



2600 Bull Street
Columbia, SC 29201-1708

August 1, 2001

MEMORANDUM

TO: Administrators, Renal Dialysis Facilities

FROM: Jerry L. Paul, Director
Division of Health Licensing

SUBJECT: Reportable Incidents and Accidents

At the July 24, 2001, Renal Dialysis Advisory Council meeting, a question arose concerning Section 310 of Regulation 61-97, Standards for Licensing Renal Dialysis Facilities, and specifically what type of incident and accident (I/A) reports are to be forwarded to this office. Section 310 reads:

"A record of each accident or incident occurring in the facility, including medication errors and adverse drug reactions, shall be prepared immediately. Accidents resulting in serious injury or death shall be reported, in writing, to the licensing agency within 10 days of the occurrence. Accidents and incidents that must be recorded include but are not limited to:

- A. Those leading to hospitalization;
- B. Those leading to death;
- C. Use of the wrong dialyzer on patient;
- D. Blood spills of more than 75 ml;
- E. Hemolytic transfusion reactions;
- F. Reactions to dialyzers."

Subsections A - F above must be recorded on an I/A form. Subsections A and B must be reported to this office. Some examples of serious injuries may include, but not be limited to: fractures of major limbs, injury resulting from a seizure episode without prior history, severe burns, severe lacerations, or severe hematomas. It should be noted that I/A recording and reporting are applicable on all parts of facility property, and include patients, staff and visitors.

Also please reference a memorandum from this office (enclosed), dated November 15, 1996, that addressed this subject. This memo notified all licensed health care facilities of I/A recording and reporting requirements, and described the information that should be included on an I/A report.

Should you have questions, please call Rob Lawyer at 803-545-4234.

JLP:GRM:gm
Enclosure