

April 8, 2010

**PROCESS FOR DRAFTING REGULATIONS AND RELATED NOTICES TO BE
PUBLISHED IN THE FEDERAL REGISTER**

1. PURPOSE: This Veterans Health Administration (VHA) Memorandum establishes VHA Central Office policy pertaining to the development and drafting of VHA regulations for publication in the Code of Federal Regulations (CFR) and the responsibilities of the VHA Office of Regulatory Affairs (VHAORA) (10B7D).

2. DEFINITION: For the purposes of this memorandum, the term “regulation” means rules published as sections in Title 38, CFR.

3. POLICY: It is VHA policy that all VHA regulations be developed and drafted through VHAORA.

4. ACTION

a. When a VHA program office becomes aware of the need for a regulation, the program office needs to contact VHAORA as early as possible.

b. When VHAORA becomes aware of the need for a regulation, VHAORA initiates a rulemaking action and contacts the relevant VHA program office (i.e., the program office with primary responsibility for the policy supporting the regulation).

c. All required policy decisions must be made by the relevant program office, which must obtain appropriate approval of the same. VHAORA needs to be invited to attend policy discussions so that VHAORA can fully understand the issues involved. Where regulations are required by law, VHAORA informs the relevant program office of statutory deadlines, and the program office must ensure that policy decisions are approved in a timely manner.

d. VHAORA drafts all VHA regulations, obtains all required VHA concurrences, and assigns regulations to the Office of Regulation Policy and Management (02REG) for coordination of legal review and concurrence by VA.

e. If VHA publishes a Notice of Proposed Rulemaking and does not receive any public comments, or if the comments do not require any changes to the proposed, substantive content of the regulation, VHAORA:

(1) Drafts the Final Rule notice in coordination with the relevant program office,

(2) Obtains the relevant program office’s concurrence on the Final Rule, and

(3) Submits the Final Rule directly to the Office of the Under Secretary for Health for signature. *NOTE: Additional VHA concurrences on the Final Rule are no longer required under these circumstances.*

f. If VHA program offices fail to timely concur on regulations, or if substantive issues arise during the regulatory drafting and concurrence process, VHAORA notifies the Chief Officer of Legislative, Regulatory, and Intergovernmental Affairs, who may consult with the VHA Chief of Staff to resolve the issue(s).

g. VHAORA is authorized to make technical changes in language or punctuation and make corrections based on comments received during the concurrence process, or from the Office of Management and Budget, but will consult the relevant program office before making any substantive changes.

5. REFERENCES: Appendix A of this VHA Memorandum, "Procedures for Promulgating VHA Regulations."

6. RESPONSIBILITY: The Director of VHAORA (10B7D) is responsible for the contents of this VHA Memorandum. Questions may be directed to 202-461-6003.

Robert A. Petzel, M.D.
Under Secretary for Health

Attachment

DISTRIBUTION: E-mailed to the VHA Publication Distribution List 4/13/10

SEQUENTIAL PROCEDURES FOR PROMULGATING

VHA REGULATIONS AND RELATED NOTICES

1. Identification of Regulatory Need. Regulatory needs are identified by the Veterans Health Administration (VHA) Office of Regulatory Affairs (VHAORA), Department of Veterans Affairs (VA) Office of General Counsel (OGC), or the relevant program office (i.e., the program office with primary responsibility for the policy supporting the regulation). Typically, regulations are required by one of the following events:

- a. New legislation,
- b. New program or benefit being introduced,
- c. Change in the method of administering or delivering an existing benefit,
- d. New or existing directive requires regulatory authority,
- e. Regulation rewrite project to update an outdated body of regulations, or
- f. Court decision.

2. Program Office, in Coordination with VHAORA, Obtains Approval for Rulemaking.

All planned regulatory actions must be approved by the Chief Officer of the relevant program office. For significant actions, approval of the Under Secretary for Health or the Secretary of Veterans Affairs is strongly encouraged and may be required or obtained by VHAORA. However, the relevant program office is ultimately responsible for obtaining timely approval.

3. Drafting. VHAORA drafts all regulations, consulting with the relevant program office as necessary. Certain technical regulations may require greater drafting support from the relevant program office.

4. Program Office Concurrence. When drafting is complete, VHAORA obtains internal concurrence from VHA program offices.

5. Impact Analysis. VHAORA prepares a regulation impact analysis and submits it to OGC's Office of Regulation Policy and Management (02REG). VHAORA will not seek concurrence from the Under Secretary for Health before 02REG receives the impact analysis. If 02REG approves the impact analysis before VHA concurrence is completed, VHAORA includes the approved impact analysis in the folder before it is presented to the Under Secretary for Health. When significant or complex issues are involved, VHAORA may hold the folder until 02REG approves the impact analysis before the folder is presented to the Under Secretary for Health.

6. VHA Concurrence in Proposed Rules, Interim Final Rules, and Direct Final Rules. (For Final Rules, see paragraph 9.)

a. VHAORA obtains required VHA concurrences below the level of the Office of the Under Secretary for Health.

b. After obtaining required VHA concurrences, VHAORA seeks concurrence from the Under Secretary for Health, through the Office of Executive Correspondence (101B).

7. OGC and VA-Wide Concurrence. VHAORA assigns the document to 02REG. 02REG obtains all required non-VHA concurrences (from 50, 002, 009, and 02), and submits the package to VA's Executive Secretary (001B) for approval.

8. Office of Management and Budget (OMB) Review and Public Comment. 02REG submits the regulation to OMB. 02REG serves as VA's liaison with OMB and will coordinate clearance of the document with VHAORA and program office involvement. 02REG will also provide copies of all public comments received.

9. VHA Concurrence in Final Rules

a. If VHA publishes a Proposed Rule and does not receive any public comments, or does not make any substantive changes to the text of the regulation, VHAORA drafts the Final Rule notice in coordination with the relevant program office, obtains that program office's concurrence on the Final Rule notice, and submits the Final Rule notice directly to the Office of the Under Secretary for Health for signature. Additional concurrences are not required

b. If VHA receives comments on a Proposed Rule that require VHA to change the substantive text of the regulation, VHAORA repeats the process outlined in paragraphs 1 thru 8 to develop and draft the Final Rule notice.