



January 3, 2017

**MEMORANDUM**

**TO:** Administrators of Renal Dialysis Facilities

**FROM:** Gwen C. Thompson, Bureau Chief  
Bureau of Health Facilities Licensing

**SUBJECT:** Condition Allowing a Provider-Wide Exception to the Requirements of Section 409.D of Regulations 61-97, Standards for Licensing Renal Dialysis Facilities

**NOTE:** **This memorandum replaces the exception to the standards regarding hepatitis testing communicated to renal dialysis facilities in a memorandum dated September 18, 2002.**

The section in the regulation mentioned above requires certain procedures to be followed regarding hepatitis testing.

In the interest of establishing reasonable standards which can be met by providers yet do not compromise the health, safety, and well-being of patients cared for in the above facilities, it has been determined that alternative standards will be considered as acceptable.

All renal dialysis facilities will be required to meet the standard outlined in R.61-97, Section 409.D, or, as an alternative:

1. For employees:
  - A. Check medical records or conduct a baseline test for HBsAG (Hepatitis B surface antigen) and HBsAb (Hepatitis B surface antibodies).
    - 1) If HBsAB is (+), the employee is considered naturally immune, either from natural infection or vaccination, and needs no further testing.
    - 2) If HBsAG is (+), the employee is likely a chronic HBV (Hepatitis B Virus) carrier, and must be re-checked every six (6) months for two (2) years.
    - 3) If HBsAb is (-), the employee shall be offered the Hepatitis B vaccine series (per CDC guidelines). If the employee declines, test for HBsAb quarterly.
  - B. One to two months after completion of this primary vaccine series re-check HBsAb.

- 1) If HBsAb (-), thereby indicating initial non-responder, recommend a second three-dose Hepatitis B vaccine series and re-check in one to two months after completion.
  - 2) If HBsAb is again (-), the employee is classified as a "known vaccine non-responder" and need not be thereafter tested for HBsAb, but must be tested for HbsAg quarterly.
- C. If HBsAb is (+) after either the primary or second series, the employee is classified as a "known vaccine responder," is considered immune to Hepatitis B infection, and needs no further testing.
- D. In the event of an occupational blood-borne pathogen exposure, all employees who are HBsAb (-) must be managed as a "known non-responder" (per CDC guidelines).
- E. If a test for HBAb indicates (+) = natural infection; (-) = no evidence of viral infection. (A (+) core Ab does not determine immunity)
2. For patients:
- A. Conduct a baseline check for HBsAg and HBAb.
    - 1) If HBsAb is (+), the patient is considered naturally immune and needs no further testing;
    - 2) If HBsAg is (+), the patient is likely a chronic HBV (Hepatitis B Virus) carrier, and must be rechecked every six (6) months for two (2) years.
    - 3) If both HBsAg and HBsAb are (-), the patient shall be offered the Hepatitis B vaccine series (per CDC guidelines). If the patient declines, test for HBsAg quarterly.
  - B. One to two months after the completion of this primary vaccine series, re-check HBsAb.
    - 1) If HBsAb is (-), indicating an initial non-responder, recommend second three-dose Hepatitis B vaccine series and recheck in one to two months after completion.
    - 2) If HBsAb is again (-), the patient is classified as a "known non-responder" and must be thereafter tested for HBsAg quarterly.
  - C. If HBsAb is (+) after either primary or second series, the patient is classified as a "known vaccine responder," is considered immune to Hepatitis B infection, and needs no further testing.
  - D. If a test for HBcAb indicates (+) = natural infection; (-) = no evidence of natural infection.

If a hospital treating a patient in its inpatient renal dialysis unit that is now desiring to discharge the patient and recommend that hemodialysis be resumed at an outpatient (OP) facility, but is unable to do so due to the requirement of Section 409 that requires the HBsAb testing to be conducted up to one month prior to admission to the OP facility. HBsAg testing, however, still must be conducted within one month prior to admission to the OP facility.

It has been determined by this Department that since HBsAb is not an active disease process (but simply that which determines the presence of an antibody), the HBaAb testing may be conducted up to one (1) month after admission to the OP facility. HBsAg testing, however, still must be conducted within one (1) month prior to admission to the OP facility

This exception applies to any renal dialysis facility licensed by the Department. It relates solely to South Carolina licensing standards. Any adverse condition(s) that may be related to this exception may result in revocation of the exception by the Department.

If there are any questions, you may contact the Bureau of Health Facilities Licensing at (803) 545-4370.

GCT/dnf