Confidentiality: Court Rules When Patient's Name May Be Revealed.

A former patient was suing her rehab facility for negligent handling during treatment which allegedly caused a neck injury.

Her lawyers sought a court order requiring the facility to divulge the name of her roommate who was allegedly present during the events in question. The facility refused, citing Federal and state medical confidentiality laws.

As long as the other patient's medical condition or the nature of her treatment is not indirectly revealed in the process, the patient's name itself is not protected by the medical confidentiality laws.

NEW YORK SUPREME COURT
NEW YORK COUNTY
May 13, 2005

The New York Supreme Court, New York County, ordered the facility to divulge the roommate's name as a potential witness in the lawsuit.

This was a general rehab facility. The court reasoned that the other patient's admission to such a facility, in and of itself, did not indirectly imply anything that was confidential about her medical condition or the treatment she had received.

On the other hand, the court said a different facility, for example "... Cardiac Institute," could never reveal another patient's name as a potential witness, as that would necessarily indirectly reveal the other patient's medical condition in violation of Federal and state medical confidentiality laws. **Rogers v. NYU Hosp. Center, 795 N.Y.S. 2d 438 (N.Y. Super., May 13, 2005).**

Medical Devices, Adverse Event Reporting: FDA Revises Rules.

On June 15, 2005 the US Food and Drug Administration (FDA) adopted in final form, effective July 13, 2005, the revisions of existing rules for reporting of adverse events related to medical devices which were first reported in the Federal Register on February 28, 2005.

According to the FDA, these revisions do not change the substance of existing regulations, but merely express the existing regulations in language that is easier for the public to understand.

The FDA's medical-device reporting regulation revisions announced February 28, 2005 take effect in final form on July 13, 2005.

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The FDA's medical-device adverse-event reporting regulations apply, in part, to hospitals and other healthcare facilities which fall under the FDA's definition of users of medical devices.

These revised rules from the FDA are far too lengthy and complex for summarization.

We have placed the full text of the FDA's February 28, 2005 Federal Register announcement on our website at http://www.nursinglaw.com/medicaldevices.pdf. The rules themselves start at Page 9561 of the announcement. Readers' attention is directed to Subpart C which deals with user-facility reporting.

The FDA's regulations published in the Federal Register are an original US Government work which we cannot copyright. Anyone can download, print and/or redistribute this material from our website.

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Tissue/Cell Donors: New Rules From FDA.

On May 25, 2005 the US Food and Drug Administration (FDA) issued an interim final rule to amend existing FDA regulations regarding the screening and testing of donors of human cells, tissues and cellular and tissue-based products and the associated labeling.

The FDA will accept public comments on the interim final rule until August 23, 2005 and at that time may issue a revised rule in final form.

The FDA's interim final rule takes effect May 25, 2005.

The rule applies to screening and testing of donors of stem/progenitor cells, bone marrow, sperm, ovaries, cytopreserved embryos, etc.

The rule also covers labeling requirements for tissue intended only for autologous use and tissue that has not been tested for infectious agents.

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These new FDA rules are too complex for summarization.

We have placed the full text of the FDA's May 25 Federal Register announcement on our website at http://www.nursinglaw.com/humancells.pdf. Anyone can download, print and/or redistribute the FDA's announcement from our website, as it is an original US Government work which we cannot copyright.

We review the Federal Register daily for pertinent content and will advise our readers of any new developments.

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