Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

Amended

April 23, 2026

VHA DIRECTIVE 8101(4)
Transmittal Sheet
May 7, 2020

VHA RULEMAKING AND NON-LEGISLATIVE FEDERAL REGISTER NOTICES UNDER THE ADMINISTRATIVE PROCEDURE ACT

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive establishes policy for the development and drafting of VHA rulemakings and non-legislative notices for publication in the Federal Register.

2. SUMMARY OF MAJOR CHANGES:

a. Amendment dated April 23, 2026, updates contact information (from Office of Regulations, Appeals, and Policy (10BRAP) to Office of Regulatory Oversight & Management (ROM) on Transmittal Sheet and in Appendix C.

b. Amendment dated January 17, 2024, updates contact information and instructions in Appendix C.

c. Amendment dated February 1, 2023, updates Appendix C which outlines 00REG's Standard Operating Procedures (SOP) on Drafting and Publishing VA Notices in the Federal Register.

d. Amendment dated September 29, 2020 incorporates Appendix C which outlines 00REG's SOP on Drafting and Publishing VA Notices in the Federal Register.

3. RELATED ISSUES: None.

4. RESPONSIBLE OFFICE: The Office of Regulations, Appeals and Policy (10BRAP) is responsible for the content of this directive. Questions may be referred to vha10bregregulations@va.gov and regulations@va.gov..

5. RESCISSIONS: VHA Memorandum 10-2010-001, Process for Drafting Regulations and Related Notices to be Published in the Federal Register, dated April 8, 2010.

6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of May 2025. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

BY DIRECTION OF THE OFFICE OF THE UNDER SECRETARY FOR HEALTH:

/s/ Lawrence B. Connell
VHA Chief of Staff

NOTE: *All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.*

DISTRIBUTION: Emailed to the VHA Publication Distribution List on October 1, 2020.

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VHA RULEMAKING AND NON-LEGISLATIVE FEDERAL REGISTER NOTICES UNDER THE ADMINISTRATIVE PROCEDURE ACT

1. PURPOSE

This Veterans Health Administration (VHA) directive establishes policy and responsibilities for the development and drafting of VHA rulemakings and non-legislative notices for publication in the Federal Register. **AUTHORITY:** Title 38 U.S.C. § 501, 7301(b).

2. BACKGROUND

a. The Administrative Procedure Act (APA), 5 U.S.C. 551 *et.seq*., governs the process by which Federal agencies develop and issue regulations. It includes requirements for publishing notices of proposed and final rulemaking (including when a proposed rulemaking is not required) in the Federal Register and provides opportunities for the public to comment on notices of proposed rulemaking.

b. The Federal Register is the official daily publication for agency rules, proposed rules, notices of general interest to the public issued by Federal agencies and organizations, as well as for Executive Orders and other presidential documents. Generally, these items can be categorized as either legislative or non-legislative in nature.

c. The term “legislative” means rulemaking under the APA. Rulemaking is the process through which Federal regulations are created pursuant to the APA. ***NOTE:*** *the terms rule, rulemaking, and regulation are used interchangeably.* A legislative rule is a rule adopted by an administrative agency according to the procedures laid down by the APA. A legislative rule has the force of law and imposes new duties or delineates benefits for eligible individuals. Most legislative rules go through a two-stage process: (1) publication of a proposed rule (the rulemaking stage in which an agency proposes to add to or change its existing regulations and solicits public comment on this proposal; and (2) publication of a final rule (the last step of the rulemaking process in which the agency responds to public comment on the proposed rule and makes appropriate revisions before publishing the final rule in the Federal Register to become effective). Some rules are published as interim final rules. An interim final rule is published when an agency finds good cause to publish a final rule without first seeking public comment through a final rule. An interim final rule is effective immediately upon publication and the agency typically solicits public comment on the rule. Rarely, an agency may publish a direct final rule, when the agency determines that a proposed rule is not necessary because it relates only to routine or noncontroversial matters. These various types of rules are published in the Federal Register. As part of the rulemaking process, a Federal agency must issue a Regulatory Impact Analysis (RIA) which is used to anticipate and evaluate the likely consequences of rules, including both costs and benefits. It provides a formal means of organizing the evidence on the key effects – both good and bad – of the various alternatives that should be considered in developing regulations.

d. Non-legislative agency notices are also published in the Federal Register. This type of notice addresses issues of general interest to the public, and may include general policy statements, announcements of scheduled hearings and meetings open to the public, notices related to funding availability and grant applications, administrative orders, and agency actions related to Federal laws such as the Privacy Act of 1974 (5 U.S.C. § 552a) or the Paperwork Reduction Act (44 U.S.C. § 3501-3521).

e. The Office of Regulations, Appeals and Policy (formerly Regulatory and Administrative Affairs (ORAA)) (10BRAP) was established in 2009 to serve as the sole VHA program office responsible for development of legislative rulemaking related to delivery of medical care to eligible Veterans, and to make VHA rulemaking more responsive, visible, and predictable. As part of the Department of Veterans Affairs' (VA's) overall mission of serving Veterans and eligible beneficiaries, 10BRAP provides centralized management and control for the formulation and coordination of all VHA regulations to publication in the Federal Register. These regulations are published in Title 38 C.F.R.

NOTE: *Administrative amendment dated April 23, 2026, updated contact information for this directive from the Office of Regulation, Appeals, and Policy to the Office Regulatory Oversight and Management. Please contact the Office of Regulatory Oversight and Management at regulations@va.gov.*

3. POLICY

It is VHA policy that 10BRAP manage the development, drafting, and publication of all VHA rulemakings. It is VHA policy that individual VHA program offices manage the development, drafting, and publication of all non-legislative VHA notices for publication in the Federal Register, and that 10BRAP provide assistance at program offices' request.

4. RESPONSIBILITIES

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

(1) Ensuring overall VHA compliance with this directive.

(2) Reviewing and providing VHA concurrence for all notices and direct final, final, interim final, and proposed rules.

b. **Executive Director, Office of Regulations, Appeals and Policy.** The Executive Director, 10BRAP is responsible for:

(1) Serving as the subject matter expert for rulemaking within VHA.

(2) Advising VA and VHA leadership and other parties on matters related to VHA rulemaking including current published regulations, active regulatory projects, and anticipated projects.

(3) Establishing processes and procedures for developing and managing VHA rulemaking, from initiation of the project through publication of a final rule. Processes and procedures for rulemaking include 10BRAP drafting the rulemaking in conjunction with the responsible VHA program office, managing the VHA concurrence process, and providing all necessary VHA action related to publication.

(4) Ensuring that statutes and VHA policies are analyzed to determine whether regulations are required to implement legal authority or address criteria for providing a health care benefit.

(5) Ensuring that VHA rulemaking is consistent with Executive Orders and Federal laws that impact VA's rulemaking authority. Examples include Executive Orders 12866, 13563, and 13771; the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1532), and the Regulatory Flexibility Act (5 U.S.C. § 601-12); and Paperwork Reduction Act of 1995 (44 U.S.C. § 3501-3521).

(6) Ensuring that 10BRAP staff actively engage the responsible program office in defining the scope of rulemaking, drafting rulemaking, and responding to queries from non-VHA offices and other federal agencies related to the rulemaking.

NOTE: *Administrative amendment dated April 23, 2026, updated contact information for this directive from the Office of Regulation, Appeals, and Policy to the Office Regulatory Oversight and Management. Please contact the Office of Regulatory Oversight and Management at regulations@va.gov.*

c. **VHA Chief Financial Officer.** The VHA Chief Financial Officer is responsible for reviewing and approving the RIA submitted by the responsible program office, analyzing the validity of models and assumptions used in the RIA, and determining whether funds are or will be available in the current and projected VHA budget to absorb the monetary impact reflected in the RIA.

d. **Director or Chief Officer, Responsible Program Office.** The Director or Chief Officer of the responsible program office is responsible for:

(1) In the case of rulemaking:

(a) Ensuring that policy decisions are made which align with or further the goals of the rulemaking.

(b) Actively engaging with 10BRAP in defining the scope of rulemaking, drafting rulemaking, and responding to queries from non-VHA offices and other Federal agencies related to the rulemaking.

(c) Drafting the RIA related to rulemaking and submitting it to the VHA Chief Financial Officer. ***NOTE:*** *See the link for RIA tools in appendix A.*

(d) Responding to public comments submitted in response to a proposed or interim final rule, analyzing the comments to determine whether changes should be made to regulatory text, and working in conjunction with 10BRAP to produce a final rulemaking.

(2) In the case of a non-legislative Federal Register notice:

(a) Determining whether a non-legislative Federal Register notice is necessary.

(b) Drafting the non-legislative Federal Register notice and managing the established VHA and VA concurrence processes (see appendix B).

(c) Submitting the non-legislative Federal Register notice to VA's Office of Regulatory Oversight and Management (ROM) for publication in the Federal Register.

5. TRAINING

There are no formal training requirements associated with this directive.

6. RECORDS MANAGEMENT

All records regardless of format (e.g., paper, electronic, electronic systems) created by this directive shall be managed as required by the National Archives and Records Administration (NARA) approved records schedules found in VHA Records Control Schedule 10-1. Questions regarding any aspect of records management should be addressed to the appropriate Records Officer.

7. REFERENCES

a. Executive Orders 12866, 13563, and 13771.

b. 2 U.S.C. § 1532.

c. 5 U.S.C. § 551.

d. 5 U.S.C. § 552a.

e. 5 U.S.C. § 601-12.

f. 38 U.S.C. § 501.

g. 44 U.S.C. § 3501-3521.

APPENDIX A

RULEMAKING AND ADDITIONAL RESOURCES

1. RULEMAKING PROCESS

a. According to the Administrative Procedure Act (APA), Title 5 United States Code (U.S.C.) § 551 et Seq., typically, the Federal agency must give a notice of a proposed rulemaking, published in the Federal Register. The notice must include:

(1) The legal authority the agency has proposed the rule under;

(2) A discussion of what the agency proposes to do as well as the rationale for pursuing the proposed rulemaking; and

(3) The substance of the proposed rule.

b. After notice is given, the agency is required to solicit and accept public comments on the rule. Most comment periods last between 30 and 60 days, and some are re-opened if the agency believes that there was insufficient time for the public to respond or that the agency did not receive as much feedback as it would like.

c. The agency must then consider all the comments that are submitted in passing the final rule.

d. When a final rule is published in the Federal Register the agency must provide notice of the effective date of the rule. Final rules are then published in the Code of Federal Regulations (C.F.R.).

2. ADDITIONAL RESOURCES

a. **Overview of the Regulatory Process.** http://vaww.va.gov/VHAREGS/process.asp. ***NOTE:*** *This is an internal VA Web site that is not available to the public.*

b. **Sample Timeline for Developing and Publishing a Regulation.** http://vaww.va.gov/VHAREGS/docs/How_Long_Does_it_Take_to_Publish_VA_Regulations.doc. ***NOTE:*** *This is an internal VA Web site that is not available to the public.*

c. **Federal Register Document Drafting Handbook (addresses both rulemaking and non-legislative Federal Register Notices).** https://www.archives.gov/federal-register/write/handbook

d. **Regulatory Impact Analysis Tools (includes Veterans Affairs guide, RIA template, RIA samples, Frequently Asked Questions).** https://vaww.va.gov/ORPM/Impact_Analysis_Procedures_Cost_Estimates.asp. ***NOTE:*** *This is an internal VA Web site that is not available to the public.*

STANDARD TEMPLATE AND FORMATTING FOR A NON-LEGISLATIVE FEDERAL REGISTER NOTICE

DEPARTMENT OF VETERANS AFFAIRS

Insert Title of Notice Here

AGENCY: Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: A brief, one or two sentence description of this notice.

FOR FURTHER INFORMATION CONTACT: Name of POC, Office, Mail code,

Veterans Health Administration, Department of Veterans Affairs, 810 Vermont

Avenue, NW., Washington, DC 20420, Phone No. This is not a toll free number.

SUPPLEMENTARY INFORMATION: Explain why VA is publishing this notice. Include information about the program or programs affected by this notice, the reason VA is required to publish it, and citations to regulations and laws that authorize the program.

Approved:

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STANDARD OPERATING PROCEDURE FOR DRAFTING AND PUBLISHING VA NOTICES IN THE FEDERAL REGISTER

Veterans Health Administration (VHA) program offices must follow the steps listed here to publish a non-legislative notice in the Federal Register. ***NOTE:*** *These standard operating procedures apply to notices other than the following, which are drafted and submitted to the Federal Register by these staff: Paperwork Reduction Act (Maribel Aponte (008); System of Records (Amy Rose (005R1A); and Advisory Committee meetings (LaTonya L. Small or Jelessa Burney (00AC).*

1. Program Offices (PO) are responsible for drafting their own Notices. ***NOTE***: *To assist with drafting, the VHA Office of Regulations, Appeals, and Policy (10BRAP) created a Federal Register notice template (see Appendix B). If the responsible program office has legal concerns about the notice, the responsible program office may consult informally with 10BRAP or with the VA Office of General Counsel (OGC).*

2. Notices must be drafted in accordance with the Federal Register Document Drafting Handbook: http://www.archives.gov/federal-register/write/handbook/.

3. The PO is responsible for submitting their Notice through their own internal concurrence within their administration.

a. The responsible program office creates a VIEWS case task, uploads the draft Federal Register notice, VA Form 0907 (Strategic Communication Review), and VA Form 4265 (Concurrence and Summary Sheet).

b. The responsible program offices then assigns the notice concurrently to the Deputy Under Secretary for Health; Deputy Under Secretary for Health for Integrated Veteran Care; Associate Deputy Under Secretary for Health for Oversight, Risk, and Ethics; Assistant Under Secretary for Health for Operations; Assistant Under Secretary for Health for Patient Care Services; Assistant Under Secretary for Health for Support: Assistant Under Secretary for Health for Quality and Patient Safety; and Deputy Under Secretary for Health for Discovery, Education, and Affiliate Networks.

c. The Deputy Under Secretary for Health, the Associate Deputy Under Secretaries for Health, and Assistant Under Secretaries for Health will assign to affected subordinate offices as needed and must respond to the assignment in VIEWS within 10 days after receiving it.

NOTE: *If the notice relates to a regulation published in Title 38 Code of Federal Regulations (C.F.R.) the responsible program office also concurrently assigns the notice to 10BRAP for review, with the same 10-day timeframe.*

4. Once the Notice is approved and signed by the appropriate authorized signer, the PO tasks the Notice to the Office of General Counsel (OGC/02) via VIEWS. ***NOTE:*** *If there is a required publication date for the Notice (e.g., due to statutory requirement or*

programmatic reason) it is recommended that the PO task it to (02) at least 45 days prior to that due date. The PO should include the following documents in their VIEWS task to OGC as **Attachments:**

a. Notice (Word Version).

b. Any supporting documents associated with the Notice.

c. VA Form 4265, Concurrence and Summary Sheet.

d. VA Form 0907, Strategic Communications Review.

5. The appropriate OGC attorney will review the Notice and may recommend edits to the PO. Once the edits are resolved between the PO and the reviewing attorney, the attorney will seek the General Counsel's (GC) concurrence.

6. Once the PO obtains information that the Notice is approved by the GC, the PO should task the Notice package to the Office of the Executive Secretariat (001B) in VIEWS. The PO should also send an email to the Executive Secretariat (Teri McClelland) and Exec Sec Intake (ExecSecIntake@va.gov) in 001B, letting them know that an assignment was made to them in VIEWS. The email must also contain the Notice package and appropriate documents in accordance with VA EXECSEC's Guidance for Preparing Electronic Packages dated May 2022. 001B will review the Notice package and may recommend edits to the PO or request additional information before obtaining the SECVA's approval and signature.

7. Once the PO obtains information that the Notice is approved/signed by the SECVA, the PO should review the Notice and ensure all aspects related to the Notice are in place and ready for publication in the Federal Register, to include making sure the Word document and pdf match exactly.

8. Once the Notice is ready for publication, the PO will **EMAIL** the following TWO documents to regulations@va.gov, Office of Regulatory Oversight & Management (ROM):

a. The **.pdf version** of the Notice approved, signed and dated by SECVA.

b. The Microsoft **Word version** of the Notice that the SECVA approved. ***NOTE:*** *The Word version* ***must*** *match the .pdf version.*

9. ROM will prepare and submit the Notice to the Federal Register for publication. The Notice typically publishes within 3 business days after submission.

10. The Federal Register will notify ROM of when the Notice is scheduled to publish, and ROM will notify the PO.

If you need further assistance, please contact the Office of Regulatory Oversight and Management at regulations@va.gov.