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United States Government Accountability Office
Washington, DC 20548

August 24, 2012

The Honorable Patty Murray
Chairman
Committee on Veterans' Affairs
United States Senate

The Honorable Bob Filner
Ranking Member
Committee on Veterans' Affairs
House of Representatives

Subject: *Veterans Health Care: Veterans Health Administration Processes for Responding to Reported Adverse Events*

The Department of Veterans Affairs' (VA) Veterans Health Administration (VHA) operates one of the largest health care delivery systems in the United States, providing care to more than 6 million veterans annually. Organized into 21 Veterans Integrated Service Networks, VHA's health care system includes 152 Veterans Affairs medical centers (VAMC) nationwide that offer a variety of outpatient, residential, and inpatient services.[1] These health care services are delivered by physicians, dentists, and other providers and range from routine examinations to complex surgical procedures.

During the course of providing health care services, adverse events[2]—clinical incidents that may pose the risk of injury to a patient as the result of a medical intervention or lack of an appropriate intervention, such as a missed or delayed diagnosis, rather than that patient's underlying medical condition[3]—may occur, resulting in potential harm to veterans. They are required to be reported to appropriate VAMC staff through each facility's incident reporting system,[4] or through

[1]In addition, VHA provides outpatient care at more than 800 community-based outpatient clinics.

[2]For the purposes of this report, the term "adverse event" includes "close calls." A close call is an event that could have the potential to result in an adverse event, but did not due to chance or timely intervention. Close calls receive the same level of scrutiny as adverse events that result in actual patient injury. Adverse events may or may not be attributable to an error made by a clinician, such as falls unrelated to patient care.

[3]An example of an adverse event is the improper sterilization of medical equipment that was reported at a VAMC, which led to veterans potentially being exposed to infectious diseases. VHA also responds to incidents in addition to adverse events, such as incidences of reported thefts or conflicts between employees. Such incidences are not considered adverse events and are not the subject of this report.

[4]Each VAMC maintains its own incident reporting system, which is used by VAMC staff to report information on adverse events.

other channels, such as anonymous phone calls or e-mails to VAMC staff, such as the patient safety manager or risk manager, according to officials.[5] VHA policy requires that appropriate action be taken to evaluate reported adverse events.[6] Once an adverse event has been evaluated, the VAMC may take actions that include correcting system or process issues and taking actions against individual clinicians when warranted. Specifically, actions taken against individual clinicians following adverse events may include adverse actions—ranging from admonishments[7] to termination of employment; as well as actions taken to limit a clinician's clinical privileges, such as the reduction or revocation of privileges.[8] Staff remediation activities, such as refresher training and proctoring, can be employed when adverse actions or limiting a clinician's privileges are not deemed necessary.

Recent adverse events have raised questions about the quality of care provided to veterans by VAMCs, and whether lessons learned at one VAMC are being translated into systemwide improvements. In response, members of Congress have raised questions as to the processes VHA has in place to respond to adverse events at VAMCs and take appropriate action, when needed, to address problems found within the VHA health care system. You asked us to describe how VHA responds to reported adverse events within its health care system. In this report, we describe VHA's processes for responding to reported adverse events within its health care system. In future work, we will examine the implementation of these processes at VAMCs. To describe VHA's processes for responding to reported adverse events, we reviewed and analyzed documentation that contains policy and guidance for these processes,[9] including VA and VHA directives and handbooks. Specifically, we examined processes that enable VAMCs to determine the cause of an adverse event and assessed the characteristics of these processes. We also reviewed VHA's processes for taking action to help prevent an adverse event from recurring, such as correcting process or system deficiencies, using remediation approaches such as retraining and proctoring, and taking adverse actions against clinicians responsible for an adverse event. We also interviewed officials from VHA's Office of Quality,

[5]When an adverse event results in serious injury or death, or is reasonably expected to result in serious injury, VAMCs are required to disclose the event to the affected veteran or their representative through a formal process known as institutional disclosure. Institutional disclosure is generally carried out by a member of the VAMC's leadership and involves providing the veteran or their representative with information on how to seek compensation. For adverse events that cause less significant harm, VAMCs are required to disclose the event to the affected veteran or his or her representative through an informal process known as clinical disclosure.

[6]In addition to identifying and reporting adverse events, VAMCs have a quality management program in place that allows them to identify and respond to other quality-of-care issues that may not rise to the level of an adverse event.

[7]An admonishment is a written statement of censure given to an employee for a minor act of misconduct, such as repeated tardiness.

[8]Clinical privileges refer to authority granted to a clinician by a VAMC to provide patient care in the facility. Such privileges are limited by the individual clinician's license, experience, and competence. Some clinicians are VA employees, who may be employed on a full-time or part-time basis under permanent or temporary appointments, and others are contractors. Actions taken against individual clinicians may vary based on the employment status of the clinician. For example, for possible incompetence or professional misconduct by a contractor, VA may terminate the contract, thereby automatically revoking the contractor's medical staff appointment and clinical privileges, rather than taking adverse action or privileging action as can be done in cases of potential misconduct for employees.

[9]Both VA and VHA handbooks and directives contain policies and guidance regarding the processes for addressing an adverse event.

Safety, and Value, about issues related to quality, safety, and risk management and adverse actions.[10] Our review was limited to VHA physicians and dentists, hereafter referred to as clinicians, as they are the primary types of licensed clinicians[11] that practice independently at VAMCs. Furthermore, our review was limited to describing VHA's processes for responding to adverse events, rather than all quality-of-care issues, such as those that did not rise to the level of an adverse event.

We conducted this performance audit from April 2012 through August 2012 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

VHA Generally Allows VAMCs Discretion in Responding to Reported Adverse Events

Through its policy and guidance, VHA has outlined processes that enable VAMCs to respond to reported adverse events that occur.[12] VHA generally grants individual VAMCs discretion on choosing which process to use. Specifically, VAMCs conduct an initial review to determine how best to respond to an adverse event. According to VHA officials, if the circumstances that led to an adverse event are clear, based on a VAMC's initial review, VAMCs can take immediate corrective action. If the circumstances that led to an adverse event need to be examined further, VAMCs are given discretion to use one or more of the following four processes: (1) root cause analysis, (2) peer review, (3) clinical care review, and (4) administrative investigation board.[13] Because VAMCs generally have discretion in which of these processes they use, different VAMCs that experience similar adverse events may not use the same processes to respond to them. Nonetheless, each process has certain purposes and limitations. For example, some of these processes may be used to examine a clinician's actions as they relate to an adverse event, while others may be used to examine whether a systems or process issue exists. Furthermore, information collected through two of these processes—clinical care reviews and administrative investigation boards—can be used to inform actions against clinicians; information collected using root cause analyses and peer reviews cannot be used to support such actions, because information collected under those processes is protected and

[10]The Office of Quality, Safety, and Value is charged with enhancing the quality, safety, reliability, and value of clinical and business systems throughout VA by enabling enterprisewide approaches to compliance, risk awareness, and continuous improvement.

[11]VA requires its physicians and dentists to possess at least one full, active, current, and unrestricted license to practice medicine or dentistry with limited exceptions, such as a state license limited on the basis of not meeting state residence requirements or a state-granted institutional license permitting full, unrestricted clinical practice at a specific VA health care facility.

[12]We use the term "processes" to refer to all policies, procedures, and processes governing VHA's response to reported adverse events.

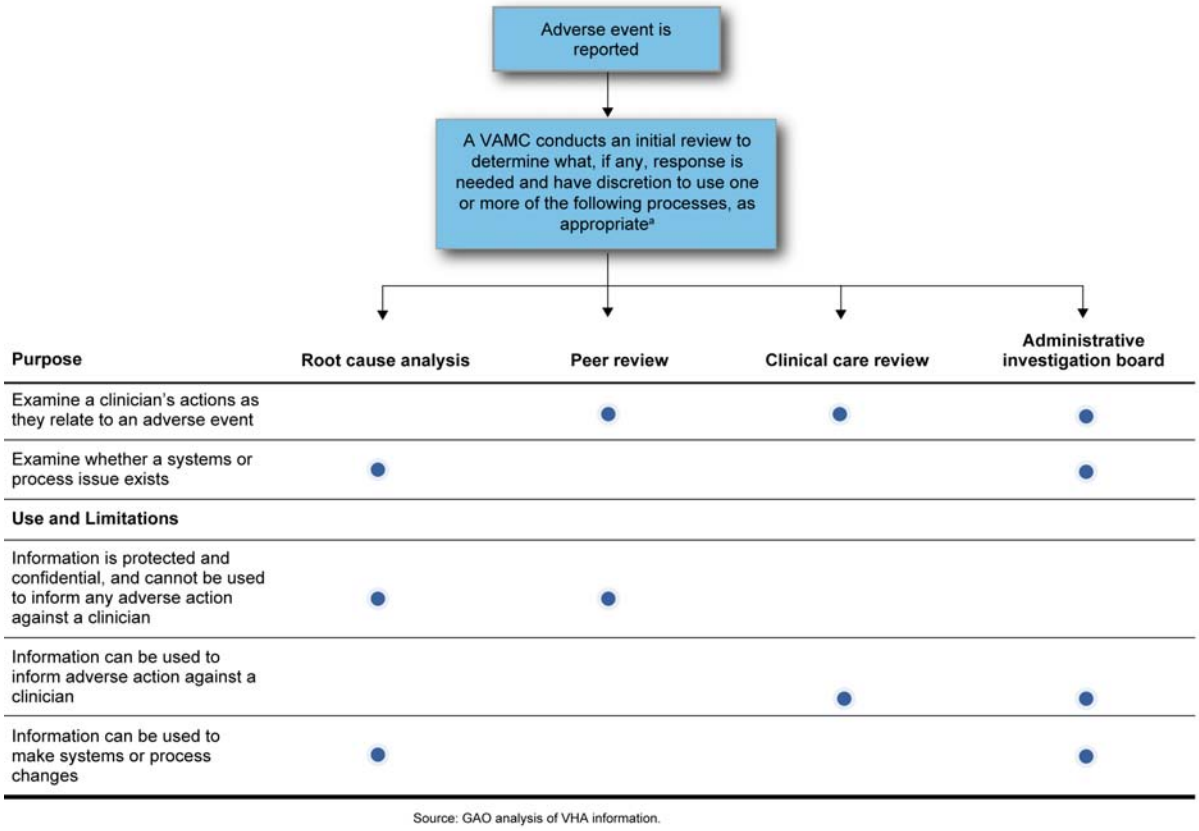
[13]Additionally, in certain cases, such as when a veteran files a complaint to VA's Office of Inspector General or VHA's Office of the Medical Inspector, either of these entities may decide to independently investigate the adverse event.

confidential, under federal law.[14] Based on the nature of an adverse event and the information gleaned through a particular review process, a VAMC may decide to conduct multiple types of reviews, as appropriate.[15] Figure 1 shows VHA's four processes for responding to reported adverse events.

[14]Under federal law, records and documents created as part of VHA's medical quality assurance program are confidential and privileged and may only be disclosed under limited circumstances. See 38 U.S.C. § 5705; 38 C.F.R. §§ 17.500-17.511. VHA's medical quality assurance program consists of systematic healthcare reviews carried out by or for VHA for the purposes of improving the quality of medical care or improving the utilization of healthcare resources in VHA medical facilities. The root cause analysis and peer review processes are part of VHA's medical quality assurance program, and as such, documents generated through these processes are confidential and privileged. 38 U.S.C. § 5705 was enacted out of concern that, unless clinicians could be assured that their remarks and assessments about possible problems with the healthcare services they deliver or one of their peers delivers to patients would be kept confidential, the necessary level of candor would be lost. Additionally, if the negative results from quality assurance activities were publicly available, the clinicians under review may be guarded or uncooperative during the review process. See 126 Cong. Rec. S10918 (Aug. 6, 1980) (excerpting S. Rep. No. 96-876).

[15]For example, a VAMC may decide to conduct an administrative investigation board and a root cause analysis in response to an adverse event to examine both a clinician's actions and to examine whether a systems or process issue exists.

Figure 1: VHA's Processes for Responding to Reported Adverse Events at VAMCs



Purpose	Root cause analysis	Peer review	Clinical care review	Administrative investigation board
Examine a clinician's actions as they relate to an adverse event		●	●	●
Examine whether a systems or process issue exists	●			●
Use and Limitations				
Information is protected and confidential, and cannot be used to inform any adverse action against a clinician	●	●		
Information can be used to inform adverse action against a clinician			●	●
Information can be used to make systems or process changes	●			●

Source: GAO analysis of VHA information.

[a]If the circumstances that led to an adverse event are clear, based on a VAMC's initial review, VAMCs can take immediate corrective action, without using any of these processes.

Root cause analysis. If the VAMC's initial review of an adverse event finds that there is a risk to the safety of veterans, a root cause analysis may be required by VHA policy. To determine if a root cause analysis is required, the patient safety manager[16] evaluates the event using VHA's "safety assessment code matrix." This scoring tool measures safety risk based on the severity of an adverse event and its likelihood of occurrence on a scale of one (lowest risk) to three (highest risk). For example, an adverse event with a score of three is one that has the potential to result in death or permanent loss of function regardless of its likelihood of occurrence.[17] As directed by VHA policy, adverse events with a score of three always require a root cause analysis, either individual or aggregated.[18]

[16]Each VAMC has a patient safety manager whose responsibilities include facilitating the root cause analysis process.

[17]An example of an adverse event with a score of two is one that has the potential to result in the permanent impairment of a bodily function which may occur occasionally—that is, several times over a 1- to 2-year period. An example of an adverse event with a score of one is one that has the potential to result in an increased length of stay for a veteran, which may occur occasionally.

[18]An aggregated root cause analysis collects information from multiple similar adverse events to conduct a single root cause analysis. An aggregated root cause analysis is required with several types of incidents: patient falls, adverse drug events, and missing patients. When not required, VAMCs have discretion to conduct aggregated root cause analyses for adverse events that receive a score of one or two.

To conduct a root cause analysis, a VAMC director convenes a multidisciplinary team, which includes appropriate subject matter experts from the VAMC, such as clinicians and quality management staff. The team attempts to identify the systemic causes for an adverse event by determining what factors contributed to the event and why those factors occurred. Furthermore, the team identifies changes that could be made in systems and processes, such as through the development of new processes that would improve performance and reduce the risk of the adverse event recurring. For example, in a case that identified the root causes of a VAMC's failure to properly sterilize a piece of reusable medical equipment, a root cause analysis was used to examine whether instructions for cleaning the equipment were clear, whether sufficient training was provided to staff, and to develop steps to address these root causes.

Information gleaned through a root cause analysis may be used to make systems or process changes within a specific VAMC or VHA's health care system more broadly. The details of a root cause analysis are protected and confidential under federal law, meaning that they are protected from disclosure within and outside of VHA and cannot be used to take any adverse action or privileging action against clinicians.[19] According to officials, the lessons learned from the root cause analysis process may be used to provide lessons to the larger healthcare system.

Peer review. If the VAMC's initial review or a root cause analysis finds there is a need to determine whether a clinician's actions associated with an adverse event were clinically appropriate—that is, whether another clinician with similar expertise would have taken similar action—a VAMC may initiate a peer review.[20]

During a peer review, the peer reviewer—a clinician or group of clinicians with similar expertise to the clinician involved in the incident being reviewed—evaluates the actions of the clinician under review to make an initial determination of whether the clinician should have taken different action when providing patient care. At the conclusion of this evaluation, the peer reviewer preliminarily rates the clinician's actions as one of the following:

- Level 1, at which the most experienced, competent clinician would have managed the case in a similar manner;
- Level 2, at which the most experienced, competent clinician might have managed the case differently; or
- Level 3, at which the most experienced, competent clinician would have managed the case differently.

[19]38 U.S.C. § 5705; 38 C.F.R. §§ 17.500-17.511.

[20]While VHA policy requires that peer reviews be considered under certain circumstances, such as when a VAMC becomes aware of a veteran's death, each VAMC maintains a facility-specific peer review policy that describes the specific circumstances under which a peer review is to be considered or required.

If the peer reviewer initially rates the clinician's actions at Level 2 or 3, the clinician's case is referred to the VAMC's peer review committee—a multidisciplinary group of clinicians and/or other clinical staff members, such as nurses—which reviews the clinician's actions. Clinicians under review are given the opportunity to appear before the peer review committee or submit written comments to explain their actions. The peer review committee either validates the initial rating or assigns a higher or lower final rating of Level 1, 2, or 3.[21] The final rating is reported to the clinician's supervisor and, when appropriate, the VAMC director. The clinician's supervisor provides the clinician feedback based on the peer review committee's findings. According to officials, clinicians may be offered training to help them improve clinical proficiency, as determined to be appropriate by the supervisor. However, as is the case for root cause analyses, information obtained through peer reviews is protected and confidential and cannot be used to inform an adverse action or privileging action against a clinician.

Clinical care review. According to VHA officials, if the initial review finds there is a need to determine whether a clinician's actions associated with an adverse event were clinically appropriate, VAMCs have discretion to conduct a clinical care review. Through a clinical care review, a clinician's competency—his or her ability to provide an appropriate standard of care—is reviewed, to determine what type of action, if any, should be taken.[22] In addition, the peer review process can trigger a subsequent clinical care review. Each VAMC is required by VHA to establish its own criteria for review, such as triggers—that is, the number of Level 1, 2, and 3 peer reviews pertaining to an individual clinician over the course of a designated period of time that result in a clinical care review. For example, at one VAMC, three Level 3 peer reviews within a 6-month period would trigger a clinical care review.

According to VHA officials, to the extent that concerns about a clinician's competency are verified through a clinical care review, VAMCs may decide to initiate a focused professional practice evaluation or pursue privileging action[23] against the clinician. According to VHA officials, through a focused professional practice evaluation, a clinician is given an opportunity to improve his or her clinical competence over a period of time as determined by the VAMC director. At the discretion of the VAMC director, this evaluation can include progressive training or proctoring aimed at helping the clinician improve clinical competence.[24] Should

[21]VHA policy also requires the peer review committee to provide a secondary review of a representative sample of Level 1 peer reviews as a way to evaluate the peer review process in general.

[22]Each VAMC determines under which circumstances a clinical care review is appropriate and how it is to be conducted. For example, during a clinical care review, a clinician's supervisor may select a number of cases to review to help determine whether the clinician provided an appropriate standard of care.

[23]The VAMC director is the final authority for all privileging decisions. This decision must be based on the recommendations of the appropriate service chief(s), chief of staff, and/or the Executive Committee of the Medical Staff. Clinicians are given the right to reply to a proposed privileging action prior to a final action. Once the VAMC director makes a final determination on a privileging action, the clinician is entitled to a fair hearing by a panel of peers. If a privileging action is sustained following a fair hearing, clinicians have the right to appeal the decision to the network director, who may ultimately sustain or reverse the privileging action. In addition, adverse action, such as termination of employment, may be taken in conjunction with, or instead of privileging action, depending on the nature of the adverse event.

[24]Proctoring refers to an objective evaluation of a clinician's clinical competence by a peer.

concerns about clinical competence remain at the conclusion of a focused professional practice evaluation, a VAMC may then pursue privileging action against the clinician. VA policy affords clinicians due process prior to any privileging action. VAMCs are required to report physicians and dentists whose privileges are reduced, revoked, or surrendered while under investigation to the National Practitioner Data Bank,[25] which tracks information including privileging actions, as well as to report to appropriate state licensing boards, which may use this information to take action against the clinicians' medical licenses, including revoking, restricting, or suspending the license.[26]

Administrative investigation board. If the initial review finds that an investigation is warranted to determine whether an adverse event was the result of a clinician's professional misconduct or potential systemic deficiencies related to VHA policies or procedures, a VAMC director may convene an administrative investigation board.[27] A VAMC director also may choose to convene an administrative investigation board if a root cause analysis or peer review indicates an adverse event may have been the result of a clinician's professional misconduct. If this occurs, any ongoing root cause analysis or peer review is terminated or suspended until the administrative investigation board is concluded. Furthermore, the same individuals involved in conducting a root cause analysis or peer review may not be members of administrative investigation boards examining the same issues. Because any information collected through a root cause analysis or peer review is protected and confidential under federal law and cannot be used to take adverse action, information must be recollected when convening an administrative investigation board—that is, the board cannot use information collected and reviewed during the root cause analysis or peer review in its investigation.

Once an administrative investigation board is convened, it collects and analyzes evidence, such as sworn witness testimony and documentation, related to the allegation under investigation. Additionally, the board may obtain all available documents, records, and other information that are material to the scope of the investigation, including VHA policies, employee personnel records, and e-mail correspondence.[28] The board analyzes the collected evidence and develops the findings and conclusions of the investigation, including whether any allegations investigated were substantiated.

[25]The National Practitioner Data Bank is an information clearinghouse that collects and releases all licensure actions or other negative actions taken against clinicians, including malpractice payments.

[26]If a clinician resigns or retires prior to privileging action being taken, VHA policy requires that he or she be reported to the National Practitioner Data Bank and appropriate state licensing boards.

[27]Administrative investigation boards also may be convened by authorities senior to a VAMC director within the network or VHA. Administrative investigation boards also are used to investigate matters besides adverse events, such as allegations of wrongdoing that involve nonclinical matters or matters involving potential systems deficiencies related to a VHA policy or procedure. See GAO, *VA Administrative Investigations: Improvements Needed in Collecting and Sharing Information*, GAO-12-483 (Washington, D.C.: Apr. 30, 2012).

[28]Some information relevant to an investigation, such as patient medical records, may not be available to the board, or may be subject to specific restrictions on disclosure or use.

The board documents results—evidence, findings, conclusions, and any recommendations—in an investigation report that is forwarded to the VAMC director, who reviews the report to verify that the board sufficiently investigated the matter.[29] The VAMC director may accept the report or may ask the board to further investigate the matter, clarify the information in the investigation report, or both. VA considers an investigation to be complete once the VAMC director certifies the investigation report.

VAMC directors may use administrative investigation boards' findings to inform their decisions of whether to take adverse action against a clinician and, if so, which type of action to pursue.[30] Although VA policy provides guidance on the type of adverse action that should be taken in the case of certain offenses, the VAMC director has discretion over what adverse action, if any, to pursue. If adverse action is taken against a clinician, a standardized process for taking such action must be followed, which is defined by VA policy and is dependent on the type of action being taken. In addition to, or instead of, taking adverse action against an individual clinician, action may be taken to address systemic deficiencies related to policy or procedure found to have contributed to adverse events identified through an administrative investigation board. Furthermore, a VAMC director may decide to take nonadverse action, such as counseling or training, to expand a clinician's knowledge about VHA policies and procedures or clinical standards.

Agency Comments

VA provided us with comments on a draft of this report, which we have reprinted in enclosure I. In its comments, VA expressed concerns about specific language in the draft report that the department believed was either incomplete or could mislead the reader, and provided technical comments to address its concerns. We maintain that the draft report accurately described VHA's processes for responding to reported adverse events as explicitly described in VA and VHA policies and communicated to us by VHA officials. We have incorporated VA's technical comments as appropriate. However, because these technical comments did not require material changes to the draft report, we did not reprint them.

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We are sending copies of this report to the Secretary of Veterans Affairs and interested congressional committees. In addition, the report is available at no charge on the GAO website at http://www.gao.gov.

[29]Upon convening an administrative investigation board, the VAMC director may authorize the board to provide recommendations for corrective actions. However, the board is prohibited from recommending a specific level or type of adverse action, such as termination or suspension. Although an administrative investigation board may provide recommendations for corrective actions, the VAMC director is not required to implement them.

[30]Although an administrative investigation board's findings may be used by a VAMC director to inform adverse actions, the board is not involved in determining such actions.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or draperd@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff members who made key contributions to this report are listed in enclosure II.

Debra A. Draper
Director, Health Care

Enclosures – 2

Enclosure I

Comments from the Department of Veterans Affairs

DEPARTMENT OF VETERANS AFFAIRS
Washington DC 20420

August 1, 2012

Ms. Debra A. Draper
Director, Health Care
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Ms. Draper:

The Department of Veterans Affairs (VA) has reviewed the Government Accountability Office's (GAO) draft report, ***"VETERANS HEALTH CARE: Veterans Health Administration Process for Responding to Reported Adverse Events"*** (GAO-12-827R).

As described in the draft report, the Veterans Health Administration (VHA) has developed and implemented robust processes to ensure that Veterans receive the highest quality health care in environments that are as safe as possible. These processes include reporting and addressing adverse events when they occur. These processes are complicated to ensure that they are comprehensive.

To ensure the delivery of the highest level of care for Veterans, VA must ensure both individual issues and systemic problems are identified and addressed. VHA quality and safety processes are intended to address systematic change wherever it is needed.

While VA appreciates GAO's effort to describe these complex processes and how they work, VA has concerns with specific language in the draft report. VA believes the current portrayal of information in a number of areas is either incomplete or could mislead the reader. The enclosure specifically addresses particular concerns and provides extensive technical comments on the draft report.

VA requests full incorporation of the recommended technical changes in order to ensure an accurate and reliable report. VA representatives are available to assist in further clarification of these issues upon request. Please contact Ms. Denese Canedo, at denese.canedo@va.gov or (202) 461-5684, should you have any further questions or desire to discuss these recommended technical changes.

VA appreciates the opportunity to comment on your draft report.

Sincerely,

John R. Gingrich
Chief of Staff

Enclosure

Enclosure II

GAO Contact and Staff Acknowledgments

GAO Contact

Debra A. Draper, (202) 512-7114 or draperd@gao.gov

Staff Acknowledgments

In addition to the contact named above, Mary Ann Curran, Assistant Director; Jennie Apter; Ashley Dixon; Kaitlin McConnell; Lisa Motley; and Michael Zose made key contributions to this report.

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