The California Division of Occupational Safety and Health ("Cal/OSHA") recently alerted employers in the health care industry to the use of certain pre-filled syringes containing one of the 2008-09 seasonal influenza ("flu") vaccines that lack a safety device to protect the user from needlesticks. Businesses that allow their employees to use these syringes are subject to enforcement by Cal/OSHA because the products do not satisfy the requirements of California’s Bloodborne Pathogens ("BBP") Standard.

Background

California’s BBP Standard applies to all occupational exposure to blood and other potentially infectious materials, as defined in the regulation.\(^1\) It includes requirements intended to reduce the incidence of needlesticks and other "sharps" injuries that can result in exposure to bloodborne pathogens such as Hepatitis B and C and HIV. See 8 Cal. Code Regs. ("CCR") 5193.\(^2\) Among other things, the BBP Standard requires the use of needleless systems for withdrawal of bodily fluids and administration of medications and fluids.\(^3\) When needleless systems are not available, the use of sharps devices with anti-stick protection is required unless no acceptable device is available.\(^4\)

The BBP Standard also requires that needles used by healthcare workers to administer flu vaccinations have "engineered sharps injury protection" or ESIP.\(^5\) To qualify as ESIP, the anti-stick feature of the sharp must be built into the device and effectively reduce the risk of an exposure incident.\(^6\)

Pre-Filled Flu Vaccine Syringes

Cal/OSHA recently issued a hazard alert after it learned of sales in California of pre-filled fixed needle syringes containing the flu vaccine "Fluvirin" manufactured by Novartis. The permanently affixed needles lack ESIP and cannot be removed and replaced with needle products that have sheaths or shields. The syringes thus do not comply with requirements of the BBP Standard.

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\(^1\) See 8 CCR 5193(b). "Occupational exposure" is defined as reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee’s duties. See id.

\(^2\) The BBP Standard defines "sharps" to include syringes and other needle devices, scalpels, lancets, broken glass, broken capillary tubes, exposed ends of dental wires and dental knives, drills and burs. See 8 CCR 5193(b).

\(^3\) See 8 CCR 5193(d)(3)(A).

\(^4\) See id.

\(^5\) See id.

\(^6\) See 8 CCR 5193(b).
The hazard alert states that Novartis replaced the non-compliant syringes that it had provided to public health departments in California, and contacted its distributors to provide replacement products for their customers. The manufacturer also provided Cal/OSHA with a list of its distributors.

Other pre-filled flu vaccine syringes that lack ESIP are on the market and may be in use in California. Cal/OSHA did not cite Novartis for violation of the BBP Standard because the agency has jurisdiction to enforce occupational safety and health standards only with respect to employers and employees. Businesses whose employees have provided flu vaccinations using products that do not meet the requirements of the BBP Standard are not similarly protected, however.

**Key Implications**

Paul Hastings attorneys have significant experience advising employers regarding compliance with California’s BBP Standard and have negotiated favorable resolutions of Cal/OSHA citations issued for alleged violation of the BBP Standard. Recent developments have the following key implications:

- Pre-filled fixed needle syringes and other products that lack a safety device to protect the user from needlesticks may not comply with the requirements of California’s BBP Standard.
- Medical clinics, pharmacies, retailers, and other businesses that employ persons in California who administer flu vaccinations and other medications should review the sharps devices used by their employees for compliance with the BBP Standard.
- Employers should provide appropriate training to all California employees with occupational exposure, as required by the BBP Standard.

**Conclusion**

Many needles and other sharps used by healthcare providers are manufactured outside California and distributed nationally. These products may not be designed to meet the applicable requirements of California’s BBP Standard even though they are sold or used in the state. Companies that employ health care providers in California can minimize future exposure by evaluating the sharps devices used by their employees.

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*If you have any questions concerning these issues, please do not hesitate to contact any of the following Paul Hastings lawyers:*

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