



# Regulatory Affairs

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Two recent developments are designed to improve the safety of health care workers. The first is federal legislation recently passed by the United States Congress and signed into law by President Clinton. The *Needlestick Safety and Prevention Act* was initially introduced into the House of Representatives (HR 5178) by Cass Ballenger (Republican from North Carolina) and Major Owens (Democrat from New York). A companion bill which mirrored the House legislation was introduced in the Senate (S 3067) by James Jeffords (Republican from Vermont). The Act modifies the current Occupational Safety and Health Administration's (OSHA) bloodborne pathogens standards to require employers to consider and implement the use of "safer medical devices." These devices are described in the law as needles and other medical equipment designed to reduce or eliminate percutaneous injuries of health care workers and thereby decrease the employees' exposure to bloodborne pathogens. In addition, the law requires health care facilities:

- To document and maintain a log of needlestick incidents of all employees
- To identify, evaluate, and introduce the use of safer devices
- To solicit employee input regarding the evaluation and selection of the devices
- To introduce improved training and education programs to familiarize employees with the new legislation, the use of the safer medical devices selected for use within the facilities, and the dangers associated with needlestick injuries and bloodborne pathogens

The Secretary of Labor is required to publish a notice of the new law in the *Federal Register* within 6 months of its enactment (December, 2000) and is afforded an additional 3 months to modify OSHA's cur-

rent bloodborne standards to incorporate these new regulations pertaining to the use of the safer medical devices. Therefore, it is possible that the health care industry in the United States could see the new requirements as early as August, 2001.

The second development includes proposed new regulations designed to reduce potential Hepatitis C (HCV) contamination of the United States blood supply. These new rules were published by the Food & Drug Administration (FDA) and the Health Care Financing Administration (HCFA) in the *Federal Register* on November 16, 2000 (search phrase = Current Good Manufacturing Practices for Blood and Blood Products). The FDA regulations will require all facilities involved in the collection, processing, testing, and administration of blood units (e.g., health care institutions, free-standing blood banks, and plasma facilities) to develop and introduce procedures to ensure the public's safety when blood and blood components are reasonably presumed to contain HCV. Specifically, the facilities will have to quarantine blood and blood components collected from a donor who has been found upon repeated testing to be HCV-positive. In addition, these same health care institutions must make at least three attempts to notify transfusion recipients within 1 year when the HCV-positive status of a donor is discovered at repeat donation. Furthermore, the facilities must inform recipients if an evaluation of its records indicates potential HCV-contaminated units from the donor were used to transfuse patients.

The HCFA proposal would require free-standing blood banks to notify hospitals when they have supplied potentially HCV-contaminated blood and blood products. As in the FDA proposed regulations, the hospitals in turn must quarantine all blood units received from such HCV-infected donors, conduct searches of

their records to determine whether donations from these or other HCV-infected individuals have been previously employed in transfusions, and notify the recipients of the donations when repeated tests of the donors indicate HCV infections. The HCFA proposal would be included in its *Conditions of Participation* under which hospitals receive reimbursement as Medicare/Medicaid providers.

If the proposals are adopted, probably sometime in

2001, facilities which do not meet these requirements will lose FDA's certification as blood banks and HCFA's approval to participate in the Medicare/Medicaid programs.

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