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**OSHA'S FINAL RULE ON
OCCUPATIONAL EXPOSURE TO BLOODBORNE PATHOGENS**

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SUMMARY PAGE

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EXPOSURE TO BLOODBORNE PATHOGENS**

This White Paper discusses the newly promulgated standard governing occupational exposure to bloodborne pathogens. This standard marks the end of a four year rule-making process and represents the first comprehensive and specific OSHA standard to deal expressly with Hepatitis B virus (HBV) and human immunodeficiency virus (HIV) exposure in the workplace. The White Paper describes the standard's scope of coverage, general requirements, and the effective dates of the various provisions. It also highlights particular obligations which employers must now assume with respect to any worker who is potentially the subject of a workplace exposure to blood or other potentially infectious materials and identifies some of the more difficult and uncertain issues that covered employers will face in attempting to comply with this standard.

OSHA'S FINAL RULE ON OCCUPATIONAL EXPOSURE TO BLOODBORNE PATHOGENS

On December 6, 1991, the Occupational Safety and Health Administration (OSHA) published its long-awaited Final Rule on "Occupational Exposure to Bloodborne Pathogens". 56 Fed. Reg. 64004, *et seq.* Concern over the spread of acquired immune deficiency syndrome (AIDS) has been dramatically heightened by recent publicity surrounding such tragic events as the death of Kimberly Bergalis, who is believed to have been infected by her dentist, and basketball star Magic Johnson's announcement that he too had fallen victim to this fatal disease. In response to a Congressional mandate to promulgate a standard by December 1991, OSHA's action ended four years of debate and speculation as to what burdens would be placed on employers to protect workers against workplace exposure to the Hepatitis B virus (HBV) and the human immunodeficiency virus (HIV) which causes AIDS.

As anticipated, OSHA's Bloodborne Pathogens Standard ("standard") adopts guidelines by the Center for Disease Control (CDC), and mandates the adoption of infection control systems based on universal precautions. Significantly, however, what was not anticipated was the scope of employers covered under the standard, reaching far beyond the health care industry, and the extent to which the standard's requirements would exceed those of the CDC.

OSHA has already identified 24 industry sectors and more than one-half million workplaces subject to the new standard. An estimated 4.9 million workers affected by the standard are employed in health care facilities, such as hospitals, nursing homes, and physicians' and dentists' offices. However, nearly three-quarters of a million workers outside health care facilities will be affected as well. By OSHA's estimate, they are employed in over 36,000 industrial plants with health clinics and over 185,500 plants with emergency health care personnel. Among other industries affected by this standard are linen and laundry services, waste removal services, funeral homes, mortuaries, and companies involved in medical equipment service and repair.

Effective Date

The standard, 29 C.F.R §1910.1030, takes effect on March 6, 1992, with specific provisions to be phased-in during the 60- to 120-day period following the effective date. "Universal precautions", which are already widely in use in health care facilities, must be in place by March 6. By July 6, 1992, affected employers must be in compliance with each of the standard's requirements.

Covered Employers

The standard applies to each employer with one or more workers who may, in the course of performing regular job duties, be "reasonably anticipated" to come into skin, eye, mucous membrane or parenteral contact with blood or other potentially infectious materials.

Key Provisions

Some of the key provisions of the new standard are set forth below:

- Universal Precautions: Protective measures and practices must be employed by the health care worker in treating every patient as though he is potentially infected and by the non-health care worker in responding to each emergency situation.

Effective Date: March 6, 1992.

- Exposure Control Plan: Employers must establish a written exposure control identifying workers with occupational exposure to blood and the methods by which it will comply with the new standard. The plan must include: (1) an occupational exposure determination by job classification or job task, as appropriate; (2) methods and a schedule to implement the standard's requirements relative to engineering and work practice controls, personal protective equipment, housekeeping, research laboratories and production facilities, Hepatitis B vaccinations, post-exposure evaluation and follow-up, hazard communication and recordkeeping; and (3) a procedure for evaluating the circumstances surrounding the occupational exposure.

Effective Date: May 5, 1992.

- Training and Information: Employees must receive hazard training within 90 days of the effective date of the standard or initially at the time of their assignment to tasks where an occupational exposure exists. Additional training will be required annually or whenever there is a change in task or procedure which affects occupational exposure. HIV and HBV research laboratories and production facilities are subject to specialized training requirements.

Effective Date: June 4, 1992.

- **Engineering and Work Practice Controls:** Engineering controls such as puncture-resistant containers for sharps, and appropriate packaging of specimens and regulated waste must be implemented. Work practice controls such as handwashing and procedures to minimize blood splashes, sprays or splatters, and to reduce needlestick injuries must be instituted. Housekeeping procedures such as cleaning schedules and decontamination procedures must be developed.

Effective Date: July 6, 1992.

- **Personal Protective Equipment:** Employers must provide and ensure the use of appropriate personnel protective equipment, such as gloves, gowns, laboratory coats, face shields, masks, eye protection, mouthpieces, resuscitation bags, pocket masks or other ventilation devices.

Effective Date: July 6, 1992.

- **Hepatitis B Vaccination:** Newly hired workers or employees who are newly assigned to jobs with potential occupational exposure, must be provided within 10 days of assignment, at no cost, Hepatitis B vaccinations. Employers must secure a Hepatitis B vaccine declination in a form specified by OSHA for employees who refuse vaccination.

Effective Date: July 6, 1992.

- **Post-Exposure Testing, Evaluation and Follow-Up:** Confidential post-exposure medical evaluation and laboratory tests must be provided to each exposed employee, along with follow-up evaluation. Follow-up must include a medical evaluation documenting the route and circumstances of the exposure along with the source individual, serologic testing of employee's blood for HBV and HIV on consent, post-exposure prophylaxis, counselling and evaluation. Specific medical records must be maintained as provided under this standard.

Effective Date: July 6, 1992.

- **Hazard Communication:** Biohazard warning labels must be affixed to all containers of regulated waste, refrigerators and freezers containing blood or other infectious material, and other containers used to store, transport or ship blood or other infectious materials, subject to certain specified

exceptions. Biohazard signs must be posted at the entrance to work areas to HIV and HBV research laboratory and production facilities.

Effective Date: July 6, 1992.

- Research Laboratories and Production Facilities: Research laboratories and production facilities are subject to additional provisions regulating engineering and work practices, spill reporting and decontamination procedures, containment equipment, hazard communication and ventilation.

Effective Date: July 6, 1992.

Major Compliance Issues

Despite substantial commentary submitted by hospitals and other affected industries, OSHA's Final Rule provides few, if any, allowances for using professional judgment in balancing the risk of worker exposure against the risk of compromising health care delivery to the patient. With limited exception, professional judgment and accepted industry practice have now been supplanted by OSHA regulation.

On its surface, the standard appears generally consistent with the CDC guidelines. However, it differs in several significant respects. For example, the CDC guidelines suggest the routine use by health care workers of barrier protections (e.g., gloves, protective eyewear, etc.) to protect against skin or mucous membrane exposure when contact with blood or other body fluid is anticipated by that worker. By contrast, the OSHA standard mandates that employers both provide and "ensure" the use of all appropriate personal protective equipment against contact with specified human body fluids, unfixed human tissue or organs, and HIV- or HBV- contaminated cells, tissues or organ cultures. It is unclear whether OSHA's use of the word "ensure" evidences an intent to hold employers liable for all violations of the standard, regardless of circumstances (e.g., employee misconduct). Such a position would be tantamount to making employers guarantors of employee safety and health, a result never intended by Congress.

The costs and operational problems inherent in applying this standard in today's health care industry may be vastly understated. Contrary to initial estimates, compliance with the provisions of the new standard may place substantially greater financial and other burdens on employers than the \$821 million originally anticipated for all affected industries. For example, to date, most health care employers have provided personal protective equipment, but often only to those employees in direct patient

contact or working in laboratories. Because OSHA's standard applies to a substantially larger employee population, including, for example, maintenance, housekeeping and medical equipment service and repair personnel, the incremental cost of providing personal protective equipment and training to each covered employee represents a significant new cost item which may prove expensive to hospitals and may be difficult to pass on.

Although certain provisions of the standard will directly regulate how employees must perform their jobs, the standard does not address critical labor and employee relations issues (e.g., discipline). The standard does not expressly preempt other laws governing the employer-employee relationship or affecting fundamental health care issues. In a time of critical shortages of health care professionals, the increased administrative and training requirements mandated by this standard may in practice not only be difficult for employers to accommodate but may be detrimental to maintaining good employee relations. With current worker shortages and varying shift schedules, health care employers already have difficulty in meeting training requirements.

The CDC has been struggling for some time with the issue of identifying infected health care providers and patients. The tension is evident in the standard's treatment of potentially conflicting issues of consent, confidentiality, and the consequences of test results of exposed workers and the sources of such exposure. In the post-exposure context, the exposed employee's right to know the identity and HIV- or HBV- status of the source individual will be determined by applicable state or local law. Thus, employee rights and employer obligations under the standard will vary from state to state. In some states, the exposed employee's right to know may have to yield to the source individual's right to remain unidentified and untested. Where prior consent is required by local law, the source individual's blood, even if available, cannot be tested or the results documented absent consent. Thus, despite OSHA's requirement that exposed employees must be provided with testing results of source individuals, employers may do so only if applicable disclosure laws permit.

Similar tension exists between the mandatory provisions regarding employer obligations and the voluntary provisions governing their employees. For example, the standard requires employers to vaccinate all workers with the potential for occupational exposure to Hepatitis B or to secure a declination form from the employee if he or she refuses. The standard is silent on what to do if an employee refuses to sign it.

States and territories with their own occupational safety and health plans are not required until June 6, 1992 to adopt a comparable standard or amend their existing standards to be "at least as effective" as OSHA's standard. Thus, the impact of this standard may be felt several months later in those states. Although state, county and

municipal employees are not covered by the new standard, OSHA has urged state-plan states, as well as all other states, to extend the protections of this standard to public sector employees, such as emergency medical service, correctional facilities and law enforcement personnel, firefighters and lifeguards.

To facilitate consistent interpretations and application of OSHA's new regulations, the agency will likely issue enforcement directives to its field compliance personnel which should clarify some of the uncertainties in the standard. Other ambiguities and inconsistencies will be resolved in litigation challenging some or all of its provisions. The American Dental Association is the first to challenge this standard, having already filed a petition for review of the standard with the United States Court of Appeals for the Seventh Circuit (American Dental Association v. Secretary of Labor, No. 91-3865, 7th Cir., filed 12/19/91). The petition does not identify the particular provisions that are being challenged. At this juncture, it is uncertain but likely that the group may seek the federal court to stay the effective date of at least some if not all of the standard's requirements pending challenge. If, however, challenges to other OSHA standards, such as lockout/tagout, provide any guidance, it is likely that the courts would permit the standard to remain in effect during the pendency of any such challenge.

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