Hepatitis B Virus Antibody Testing is Required: Guidelines for the Immunization of Health Care Workers

Standard Number: 1910.1030(f)(1)(i); 1910.1030(f)(2)(v)

OSHA requirements are set by statute, standards and regulations. Our interpretation letters explain these requirements and how they apply to particular circumstances, but they cannot create additional employer obligations. This letter constitutes OSHA's interpretation of the requirements discussed. Note that our enforcement guidance may be affected by changes to OSHA rules. Also, from time to time we update our guidance in response to new information. To keep apprised of such developments, you can consult OSHA's website at http://www.osha.gov.

March 10, 2000

Christopher S. Taylor, M.D.
Deputy Regional Flight Surgeon
Federal Aviation Administration Aviation Medicine
Northwest Mountain Region
1601 Lind Avenue, S.W.
Renton, WA 98055-4056

Dear Dr. Taylor:

Thank you for your February 10 letter addressed to the Occupational Safety and Health Administration's (OSHA's) [Office of Health Enforcement]. You have a question regarding whether a Hepatitis B vaccination booster is required by OSHA under the Bloodborne Pathogens Standard, 29 CFR 1910.1030. This letter supplements our phone conversation and we hope it better serves your needs.

According to the standard and the recently published directive, Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens, [CPL 2-2.69], an employer's responsibility for providing the hepatitis B vaccination series is clear. Paragraph (f)(1)(i) of the standard states, "the employer shall make available the hepatitis B vaccine and vaccination series to all employees who have occupational exposure, and post-exposure follow-up to all employees who have had an exposure incident." This includes employer provision of, "the hepatitis B vaccine and vaccination series and post-exposure evaluation and follow-up, including prophylaxis... at no cost to the employee,...at a reasonable time and place, and...according to recommendations of the U.S. Public Health Service current at the time these evaluations and procedures take place."

Regarding your letter, a hepatitis B vaccination booster is not currently required by the U.S. Public Health Service, Centers for Disease Control and Prevention's (CDC's) Guidelines for the Immunization of Health-Care Workers. However, the December 26, 1997 CDC Guidelines does indicate that "postvaccination testing for antibody to hepatitis B surface antigen (anti- HBs) response is indicated for healthcare workers who have blood or patient contact and are at ongoing risk for injuries with sharp instruments or needlesticks." This means that a titer or antibody testing is required approximately two months after the employee finishes the vaccination series. The indicated guidelines can be found in [Appendix E of CPL 2-2.69], which is available on OSHA's website at http://www.osha.gov.

Thank you for your interest in occupational safety and health. We hope you find this information helpful.

Please be aware that OSHA's enforcement guidance contained in this response represents the views of OSHA at the time the letter was written based on the facts of an individual case, question, or scenario and is subject to periodic review and clarification, amplification, or correction. It could also be affected by subsequent rulemaking; past interpretations may no longer be applicable. In the future, should you wish to verify that the guidance provided herein remains current, you may consult OSHA's website at http://www.osha.gov. If you wish to obtain a hard copy of the standard or its directive, you may contact OSHA's Office of Publications at (202) 693-1888. If you have any further questions, please feel free to contact the [Office of Health Enforcement] at (202) 693-2190.

Sincerely,

Richard E. Fairfax, Director Directorate of Compliance Programs [Corrected 10/29/02]

Accessed at

https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=INTERPRETATIONS&p_id=23452 on 06/03/2014

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August 17, 2015

Richard L. Raimondo, Jr., D.D.S. 12521 Nacogdoches #103 San Antonio, Texas78217

Dear Dr. Raimondo:

Thank you for your February 17, 2015, follow-up letter to the Occupational Safety and Health Administration's (OSHA) Directorate of Enforcement Programs. After our <u>previous correspondence</u>, you requested additional clarification of OSHA's Bloodborne Pathogens (BBP) standard, 29 CFR 1910.1030, concerning its requirements for hepatitis B virus (HBV) vaccination and antibody testing. This letter constitutes OSHA's interpretation only of the requirements discussed and may not be applicable to any question not delineated within your original correspondence. For clarification, your specific questions are paraphrased below, followed by OSHA's responses.

Question 1: When did the U.S. Public Health Service (USPHS) first recommend hepatitis B antibody (titer) testing after the hepatitis B vaccination series has been completed? Several of my employees were vaccinated shortly after the OSHA BBP standard went into effect in 1991, when there was no requirement for titer testing.

Response: The Centers for Disease Control and Prevention (CDC) is the United States Public Health Service agency responsible for issuing guidelines and making recommendations regarding infectious diseases. OSHA's BBP standard requires compliance with the CDC guidelines for hepatitis B vaccination, among other things, current at the time of the evaluation or procedure. [29 CFR 1910.1030(f)(1)(ii)(D)] The CDC made a recommendation as early as December 1997 that healthcare workers who have contact with patients or blood and are at ongoing risk for percutaneous injuries be tested for antibody to hepatitis B surface antigen (anti-HBs) 1-2 months after completion of the 3-dose vaccination series. See *Immunization of Health-Care Workers: Recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Hospital Infection Control Practices Advisory Committee (HICPAC)*. [MMWR December 26, 1997 / Vol. 46 / No. RR-18]

Question 2: If my employees received the HBV vaccine before the USPHS recommendations for titer testing went into effect, what do I do now? Do I offer titer testing, or should I offer them revaccination? What if the employees were vaccinated after the titer testing recommendations became effective?

Response: In a situation as you describe, where employees received the HBV vaccine several years prior to the CDC recommendations, there was no specific recommendation for additional vaccination or serologic testing to monitor antibody concentrations of those employees at that time. Therefore, the standard does not require titer testing after hepatitis B vaccinations given before December 26, 1997. [29 CFR 1910.1030(f)(1)(ii)(D)]

With regard to employees vaccinated after the 1997 guidance was issued, the recommendation for titer testing currentat the time of this letter is in *CDC Guidance for Evaluating Health-Care Personnel for Hepatitis B Virus Protection and for Administering Post-exposure Management*, MMWR (December 20, 2013 / Vol. 62 / No 10.). This document states on p. 12: "All HCP [health-care personnel] recently vaccinated or recently completing HBV vaccination who are at risk for occupational blood or body fluid exposure should undergo anti-HBs [titer] testing. Anti-HBs testing should be performed 1-2 months after administration of the latest dose of the vaccine series when possible." The recommendation about testing 1-2 months after the completion of the vaccination series is not a hard and fast deadline. For further guidance on whether titer testing should be conducted when more than 2 months has passed since the vaccination you should contact the CDC.

Regardless of when your employees received the HBV vaccination, following an exposure incident you are still required by OSHA's BBP standard to "...make immediately available to the exposed employee a confidential medical evaluation and follow-up..."[29 CFR 1910.1030(f)(3)] The BBP standard has provisions on HBV and HIV testing after an exposure incident. Paragraph 1910.1030(f)(3)(ii) requires, among other provisions, the following HBV testing after an exposure incident:

- (ii) Identification and documentation of the source individual, unless the employer can establish that identification is infeasible or prohibited by state or local law;
- (A) The source individual's blood shall be tested as soon as feasible and after consent is obtained in order to determine HBV and HIV infectivity. If consent is not obtained, the employer shall establish that legally required consent cannot be obtained. When the source individual's consent is not required by law, the source individual's blood, if available, shall be tested and the results documented.
- (B) When the source individual is already known to be infected with HBV or HIV, testing for the source individual's known HBV or HIV status need not be repeated.
- (C)Results of the source individual's testing shall be made available to the exposed employee, and the employee shall be informed of applicable laws and regulations concerning disclosure of the identity and infectious status of the source individual.
- (iii) Collection and testing of blood for HBV and HIV serological status;
- (A) The exposed employee's blood shall be collected as soon as feasible and tested after consent is obtained.

After an exposure incident, the BBP standard also requires documentation of the route(s) of exposure and the circumstances under which the exposure incident occurred, counseling of the exposed employee, and evaluation of any reported illness, as well as prophylaxis, when medically indicated, in accordance with current CDC guidelines. [29 CFR 1910.1030(f)(3)(i) and (iv)-(vi)]. The 2013 CDC guidance referenced above provides guidance to manage post-exposure prophylaxis for percutaneous exposure of your workers, even those with unknown HBV immunity. The CDC's post-exposure guidance is based on the HBV immunity status of the exposed employee (unvaccinated, incompletely vaccinated, or unknown). Please refer to that document for more information about type(s) and frequency of follow-up testing that should be done after the initial baseline testing of employees for HBV infection that is required by the OSHA

standard. Treatment of the exposed employee must also follow the guidance provided by the 2013 CDC guidance document.

For additional information, we are also enclosing copies of three OSHA guidance publications: *Medical and Dental Offices - A Guide to Compliance with OSHA Standards; OSHA Fact Sheet - Hepatitis B Vaccination Protection;* and, *OSHA Fact Sheet - Updates to OSHA's Reporting and Recordkeeping Rule.*Thank you for your interest in occupational safety and health. We hope this provides the clarification you were seeking and apologize for any confusion the earlier documents may have caused. As this letter demonstrates, OSHA's re-examination of an issue may result in the clarification or correction of previously stated enforcement guidance. OSHA requirements are set by statute, standards and regulations. Our interpretation letters explain these requirements and how they apply to particular circumstances, but they cannot create additional employer obligations. This letter constitutes OSHA's interpretation of the requirements discussed. Note that our enforcement guidance may be affected by changes to OSHA rules.

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Sincerely,

Thomas Galassi, Director

https://www.osha.gov/laws-regs/standardinterpretations/2015-08-17