

SARS: FDA Announces Recommendations For Blood Donor Suitability And Blood Product Safety In Cases Of Suspected Severe Acute Respiratory Syndrome.

On April 23, 2003 the US Food and Drug Administration (FDA) announced the availability of a guidance document containing the FDA's current recommendations for blood-product safety with respect to suspected cases of Severe Acute Respiratory Syndrome (SARS).

We have placed the FDA's guidance document on our website at <http://www.nursinglaw.com/fdasars.pdf>. It is not copyrighted by the US Government and anyone may download, print and re-distribute it from our website.

The new guidance document and the rest of the FDA's current recommendations on the subject of SARS are available on the FDA's website at <http://www.fda.gov/cber/guidelines.htm>.

The FDA has also indicated that printed copies of its current recommendation documents on the subject of SARS can be obtained by writing to the FDA at:

Office of Communication, Training and Manufacturers Assistance (HFM-40)
Center for Biologics Evaluation and Research (CBER)

Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20852-1448

(Enclose a self-addressed adhesive return address label, the FDA asks.)
1-800-835-4709 or (301) 827-1800

The new guidance document deals with donor assessment, product retrieval and labeling, post-donation lookback investigation, physician notification about potential transfusion-transmitted SARS and notification of state and local health authorities about suspected donor cases of SARS.

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Patient Falls From Wheelchair: Is It Malpractice Or Ordinary Negligence? Court Debates Issues.

The specifics vary widely from state to state, but it is a valid generalization that there are special procedural rules for medical malpractice litigation that sets it apart from garden-variety negligence and other civil court cases.

It is also true across the board that a plaintiff's failure to follow whatever special procedural rules are in place for malpractice cases gives the defendant a trump-card legal-technicality defense.

The Court of Appeal of Louisiana recently set out six factors for the court to weigh in distinguishing medical malpractice from ordinary negligence, in a case where a nursing home resident falls from a wheelchair:

1. The injury is treatment-related or caused by a dereliction of professional skill;

When a caregiver's fault is alleged as the cause of an adverse incident in a nursing home, it may be malpractice, a violation of the nursing home residents' bill of rights, ordinary negligence or none of the above. It makes a big difference which pre-suit formalities the plaintiff must follow. Failing to request a medical review panel is a defense to malpractice liability.

COURT OF APPEAL OF LOUISIANA
May 7, 2003

2. Expert medical evidence is required to determine whether the appropriate standard of care was breached;

3. The act or omission involved an assessment of the patient's condition;

4. The incident occurred in the context of a physician-patient relationship or was within the scope of activities a hospital or other care facility is licensed to perform;

5. The injury occurred because the patient sought treatment;

6. The act or omission was unintentional.

The Court of Appeal asked the local parish court to reconsider exactly what happened, how it happened and what the patient alleged, in light of these six factors. **Pender v. Natchitoches Parish Hosp.**, __ So. 2d __, 2003 WL 21017325 (La. App., May 7, 2003).