JEFFREY S. BUCHOLTZ
Acting Assistant Attorney General
JOSEPH P. RUSSONIELLO California Bar No. 44332
United States Attorney
RICHARD LEPLEY
Assistant Branch Director
DANIEL BENSING D.C. Bar No. 334268
STEVEN Y. BRESSLER D.C. Bar No. 482492
KYLE R. FREENY California Bar No. 247857
Attorneys
United States Department of Justice
Civil Division, Federal Programs Branch

P.O. Box 883
Washington, D.C. 20044
Telephone: (202) 514-5108
Facsimile: (202) 616-8460
Email: Kyle.Freeny@USDOJ.gov

Attorneys for Defendants Hon. James B. Peake, the U.S. Department of Veterans Affairs, Hon. James P. Terry, Hon. Daniel L. Cooper, Hon. Bradley G. Mayes, Hon. Michael J. Kussman, Ulrike Willimon, the United States of America, Hon. Michael B. Mukasey, and Hon. William P. Greene, Jr.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO

VETERANS FOR COMMON SENSE and VETERANS UNITED FOR TRUTH, Plaintiffs, v. Hon. JAMES B. PEAKE, Secretary of Veterans Affairs, *et al.*, Defendants.	No. C 07-3758-SC **DECLARATION OF TONY A. GUAGLIARDO IN SUPPORT OF DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION**

I, Tony A. Guagliardo, hereby declare:

1. I am currently the Director, Business Policy of the Chief Business Office, a subunit of the Veterans Health Administration (VHA). The information contained in this declaration is based on my personal knowledge and on information made available to me in the course of my official duties.

2. Prior to my employment at the Department of Veterans Affairs (VA), I was honorably discharged from the Army with medical retirement based on a service-connected disability. I received a Master of Science degree from the University of Maryland University College in 1996. I am a lifetime member of the Disabled American Veterans association as well as a member of The American Legion. In 2005, I participated and completed the Federal Executive Institute's month long "Leadership in a Democratic Society" program as well as a two week seminar/program at the Interagency Institute for Healthcare Executives conducted at George Washington University, Washington, DC. I was accepted as a member of the American College of Healthcare Executives (ACHE) in 2004.

3. I joined the Department of Veterans Affairs (VA) in 1994. Before my appointment to my current position, I was Deputy Director of Business Policy and have also previously held positions in a medical center. I was assigned to my current position in 2004. My office develops policies governing the administration of medical centers, and my staff advises VA officials and veterans on matters relating to patient administration, including the processing of administrative appeals, eligibility for medical care, first and third party reimbursements, and veterans' co-payments. We work collaboratively with other offices to ensure that veterans are aware of the mechanisms for disputing health care decisions with which they disagree. My office is responsible for all administrative aspects of patient administration and eligibility determinations. We also provide legislative analysis and propose business policy-related legislative initiatives.

4. Veterans generally must enroll in the VA health care system to receive VA hospital and outpatient care. 38 C.F.R. 17.36(a). They may do so by submitting a completed application form (VA 10-10EZ) to a VA medical facility. 38 U.S.C. 17.36(d), (f). They may also enroll online.

Veterans are asked to submit information about, among other things, their military service, disabilities, and financial situation. Enrollment determinations are based on whether a veteran meets the eligibility criteria set forth in VA's governing statutes and regulations. The VA's Health Eligibility Center in Atlanta, Georgia, is responsible for notifying veterans, by letter, of their enrollment status.

5. Veterans who seek enrollment are placed in eight priority categories based on various factors, such as disability, previous military service, and income. These categories are set forth by regulation. 38 C.F.R. 17.36. Once enrolled, veterans are provided with VA's medical benefits package. Currently, VA is enrolling all priority categories, except two subcategories of Category 8. 38 U.S.C. 17.36(c)(2). A veteran's priority category does not refer to the veteran's priority in scheduling medical appointments, however. By regulation, preference must be given to certain service-connected veterans in the scheduling of appointments. 38 C.F.R. 17.49. It is not necessarily the case, however, that a veteran enrolled in Category 6 has less priority in the scheduling of appointments than a veteran in Category 4 or 5. The scheduling of appointments is generally made based on medical need and the availability of both the veteran and the provider, and in accordance with VA timeliness standards.

6. For a period of two years after discharge, veterans who served in combat after November 11, 1998, are eligible to enroll for cost-free VA medical care for any illness that may be related to their combat service. 38 U.S.C. 1710(a), (e); 38 C.F.R. 17.36(b)(6). Unless a veteran is eligible to be enrolled in a higher category (such as when he or she has an established service-connected disability), returning combat veterans are enrolled in Priority Category 6. After the two year period elapses, a combat veteran is not disenrolled. Rather, the veteran is moved to the highest priority category for which he or she is then eligible. Typically, for a veteran who has not been adjudicated as having a service-connected disability, this means that the veteran is shifted to Category 7 or 8, depending on the veteran's income level. Regardless, a veteran who has enrolled for medical care within two years of returning from combat remains eligible for VA medical care after that two years elapses; the only difference is that he or she may be responsible for a

co-payment for care that previously was not subject to a co-payment, as is the case with many private insurance policies. The VA has publicly supported extending the period of enrollment eligibility for returning combat veterans under 38 U.S.C. 1710(e) from two to five years, and President Bush just signed into law the National Defense Authorization Act which will have this effect.

7. If a veteran is dissatisfied with a decision about eligibility for medical benefits, the veteran is provided with a notice of right to appeal, VA Form 4107VHA (October 2007). A true and correct copy is attached to this declaration as Exhibit A. This form provides a toll-free number, internet links, notice of the one-year statutory limitation, and other information regarding appeals to the Board of Veterans Appeals ("Board").

8. A veteran may, but need not, request reconsideration of an eligibility decision or a denial of benefits prior to an appeal to the Board. 38 CFR 17.133. An individual who disagrees with the initial decision denying the claim in whole or in part may obtain reconsideration by submitting a reconsideration request in writing to the healthcare facility of jurisdiction. The reconsideration decision will then be made by the immediate supervisor of the initial VA decision-maker.

9. A veteran may appeal a decision about eligibility for medical benefits to the Board by informing the VHA decisionmaker that he or she disagrees with it and wants to appeal it. This is called a notice of disagreement. 38 C.F.R. 20.201. The veteran will then receive a statement of the case, a VA Form 9, and information on the appeal process from VHA. 38 C.F.R. 19.29, 19.30. To finalize the appeal to the Board, the veteran generally must complete this form and return it to VHA. 38 C.F.R. 20.202. VHA then must certify the appeal to the Board. VHA employees are given training on how to handle the initiation of the administrative appeals process, and VHA has set up a website to provide guidance to staff.

10. When a veteran is not satisfied with a medical determination, such as a diagnosis or treatment decision, the process for appeal is different. By regulation, the Board does not have jurisdiction to consider medical challenges. 38 C.F.R. 20.101(b). VHA nevertheless provides

patients or their representatives with access to fair and impartial review of disputes regarding clinical determinations. In fact, the use of informal procedures to resolve clinical appeals generally permits swifter resolution of disputes.

11. Where a veteran disputes a diagnosis or course of treatment, the medical facility will initially attempt to resolve a veteran's dispute internally. Typically, the veteran's treatment team would review the dispute and seek the input from the appropriate chief of service. If they cannot resolve the dispute, the facility director, in consultation with the chief of staff, would make the ultimate decision for the facility, relying on input from the treatment team and the veteran. Every medical center has at least one patient advocate on staff who can assist veterans in disputing a decision and in presenting the veterans' perspective to the relevant personnel. Medical facilities are required to publicize the availability of patient advocates by posting information on their services with their phone numbers in all high-traffic areas throughout the facility and including this information in inpatient information brochures.

12. Once a veteran is given written notice of a facility director's decision about a clinical dispute, the veteran has the option of appealing the decision to the Director of the Veterans Integrated Service Network (VISN) that oversees the facility. The facility director must notify the veteran of this option in writing. A uniform clinical appeals process at the VISN level was initiated in 2001 as a means of standardizing the handling of clinical disputes throughout VHA. See VHA Directives 2001-033 (May 23, 2001) and 2006-057 (October 16, 2006). A true and correct copy of each directive is attached to this declaration as Exhibits B and C, respectively. Based on the advice of the Chief Medical Officer of the VISN and on information obtained from the medical facility and the veteran or the patient advocate, the VISN director makes the ultimate decision on a clinical appeal. A VISN Director may request an impartial review of a clinical decision by an external professional board to assist in this decision. The VISN Director's final decision must be issued to the veteran within 30 days after initial receipt of the clinical appeal, or within 45 days if external review is requested. VISN directors can and should expedite this process when there is an urgent medical need.

I declare under penalty of perjury that the foregoing is true and correct. Executed on January 30, 2008.

TONY A. GUAGLIARDO

Exhibit A to the Declaration of Tony A. Guagliardo

Department of Veterans Affairs

YOUR RIGHTS TO APPEAL OUR DECISION

After careful and compassionate consideration, a decision has been reached on your claim. If we were not able to grant some or all of the VA benefits you asked for, this form will explain what you can do if you disagree with our decision. If you do not agree with our decision, you may:

- appeal to the Board of Veterans' Appeals (the Board) by telling us you disagree with our decision
- give us evidence we do not already have that may lead us to change our decision

This form will tell you how to appeal to the Board and how to send us more evidence. You can do either one or both of these things.

NOTE: Please direct all new evidence to the address at the top of our letter. Do not send evidence directly to the Board until you receive written notice from the Board that they received your appeal.

WHAT IS AN APPEAL TO THE BOARD OF VETERANS' APPEALS?

An appeal is your formal request that the Board review the evidence in your VA file and review the law that applies to your appeal. The Board can either agree with our decision or change it. The Board can also send your file back to us for more processing before the Board makes its decision.

HOW CAN I APPEAL THE DECISION?

How do I start my appeal? To begin your appeal, write us a letter telling us you disagree with our decision. This letter is called your "Notice of Disagreement." If we denied more than one claim for a benefit (for example, if you claimed compensation for three disabilities and we denied two of three), please tell us in your letter which claims you are appealing. ***Send your Notice of Disagreement to the address at the top of our letter.***

For any matter that involves **VA enrollment related benefits**, send your Notice of Disagreement to the Enrollment Coordinator at your local VA health care facility. For the local facility address, contact the VA Health Benefits Service Center at the toll-free number, 1-877-222-VETS (8387).

For other matters, send your Notice of Disagreement to the address shown at the top of the letter notifying you of our decision.

What happens after VA receives my Notice of Disagreement? We will either grant your claim or send you a Statement of the Case. A Statement of the Case describes the facts, laws, regulations, and reasons that we used to make our decision. We will also send you a VA Form 9, "Appeal to Board of Veterans' Appeals," with the Statement of the Case. You must complete this VA Form 9 and return it to us if you want to continue your appeal.

How long do I have to start my appeal? You have one-year to appeal our decision. ***Your*** letter saying that you disagree with our decision must be postmarked (or received by us) within one-year from the date of ***our*** letter denying you the benefit. In most cases, you cannot appeal a decision after this one-year period has ended.

What happens if I do not start my appeal on time? If you do not start your appeal on time, our decision will become final. Once our decision is final, you cannot get the VA benefit we denied unless you either:

- show that we were clearly wrong to deny the benefit **or**
- send us new evidence that relates to the reason we denied your claim

Can I get a hearing with the Board? Yes. If you decide to appeal, the Board will give you a hearing if you want one. The VA Form 9 we will send you with the Statement of the Case has complete information about the kinds of hearings the Board offers and convenient check boxes for requesting a Board hearing. The Board does not require you to have a hearing. It is your choice.

Where can I find out more about appealing to the Board?

- You can find a "plain language" booklet called "How Do I Appeal," on the Internet at: **http://www.va.gov/vbs/bva/pamphlet.htm**. The booklet also may be requested by writing to Hearings and Transcription Unit (014HRG), Board of Veterans' Appeals, 810 Vermont Avenue, NW, Washington, DC 20420.

- You can find the formal rules for appealing to the Board in the Board's Rules of Practice at title 38, Code of Federal Regulations, Part 20. You can find the complete Code of Federal Regulations on the Internet at: **http://www.access.gpo.gov/nara/cfr**. A printed copy of the Code of Federal Regulations may be available at your local law library.

(Please continue reading on page 2)

Can I get someone to help me with my appeal to the Board? Yes. You can have a veterans' service organization representative, an attorney-at-law, or an "agent" help you with your appeal. But you are not required to have someone represent you. It is your choice.

- Representatives who work for accredited veterans' service organizations know how to prepare and present claims and will represent you. You can find a listing of these organizations on the Internet at: **http://www.va.gov/vso.**

- A private attorney or an "agent" can also represent you. If applicable, your local bar association may be able to refer you to an attorney with experience in veterans' law. VA only recognizes attorneys who are licensed to practice in the United States or in one of its territories or possessions. An agent is a person who is not a lawyer, but who VA recognizes as being knowledgeable about veterans' law. Contact us if you would like to know if there is a VA accredited agent in your area.

Do I have to pay someone to help me with my appeal to the Board? It depends on who helps you. The following explains the differences.

- Veterans' service organizations will represent you for free.
- Attorneys or agents can charge you for helping you under some circumstances. Paying their fees for helping you with your appeal to the Board is your responsibility. If you do hire an attorney or agent to represent you, one of you must send a copy of any fee agreement to the following address within 30 days from the date the agreement is signed: Office of the Chief Counsel for Policy (01C3), Board of Veterans' Appeals, 810 Vermont Avenue, NW, Washington, DC 20420; facsimile (202) 565-5643.

CAN I GIVE VA ADDITIONAL EVIDENCE?

Yes. You can send us more evidence to support a claim whether or not you appeal to the Board. **If you want to appeal, though, do not forget the one-year time limit!**

If you have more evidence to support a claim, it is in your best interest to give us that evidence as soon as you can. We will consider your evidence and let you know whether it changes our decision. Please keep in mind that we can only consider new evidence that: (1) we have not already seen and (2) relates to your claim. You may give us this evidence either in writing or at a personal hearing.

In writing. To support your claim, you may send documents and written statements to us at the address on the top of our letter. Tell us in a letter how these documents and statements should change our earlier decision.

At a personal hearing. You may request a local hearing with us at any time. This hearing is separate from any Board hearing you might ask for later if you appeal. We do not require you to have one. It is your choice. At this hearing, you may speak, bring witnesses to speak on your behalf, and hand us written evidence. If you want a hearing, send us a letter asking for a hearing. Use the address at the top of our letter. We will then:

- arrange a time and place for the hearing
- provide a room for the hearing
- assign someone to hear your evidence
- make a written record of the hearing

WHAT HAPPENS AFTER I GIVE VA EVIDENCE?

We will review the record of the hearing and other new evidence, together with the evidence we already have. We will then decide if we can grant your claim. If we cannot grant your claim and you appeal, we will send the new evidence and the record of any local hearing to the Board.

Exhibit B to the Declaration of Tony A. Guagliardo

Department of Veterans Affairs **VHA DIRECTIVE 2001-033**
Veterans Health Administration
Washington, DC 20420 **May 23, 2001**

VHA CLINICAL APPEALS

1. PURPOSE: This Veterans Health Administration (VHA) Directive creates a mechanism for both Internal and External Appeals. It is designed to establish policies, responsibilities, and procedures for handling of patient issues and/or concerns when an impasse occurs between a patient (or the patient's representative) and a health care facility pertaining to the following:

a. Provision of clinical care that potentially could result in a different and/or improved clinical outcome for the veteran.

b. Denial of clinical care that potentially could result in a different and/or improved clinical outcome for the veteran.

2. BACKGROUND

In 1991, VHA first issued a Directive mandating all medical centers to operate a Patient Advocate Program for handling patient inquiries and complaints. In Fiscal Year (FY) 1999, in response to Eligibility Reform and the implementation of an enrollment system with the provision of a fixed benefits package, VHA initiated a review of how clinical disputes were being handled throughout the system. As an outgrowth of that review, in FY 2000, VHA instituted an External Appeal system, which allows Networks to request prompt, impartial reviews of clinical determination decisions by a professional board external to the Agency. As an additional development, this FY 2001 Directive addresses the handling of Clinical Appeals internal to the Agency, with the goal of creating a more efficient and consistent system that incorporates Veterans Integrated Service Network (VISN)-based management into review and associated veteran customer service improvement activities.

3. POLICY: It is the policy of VHA that patients or their representatives have access to a fair and impartial review of disputes regarding clinical determinations or services that are not resolved at the facility level. ***NOTE:*** *This supports the vital concept that patients will be actively involved in all aspects of care that influence clinical outcomes, including decisions regarding referrals, transfers, discharge planning, and other factors which influence the clinical outcomes of care.*

4. ACTION

a. **Facility Responsibilities**

(1) VHA health care facilities are the first point of contact for attempting to resolve clinical disputes. Every effort is to be made to resolve disputes as close to the point of care as possible.

(2) Facilities must provide written notification of the facility's final determination to the patient, or their representatives. In addition, this notification must describe the Network Clinical Appeals process.

THIS VHA DIRECTIVE EXPIRES MAY 31, 2006

b. **Network Responsibilities.** VHA Networks administer an Internal Clinical Appeals process regarding clinical determinations or services that are not resolved at the facility level. They ensure that the process at each level provides for a fair and impartial review. Networks must review Clinical Appeals and provide a decision to the patient within 30 days after receipt of the appeal request. That time frame may be extended to 45 days, should the Network request an External Clinical Review (see subpar. 4b(2)(c)). VHA facilities and Networks render decisions that are founded on national evidence based standards. Where there is an absence of a national evidence base standard for treatment, the local community standard prevails. ***NOTE:*** *VHA operates an External Clinical Review program that allows for independent review and recommendation regarding Clinical Appeals by a professional board external to the Agency. Networks have the authority to request an External Review at any time during the Clinical Appeals process, prior to rendering a final decision.*

(1) By September 1, 2001, Networks must have a written policy and procedure in place for how Internal Clinical Appeals are handled, including identification of roles and responsibilities, time frames, and requirements for data entry into the national computerized Patient Complaint database.

(2) Upon receipt of a Clinical Appeal from the patient, or their representative, the Network must conduct a preliminary review 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 Network must arrange for immediate transfer of the patient to an appropriate setting.

(b) Medical facility had an opportunity to formally address the issue. If the facility has not attempted resolution, the request for review is forwarded to the facility Director.

(c) Dispute is an appropriate case for the Network Clinical Appeals process. ***NOTE:*** *Issues that fall outside the scope of that process (i.e., administrative disputes, other complaints) will be referred to the appropriate office or location. This directive does not impact other appeals processes available to veterans, specifically the reconsideration process and appeals to the Veterans Benefits Administration.*

(3) Once a clinical dispute is accepted as an Internal Clinical Appeal, the Network requests documentation and supporting arguments from both the facility and the patient, or as appropriate, the patient's representative. The Network will either independently review the documentation or convene an impartial Network Clinical Panel to review the documentation and make a recommendation. ***NOTE:*** *The Network can request an independent External Review at any time during the process.*

(4) When an independent External Review is requested, the Network Director forwards the clinical record, the statement of appeal, and other relevant documentation and/or information produced by any Internal Review, to the Office of Quality and Performance (OQP). Upon receipt, OQP arranges for the External Review through its Contractor for the External Peer Review Program. The Contractor reviews the clinical record and all accompanying documentation, as well as any evidence regarding the relevant practice described in the literature, to determine whether appropriate and/or reasonable and necessary clinical service was provided and/or denied. A final written report, fully documenting the findings and recommendations of

the reviewer(s), is provided to the Network Director within 10 days of the receipt of the full documentation request.

(5) The Network Director renders a written final 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:*** *The time frame for final decision may be extended to 45 days for those Clinical Appeals undergoing External Review.*

(6) Networks must ensure that the Patient Advocate at the facility enters the Clinical Appeals into the national computerized Patient Complaint database where the appeal was originated. All details and decisions must be included in the final documentation before the case is closed.

(7) Attachment A provides a sample cascade for the process management of Clinical Appeals by a Network.

(8) Attachment B provides a sample memo for written documentation to support a final appeal recommendation.

(9) Attachment C provides sample considerations for decision-making.

c. **OQP.** OQP administers VHA's External Clinical Appeals program using an outside vendor. OQP must ensure that all requests for External Review are conducted in a timely and efficient manner.

d. **National Patient Advocate Program of the VISN Support Service Center Responsibility.** The National Patient Advocate Program of the VISN Support Service Center provides support for the national computerized Patient Complaint database. ***NOTE:*** *The national computerized Patient Complaint database is to be used for documenting Clinical Appeals and producing reports for the tracking and trending of issues.*

5. REFERENCES: None.

6. FOLLOW-UP RESPONSIBILITY: The Office of the Assistant Deputy Under Secretary for Health (10N) is responsible for the contents of this directive. Questions may be referred to (202) 273-5852.

7. RECISSIONS: None. This VHA Directive expires May 31, 2006.

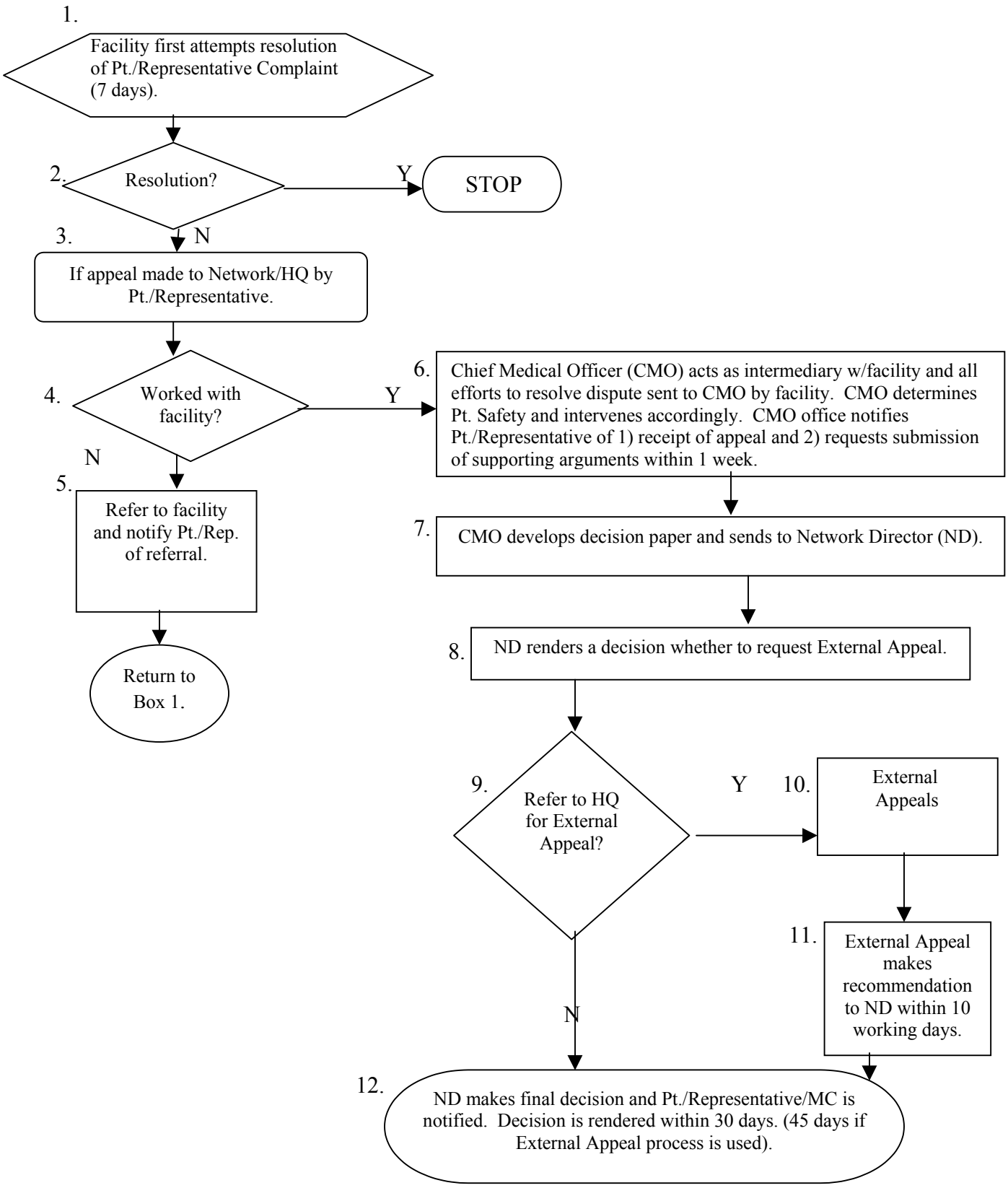
S/ by Frances Murphy, M.D. for
Thomas L. Garthwaite, M.D.
Under Secretary for Health

Attachments

DISTRIBUTION: CO: E-mailed 5/24/2001
FLD: VISN, MA, DO, OC, OCRO, and 200 – E-mailed 5/24/2001

ATTACHMENT A

SAMPLE CLINICAL APPEALS PROCESS



ATTACHMENT B

SAMPLE EXECUTIVE DECISION MEMO

FACILITY:

TO: Network Director (10N___)

THROUGH:

FROM: Chief Medical Officer ( )

SUBJECT:

PREPARED BY:

1. For Further Information Contact:

2. Action Requested:
_____ Request for approval
_____ Request for discussion or further review
_____ 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.

APPROVED/DISAPPROVED

_____

_____ _____
Name of VISN Director (Date)

Network Director, VISN _____

ATTACHMENT C

SAMPLE CONSIDERATIONS FOR DECISION-MAKING

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 (one to three 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 who was worked with (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 opinion 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 OR LEGISLATIVE CONSIDERATIONS OF THE RECOMMENDED OPTION: A brief discussion of any legal or legislative issues, concerns, or consideration stemming from the recommended action.

11. BUDGET OR FINANCIAL CONSIDERATIONS OF THE RECOMMENDED OPTION: A discussion of any costs and/or financial or budgetary effects of the recommended action including the present availability of any needed resources. ***NOTE:*** *No decision will be based solely on budgetary effects.*

12. PUBLIC RELATIONS OR MEDIA CONSIDERATIONS OF THE RECOMMENDED OPTION: A discussion of any potential public relations or media problems, opportunities, etc., raised by the recommended action.

13. CONGRESSIONAL OR OTHER PUBLIC OFFICIAL OR AGENCY CONSIDERATIONS OF THE RECOMMENDED OPTION: A discussion of any congressional and/or other public official/agency notification or involvement considerations raised by the recommended action.

14. 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.

15. 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.

Exhibit C to the Declaration of Tony A. Guagliardo

Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

VHA DIRECTIVE 2006-057

October 16, 2006

VHA CLINICAL APPEALS

1. PURPOSE: This Veterans Health Administration (VHA) Directive defines the mechanism for both internal and external clinical appeals.

2. BACKGROUND

a. In 1991, VHA issued a Directive mandating that all medical centers operate a Patient Advocate Program to address patient inquiries and complaints. In Fiscal Year (FY) 1999, in response to Eligibility Reform and the implementation of an enrollment system with the provision of a fixed benefits package, VHA initiated a review of how clinical disputes were being handled throughout the system. As an outgrowth of that review, in FY 2000, VHA instituted an External Appeal system, which allows Veterans Integrated Service Networks (VISNs) to request prompt, impartial reviews of clinical determination decisions by a professional board external to the agency. As an additional development, this Directive addresses the handling of clinical appeals internal to the agency, with the goal of creating a more efficient and consistent system that incorporates VISN-based management into the reviews and associated veteran customer service improvement activities.

b. It is designed to establish policies, responsibilities, and procedures for handling of patient issues and/or concerns when an impasse occurs between a patient, or the patient's representative, and a health care facility pertaining to the following:

(1) Provision of clinical care that potentially could result in a different and/or improved clinical outcome for the veteran.

(2) Denial of clinical care that potentially could result in a different and/or improved clinical outcome for the veteran.

3. POLICY: It is VHA policy that patients or their representatives must have access to a fair and impartial review of disputes regarding clinical determinations or services that are not resolved at the facility level. ***NOTE:*** *This supports the vital concept that patients are to be actively involved in all aspects of care that influence clinical outcomes, including decisions regarding referrals, transfers, discharge planning, and other factors which influence the clinical outcomes of care.*

4. ACTION

a. **Facility Director.** The facility Director is responsible for:

(1) Attempting to resolve clinical disputes. VHA health care facilities are the first point of contact for disputes and every effort is to be made to resolve disputes as close to the point of care as possible.

(2) Providing written notification of the facility's final determination to the patient, or the patient's representatives. This notification must describe the VISN clinical appeals process (see Att. A).

b. **The Veterans Integrated Service Network (VISN) Director.** The VISN Director, or designee, is responsible for:

(1) Administering an internal clinical appeals process regarding clinical determinations or services that are not resolved at the facility level. ***NOTE:*** *The VISN Director must ensure that the process at each level provides for a fair and impartial review.*

(2) Reviewing clinical appeals and providing a decision to the patient within 30 days after receipt of the appeal request. That time frame may be extended to 45 days, should the VISN request an external clinical review (see subpar. 4b(4)(c)). VHA facilities and VISNs render decisions that are founded on national evidence-based standards. Where there is an absence of a national evidence-based standard for treatment, the local community standard prevails. ***NOTE:*** *VHA operates an external clinical review program that allows for independent review and recommendation regarding clinical appeals by a professional board external to the Agency. VISNs have the authority to request an external review at any time during the clinical appeals process, prior to rendering a final decision.*

(3) Having written policy and procedures in place for how internal clinical appeals are to be handled, including identification of roles and responsibilities, time frames, and requirements for data entry into the national computerized Patient Complaint database.

(4) Conducting a preliminary review upon receipt of a clinical appeal from the patient, or the patient's representative 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 arrange for immediate transfer of the patient to an appropriate setting.

(b) The medical facility had an opportunity to formally address the issue. If the facility has not attempted resolution, the request for review is forwarded back to the facility Director.

(c) Dispute is an appropriate case for the VISN clinical appeals process. ***NOTE:*** *Issues that fall outside the scope of the VISN clinical appeal process (i.e., administrative disputes, other complaints) are referred to the appropriate office or location. This Directive does not impact other appeals processes available to veterans, specifically the reconsideration process and appeals to the Veterans Benefits Administration.*

(5) Requesting documentation and supporting arguments from both the facility and the patient, or as appropriate, the patient's representative once a clinical dispute is accepted as an internal clinical appeal. The VISN either independently reviews the documentation or convenes an impartial VISN clinical panel to review the documentation and make a recommendation. ***NOTE:*** *The VISN can request an independent external review at any time during the process.*

(6) When an independent external review is requested, the clinical record, the statement of appeal, and other relevant documentation and/or information produced by any internal review, must be forwarded to the Office of Quality and Performance (OQP). Upon receipt, OQP arranges for the external review through its contractor for the external peer review program. The

contractor reviews the clinical record and all accompanying documentation, as well as any evidence regarding the relevant practice described in the literature, to determine whether appropriate and/or reasonable and necessary clinical service was provided and/or denied. A final written report, fully documenting the findings and recommendations of the reviewer(s), is provided to the VISN Director within 10 days of the receipt of the full documentation request.

(7) Rendering a written final decision to the patient, or the patient's representative, and the medical facility Director within 30 days after initial receipt of the clinical appeal (see Att. B and Att. C). *NOTE: The time frame for final decision may be extended to 45 days for those clinical appeals undergoing external review.*

(8) Ensuring that the Patient Advocate at the facility enters the clinical appeals into the national computerized Patient Complaint database where the appeal was originated. All details and decisions must be included in the final documentation before the case is closed.

c. **Office of Quality and Performance.** The Office of Quality and Performance Director is responsible for administering VHA's external clinical appeals program using an outside vendor. OQP must ensure that all requests for external review are conducted in a timely and efficient manner.

d. **National Veteran Service and Advocacy Program, VHA Support Service Center.** The National Veteran Service and Advocacy Program Director, VHA Support Service Center, is responsible for providing support for the national computerized Patient Complaint database. *NOTE: The national computerized Patient Complaint database is to be used for documenting clinical appeals and producing reports for the tracking and trending of issues.*

5. REFERENCES: None.

6. FOLLOW-UP RESPONSIBILITY: 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 Director, National Veteran Service and Advocacy Program at 518-626-5673.

7. RESCISSIONS: VHA Directive 2001-033 is rescinded. This VHA Directive expires October 31, 2011.

Michael J. Kussman, MD, MS, MACP
Acting Under Secretary for Health

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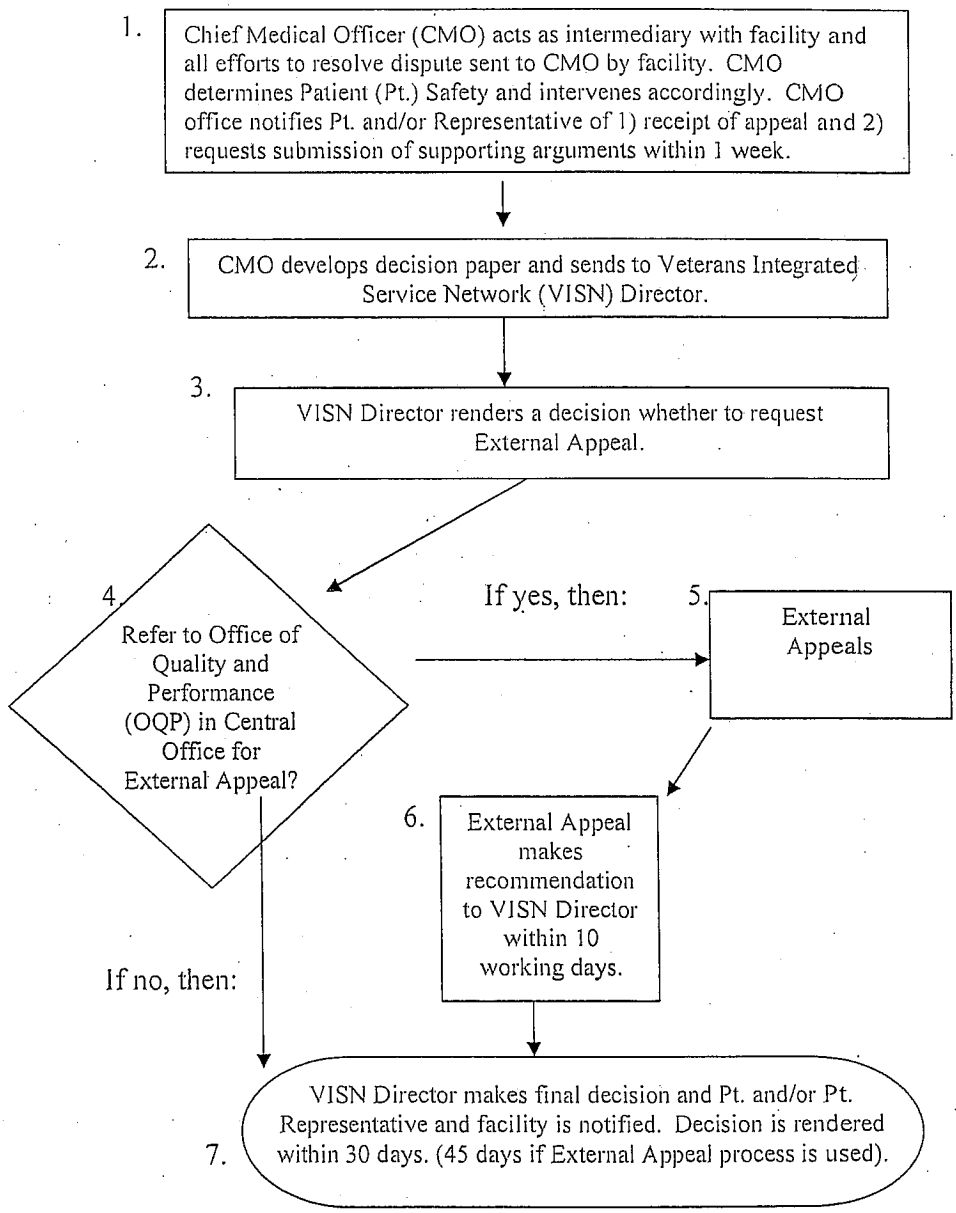
ATTACHMENT A

SAMPLE CLINICAL APPEALS PROCESS



ATTACHMENT B

SAMPLE EXECUTIVE DECISION MEMO

FACILITY:

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

THRU:

FROM: Chief Medical Officer ( )

SUBJ:

PREPARED BY:

1. **For Further Information Contact:**

2. **Action Requested:**

_____ Request for approval

_____ Request for discussion or further review

_____ 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.

APPROVED/DISAPPROVED

_____

_____ _____
Name of VISN Director
(Date)

VISN Director, VISN _____

ATTACHMENT C

SAMPLE 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 (one to three 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 OR LEGISLATIVE CONSIDERATIONS OF THE RECOMMENDED OPTION: A brief discussion of any legal or legislative issues, concerns, or considerations stemming from the recommended action.

11. BUDGET OR FINANCIAL CONSIDERATIONS OF THE RECOMMENDED OPTION: A discussion of any costs and/or financial or budgetary effects of the recommended action including the present availability of any needed resources. *NOTE: No decision will be based solely on budgetary effects.*

12. PUBLIC RELATIONS OR MEDIA CONSIDERATIONS OF THE RECOMMENDED OPTION: A discussion of any potential public relations or media problems, opportunities, etc., raised by the recommended action.

13. CONGRESSIONAL OR OTHER PUBLIC OFFICIAL OR AGENCY CONSIDERATIONS OF THE RECOMMENDED OPTION: A discussion of any congressional and/or other public official/agency notification or involvement considerations raised by the recommended action.

14. 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.

15. 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.