

APPEAL OF VHA CLINICAL DECISIONS

- 1. REASON FOR ISSUE:** This Veterans Health Administration (VHA) directive communicates the policy and responsibilities for handling clinical disputes. **NOTE:** *As a result of a recommendation by the Commission on Care (see https://commissiononcare.sites.usa.gov/files/2016/07/Commission-on-Care_Final-Report_063016_FOR-WEB.pdf, Recommendation #3), a workgroup is being convened to further review these processes and to develop a regulation on clinical appeals.* This directive will be updated accordingly.
- 2. SUMMARY OF MAJOR CHANGES:** This VHA directive updates the processes for internal and external appeals of clinical decisions.
- 3. RELATED ISSUES:** None.
- 4. RESPONSIBLE OFFICE:** The Office of the Deputy Under Secretary for Health for Operations and Management (10N) is responsible for the contents of this directive. Questions may be referred to the Office of Patient Centered Care and Cultural Transformation at 202-461-0410.
- 5. RESCISSIONS:** VHA Directive 2006-057, dated October 16, 2006, is rescinded.
- 6. RECERTIFICATION:** This VHA directive is scheduled for recertification on or before the last working day of October 2021. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

David J. Shulkin, M.D.
Under Secretary for Health

DISTRIBUTION: Emailed to the VHA Publications Distribution List on October 25, 2016.

CONTENTS

APPEAL OF VHA CLINICAL DECISIONS

1. PURPOSE..... 1

2. BACKGROUND..... 1

3. DEFINITION..... 1

4. POLICY..... 1

5. RESPONSIBILITIES 1

APPENDIX A

GUIDANCE FOR DEVELOPING A FACILITY CLINICAL APPEAL PROCESSA-1

APPENDIX B

SAMPLE EXECUTIVE DECISION MEMORANDUMB-1

APPENDIX C

CONSIDERATIONS FOR DECISION-MAKING MEMORANDUM C-1

APPEAL OF VHA CLINICAL DECISIONS

1. PURPOSE

This Veterans Health Administration (VHA) directive communicates the policy and responsibilities for handling clinical disputes. **AUTHORITY:** Title 38 United States Code (U.S.C.) 7301(b). **NOTE:** *This directive does not apply to VHA's reconsideration process set forth in Title 38 Code of Federal Regulations (CFR) §17.133 or to appeals filed with the Board of Veterans' Appeals (which are governed by 38 CFR part 20).*

2. BACKGROUND

In Fiscal Year (FY) 1999, VHA initiated an internal review of its clinical dispute process in response to VHA health care eligibility reform and the implementation of an enrollment system with the provision of a defined medical benefits package. In FY 2000, VHA instituted an external appeals system, which allows Veterans Integrated Service Networks (VISN) to request prompt, impartial review of disputed clinical decisions by a non-VHA, external reviewer. In 2006, VHA created a more efficient and consistent system of review that incorporates internal and external review, VISN-based management, and Veteran customer-service improvement activities.

3. DEFINITION

Clinical Dispute. A clinical dispute is an impasse that occurs between a patient, or the patient's representative, and a VHA medical facility over the provision or denial of clinical care that potentially could result in a different and/or improved clinical outcome for the Veteran. Clinical disputes generally arise when a patient and a provider disagree with medical determinations of the need for and appropriateness of specific types of medical care and treatment for an individual. Typical examples of these issues are whether a particular drug should be prescribed, whether a specific type of physiotherapy should be ordered, and similar judgmental treatment decisions with which an attending physician may be faced.

4. POLICY

It is VHA policy that patients and their representatives have access to a fair and impartial review of disputes regarding clinical decisions. Appeals of clinical decisions must be filed in writing, by the patient or by their representative and submitted to the medical facility, and if not resolved, directly to the VISN.

5. RESPONSIBILITIES

- a. **VISN Director.** The VISN Director, or designee, is responsible for:

- (1) Administering an internal clinical decision appeals process to resolve disputes of clinical decisions that are not resolved at the medical facility level. The VISN Director must ensure that the process at each level provides for a fair and impartial review.

(2) Reviewing clinical disputes to ensure that clinical decisions are founded on national evidence-based standards, where they exist. The Office for Quality, Safety, and Value (QSV) can make provisions on behalf of the VISN Director to obtain an independent external review and recommendations regarding clinical appeals. VISNs have the authority to request such an independent external review to inform the VISN Director's deliberations at any time during the clinical appeals process prior to rendering a final decision. **NOTE:** *As the purpose of an external clinical review obtained through QSV is to inform the VISN Director's deliberations regarding the clinical appeal, it is provided only to the VISN Director. Any requests for a copy of the external reviewer's work product from the patient or other parties must be made via the Freedom of Information Act (FOIA) process.*

(3) Ensuring that the Network and each facility has written policy and procedures for handling internal clinical appeals, including identification of roles and responsibilities, time frames, and requirements for data entry into PATS. See Appendix A for guidance.

(4) Conducting a preliminary review upon receipt of a clinical appeal in order to determine whether the:

(a) Patient can be maintained safely in the current environment of care. If it is determined that the patient cannot be safely maintained in the current environment of care, the VISN must ensure that arrangements necessary to maintain safety are implemented (e.g., arrange for immediate transfer of the patient to an appropriate setting).

(b) Dispute meets the definition of a "clinical dispute" as defined by paragraph 3 of this directive. **NOTE:** *Issues that fall outside the scope of the appeals of clinical decisions process (i.e., administrative disputes, issues that are appropriate for ethics consultation, other complaints, etc.) should be referred to the appropriate office.*

(c) Medical facility had an opportunity to formally address the issue. If the medical facility has not attempted resolution, the VISN Chief Medical Officer (CMO) will work with the medical facility Director and Chief of Staff to attempt to determine a resolution.

(5) Requesting documentation and supporting arguments about the clinical dispute from both the facility and the patient or the patient's representative to inform the VISN Director and, if applicable, the independent external reviewer. The VISN Director either independently reviews the documentation or convenes an impartial VISN clinical panel to review the documentation and make a recommendation.

(6) Ensuring that, when an independent external review is requested, the clinical record, the documentation and supporting arguments regarding the clinical appeal, relevant Department of Veterans Affairs (VA) policy or national guidance, and other relevant documentation and information produced by any internal review, is forwarded to the Office of Quality, Safety and Value (QSV).

(7) Rendering a written decision to the patient, or the patient's representative, and the medical facility Director within 30 days after initial receipt of the clinical appeal.

NOTE: If the VISN Director has requested an external review from QSV, the time frame for final decision will be extended to 45 days to obtain the external review.

(8) Ensuring the patient, or the patient's representative, understands that they always have the right to accept or reject any solution offered.

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

(1) Instituting a local clinical appeals process based on this policy that establishes procedures for handling internal appeals of clinical decisions, including identification of roles and responsibilities, time-frames, and requirements for data entry into the national Patient Advocate Tracking System (PATS). See Appendix A for guidance.

(2) Ensuring that patients and their representatives are aware of their right to dispute a clinical decision and the process involved in appealing that decision.

(3) Ensuring staff are aware of the appeals process when a patient or patient's representative expresses disagreement with clinical decisions.

(4) Local processes to resolve disputes of clinical decisions, must be based on the following:

(a) Clinical decisions are founded on national evidence-based standards where they exist.

(b) Attempting to resolve clinical disputes at the patient's clinical team level, which includes assistance from facility or medical center patient advocates. The patient's clinical team and the medical facility patient advocates are the first points of contact to resolve clinical disputes. **NOTE:** *The clinical team should be made aware of any resources available at the facility level that may assist them in facilitating informal resolution of the clinical dispute (e.g., family conferences, ethics consultation, mediation, etc.).*

(c) Clinical disputes not resolved at the clinical team level should be elevated to the medical facility's Chief of Staff who will review, attempt to resolve the dispute, and make a determination on the issue. The Chief of Staff should also determine whether the patient can be maintained safely in the current environment of care while the dispute is pending. If it is determined that the patient cannot be safely maintained in the current environment of care, the Chief of Staff must ensure that arrangements necessary to maintain safety are implemented (e.g., immediate transfer of the patient to an appropriate setting).

(5) Providing written notification to the patient or the patient's representative of the medical facility's final determination. This notification must describe the process and rationale that was used to reach the decision, as well as information on how the patient or patient's representative can appeal the medical facility decision to the VISN.

(6) Ensuring the patient or the patient's representative understands that they always have the right to accept or reject any solution offered.

(7) Ensuring that the medical facility patient advocate enters clinical dispute appeals (medical facility and VISN appeals) into PATS. All details and decisions must be included in the final documentation before the case is closed.

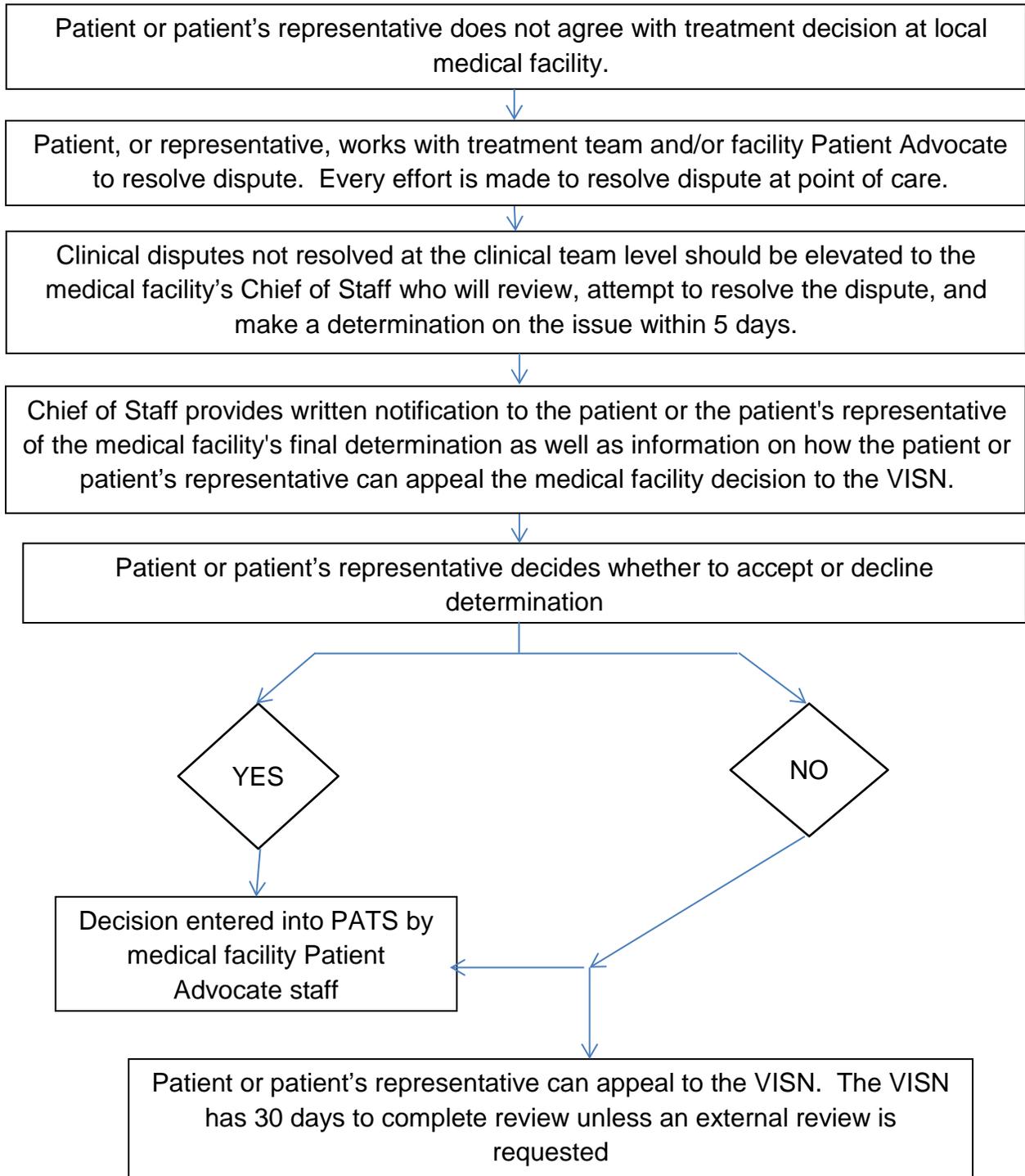
c. **Office for Quality, Safety and Value.** The Office for Quality, Safety and Value is responsible for arranging external reviews of clinical issues involved in VHA clinical appeals using a reviewer who is not a VA employee. Upon receipt of a request for external review and all information needed for the review from the VISN, the Office for Quality, Safety and Value:

(1) Arranges for the external review. The external reviewers examine the clinical record and all accompanying documentation, as well as any evidence regarding the relevant practice described in the literature, to determine whether appropriate or reasonable and necessary clinical services were provided or denied.

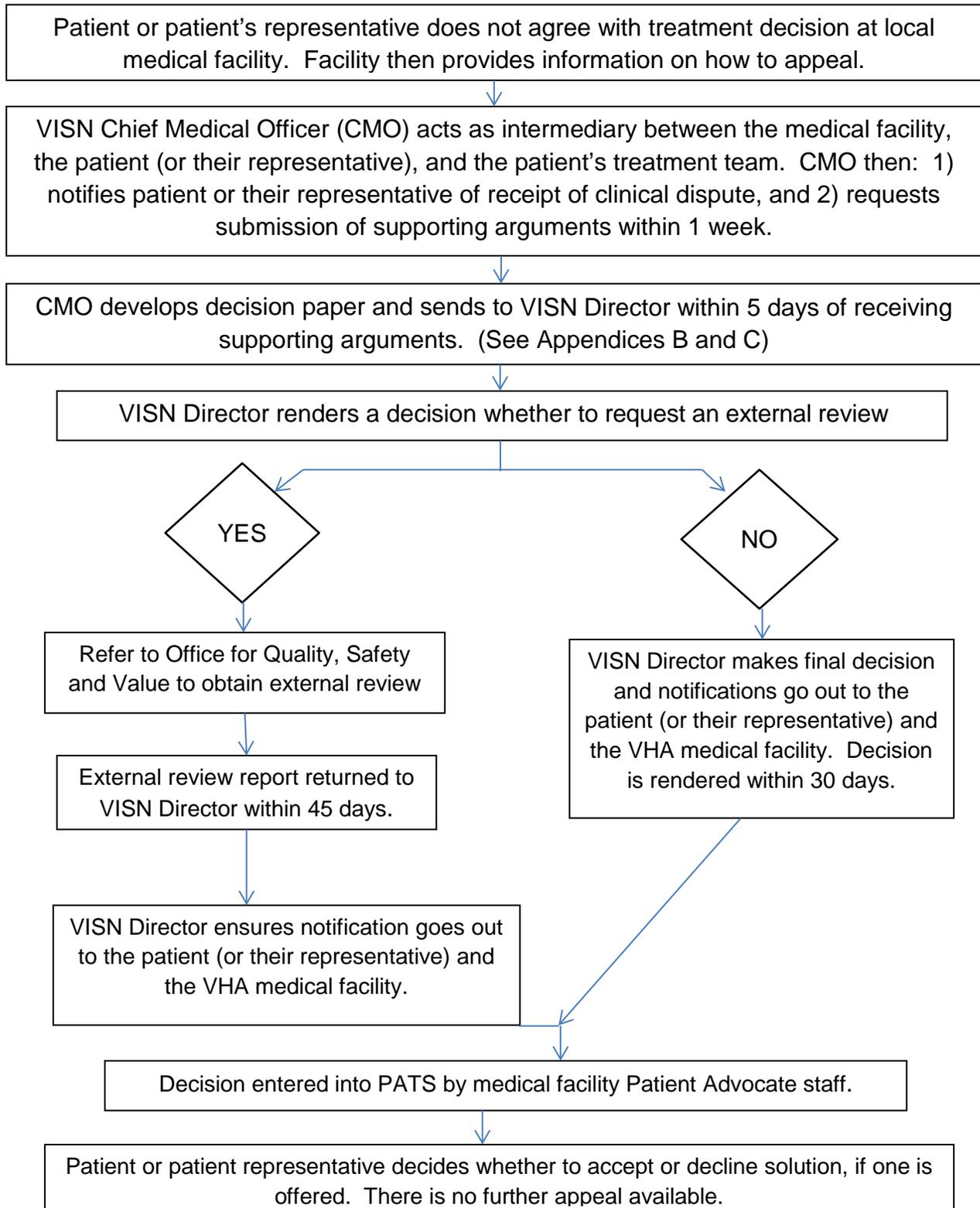
(2) Ensures that a final written report, fully documenting the findings and recommendations of the reviewer(s), is provided to the VISN Director within 45 days of the receipt of the complete appeal documentation in support of a request for external review. This may be extended if there are extenuating circumstances.

d. **Office of Patient Centered Care and Cultural Transformation.** The Office of Patient Centered Care and Cultural Transformation is responsible for providing support for PATS. ***NOTE: PATS is used for documenting disputes of clinical decisions and producing reports for the tracking and trending of issues.***

GUIDANCE FOR DEVELOPING A FACILITY CLINICAL APPEAL PROCESS



GUIDANCE FOR DEVELOPING A VISN CLINICAL APPEAL PROCESS



SAMPLE EXECUTIVE DECISION MEMORANDUM

FACILITY:

TO: Veterans Integrated Service Network (VISN) Director (10N_)

THRU:

FROM: Chief Medical Officer (10N-)

SUBJ: PREPARED BY:

1. For Further Information Contact:

2. Action Requested:

- Approval
- Discussion or further review
- None; For your Information
- Other (specify)

3. Statement Of Issue: A concise statement of the issue, circumstance, or situation that needs to be addressed or resolved.

4. RECOMMENDATION: A succinct statement of what action is being recommended to address or resolve the issue.

Name of Chief Medical Officer	Date

APPROVED/DISAPPROVED

Name of Network Director	Date

CONSIDERATIONS FOR DECISION-MAKING MEMORANDUM

- 1. STATEMENT OF ISSUE:** A concise statement of the issue, circumstance, or situation that needs to be addressed or resolved.
- 2. SUMMARY OF FACTS AND/OR BACKGROUND:** A succinct discussion, or review, of the relevant facts or circumstances bearing on the issue (one to three paragraphs).
- 3. SYNOPSIS OF SIGNIFICANT RELATED ISSUES:** A statement of any related or peripheral issues not covered in Consideration Item #2 that also should be considered (1 to 3 paragraphs).
- 4. CRITERIA FOR DECISION-MAKING:** A listing of all significant criteria upon which the options for addressing the issue will be judged, pro or con. **NOTE:** *This section is to specify precisely the basis for making the decision.*
- 5. STAKEHOLDER INVOLVEMENT:** A brief description of all parties involved (i.e., internal and external stakeholders) and what process was used to develop the decision criteria and options.
- 6. OPTIONS AND ARGUMENTS:** A listing of the various options for actions that could be taken to address or resolve the issue or situation, and the arguments for and against each.

Option 1:

Arguments Pro:

Arguments Con:

Option 2:

Arguments Pro:

Arguments Con:

- 7. RECOMMENDED OPTION:** A succinct statement of what action is being recommended to address or resolve the issue.
- 8. DISSENTING OPINIONS REGARDING RECOMMENDED OPTION:** When the recommended option is the result of a committee or group process, then major dissenting views or minority opinions need to be noted as well.
- 9. EFFECT OF RECOMMENDED OPTION ON EXISTING PROGRAMS AND/OR FACILITIES:** An assessment of the effect of the recommended action on existing programs or facilities.

10. LEGAL CONSIDERATIONS OF THE RECOMMENDED OPTION: Is the recommended option included in the VA medical benefits package, and is the Veteran eligible to receive it?

11. ETHICAL CONSIDERATIONS OF THE RECOMMENDED OPTION: A brief discussion of the values underlying the issue as well as any ethical issues, concerns, or considerations stemming from the recommended action. (See VHA Handbook 1004.06, INTEGRATEDETHICS®, dated August 29, 2013.

12. IMPLEMENTATION: A brief discussion of the timing, sequence, and implementation of the recommended action, including major implementation milestones. The proposed lead office or lead person and support office need to be clearly identified. Likewise, any anticipated obstacles must be noted.

13. LESSONS LEARNED: A brief discussion of any lessons learned stemming from either the issue, or the way the issue was handled at any point along the continuum.