

## UNANTICIPATED OUTCOME DISCLOSURES: EVIDENTIARY ISSUES

IF YOU HAVE QUESTIONS REGARDING  
THIS MATTER, PLEASE CONTACT:



**Cynthia Schafer Marietta**  
Partner, Houston  
1401 McKinney Street, Suite 2200  
Houston, Texas 77010.4035  
713.951.5686  
Cynthia.marietta@strasburger.com

### EDITORS

Kathy Darling & David Bain

### HEALTHCARE GROUP

David Andrew Bain  
Virginia A. Barry  
Debra W. Biehle  
Thomas W. Burton  
Renee Chafitz  
Merritt M. Clements  
Joseph F. Coniglio  
Kathryn Midboe Darling  
William Duane Darling  
Rebecca L. Davis  
R. Bradley Fletcher  
Brian G. Hamilton  
John R. Lowry  
Bryan J. Maedgen  
Cynthia Schafer Marietta  
Stuart Miller  
David G. Moore  
Craig H. Myers  
C. Scott Nichols  
Laura Reilly O'Hara  
Jeffrey S. Osgood  
David L. Ovard  
Donald Patrick Owens  
Paul W. Sheldon  
Layne Thompson  
Joseph A. Turano  
Melissa Webb  
Carol D. Williamson  
Ivan Wood  
Kevin M. Wood

It has been almost five years since the Joint Commission on Accreditation for Healthcare Organizations ("JCAHO") issued the "unanticipated outcomes disclosure" standard. This standard, which became effective on July 1, 2001, requires health care organizations to disclose unanticipated adverse outcomes of care and treatment to its patients. Stated in full, the standard requires:

Patients and, when appropriate, the families are informed about the outcomes of care, treatment, and services that have been provided, including unanticipated outcomes.

**2005 COMPREHENSIVE ACCREDITATION MANUAL FOR HOSPITALS: THE OFFICIAL HANDBOOK, Update 3, Standard RI.2.90, *previously numbered*, Standard RI.1.2.2.**

The disclosure standard does not define "unanticipated outcomes" nor does it give instructions on what information should be disclosed to patients or how it should be communicated. Rather, it is JCAHO's intent that each healthcare organization develop its own protocol to effectively implement the standard.

Although the disclosure standard appears benign on its face, it raises a number of legal issues for healthcare organizations. Not surprisingly, this standard has been the subject of much debate and the topic of discussion at healthcare trade industry seminars and in publications. One prevailing concern is the legal and evidentiary implications that disclosure poses in a medical malpractice lawsuit based on the "unanticipated outcome." Healthcare facilities in this situation are confronted with the dilemma of trying to comply with the disclosure standard without jeopardizing their legal defense in a lawsuit. Undoubtedly, if admissible at trial, the content of the information disclosed and how it is communicated could be the pivotal factor between a favorable or unfavorable verdict.

Since the inception of the disclosure standard, and in the wake of the perplexities it has created, federal and state legislative bodies have proposed, amended and/or enacted laws to encourage patient apologies and disclosure, yet provide some evidentiary protection in lawsuits. These laws include provisions in the federal

Patient Safety and Quality and Improvement Act of 2005, Pub. L. No. 109-41, 119 Stat. 424 (2005) (“PSQIA”), and state “apology laws.” Existing state peer review committee privilege laws may provide some relief, as well.

Healthcare organizations should be cognizant of the following concepts and may want to consider integrating their respective state evidentiary protections and privilege laws into their disclosure protocols.

**1. The JCAHO standard requires disclosure of “unanticipated outcomes”; it does not require an admission of liability.**

The JCAHO standard requires the disclosure of “unanticipated outcomes.” It does not reference “error” or mandate an admission of liability. An adverse unanticipated outcome is not necessarily caused by error or even negligence. Simply stated, a bad outcome does not mean negligence occurred. Except for the adverse outcomes that are clearly caused by medical error, most “unanticipated adverse outcomes” require peer review committee investigations, deliberations, and reviews to determine whether a medical error occurred, and more importantly, whether it caused the adverse outcome. More likely than not, at the time when disclosure should be made, an investigation is still pending. Any comment on whether negligence occurred would be nothing more than speculation.

It is feasible to discuss an “unanticipated outcome” without commenting on negligence or making an admission of liability. Designated members of the disclosure team should provide a simple factual explanation about the unanticipated event without discussing fault or blame. The focus then should be directed to the patient’s future treatment plan, if he is not deceased, and any medical monitoring that should be conducted. When, under the circumstances, it may be appropriate to express sympathy and compassion, offer an apology or a kind gesture of assistance, such as reducing the medical bill, team members should be cognizant of their respective state’s apology laws in deciding what approach to take.

The “apology laws” vary from state to state, and not every state is afforded one. In Texas, health care providers may take advantage of a partial “apology law,” as found in TEX. CIV. PRAC. & REM. CODE ANN. §18.061. This statute provides that any communication in the

form of an oral statement, written statement, or gesture, that expresses sympathy or a general sense of benevolence relating to the pain, suffering, or death of an individual is not admissible at trial to prove liability of the communicator; however, any communication that concerns negligence or culpable conduct pertaining to the event at issue is admissible.<sup>7</sup> While this statute encourages expressions of compassion and sympathy, it certainly presents cause to be wary of making apologies that reference negligence or could be construed as an admission of liability. This underscores the need for disclosure team members to plan and prepare in advance what particular information should be disclosed to patients.

**2. *The JCAHO mandated disclosure process should be conducted as a peer review committee process to maintain the protection of evidentiary privilege.***

To date, no court has addressed whether the JCAHO “unanticipated outcomes” disclosure process should be afforded the same privilege and discovery exemptions as a state-recognized peer review committee process. However, it stands to reason that it should, and particularly in Texas and in other states with comparable peer review committee statutes.

In Texas, all records, proceedings, and communications of a peer review committee are considered privileged and exempt from discovery. TEX. OCC. CODE §160.007 (Vernon Pamph. 2005). Texas case law supports the notion that JCAHO surveys and other documents, including hospital committee generated documents used in the JCAHO accreditation process, are considered privileged and protected from discovery under the peer review statutes. *Humana Hosp. Corp. v. Spears-Petersen*, 867 S.W.2d 858 (Tex. App.--San Antonio 1993, orig. proceeding). One Texas court has also acknowledged the peer review statutes confer the privilege on JCAHO mandated quality assurance committee activities, as well. *In re Christus Health Southeast Texas*, No. 09-05-497-CV, slip op., 2006 Tex. App. LEXIS 1050 (Tex.App.—Beaumont Feb. 9, 2006) Presumably, this should include other quality assurance/patient safety activities mandated by JCAHO, such as disclosure of unanticipated adverse outcomes.

As outlined in the PSQIA, when considering the confidentiality/privilege provisions that protect patient safety work product, along with the language in the Texas peer review committee statutes and the analogous case law recognizing the

privileged nature of JCAHO activities, a viable argument can be made to extend the umbrella of the peer review committee privilege to the JCAHO-mandated process requiring disclosure of unanticipated outcomes.

Arguably, submitting/making a disclosure to a patient when mandated to do so by JCAHO should not constitute waiver. For waiver of the privilege to occur, there must be an intent to waive the privilege. The disclosure of an unanticipated outcome without divulging the root cause analysis or the committee's investigations and deliberations, should not give rise to waiver. The question of how to engage in frank discussions with a patient about an unanticipated outcome in a way not to reveal the committee processes, including investigations and deliberations, requires preparation with a distinct plan to adhere to the confidential peer review committee process to maintain the privilege. For now, unless and until a court issues a ruling otherwise, healthcare organization disclosure teams should consider implementing and following confidential peer review committee processes when preparing for and making disclosures, and then documenting and maintaining records of the disclosure.

---

<sup>1</sup> During the Texas legislative session, HB 2306 was proposed in committee, which would purportedly expand the scope of the existing apology law to preclude admissibility of:

. . . any statement, affirmation, gesture or conduct expressing apology, sympathy, commiseration, condolence, compassion, or a general sense of benevolence . . .

The bill remained pending in committee at the close of the session.