DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Medicare & Medicaid Services

7500 Security Boulevard
Baltimore, MD 21244-1850

Ref: S&C-02-43

DATE: **September 12, 2002**

FROM: Director
Survey and Certification Group
Center for Medicaid and State Operations

SUBJECT: Centers for Disease Control and Prevention (CDC) Revised Recommendations for Single-Use Intravenous Medication Vials in End-Stage Renal Disease (ESRD) Facilities

TO: Associate Regional Administrator, DMSO
State Survey Agency Directors

The purpose of this program memorandum is to provide information and guidance to regional offices, state survey agency personnel, and ESRD facilities regarding revised guidance issued by the Centers for Disease Control and Prevention (CDC) on infection control practices to be followed in End-Stage Renal Disease (ESRD) facilities.

The Survey Procedures and Interpretive Guidelines for End Stage Renal Disease Facilities state that facilities should institute the current recommendations of the CDC relative to infection control and prevention. The current (April 27, 2001) guidelines from the CDC state "intravenous medication vials labeled for single use, including erythropoietin, should not be punctured more than once." Accordingly, surveyors have been citing the practice of multiple-use of single-use vials since the CDC issued that recommendation.

However, we have been aware that for several months the CDC has been reconsidering its position on the repeated use of single-use vials. Please find in the attachment, CDC's revised recommendations. As a result of this issuance, CMS is altering the guidance to states and regions regarding infection control and multiple-use of single use vials.

Effective immediately, ESRD facilities will be expected to follow the revised CDC recommendations for injectable medications administered by ESRD facilities. The CDC has stated that failure to comply with the following recommendations poses a significant health and safety risk to patients. Therefore, we expect that either facilities will continue the practice of single use of single-use vials or facilities will follow the following recommendations:

1. All doses must be drawn-up by a licensed professional whose scope of practice includes administration of parenteral medications and knowledge of aseptic technique.

2. All doses from a given vial should be drawn-up and administered within a 4-hour period.

3. Only one vial of a given concentration of the medication should be opened and used by the administering professional at any given time. A second vial of the same medication must not be opened until the previous vial is discarded.

4. Any opened vials or filled syringes (with epoetin alpha, iron, or vitamin D) must be discarded if not used within 4 hours of first puncture of the vial. Vials must be labeled to document the time of first entry and maintained at a temperature of 2-8 degrees Celsius (or 36-46 degrees Fahrenheit) during non-use.

5. Residual amounts of these medications (either in the vial or syringes) must never be pooled with medication from another vial or syringe. If a patient requires more medication than is in a single, drawn syringe, then medication from a separate vial should be drawn into a separate syringe for administration.

6. Each facility must have in place a process monitoring (quality assurance) program which ensures compliance with these policies and procedures. These policies must include: a) recording data on infections in treated dialysis patients; and b) unannounced practice audits involving quality assurance staff observing performance of re-use techniques.

Regional offices and state survey agencies are now asked to monitor ESRD facilities based upon these revised CDC guidelines. The CDC emphasized, when issuing the new guidelines, that these procedures must be followed strictly to ensure patient health and safety.

This revised information will be added to the SOM, Appendix H, the next time it is revised. Please share additional copies of this memorandum as necessary. If you have further questions, please contact Judith Kari of my staff at jkari@cms.hhs.gov or (410) 786-6829.

/s/
Steven A. Pelovitz

Attachment

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

July 5, 2002

Sean Tunis, M.D.
Acting Chief Medical Officer
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Dear Dr. Tunis:

On May 17, 2001, we published the article "*Serratia Liquefaciens* Bloodstream Infections from Contaminated Epoetin Alfa at a Hemodialysis Center" in the New England Journal of Medicine. Our investigation documented that at the hemodialysis center involved, overfill doses from single-use vials of epoetin alfa were saved after use on one or more patients and the residual volume was pooled into one vial and then subsequently given to other patients. In addition, gloves often were not used when pooling the medication, vials were repeatedly entered, and these practices together with extrinsic contamination of the hand soap used in the room where pooling occurred, led to extrinsic contamination of the vials and infections in the patients who received the pooled epoetin alfa. In addition, the Morbidity and Mortality Weekly Report, entitled "Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients" (2001;50:RR05) states that "intravenous medication vials labeled for single use, including erythropoetin, should not be punctured more than once. Once a needle has entered a vial labeled for single use, the sterility of the product can no longer be guaranteed. Residual medication from two or more vials should not be pooled into a single vial." It is my understanding that the Centers for Medicare and Medicaid Services (CMS) has incorporated the recommendations from these publications into the review protocols for the Conditions for Coverage for End-Stage Renal Disease Facilities.

I have been contacted by personnel from a number of dialysis centers to discuss these recommendations. They have argued that, if scrupulous infection control and aseptic practices are used in entering an epoetin alfa vial minimizing the number of times the vial was entered, that growth of bacteria, even if introduced, would be very low and subsequent adverse events very unlikely, if the material in the vial is used over a short period of time. In reviewing the growth characteristics in other much more nutrient fluids, we agree that bacterial growth in 2-4 hours would be unlikely, even if they were introduced during manipulation. As a result, after discussions with appropriate Food and Drug Administration, CMS, and dialysis community personnel, we have developed a

series of recommendations that apply only to epoetin alfa, and other injectable medications administered to hemodialysis patients (i.e., intravenous iron preparations and vitamin D preparations) in vials labeled for single-use.

If the following procedures are strictly adhered to and enforced, re-entry and re-use of vials of intravenous epoetin alfa, iron, or vitamin D, labeled for single-use, hereafter referred to as medications, during 4 hours or less would have a low risk of patient infection.

1. All doses must be drawn-up by a licensed professional whose scope of practice includes administration of parenteral medications and knowledge of aseptic technique.

2. All doses from a given vial should be drawn-up and administered within a 4-hour period.

3. Only one vial of a given concentration of the medication should be opened and used by the administering professional at any given time. A second vial of the same medication must not be opened until the previous vial is discarded.

4. Any opened vials or filled syringes (with epoetin alpha, iron, or vitamin D) must be discarded if not used within 4 hours of first puncture of the vial. Vials must be labeled to document the time of first entry and maintained at a temperature of 2-8 degrees Celsius (or 36-46 degrees Fahrenheit) during non-use.

5. Residual amounts of these medications (either in the vial or syringes) must never be pooled with medication from another vial or syringe. If a patient requires more medication than is in a single, drawn syringe, then medication from a separate vial should be drawn into a separate syringe for administration.

6. Each facility must have in place a process monitoring (quality assurance) program which ensures compliance with these policies and procedures. These policies must include: a) recording data on infections in treated dialysis patients; and b) unannounced practice audits involving quality assurance staff observing performance of re-use techniques.

7. Failure to comply with these recommendations, particularly re-entry and re-use of single use vials of epoetin alpha, iron, or vitamin D over a longer period of time or pooling of these medications from multiple vials, represents a potential hazard and must be avoided, since it would pose significant health and safety risks to patients.

We believe that if these procedures are strictly followed and enforced, re-entry and re-use of single-dose vials of epoetin alfa or other injectable medications (i.e., intravenous iron preparations or vitamin D preparations) administered to hemodialysis patients during the specified time periods would have a low risk of patient infection.

We appreciate your cooperation and support on this matter.

Sincerely yours,

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