DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 17-31-ESRD

DATE: **June 02, 2017**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: End Stage Renal Disease (ESRD) Facilities: Filling Saline Syringes at the Patient Treatment Station

Memorandum Summary

- **Preparation of Medications**: ESRD facilities must follow aseptic technique when preparing and administering intravenous medications; including the filling of syringes with sterile saline for use during the dialysis procedure.

- **Filling Saline Syringes at the Station**: Pursuant to current recommendations from the Centers for Disease Control (CDC), ESRD facilities may not fill syringes with saline from the single dose saline bag or IV tubing connected to the patient at the dialysis station. To comply with recommended safe injection practices, the facility may acquire pre-filled syringes or may prepare saline syringes for an individual patient in a clean area away from the patient treatment area.

Background

The 2008 ESRD Conditions for Coverage at 42 CFR 494.30(b)(2) state that the facility must "ensure that the clinical staff demonstrate compliance with current aseptic techniques when dispensing and administering intravenous medications…"

Dialysis procedures for initiation and discontinuation of hemodialysis treatments require the use of sterile normal saline in syringes to aid in the care of a patient's vascular access. During survey observations, ESRD facilities have been noted to fill syringes with saline for vascular access care or to flush medications by drawing saline from the single dose saline bag or the IV tubing connected to the patient at the dialysis station. This is not consistent with CDC recommended safe injection practices, including aseptic technique. The CDC recommends that "parenteral medications should be prepared in a clean area separate from potentially contaminated items and surfaces. In hemodialysis setting medication preparation should occur in a clean area removed from the patient treatment area".

Discussion

When saline syringes are required for vascular access care or to flush medications, ESRD facilities should obtain syringes pre-filled with sterile saline from a manufacturer, Food and Drug Administration (FDA) registered outsourcing facility, or pharmacy whenever possible.

However, when saline syringes must be prepared in an ESRD facility for administration, the following safe injection practices must be followed:

- Fill syringes with sterile saline for an individual patient in a dedicated clean area removed from the patient treatment area. Although not required, a clean room separate from the patient treatment area is the preferred location.
- Prepare syringes for an individual patient as close as possible to the time of administration to prevent compromised sterility or stability.
- Use aseptic technique for disinfection of saline vials prior to entry and follow the suggested standards from the Association for Professionals in Infection Control and Epidemiology (APIC) when preparing saline flushes including:
    - Medication containers labeled single-dose or single-use (e.g., saline bags, single- dose vials, ampules) may not be used to prepare flush syringes for more than one patient. Any unused saline in the opened single-dose or single-use container must be discarded and may not be stored for future use on the same patient.
    - If multi-dose vials are used to prepare saline flush syringes, they must be dated upon opening and discarded within 28 days unless the manufacturer specifies a different date for that vial. The beyond-use date should never exceed the manufacturer's expiration date.

This memorandum clarifies and supersedes any information that may have been previously communicated allowing the filling of syringes from the saline bag in the station.

Contact: Please email any questions 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

The contents of this letter support activities or actions to improve patient or resident safety and increase quality and reliability of care for better outcomes.