



Doctor's docket

Special doctor's docket: discovery of patient safety materials in the Veterans Affairs system

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1. Facts

On September 10, 2003, Mr B was scheduled to undergo a surgical procedure to repair an anal fistula at the Veterans Affairs (VA) Medical Center. Resident Dr S was the anesthesiologist and an employee of the VA. Mr B was taken to an operating room and administered 2 mg of Versed (Roche Laboratories, Nutley, NJ). After the administration of Versed, Mr B became agitated and experienced obvious troubled ventilation. Several attempts were made to intubate Mr B by Dr S. During the failed attempts to intubate Mr B, his arterial oxygen percentage of saturation failed to register on the oxygen monitors. Chest compressions were then performed on Mr B for approximately 10 minutes. Ultimately, an emergency tracheotomy was performed. However, as a result of the multiple failed attempts to intubate Mr B and the management of his anesthesia, Mr B had cardiac arrest and significant hypoxia, lasting between 10 and 20 minutes. As a result, Mr B had a disabling brain injury.

Mr B's estate sued the US government, the VA Medical Center owner and operator, in federal court under the Federal Tort Claims Act, which applies to liability claims against the US government. In the suit, Mr B's estate requested discovery of a wide array of materials, including root cause analysis of the case, earlier peer review of Dr S, morbidity and mortality reviews, anesthesiology quality assurance control drug

records, and a patient safety report by an operating room (OR) nurse.

The US government responded that all documents relating to the root cause analysis of the case, peer review, morbidity and mortality reviews, anesthesiology quality assurance control drug records, and patient safety reports were covered by the VA statutory quality assurance privilege against discovery. The US government hence refused to disclose the documents. The plaintiffs disputed the applicability of the privilege.

2. Legal analysis

The federal court concluded that the VA privilege law did not apply to any documents except the patient safety report, and hence, all other requested materials must be disclosed by the US government [*Bethel vs United States ex rel VA Medical Center of Denver, CO, 242 FRD 580 (D. Colo 2007)*].

Legal discovery in the federal courts is governed by the federal rules of civil procedure. The court noted that where there is a claim that a discovery request should be denied based on a privilege, it must determine whether federal or state law governs the existence of the claimed privilege. In this case, federal law governs the application of privileges brought under the Federal Tort Claims Act.

The United States, as the party asserting the VA quality assurance privilege, had the burden to show that the privilege applied. The court noted that discovery established by the federal rules of civil procedure expresses a policy favoring

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full disclosure and privileges are disfavored because they are “in derogation of the search for the truth” and thus are “not lightly created nor expansively construed.”

The court then reviewed the specific privilege law claimed by the US government. The law, section 5705, title 38 of the US code, establishes a statutory privilege for documents created by or for the VA as part of a medical quality assurance program. The statute defines a “medical quality assurance program” as a “department systemic health care review activity designated by the secretary to be carried out by or for the department for either [improving the quality of medical care or improving the utilization of health care facilities].” The court pointed to regulations that defined categories of quality assurance reviews subject to the privilege:

- (1) “Monitoring and evaluation reviews conducted by a facility,”
- (2) “Focused reviews that address specific issues or incidents and that are designated by the reviewing office at the outset of the review as protected by [the VA quality assurance statute and regulations];”
- (3) “VA central office or regional general oversight reviews to assess facility compliance with VA program requirements if the reviews are designated by the reviewing office at the outset of the review as protected by [the VA quality assurance statute and regulations];”
- (4) “Contracted external reviews of care, specifically designated in the contract or agreement as reviews protected by [the VA quality assurance statute and regulations].”

“The court noted that for any quality assurance review to be subjected to the privilege, it must also comply with regulatory requirements, which note that:

The undersecretary for health, regional director, or facility director will describe in advance in writing those quality assurance activities included under the classes of health care quality assurance reviews listed... Only documents and parts of documents resulting from those activities which have been so described are protected... If an activity is not described in a VA central office or regional policy document, this requirement may be satisfied at the facility level by description in advance of the activity and its designation as protected in the facility quality assurance plan or other policy document.”

In this case, the US government relied on VHA directive 2002-043 titled quality management (QM) and patient safety activities that can generate confidential documents as the writing prepared in advance satisfying the regulatory requirements. The directive authorized review categories under the VA privilege, including:

- (1) “Monitoring and evaluation reviews,” which include “tort claim peer reviews,” “morbidity and mortality

reviews,” “drug usage evaluation,” and “adverse event and close call reporting”;

- (2) “Focused reviews,” which address specific issues or incidents and may take the form of a root cause analysis;
- (3) “General oversight reviews;”
- (4) “External, clinically-oriented reviews;” and
- (5) “Clinical education program accreditation reviews.”

The court then began its assessment of the specific documents in the case. It first addressed documents claimed to be root cause analysis-related and hence subject to privilege as a focused review. The court concluded that no documents associated with the root cause analysis were subject to privilege protection. It emphasized that a focused review must be “designated by the reviewing office at the outset of the review as protected...” It observed that no information was provided by the US government that demonstrated that a root cause analysis has been so designated in this case, or established that the reviewing office designated the root cause analysis as protected under the privilege “at the outset of the review.”

The court then addressed the documents that the US government withheld on the basis that they were privileged as peer review. It concluded that these documents were also not protected. The court began by noting that the directive recognizes tort claim peer reviews as a privileged quality assurance activity. A *tort claim peer review* is defined as “the review of the care provided in cases in which malpractice claims have been filed to identify, evaluate, and, where appropriate, correct circumstances having the potential to adversely affect the delivery of care.” However, the court noted that in this case, documents claimed by the US government as privileged did not qualify as a tort claim peer review. Plaintiffs were requesting documents regarding peer review of Dr S that were prepared before any malpractice claim was filed. Hence, as a matter of law, they were not subject to the tort claim peer review protection under the VA privilege.

The court then turned to the documents the US government claimed were privileged as morbidity and mortality reviews. The directive defined a morbidity and mortality review as:

discussions among clinicians of the care provided to individual patients who died or experienced complications... Activities which involve preliminary reviews of care to provide material for consideration at Morbidity and Mortality Conferences are included [within the privilege]. If non-VA practitioners from affiliated facilities attend Morbidity and Mortality Conferences, there needs to be prior written designation of the role of these individuals if documents from these conferences are to be confidential. In addition, [the privilege law] bars access to non-VA personnel to VA medical records or other documents identifying individual VA patients unless the identifying information has been deleted.

The court then rejected the US government’s claims of VA privilege as morbidity and mortality review. The specific

case documents at issue were those described as “anesthesiology morbidity and mortality review sheet[s].”

The court noted that the US government indicated that the intended recipients of these review sheets included (1) VA general counsel and regional counsel staff; (2) VA Medical Center leadership; (3) QM staff; (4) medical staff personnel; (5) Professional Standards board members; and (6) university hospital anesthesia staff at Morbidity and Mortality Conference. The court found that because the review sheets were intended to be distributed to lawyers and university hospital staff, who are non-VA personnel, and that there was no indication that the US government complied with the “prior written designation” requirement, the US government failed to demonstrate that the privilege applied.

The US government also attempted to withhold documents under a claim that they were anesthesiology quality assurance control drug records subject to the VA privilege. The court also rejected these claims.

The directive indicates that drug usage evaluations are a privileged quality assurance activity and defined these evaluations as:

[R]eviews to assess the safety, appropriateness, and effectiveness of drugs prescribed by physicians. The dose, route, and time schedule chosen are often reviewed, as well as the drug selected. Adverse drug event reports are included.

The US government indicated that these documents intended recipients were “VA general counsel and regional counsel staff, VA Medical Center leadership, QM staff, medical staff personnel, [and] Professional Standards board members.”

The court indicated the documents in question were not drug usage evaluations subject to the privilege. It noted that there was no indication that the documents concerned drug dosage, routing, or schedule of use, nor any evaluation of the drugs selected, and it expressed skepticism that the documents were covered by the privilege when “documents purportedly prepared to ‘assess safety, appropriateness, and effectiveness of drugs prescribed’ are sent to lawyers.” The court also noted that the plaintiffs stated, without objection by the US government, that no one in the OR “contemporaneously documented the amounts and identity of the medications administered” to Mr B, and hence, it was unlikely that documents covered by the drug usage evaluation privilege were involved in this case when there were in fact no records of the drugs administered.

Finally, the court assessed the US government’s claim that a patient safety report describing the events of Mr B’s surgery made by an OR nurse was privileged. The court concluded that this report was within the quality assurance privilege.

The directive recognizes adverse event and close call reporting as a privileged quality assurance activity. Adverse event and close call reporting is:

the reporting, review, or analysis of incidents involving patients that cause harm or have the potential for causing harm. Employees becoming aware of such incidents report them to the medical center using [the] “report of special incident involving a beneficiary,” or similar forms, and follow-up documents, unless developed during or as a result of a board of investigation, are confidential and privileged.

The court concluded that the patient safety incident report document was an adverse event or close call report within the contemplation of the directive.

The court then ordered the VA to provide plaintiffs with all requested root cause analysis, peer review, morbidity and mortality, and anesthesiology quality assurance control drug records documents.

Commentary

This decision has tremendous implications for anesthesia and patient safety efforts. Generally, in federal courts, traditional civilian cases of malpractice adjudicated therein have little in the way of privilege protection against discovery [1]. The primary privilege asserted there by defendants is the peer review privilege, as is generally the case in state courts. However, federal courts usually reject these claims of privilege because of the federal policy against evidentiary exclusion, as indicated by US Supreme Court precedent [2].

The VA has been an exception to this federal court rejection of privilege in patient injury cases. Under the medical quality assurance privilege law [3], the VA has been granted broad-based quality assurance privilege against discovery requests. Indeed, the VA system has been noted to be a model in part because of its statutory protection that allows it to perform patient safety activities and analysis that in the civilian context would be deemed discoverable in a malpractice suit [4].

However, this protection now seems emasculated. With the extensive safety and quality materials deemed not covered by the federal court in this case, the VA privilege has been significantly limited. Root cause analyses, peer review, morbidity and mortality, and drug evaluation reviews that are now deemed discoverable extend the scope of discovery even beyond what is often nondiscoverable in civilian contexts. Indeed, it is ironic that the only document found by the federal court that was deemed to be within the VA privilege in this case was a patient safety incident report. Yet incident reports in the traditional malpractice suits are generally considered discoverable as documents made in the ordinary course of business [5].

Hence, it is important that other legal avenues be used to ensure that the progress in patient safety is not thwarted on the basis of this case. There is such an avenue. The Patient Safety and Quality Improvement Act of 2005 created broad

privilege for all health care providers engaged in patient safety activities [6]. Through use of a patient safety evaluation system, safety and quality activities are protected, with the protection traveling with the document rather than being subject to requirements associated with a particular forum. Such a uniform regulatory structure for safety and quality materials as applying to government and community providers on the outpatient and inpatient levels would clarify the scope and extent of protections available. This clarity and overarching national set of rules would provide significant incentives to engage in safety and quality efforts.

However, as of yet, final regulations have not been written, despite broad calls for the law's implementation [7]. It is therefore imperative that health care groups within anesthesia and outside it advocate vociferously for progress on this front in the context of legal cases such as this one that are limiting the ability of good faith providers to analyze and act to promote patient safety. Otherwise, a powerful statute in the effort to promote patient safety may be left unused, and the

legal conclusions in cases such as this one may erode away the incentives and enthusiasms to pursue safety activities.

References

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