entities, directly, or indirectly, own 5 percent or more of each ESRD facility.

(f) To receive the low-volume adjustment, an ESRD facility must provide an attestation statement to their Medicare administrative contractor that the facility has met all the criteria as established in paragraphs (a), (b), (c), and (d) of this section.

(g) The low-volume adjustment applies only for dialysis treatments provided to adults (18 years or older).

[75 FR 49200, Aug. 12, 2010]

§ 413.235 Patient-level adjustments.

Adjustments to the per-treatment base rate may be made to account for variation in case-mix. These adjustments reflect patient characteristics that result in higher costs for ESRD facilities.

(a) CMS adjusts the per treatment base rate for adults to account for patient age, body surface area, low body mass index, onset of dialysis (new patient), and co-morbidities, as specified by CMS.

(b) CMS adjusts the per treatment base rate for pediatric patients in accordance with section 1881(b)(14)(D)(iv)(I) of the Act, to account for patient age and treatment modality.

(c) CMS provides a wage-adjusted add-on per treatment adjustment for home and self-dialysis training.

[75 FR 49201, Aug. 12, 2010]

§ 413.237 Outliers.

(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) ESRD-related drugs and biologicals that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B;

(ii) ESRD-related laboratory tests that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B;

(iii) Medical/surgical supplies, including syringes, used to administer ESRD-related drugs that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; and

(iv) Renal dialysis service drugs that were or would have been, prior to January 1, 2011, covered under Medicare Part D, excluding ESRD-related oral-only drugs effective January 1, 2014.

(2) *Adult predicted ESRD outlier services Medicare allowable payment (MAP) amount* means the predicted per-treatment case-mix adjusted amount for ESRD outlier services furnished to an adult beneficiary by an ESRD facility.

(3) *Pediatric predicted ESRD outlier services Medicare allowable payment (MAP) amount* means the predicted per-treatment case-mix adjusted amount for ESRD outlier services furnished to a pediatric beneficiary by an ESRD facility.

(4) *Adult fixed dollar loss amount* is the amount by which an ESRD facility's imputed per-treatment MAP amount for furnishing ESRD outlier services to an adult beneficiary must exceed the adult predicted ESRD outlier services MAP amount to be eligible for an outlier payment.

(5) *Pediatric fixed dollar loss amount* is the amount by which an ESRD facility's imputed per-treatment MAP amount for furnishing ESRD outlier services to a pediatric beneficiary must exceed the pediatric predicted ESRD outlier services MAP amount to be eligible for an outlier payment.

(6) *Outlier Percentage:* This term has the meaning set forth in § 413.220(b)(4).

(b) *Eligibility for outlier payments*—(1) *Adult beneficiaries.* An ESRD facility will receive an outlier payment for a treatment furnished to an adult beneficiary if the ESRD facility's per-treatment imputed MAP amount for ESRD outlier services exceeds the adult predicted ESRD outlier services MAP amount plus the adult fixed dollar loss amount. To calculate the ESRD facility's per-treatment imputed MAP amount for an adult beneficiary, CMS divides the ESRD facility's monthly imputed MAP amount of providing ESRD outlier services to the adult beneficiary by the number of dialysis treatments furnished to the adult beneficiary in the relevant month. A beneficiary is considered an adult beneficiary if the beneficiary is 18 years old or older.

(2) *Pediatric beneficiaries.* An ESRD facility will receive an outlier payment