing policy must be the appropriate type and are limited to the document types listed in Appendix A. **NOTE:** *To determine the appropriate document type, use the definitions in Appendix A and additional local document assessment tools 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.**

(3) VISN policies and MCPs must not be developed or recertified where citation of national policy is sufficient for operation at the VISN or VA medical facility, as determined by appropriate VISN or VA medical facility leadership. **NOTE:** *VISN policies or MCPs that are copied and pasted from the corresponding national policy must not be developed.*

(4) Where applicable, a template provided by the responsible VHA program office or entity must be used where there is mandatory local document development in national policy, and necessary diversions from the provided template must be reported to the responsible VHA program office or entity.

b. **1 Month After Effective Date.** Within 1 month after the effective date of this notice, by February 2, 2020, all VHA employees must be granted access to any site that hosts VISN policies and MCPs.

c. **2 Months After Effective Date.** Within 2 months after the effective date of this notice, by March 2, 2020, the following requirements apply:

(1) VISN policies and MCPs that restate national policy, regulations, or clinical practice guidelines must be rescinded.

(2) VISN policies and MCPs that establish or outline councils, boards, committees, subcommittees, or equivalent types of standing groups must be rescinded and converted into charters, where appropriate. **NOTE:** See Appendix A for the full definition of a charter.

(3) All VA medical facility employees must be granted access to all of their VA medical facility's SOPs in a local SOP repository, with exceptions 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. Access to the VA medical facility's SOPs must also be granted to "VHA Publications Access" mail group to facilitate oversight. **NOTE:** VA medical facilities are highly encouraged to populate and utilize a voluntary SOP Library to share SOPs among services in similarly situated VA medical facilities. VA medical facilities should continue to use their local development and approval process for SOPs, including SOPs taken from the SOP Library. The SOP Library/"Swap" 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.

d. **3 Months After Effective Date.** Within 3 months after the effective date of this notice, by April 2, 2020, all VISN policies and MCPs must be published on a 5-year recertification cycle. **NOTE:** This recertification cycle only applies to VISN policies and MCPs that begin development or recertification after publication of this notice; there must be no extensions for previously published policies. This recertification cycle does not preclude review or recertification on a more frequent basis if content change is required.

e. **12 Months After Effective Date.** Within 12 months after the effective date of this notice, by January 2, 2021, the following requirements apply:

(1) VISN policies and MCPs that are procedural in nature or describe processes must be rescinded and converted to SOPs, where appropriate. **NOTE:** See Appendix A for the full definition of an SOP.

(2) VISN policies and MCPs that describe mandatory standards and procedures for VA employees to conduct work duties and access benefits (for example, human resources topics) and VA medical facility's internal processes and employee requirements must be rescinded and converted to an employee handbook, where appropriate. **NOTE:** See Appendix A for the full definition of an employee handbook.

5. IMPLEMENTATION GUIDANCE

ORAA has developed implementation guidance to provide assistance and guidance in implementation of these requirements at each VISN and VA medical facility. The implementation guidance is 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.*

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

7. 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.

c. In accordance with this notice, all new or recertified local documents used to develop or implement policy at the VA medical facility level must be the appropriate type and are limited to the document types listed in paragraph 3 of this appendix. **NOTE:** *See paragraph 4.a.2 of the body of this notice. 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

a. **Clinical Practice Guidelines.** Clinical practice guidelines are guidance or non-mandatory recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options. **NOTE:** *More information is available at:* <https://www.healthquality.va.gov/policy/index.asp> and <http://www.nationalacademies.org/hmd/~media/Files/Report%20Files/2011/Clinical-Practice-Guidelines-We-Can-Trust/Clinical%20Practice%20Guidelines%202011%20Report%20Brief.pdf>. *This linked document is outside of VA control and may not be conformant with Section 508 of the Rehabilitation Act of 1973.*

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.*