FDA Expands Requirements for Tissue Product Safety

The FDA issued a final rule January 19, 2001, requiring establishments that manufacture human cellular or tissue-based products to register their business and list their products with the FDA. The rule is part of a series of three rules proposed as a result of the agency's plan to improve regulation of such products. The other two rules, which have not been finalized, are a proposed rule for donor-suitability requirements and a good tissue practice (GTP) regulation proposed in early January 2001.

Establishments that recover, screen, test, process, store, or distribute human tissue intended for transplantation must begin complying with the rule April 4, 2001. The effective date for all other human cells, tissues, and cellular and tissue-based products is January 19, 2003. The FDA expects the other two proposals to be finalized by then, the rule says.

The proposed regulation on current GTP (GTP covers the methods, facilities, and controls used for the manufacture of all human cellular and tissue-based products and includes adequate organizational structure and sufficient personnel, standard operating procedures for all significant steps in manufacturing, control and validation of manufacturing processes, maintenance of a complaint file, and procedures for tracking the product from donor to recipient and from recipient to donor).

Also under the proposed GTP rule, manufacturers would be required to report adverse reactions and certain product deviations, to have adequate labeling, and to allow FDA inspections. Certain cellular and tissue-based products that require licensing or premarket approval as biological products or medical devices would be subject to more comprehensive requirements based on their risks, the FDA says.

FROM: Food and Drug Administration. Human cells, tissues, and cellular and tissue-based products. Establishment registration and listing. Final rule. *Federal Register* January 19, 2001;66(13):5447-5469. http://www.fda.gov.

JCAHO to Assess Effectiveness of Staffing

On January 11, 2001, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) announced plans to develop a new approach to assessing the effectiveness of staffing in healthcare organizations nationwide. The new process will use performance indicators to screen for potential staffing issues and will be pilot tested during 2001.

The effort is part of JCAHO's continuing commitment to identify and address potential opportunities to improve patient-care quality and patient safety through its accreditation process. Effective staffing has been identified as a current issue of significant concern among healthcare professionals and the public.

The new assessment initiative will draw upon both human resources and clinical outcome measures. Human resources measures will encompass all staff that provide healthcare services, including direct patient caregivers, such as registered nurses and respiratory therapists, as well as clinical-support professionals responsible for pharmacy, laboratory, and radiology services. The approach is designed to emphasize the relation between human resources and clinical outcomes and recognizes that no single measure can reliably describe staffing effectiveness.

Current JCAHO standards require accredited healthcare organizations to determine and provide the right number of qualified and competent staff to meet the needs of patients. These determinations are usually based on internal formulae that reflect numbers of patients and how sick they are.

FROM: JCAHO. Joint Commission to develop a new approach to assessing the effectiveness of staffing in healthcare organizations. www.jcaho.org/news.frm.html.

GAO Report: Needlestick Prevention Devices Are Cost Effective for High-Risk Exposures

In response to a request by Congress to examine the potential cost benefit of needlestick prevention devices, on November 17, 2000, the US General Accounting Office (GAO) reported that needlestick prevention devices are cost-effective. The report showed the cost-effectiveness for postexposure treatment of a moderate- to high-risk exposure if the increased cost of the safety device was medium (2.0 times more costly) to low (1.5 times more costly), compared to a conventional device.

GAO assumes postexposure treatment (ie, tests and treatment for exposure to bloodborne pathogens) costs from $500 to $2,500, and estimates that eliminating 69,000 needlesticks per year would reduce postexposure treatment costs for injured healthcare workers in hospitals by between $37 million and $173 million per year.

They also note that, while only a subset of healthcare workers who suffer needlestick injuries subsequently become infected, adoption of needles with safety features also may reduce costs associated with longer term treatment for those workers. For example, the average annual cost of treating a person with HIV has been estimated at between $20,000 and $24,700 in 1996.

FROM: General Accounting Office. Occupational safety: selected cost and benefit implications of needlestick prevention devices for hospitals. http://www.gao.gov/new.items/d0160r.pdf.

OSHA Revises Bloodborne Pathogen Standard—Mandates Sharps Safety Devices

On January 18, 2001, OSHA published a revision to the Bloodborne Pathogen Standard, to comply with the mandate of the Needlestick Safety and Prevention Act signed by