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## 42 C.F.R. § 413.237

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### Outliers.

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(a) The following definitions apply to this section.

(1) *ESRD outlier services* are the following items and services that are included in the ESRD PPS bundle:

- (i) Renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B.
- (ii) Renal dialysis laboratory tests that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B.
- (iii) Renal dialysis medical/surgical supplies, including syringes, used to administer renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B.
- (iv) Renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, covered under Medicare Part D, including renal dialysis oral-only drugs effective January 1, 2025.
- (v) Renal dialysis equipment and supplies, except for capital-related assets that are home dialysis machines (as defined in § 413.236(a)(2)), that receive the transitional add-on payment adjustment as specified in § 413.236, after the payment period has ended.

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