
42 C.F.R. § 494.50

Condition: Reuse of hemodialyzers and bloodlines.

(a) *Standard: General requirements for the reuse of hemodialyzers and bloodlines.* Certain hemodialyzers and bloodlines—

- (1) May be reused for certain patients with the exception of Hepatitis B positive patients;
- (2) Must be reused only for the same patient; and
- (3) Must be labeled for multiple reuse in accordance with the premarket notification provisions of section 510(k) of the Food, Drug, and Cosmetics Act and 21 CFR 876.5860.

(b) *Standard: Reprocessing requirements for the reuse of hemodialyzers and bloodlines.* A dialysis facility that reuses hemodialyzers and bloodlines must adhere to the following reprocessing guidelines:

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