



Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C 17-33-ESRD

DATE: June 16, 2017

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Infection Control: Clarification of Hepatitis C (HCV) Screening Exception

Memorandum Summary

- **Infection Control:** The Conditions for Coverage (CfCs) for End Stage Renal Disease (ESRD) facilities include infection control requirements for the safety of each dialysis patient, their family and staff members.
- **HCV Screening:** Recommendations for infection control, developed by the Centers for Disease Control and Prevention (CDC), are incorporated by reference into the ESRD CfCs and must be followed (with the exception of HCV screening per 42 CFR 494.30(a)(1)(i)) by all Medicare certified ESRD facilities.

Background

The CfCs for ESRD facilities require infection control procedures which demonstrate that a facility follows standard infection control precautions including routine serological testing and immunization, surveillance, training and education. The CfCs incorporate, within its provisions, recommendations found in “Recommendations for Preventing Transmission of Infections among Chronic Hemodialysis Patients,” developed by the CDC. Specifically, the CfCs at §494.30(a) require dialysis facilities to follow the above CDC recommendations for routine serologic testing and immunization, surveillance, and training and education, *with the exception of screening for HCV*.

Discussion

Pursuant to the above regulatory exclusion, surveyors should not cite ESRD facilities for a failure to conduct routine, or periodic screening for HCV. Most hemodialysis patients with a newly acquired HCV infection have elevated liver enzyme results, specifically serum Alanine Aminotransferase (ALT) results. ALT testing is performed monthly for all patients in renal dialysis facilities. Consequently, if a patient has an elevated ALT, the provider may order a diagnostic hepatitis panel, which includes a HCV antibody test as part of the panel. Any indication that there may have been a transmission of HCV among facility patients or staff would indicate the need for the ESRD facility to evaluate the adequacy of its infection control practices.

Contact: Please email any questions regarding the content of this memorandum to the ESRD mailbox at ESRDQuestions@cms.hhs.gov.

Effective Date: Immediately. This document should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/
David R. Wright

cc: Survey and Certification Regional Office Management