



California Dialysis Council

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Infection Control Requirements for Dialysis Facilities and Clarification Regarding Guidance on Parenteral Medication Vials

In April 2008, the Centers for Medicare and Medicaid Services (CMS) published in the *Feder Register* its final rule on *Conditions for Coverage for End-Stage Renal Disease (ESRD) Facil. (1)*. The rule establishes new conditions dialysis facilities must meet to be certified under the Medicare program and is intended to update CMS standards for delivery of quality care to dialysis patients. CDC's 2001 *Recommendations for Preventing Transmission of Infections among Chronic Hemodialysis Patients (2)* have been incorporated by reference into the new CMS conditions for coverage. Thus, effective October 14, 2008, all ESRD facilities are expected to follow the CDC recommendations as a condition for receiving Medicare payment for outpatient dialysis services.

In recent years, outbreak investigations in dialysis and other health-care settings have demonstrated that mishandling of parenteral medication vials can contribute to the risk for hepatitis C virus (HCV) infection and bacterial and other infections (3--7). In 2002, a CDC communication to CMS suggested that reentry into single-use parenteral medication vials (i.e. administer medication to more than one patient), when performed on a limited basis and under strict conditions in hemodialysis settings, likely would result in low risk for bacterial infection (8). However, the 2002 communication did not address risks for bloodborne viral infections (i.e. HCV and hepatitis B virus infection). This report is intended to clarify and restate CDC's recommendation on parenteral medication to include bloodborne viral infections. The recommendations in this report supersede the 2002 CDC communication to CMS.

To prevent transmission of both bacteria and bloodborne viruses in hemodialysis settings, CDC recommends that all single-use injectable medications and solutions be dedicated for use on a single patient and be entered one time only. Medications packaged as multidose should be assigned to a single patient whenever possible. All parenteral medications should be prepared in a clean area separate from potentially contaminated items and surfaces. In hemodialysis settings where environmental surfaces and medical supplies are subjected to frequent blood contamination, medication preparation should occur in a clean area removed from the patient treatment area. Proper infection control practices must be followed during the preparation and

administration of injected medications (9). This is consistent with official CDC recommendations for infection control precautions in hemodialysis (2) and other health-care settings (9).

Health departments and other public health partners should be aware of the new CMS conditions for ESRD facilities. All dialysis providers are advised to follow official CDC recommendations regarding Standard Precautions and infection control in dialysis settings (2,9). Specifically, CDC has recommended the following: "Intravenous medication vials labeled for single use, including erythropoietin, should not be punctured more than once. Once a needle has entered a vial label for single use, the sterility of the product can no longer be guaranteed" (2). Additional guidance on safe injection practices can be found in the *Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007* (9).

Dialysis providers also should be aware of their responsibility to report clusters of infections or other adverse events to the appropriate local or state public health authority. Failure to report illness clusters to public health authorities can result in delays in recognition of disease outbreaks (10) and implementation of control measures. Additional information regarding the new CMS Conditions for Coverage for End-Stage Renal Disease Facilities is available at http://www.cms.hhs.gov/cfcsandcops/13_esrd.asp.

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