

Summary of “Statement of Deficiencies” Documented in Inspection of the Champaign Urbana Dialysis Unit (owned and operated by Renal Research Institute)

This summary has been prepared by the Champaign County Health Care Consumers (CCHCC). CCHCC obtained the dialysis unit inspection records from the Illinois Department of Public Health through a Freedom of Information Act request.

Background: What is hemodialysis and why is it utilized?

Patients with end-stage renal disease (ESRD) suffer from permanent kidney failure and must undergo either regular dialysis treatment or a kidney transplant to stay alive. Most patients with ESRD must rely on dialysis treatments to compensate for kidney failure. Chronic kidney disease causes the kidneys to lose their ability of removing wastes and extra fluid from the body.

In hemodialysis, a patient’s blood is filtered through an external machine that acts as an artificial kidney to withdraw excess fluids and toxic materials before returning cleansed blood to the patient. The machine uses a semipermeable membrane, called a hemodialyzer to filter out the toxins. ESRD patients spend 3 to 5 hours at dialysis centers three times a week, where dialysis machines remove toxins from their blood streams. ESRD patients are immunosuppressed, which means their immune system is weakened and their bodies are more susceptible to infection. Therefore infection control is essential to the health and well-being of the ESRD patient.

Summary of Inspection (referred to as a “survey” of the facility)

Surveyor: Illinois Department of Public Health (IDPH), on behalf of Centers for Medicare and Medicaid Services (CMS)

Surveyed: Champaign Urbana Dialysis Center, owned and operated by the Renal Research Institute, located on the Provena Covenant Medical Center Campus (Address: 1405 West Park Street, Urbana, IL 61801)

Date survey completed: August 6, 2003

Chronology of Events:

- **August 22, 2003:** CMS issued a termination notice to the Champaign Urbana Dialysis Center for a serious and immediate threat.
- **September 5, 2003:** Champaign Urbana Dialysis Center’s Plan of Correction is received by CMS.
- **September 9, 2003:** CMS notifies Dialysis Center that Plan of Correction is unacceptable and a revised plan is required.
- **September 10, 2003:** Immediate and serious threat resolved. However, CMS notifies Champaign Urbana Dialysis Center that it still has remaining deficiencies that limit the facility’s capacity to render adequate care and ensure the health and safety of its patients. Effective date of termination is extended from 23 to 90 days, until November 20.

- **September 12, 2003:** Renal Research Institute mailed letters to patients stating that the facility was in full compliance with Medicare federal regulations.
- **September 25, 2003:** CMS notifies the Dialysis Center that “contrary to information apparently disseminated by representatives of your facility, Champaign Urbana Dialysis Center is not in compliance with Medicare requirements... We have determined that the deficiencies limit the capacity of your facility to render adequate care and ensure the health and safety of your patients. Consequently, we must terminate your participation in the Medicare program.”

How the Survey Was Conducted and How Problems Were Identified:

Evidence was gathered from reviews of Dialysis Center documents and policies, interviews with staff and management, and direct observation of clinical practices.

Findings from the Survey

Violation of 405.2136 COP: Governing Body and Management

A. Facility Failed to:

- 1) provide Quality Assurance monitoring of the water system;
- 2) establish and implement policies;
- 3) ensure staff training;
- 4) label Heparin syringes; and
- 5) an Immediate Jeopardy was identified as the Facility failed to ensure that the sole employee responsible for inspecting the water system, had been trained on the system.**

Violation of 405.2136 GB: Health and Safety

A. Facility failed to have a Quality Assurance Program for monitoring the water system:

- 1) the technician stated the facility did not have a technical audit tool to monitor completion of logs and accuracy of documentation for the water system.

B. Facility failed to document communication from the City to the Facility when additional Chlorine was added to City water.

- 1) Nurse Administrator who was interviewed failed to have documentation of notifications or how the information was communicated to staff or whether the increase in Chlorine affected patients or the water system.

C. Facility failed to ensure adherence to Facility policy governing treating fever/chills reactions.

- 1) In incident of fever/chills reaction, there was no documentation to indicate that the water and dialysate samples for bacteria culture and pyrogen testing were collected at the time of incident.
- 2) There was no documentation of an incident report for the noted incident.

Violation of 405.1236(d) Personnel P/P: Good Care

A. Dialysis Center’s policies were incomplete and did not represent current staff practice in these cases:

- 1) The policy stated that the bicarbonate mixer is to be bleached; however, the policy lacked the frequency for the disinfectant procedure.

- 2) The facility failed to have a policy for the documentation requirements for daily and weekly dialysis machine disinfection.
- 3) Procedures did not correspond with the parameters used on the current “reverse osmosis control log.”

Violation of 405.2136(d)(6) Personnel P/P: Staff Education

A. Nurse Administrator was unable to provide evidence of water system training for the Equipment Technician, who was the sole employee responsible for inspecting the water system.

Violation of 405.2136(f)(1)(vi) PT Care Policies: RX Services

A. Failed to follow policy on labeling medications. Unlabeled syringes that contained a clear solution were observed attached to dialysis machines. Failed to ensure that 3 of 5 Heparin syringes were labeled in accordance with policy. Staff acknowledge that syringes were not labeled.

Violation of 405.2140 COP: Physical Environment

A. Based on review of operational logs for the water system and interview it was determined that the Facility failed to:

- 1) provide safe functioning of the water system;
- 2) maintain accurate water system logs;
- 3) disinfect dialysis machines;
- 4) adhere to infection control procedures; and

5) An Immediate Jeopardy was identified as a result of the Facility’s failure to ensure the heat disinfection unit was functioning properly, in order to provide for the safety of the water system.

Violation of 410.2140(a) PE: Construction and Maintenance for Safety

A. Facility failed to ensure that the heat disinfection unit was functioning properly for the safety of the water system. Documentation and staff interview indicated that the technician reported this problem 2 weeks prior to inspection. At the time of inspection, the problem had not yet been resolved.

Violation of 405.2140(a)(5) PE: Water treatment

A. Based on policy review, review of disinfectant logs and interview, it was determined that the **Facility failed to ensure dialysis machine disinfection for 33 of 33 dialysis machines.**

B. The Facility failed to ensure daily water testing for the level of Chlorine.

C. The Facility failed to ensure daily disinfection of the bicarbonate mixer.

D. The Facility failed to ensure that the parameters used to measure the function of the water system were accurate.

- 1) The “Reverse osmosis quality control log” contained documentation that the readings were beyond the range for the “micron filter and post micron filter” and even when a range of 25 points higher was documented, there was no explanation for the higher reading.

- 2) Readings for the “feed water temperature” should be between 70–85 degrees Fahrenheit, but temperatures were documented as 22.6 and 26.9 without an explanation for the low readings. Etc.
- 3) The Equipment Technician and Nurse Director were interviewed and neither were aware of what the correct parameters should be for the “softener quality control log.”

E. Facility failed to ensure that the heat sanitization of the water system was completed in accordance with Facility policy.

- 1) The log lacked documentation that the water system had been heat disinfected.
- 2) The technician indicated that the program timer on the water system malfunctioned and programs were lost hence, not allowing the heat disinfection to be completed. There was no available Facility documentation to indicate that this timer malfunctioned, and the date of the occurrence.

Violation of 405.2140(b)(1) PE: Infection Control

A. Facility failed to ensure that hand washing was performed in accordance with policy. Observations included staff failing to wash hands between patients, using bare hands to handle used equipment and without washing hands proceed to machine handling clean tubing.

B. It was determined that for 4 of 6 treatment terminations observed, the Facility failed to ensure that the dialysis stations and equipment were appropriately disinfected between patients.

Violation of 405.2140(c): Prevent Cross Contamination

A. Based on observation it was determined that 4 of 6 staff observed, the Facility failed to ensure the prevention of cross-contamination in the patient care area.

- 1) Products at individual stations were returned to a general area for further patient use.
- 2) A staff person dropped a barrier cloth on the floor, retrieved it, and placed it under the patient’s arm, where the access had just been decannulated, and pressure was being applied to the bleeding site.

	<p><i>For more information, please contact Claudia Lennhoff at:</i></p> <p>Champaign County Health Care Consumers 44 East Main Street, Suite #208 • Champaign, IL 61820 Phone = (217) 352-6533 Email = cchcc@prairienet.org Web = www.prairienet.org/cchcc</p> <p><i>Helping the people of Champaign County who have problems with the health care system and working to change the system so that everyone has access to quality affordable health care!</i></p>
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