FDA Initiates Stricter Medical Glove Standards

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The Food and Drug Administration has issued a final rule that would require medical glove makers to improve their products' ability to serve as a barrier against pathogens.

Manufacturers are being given 2 years to comply with the new regulations.

The goal is to reduce the risk of transmission of bloodborne pathogens such as HIV and hepatitis B, according to the FDA. While the agency can't quantify how many cases might be prevented with better barriers, it estimated that approximately 2.4 HIV infections occur each year due to "problems with the barrier protection properties of gloves used in health-care settings."

The FDA estimates that 140 health care workers are infected with the hepatitis B virus (HBV) on the job each year, primarily from percutaneous injuries. About a third, or 40 cases, may be due to glove defects, according to the agency.

There is less evidence that glove defects are associated with hepatitis C, said the agency, noting that most occupational exposures are from needle sticks.

The agency has inspected gloves—used for patient examinations and surgical procedures—since 1990. At that time, the International Organization for Standardization (ISO), ASTM International, and the FDA had the same standards for glove quality. A few years later, the ISO and ASTM began requiring higher standards.

The agency has allowed a defect rate of 4% for gloves used during patient exams and 2.5% for gloves used in surgery.

With more and more brands of gloves being marketed and sold, the agency hopes to maintain that defect rate. To do so means increasing the quality standards, said the agency.

The FDA estimates that about 2% of the 39.2 billion gloves currently marketed are defective—some 940 million gloves. ■