

(e) *Add-on amounts.* If all the physicians furnishing services to patients in an ESRD facility elect the initial method of payment (as described in §414.313(c) of this chapter), the prospective rate (as described in paragraph (a) of this section) paid to that facility is increased by an add-on amount as described in §414.313.

(f) *Additional payment for separately billable drugs and biologicals.* Prior to January 1, 2011, CMS makes additional payment directly to an ESRD facility for certain ESRD-related drugs and biologicals furnished to ESRD patients.

(1) Only on an assignment basis, directly to the facility which must accept, as payment in full, the amount that CMS determines;

(2) Subject to the Part B deductible and coinsurance;

(3) For drugs furnished prior to January 1, 2006, payment is made to hospital-based ESRD providers of services on a reasonable cost basis. Effective January 1, 2006, and prior to January 1, 2011, payment for drugs furnished by a hospital-based ESRD provider of service is based on the methodology specified in §414.904 of this chapter.

(4) For drugs furnished prior to January 1, 2006, payment is made to independent ESRD facilities based on the methodology specified in §405.517 of this chapter. Effective January 1, 2006, and prior to January 1, 2011, payment for drugs and biologicals furnished by independent ESRD facilities is based on the methodology specified in §414.904 of this chapter.

(5) Effective January 1, 2011, except as provided below, payment to an ESRD facility for renal dialysis service drugs and biologicals as defined in §413.171, furnished to ESRD patients on or after January 1, 2011 is incorporated within the prospective payment system rates established by CMS in §413.230 and separate payment will no longer be provided.

(6) Effective January 1, 2025, payment to an ESRD facility for renal dialysis service drugs and biologicals with only an oral form furnished to ESRD patients is incorporated within the prospective payment system rates estab-

lished by CMS in §413.230 and separate payment will no longer be provided.

[62 FR 43668, Aug. 15, 1997, as amended at 70 FR 70330, Nov. 21, 2005; 73 FR 69935, Nov. 19, 2008; 75 FR 49198, Aug. 12, 2010; 78 FR 72252, Dec. 2, 2013; 79 FR 66262, Nov. 6, 2014; 80 FR 69076, Nov. 6, 2015]

#### §413.176 Amount of payments.

For items and services, for which payment is made under section 1881(b)(7), section 1881(b)(12), and section 1881(b)(14) of the Act:

(a) If the beneficiary has incurred the full deductible applicable under Part B of Medicare before the dialysis treatment, Medicare pays the ESRD facility 80 percent of its prospective rate.

(b) If the beneficiary has not incurred the full deductible applicable under Part B of Medicare before the dialysis treatment, CMS subtracts the amount applicable to the deductible from the ESRD facility's prospective rate and pays the facility 80 percent of the remainder, if any.

[75 FR 49199, Aug. 12, 2010]

#### §413.177 Quality incentive program payment.

(a) With respect to renal dialysis services as defined under §413.171, except for those renal dialysis services furnished during payment year 2022, in the case of an ESRD facility that does not earn enough points under the program described at §413.178 to meet or exceed the minimum total performance score (as defined at §413.178(a)(8)) established by CMS for a payment year (as defined at §413.178(a)(10)), payments otherwise made to the facility under §413.230 for renal dialysis services during the payment year will be reduced by up to 2 percent as follows:

(1) For every 10 points that the total performance score (as defined at §413.178(a)(14)) earned by the ESRD facility falls below the minimum total performance score, the payments otherwise made will be reduced by 0.5 percent.

(2) [Reserved]

(b) Any payment reduction will apply only to the payment year involved and will not be taken into account in computing the single payment amount

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under this subpart for services provided in a subsequent payment year.

[76 FR 646, Jan. 5, 2011, as amended at 83 FR 57068, Nov. 14, 2018; 86 FR 62020, Nov. 8, 2021]

### § 413.178 ESRD quality incentive program.

(a) *Definitions.* As used in this section:

(1) *Achievement threshold* means the 15th percentile of national ESRD facility performance on a clinical measure during the baseline period for a payment year.

(2) *Baseline period* means, with respect to a payment year, the time period used to calculate the performance standards, benchmark, improvement threshold and achievement threshold that apply to each clinical measure for that payment year.

(3) *Benchmark* means, with respect to a payment year, the 90th percentile of national ESRD facility performance on a clinical measure during the baseline period that applies to the measure for that payment year.

(4) *Clinical measure* means a measure that is scored for a payment year using the methodology described in paragraphs (e)(1)(i) through (v) of this section.

(5) *End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP)* means the program authorized under section 1881(h) of the Social Security Act.

(6) *ESRD facility* means an ESRD facility as defined in § 413.171.

(7) *Improvement threshold* means an ESRD facility's performance on a clinical measure during the baseline period that applies to the measure for a payment year.

(8) *Minimum total performance score (mTPS)* means, with respect to a payment year except payment year 2023, the total performance score that an ESRD facility would receive if it performed at the 50th percentile of national ESRD facility performance on all clinical measures during the baseline period, and it performed at the median of national ESRD facility performance on all reporting measures using data from the most recently available year before the performance period.

(9) *Payment reduction* means the reduction, as specified by CMS, to each

payment that would otherwise be made to an ESRD facility under § 413.230 for a calendar year based on the TPS earned by the ESRD facility for the corresponding payment year that is lower than the mTPS score established for that payment year.

(10) *Payment year* means the calendar year for which a payment reduction, if applicable, is applied to the payments otherwise made to an ESRD facility under § 413.230.

(11) *Performance period* means the time period during which data are collected for the purpose of calculating an ESRD facility's performance on measures with respect to a payment year.

(12) *Performance standards* are, for a clinical measure, the performance levels used to award points to an ESRD facility based on its performance on the measure, and are, for a reporting measure, the levels of data submission and completion of other actions specified by CMS that are used to award points to an ESRD facility on the measure.

(13) *Reporting measure* means a measure that is scored for a payment year using the methodology described in paragraph (e)(1)(vi) of this section.

(14) *Total performance score (TPS)* means the numeric score ranging from 0 to 100 awarded to each ESRD facility based on its performance under the ESRD QIP with respect to a payment year.

(b) *Applicability of the ESRD QIP.* The ESRD QIP applies to ESRD facilities as defined at § 413.171 beginning the first day of the month that is 4 months after the facility CMS Certification Number (CCN) effective date.

(c) *ESRD QIP measure selection, retention, and removal*—(1) *ESRD QIP measure selection.* CMS specifies measures for the ESRD QIP for a payment year and groups the measures into domains. The measures for a payment year include:

(i) Measures on anemia management that reflect the labeling approved by the Food and Drug Administration for such management;

(ii) Measures on dialysis adequacy;

(iii) To the extent feasible, a measure (or measures) of patient satisfaction;