

(2) *Acquisitions after July 1970.* With respect to a facility or any tangible assets of a facility acquired on or after August 1, 1970, the excess of the price paid for such facility or such tangible assets over the historical cost, as defined in §413.134(b), or the cost basis, as determined under §413.134(g) (whichever is appropriate), is not includable in equity capital, and loans made to finance such excess portion of the cost of such acquisitions (see §413.153(d)) are excluded in computing equity capital.

(3) *Acquisitions prior to August 1970.* With respect to a facility or any tangible assets of a facility acquired before August 1970, the excess of the price paid for such facility or assets over the fair market value of tangible assets at the time of purchase is includable in equity capital to the extent that it is reasonable except that the cumulative allowable return for such excess may not exceed 100 percent of such excess. For purposes of this section, the cumulative allowable return means the sum of the allowable rate of return on equity capital for all months starting from August 1, 1970. For example, if the allowable rates of return on equity capital for a provider are 9 percent for the first year (and such year started August 1, 1970), 8.5 percent for the second year, and 10.5 percent for the third year, the cumulative allowable return at the end of the third year would be 28 percent. After the cumulative allowable return equals 100 percent, the inclusion in equity capital of the excess is no longer allowable.

(4) *Computation of return on equity capital.* For purposes of computing the allowable return, the amount of equity capital is the average investment during the reporting period. The rate of return allowed, as derived from time to time based upon interest rates in accordance with this principle, is determined by CMS and communicated through contractors. Return on investment as an element of allowable costs is subject to apportionment in the same manner as other elements of allowable costs.

Example of calculation of cumulative allowable return. X purchased a provider on July 1, 1969, paying \$100,000 in excess of the fair market value of the assets acquired. Provider X files its cost report on a calendar-year basis.

The allowable rate of return on equity capital for August 1, 1970-December 31, 1970 (4.538 percent), is obtained by multiplying the allowable rate of return for the period ending December 31, 1970 (10.891) by $\frac{5}{12}$ (a fraction of which the numerator is the number of months from August 1, 1970, to the end of the cost-reporting period and the denominator is the number of months in the cost-reporting period). The cumulative allowable return for Provider X for the period August 1, 1970-December 31, 1973, (32.367 percent) is computed as follows:

Cost reporting year ending	Rate of return on equity capital (percent)
Dec. 31, 1970	4.538
Dec. 31, 1971	8.969
Dec. 31, 1972	8.891
Dec. 31, 1973	9.969
Total	32.367

(The \$100,000 paid in excess of the fair market value of the assets acquired is included in equity capital until the sum of the allowable rate of return on equity capital equals 100 percent. Of course, no portion of the \$100,000 may be amortized as an allowable cost or is otherwise allowable for any program reimbursement purposes other than for determining the provider's equity capital.

[51 FR 34793, Sept. 30, 1986, as amended at 52 FR 21225, June 4, 1987; 52 FR 23398, June 19, 1987; 52 FR 32921, Sept. 1, 1987; 53 FR 12017, Apr. 12, 1988; 57 FR 39830, Sept. 1, 1992; 59 FR 26960, May 25, 1994]

Subpart H—Payment for End-Stage Renal Disease (ESRD) Services

SOURCE: 62 FR 43668, Aug. 15, 1997, as amended at 86 FR 73515, Dec. 27, 2021, unless otherwise noted.

§413.170 Scope.

This subpart implements sections 1881(b)(2), (b)(4), (b)(7), and (b)(12) through (b)(14) of the Act by—

(a) Setting forth the principles and authorities under which CMS is authorized to establish a prospective payment system for outpatient maintenance dialysis services in or under the supervision of an ESRD facility that meets the conditions of coverage in part 494 of this chapter and as defined in §413.171(c).

(b) Providing procedures and criteria under which a pediatric ESRD facility

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(an ESRD facility with at least a 50 percent pediatric patient mix as specified in § 413.184 of this subpart) may receive an exception to its prospective payment rate prior to January 1, 2011; and

(c) Establishing procedures that a facility must follow to appeal its payment amount under the prospective payment system.

[62 FR 43668, Aug. 15, 1997, as amended at 70 FR 70330, Nov. 21, 2005; 73 FR 20474, Apr. 15, 2008; 75 FR 49198, Aug. 12, 2010]

§ 413.171 Definitions.

For purposes of this subpart, the following definitions apply:

Base rate. The average payment amount per-treatment, standardized to remove the effects of case-mix and area wage levels and further reduced for budget neutrality and the outlier percentage. The base rate is the amount to which the patient-specific case-mix adjustments and any ESRD facility adjustments, if applicable, are applied.

Composite Rate Services. Items and services used in the provision of outpatient maintenance dialysis for the treatment of ESRD and included in the composite payment system established under section 1881(b)(7) and the basic case-mix adjusted composite payment system established under section 1881(b)(12) of the Act.

ESRD facility. An ESRD facility is an independent facility or a hospital-based provider of services (as described in § 413.174(b) and (c) of this chapter), including facilities that have a self-care dialysis unit that furnish only self-dialysis services as defined in § 494.10 of this chapter and meets the supervision requirements described in part 494 of this chapter, and that furnishes institutional dialysis services and supplies under § 410.50 and § 410.52 of this chapter.

New ESRD facility. A new ESRD facility is an ESRD facility (as defined above) that is certified for Medicare participation on or after January 1, 2011.

Pediatric ESRD Patient. A pediatric ESRD patient is defined as an individual less than 18 years of age who is receiving renal dialysis services.

Renal dialysis services. Effective January 1, 2011, the following items and

services are considered “renal dialysis services,” and paid under the ESRD prospective payment system under section 1881(b)(14) of the Act:

(1) Items and services included in the composite rate for renal dialysis services as of December 31, 2010;

(2) Erythropoiesis stimulating agents and any oral form of such agents that are furnished to individuals for the treatment of ESRD;

(3) Other drugs and biologicals that are furnished to individuals for the treatment of ESRD and for which payment was (prior to January 1, 2011) made separately under Title XVIII of the Act (including drugs and biologicals with only an oral form),

(4) Diagnostic laboratory tests and other items and services not described in paragraph (1) of this definition that are furnished to individuals for the treatment of ESRD.

(5) Renal dialysis services do not include those services that are not essential for the delivery of maintenance dialysis.

Separately billable items and services. Items and services used in the provision of outpatient maintenance dialysis for the treatment of individuals with ESRD that were or would have been, prior to January 1, 2011, separately payable under Title XVIII of the Act and not included in the payment systems established under section 1881(b)(7) and section 1881(b)(12) of the Act.

[75 FR 49198, Aug. 12, 2010]

§ 413.172 Principles of prospective payment.

(a) Payment for renal dialysis services as defined in § 413.171 and home dialysis services as defined in § 413.217 of this chapter are based on payment rates set prospectively by CMS.

(b) All approved ESRD facilities must accept the prospective payment rates established by CMS as payment in full for covered renal dialysis services as defined in § 413.171 or home dialysis services. Approved ESRD facility means—

(1) Any independent ESRD facility or hospital-based provider of services (as defined in § 413.174(b) and § 413.174(c) of this part) that has been approved by

CMS to participate in Medicare as an ESRD supplier; or

(2) Any approved independent facility with a written agreement with the Secretary. Under the agreement, the independent ESRD facility agrees—

(i) To maintain compliance with the conditions for coverage set forth in part 494 of this chapter and to report promptly to CMS any failure to do so; and

(ii) Not to charge the beneficiary or any other person for items and services for which the beneficiary is entitled to have payment made under the provisions of this part.

(c) CMS publishes the methodology used to establish payment rates and the changes specified in §413.196(b) in the FEDERAL REGISTER.

[62 FR 43668, Aug. 15, 1997, as amended at 73 FR 20474, Apr. 15, 2008; 75 FR 49198, Aug. 12, 2010]

§413.174 Prospective rates for hospital-based and independent ESRD facilities.

(a) *Establishment of rates.* CMS establishes prospective payment rates for ESRD facilities using a methodology that—

(1) Differentiates between hospital-based providers of services and independent ESRD facilities for items and services furnished prior to January 1, 2009;

(2) Does not differentiate between hospital-based providers of services and independent ESRD facilities for items and services furnished on or after January 1, 2009; and

(3) Requires the labor share be based on the labor share otherwise applied to independent ESRD facilities when applying the geographic index to hospital-based ESRD providers of services, on or after January 1, 2009.

(b) *Determination of independent facility.* For purposes of rate-setting and payment under this section, CMS considers any facility that does not meet all of the criteria of a hospital-based facility to be an independent facility. A determination under this paragraph (b) is an initial determination under §498.3 of this chapter.

(c) *Determination of hospital-based facility.* A determination under this paragraph (c) is an initial determination

under §498.3 of this chapter. CMS determines that a facility is hospital-based if the—

(1) Facility and hospital are subject to the bylaws and operating decisions of a common governing board. This governing board, which has final administrative responsibility, approves all personnel actions, appoints medical staff, and carries out similar management functions;

(2) Facility's director or administrator is under the supervision of the hospital's chief executive officer and reports through him or her to the governing board;

(3) Facility personnel policies and practices conform to those of the hospital;

(4) Administrative functions of the facility (for example, records, billing, laundry, housekeeping, and purchasing) are integrated with those of the hospital; and

(5) Facility and hospital are financially integrated, as evidenced by the cost report, which reflects allocation of overhead to the facility through the required step-down methodology.

(d) *Nondetermination of hospital-based facility.* In determining whether a facility is hospital-based, CMS does not consider—

(1) An agreement between a facility and a hospital concerning patient referral;

(2) A shared service arrangement between a facility and a hospital; or

(3) The physical location of a facility on the premises of a hospital.

(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;

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(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 established 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

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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 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, during the baseline period, it performed at the 50th percentile of national ESRD facility performance on all clinical measures and the median of national ESRD facility performance on all reporting measures.

(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.* CMS specifies measures for the ESRD QIP for a payment year and groups the measures into domains. The measures for a payment year include, but are not limited to:

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

(2) Measures on dialysis adequacy.

(3) To the extent feasible, a measure (or measures) of patient satisfaction.

(4) To the extent feasible, measures on iron management, bone mineral metabolism, and vascular access (including for maximizing the placement of arterial venous fistula).

(5) Beginning with the 2016 payment year, measures specific to the conditions treated with oral-only drugs and that are, to the extent feasible, outcomes-based.

(d) *Data submission requirement.* (1) Except as provided in paragraph (d)(3) and (4) of this section, and for a payment year, facilities must submit to CMS data on each measure specified by CMS under paragraph (c) of this section. Facilities must submit these data in the form, manner, and at a time specified by CMS.

(2) For purposes of paragraph (d)(1) of this section, the baseline period that applies to each of payment year 2023 and payment year 2024 is calendar year 2019 for purposes of calculating the achievement threshold, benchmark and minimum total performance score, and calendar year 2019 for purposes of calculating the improvement threshold.

The baseline period that applies to payment year 2025 is calendar year 2021 for purposes of calculating the achievement threshold, benchmark and minimum total performance score, and calendar year 2022 for purposes of calculating the improvement threshold, and the performance period that applies to payment year 2025 is calendar year 2023. Beginning with payment year 2026, the performance period and corresponding baseline periods are each advanced 1 year for each successive payment year.

(3) A facility may request and CMS may grant exceptions to the reporting requirements under paragraph (d)(1) of this section for one or more calendar days, when there are certain extraordinary circumstances beyond the control of the facility.

(4) A facility may request an exception within 90 days of the date that the extraordinary circumstances occurred by submitting the Extraordinary Circumstances Exception request form, which is available on the QualityNet website (<https://www.qualitynet.org/>), to CMS via email to the ESRD QIP mailbox at ESRDQIP@cms.hhs.gov. Facilities must provide the following information on the form:

- (i) Facility CCN.
- (ii) Facility name.
- (iii) CEO name and contact information.
- (iv) Additional contact name and contact information.
- (v) Reason for requesting an exception.
- (vi) Dates affected.
- (vii) Date the facility will start submitting data again, with justification for this date.
- (viii) Evidence of the impact of the extraordinary circumstances, including but not limited to photographs, newspaper, and other media articles.

(5) CMS will not consider an exception request unless the facility requesting such exception has complied with the requirements in paragraph (d)(4) of this section.

(6) CMS may grant exceptions to facilities without a request if it determines that one or more of the following has occurred:

- (i) An extraordinary circumstance affects an entire region or locale.

- (ii) An unresolved issue with a CMS data system affected the ability of a facility to submit data in accordance with paragraph (d)(1) of this section and CMS was unable to provide the facility with an alternative method of data submission.

(7) With the exception of first and second quarter 2020 ESRD QIP data for which CMS granted an exception under paragraph (d)(6) of this section, a facility that has been granted an exception to the data submission requirements under paragraph (d)(6) of this section may notify CMS that it will continue to submit data under paragraph (d)(1) of this section by sending an email signed by the CEO or another designated contact to the ESRD QIP mailbox at ESRDQIP@cms.hhs.gov. Upon receipt of an email under this clause, CMS will notify the facility in writing that CMS is withdrawing the exception it previously granted to the facility. With respect to fourth quarter 2019 ESRD QIP data for which CMS granted an exception under paragraph (d)(6) of this section, a facility is deemed to have met the requirements of this paragraph if the facility actually submitted the data by the March 31, 2020 submission deadline but did not notify CMS that it would do so.

(e) *Performance scoring under the ESRD QIP.* (1) CMS will award points to an ESRD facility based on its performance on each clinical measure for which the ESRD facility reports the applicable minimum number of cases during the performance period for a payment year, and based on the degree to which the ESRD facility submits data and completes other actions specified by CMS for a reporting measure during the performance period for a payment year.

(i) CMS will award from 1 to 9 points for achievement on a clinical measure to each ESRD facility whose performance on that measure during the applicable performance period meets or exceeds the achievement threshold but is less than the benchmark specified for that measure.

(ii) CMS will award 0 points for achievement on a clinical measure to each ESRD facility whose performance on that measure during the applicable performance period falls below the

achievement threshold specified for that measure.

(iii) CMS will award from 0 to 9 points for improvement on a clinical measure to each ESRD facility whose performance on that measure during the applicable performance period meets or exceeds the improvement threshold but is less than the benchmark specified for that measure.

(iv) CMS will award 0 points for improvement on a clinical measure to each ESRD facility whose performance on that measure during the applicable performance period is below the improvement threshold specified for that measure.

(v) CMS will award 10 points to each ESRD facility whose performance on a clinical measure during the applicable performance period meets or exceeds the benchmark specified for that measure.

(vi) CMS will award from 0 to 10 points to each ESRD facility on a reporting measure based on the degree to which, during the applicable performance period, the ESRD facility reports data and completes other actions specified by CMS with respect to that measure.

(2) CMS calculates the TPS for an ESRD facility for a payment year as follows:

(i) CMS calculates a domain score for each domain based on the total number of points the ESRD facility has earned under paragraph (e)(1) of this section for each measure in the domain and the weight that CMS has assigned to each measure.

(ii) CMS weights each domain score in accordance with the domain weight that CMS has established for the payment year.

(iii) The sum of the weighted domain scores is the ESRD facility's TPS for the payment year.

(f) *Public availability of ESRD QIP performance information.* (1) CMS will make information available to the public regarding the performance of each ESRD facility under the ESRD QIP on the Dialysis Facility Compare website, including the facility's TPS and scores on individual measures.

(2) Prior to making the information described in paragraph (f)(1) of this section available to the public, CMS will

provide ESRD facilities with an opportunity to review that information, technical assistance to help them understand how their performance under the ESRD QIP was scored, and an opportunity to request and receive responses to questions that they have about the ESRD QIP.

(3) CMS will provide each ESRD facility with a performance score certificate on an annual basis that describes the TPS achieved by the facility with respect to a payment year. The performance score certificate must be posted by the ESRD facility within 15 business days of the date that CMS issues the certificate to the ESRD facility, with the content unaltered, in an area of the facility accessible to patients.

(g) *Limitation on review.* There is no administrative or judicial review of the following:

(1) The determination of the amount of the payment reduction under section 1881(h)(1) of the Act.

(2) The specification of measures under section 1881(h)(2) of the Act.

(3) The methodology developed under section 1881(h)(3) of the Act that is used to calculate TPSs and performance scores for individual measures.

(4) The establishment of the performance standards and the performance period under section 1881(h)(4) of the Act.

(h) *Special rule for payment year 2022.*

(1) CMS will calculate a measure rate for all measures specified by CMS under paragraph (c) of this section for the PY 2022 ESRD QIP but will not score facility performance on any of those measures or calculate a TPS for any facility under paragraph (e) of this section.

(2) CMS will not establish a mTPS for PY 2022.

(i) *Special rules for payment year 2023.*

(1) CMS will calculate a measure rate for, but will not score facility performance on or include in the TPS for any facility under paragraph (e) of this section, the following measures: Standardized Hospitalization Ratio (SHR) clinical measure, Standardized Readmission Ratio (SRR) clinical measure, Long-Term Catheter Rate clinical measure, Standardized Fistula Rate clinical measure, ICH CAHPS clinical

measure, Percentage of Prevalent Patients Waitlisted (PPPW) clinical measure, and Kt/V Dialysis Adequacy clinical measure.

(2) The mTPS for payment year 2023 is the total performance score that an ESRD facility would receive if, during the calendar year 2019 baseline period, it performed at the 50th percentile of national ESRD facility performance on Hypercalcemia clinical measure, NHSN Blood Stream Infection (BSI) clinical measure, and the median of national ESRD facility performance on Clinical Depression Screening and Follow-Up reporting measure, Standardized Transfusion Ratio (STrR) reporting measure, Ultrafiltration Rate reporting measure, NHSN Dialysis Event reporting measure, and Medication Reconciliation (MedRec) reporting measure.

[83 FR 57068, Nov. 14, 2018, as amended at 84 FR 60803, Nov. 8, 2019; 85 FR 54872, Sept. 2, 2020; 86 FR 62020, Nov. 8, 2021; 87 FR 67302, Nov. 7, 2022]

§ 413.180 Procedures for requesting exceptions to payment rates.

(a) *Outpatient maintenance dialysis payments.* All payments for outpatient maintenance dialysis furnished at or by facilities are made on the basis of prospective payment rates.

(b) *Criteria for requesting an exception.* If a pediatric ESRD facility projects on the basis of prior year costs and utilization trends that it has an allowable cost per treatment higher than its prospective rate set under § 413.174, and if these excess costs are attributable to one or more of the factors in § 413.182, the facility may request, in accordance with paragraph (e) of this section, that CMS approve an exception to that rate and set a higher prospective payment rate.

(c) *Application of deductible and coinsurance.* The higher payment rate is subject to the application of deductible and coinsurance in accordance with § 413.176.

(d) *Payment rate exception request.* Effective October 1, 2002, CMS may approve exceptions to a pediatric ESRD facility's updated prospective payment rate, if the pediatric ESRD facility did not have an approved exception rate as of October 1, 2002. A pediatric ESRD fa-

cility may request an exception to its payment rate at any time after it is in operation for at least 12 consecutive months.

(e) *Documentation for a payment rate exception request.* If the facility is requesting an exception to its payment rate, it must submit to CMS its most recently completed cost report as required under § 413.198 and whatever statistics, data, and budgetary projections as determined by CMS to be needed to adjudicate each type of exception. CMS may audit any cost report or other information submitted. The materials submitted to CMS must—

(1) Separately identify elements of cost contributing to costs per treatment in excess of the facility's payment rate;

(2) Show that the facility's costs, including those costs that are not directly attributable to the exception criteria, are allowable and reasonable under the reasonable cost principles set forth in this part;

(3) Show that the elements of excessive cost are specifically attributable to one or more conditions specified in § 413.182;

(4) Specify the amount of additional payment per treatment the facility believes is required for it to recover its justifiable excess costs; and

(5) Specify that the facility has compared its most recently completed cost report with cost reports from (at least 2) prior years. The facility must explain any material statistical data or cost changes, or both, and include an explanation with the documentation supporting the exception request.

(f) *Completion of requirements and criteria.* The facility must demonstrate to CMS's satisfaction that the requirements of this section and the criteria in § 413.182 are fully met. The burden of proof is on the facility to show that one or more of the criteria are met and that the excessive costs are justifiable under the reasonable cost principles set forth in this part.

(g) *Approval of an exception request.* An exception request is deemed approved unless it is disapproved within 60 working days after it is filed with its contractor.

(h) *Determination of an exception request.* In determining the facility's payment rate under the exception process, CMS excludes all costs that are not reasonable or allowable under the reasonable cost principles set forth in this part.

(i) *Period of approval: Payment exception request.* A prospective exception payment rate approved by CMS applies for the period from the date the complete exception request was filed with its contractor until 30 days after the contractor's receipt of the facility's letter notifying the contractor of the facility's request to give up its exception rate and be subject to the basic case-mix adjusted composite payment rate methodology. ESRD facilities electing to retain their nonpediatric or pediatric exception rates (including self-dialysis training) do not need to notify their contractors. Once a facility notifies its contractor in writing that it cannot retain its current exception rate, that decision cannot be subsequently reversed.

(j) *Denial of an exception request.* CMS denies exception requests submitted without the documentation specified in §413.182 and the applicable regulations cited there.

(k) *Criteria for refiling a denied exception request.* A pediatric ESRD facility that was denied an exception request may immediately file another exception request. Any subsequent exception request must address and document the issues cited in CMS' denial letter.

(l) *Periods of exceptions.* (1) Prior to December 31, 2000, an ESRD facility may receive an exception to its composite payment rate for isolated essential facilities, self dialysis training costs, atypical service intensity (patient mix) and pediatric facilities.

(2) Effective December 31, 2000, an ESRD facility not subject to paragraph (1)(3), is no longer granted any new exception to the composite payment rate as defined in §413.180(1).

(3) Effective April 1, 2004 through September 27, 2004, and on an annual basis, an ESRD facility with at least 50 percent pediatric patient mix as specified in §413.184 of this part, that did not have an exception rate in effect as of October 1, 2002, may apply for an exception to its composite payment rate.

(4) For ESRD facilities that are paid a blended rate for renal dialysis services provided during the transition described in §413.239 of this part, any existing exceptions for isolated essential facilities, self dialysis training costs, atypical service intensity (patient mix) and pediatric facilities are used as the payment amount in place of the composite rate, and will be terminated for ESRD services furnished on or after January 1, 2014.

(5) For ESRD facilities that, in accordance with §413.239(b) of this part, elect to be paid for renal dialysis services provided during the transition based on 100 percent of the payment amount determined under §413.220, any existing exceptions for isolated essential facilities, self dialysis training costs, atypical service intensity (patient mix) and pediatric facilities are terminated for ESRD services furnished on or after January 1, 2011.

[62 FR 43668, Aug. 15, 1997, as amended at 70 FR 70331, Nov. 21, 2005; 75 FR 49199, Aug. 12, 2010]

§413.182 Criteria for approval of exception requests.

(a) CMS may approve exceptions to a pediatric ESRD facility's prospective payment rate if the pediatric ESRD facility did not have an approved exception rate as of October 1, 2002.

(b) The pediatric ESRD facility must demonstrate, by convincing objective evidence, that its total per treatment costs are reasonable and allowable under the relevant cost reimbursement principles of part 413 and that its per treatment costs in excess of its payment rate are directly attributable to any of the following criteria:

(1) Pediatric patient mix, as specified in §413.184.

(2) Self-dialysis training costs in pediatric facilities, as specified in §413.186.

[70 FR 70331, Nov. 21, 2005]

§413.184 Payment exception: Pediatric patient mix.

(a) *Qualifications.* To qualify for an exception to its prospective payment rate based on its pediatric patient mix a facility must demonstrate that—

(1) At least 50 percent of its patients are individuals under 18 years of age;

(2) Its nursing personnel costs are allocated properly between each mode of care;

(3) The additional nursing hours per treatment are not the result of an excess number of employees;

(4) Its pediatric patients require a significantly higher staff-to-patient ratio than typical adult patients; and

(5) These services, procedures, or supplies and their per treatment costs are clearly prudent and reasonable when compared to those of pediatric facilities with a similar patient mix.

(b) *Documentation.* (1) A pediatric ESRD facility must submit a listing of all outpatient dialysis patients (including all home patients) treated during the most recently completed and filed cost report (in accordance with cost reporting requirements under § 413.198) showing—

(i) Age of patients and percentage of patients under the age of 18;

(ii) Individual patient diagnosis;

(iii) Home patients and ages;

(iv) In-facility patients, staff-assisted, or self-dialysis;

(v) Diabetic patients; and

(vi) Patients isolated because of contagious disease.

(2) The facility also must—

(i) Submit documentation on costs of nursing personnel (registered nurses, licensed practical nurses, technicians, and aides) incurred during the most recently completed fiscal year cost report showing—

(A) Amount each employee was paid;

(B) Number of personnel;

(C) Amount of time spent in the dialysis unit; and

(D) Staff-to-patient ratio based on total hours, with an analysis of productive and nonproductive hours.

(ii) Submit documentation on supply costs incurred during the most recently completed fiscal or calendar year cost report showing—

(A) By modality, a complete list of supplies used routinely in a dialysis treatment;

(B) The make and model number of each dialyzer and its component cost; and

(C) That supplies are prudently purchased (for example, that bulk discounts are used when available).

(iii) Submit documentation on overhead costs incurred during the most recently completed fiscal or calendar year cost reporting year showing—

(A) The basis of the higher overhead costs;

(B) The impact on the specific cost components; and

(C) The effect on per treatment costs.

[62 FR 43668, Aug. 15, 1997, as amended at 70 FR 70331, Nov. 21, 2005]

§ 413.186 Payment exception: Self-dialysis training costs in pediatric facilities.

(a) *Qualification.* To qualify for an exception to the prospective payment rate based on self-dialysis training costs, the pediatric ESRD facility must establish that it incurs per treatment costs for furnishing self-dialysis and home dialysis training that exceed the facility's payment rate for the training sessions.

(b) *Justification.* To justify its exception request, a facility must—

(1) Separately identify those elements contributing to its costs in excess of the composite training rate; and

(2) Demonstrate that its per treatment costs are reasonable and allowable.

(c) *Criteria for determining proper cost reporting.* CMS considers the pediatric ESRD facility's total costs, cost finding and apportionment, including its allocation of costs, to determine if costs are properly reported by treatment modality.

(d) *Limitation of exception requests.* Exception requests for a higher training rate are limited to those cost components relating to training such as technical staff, medical supplies, and the special costs of education (manuals and education materials). These requests may include overhead and other indirect costs to the extent that these costs are directly attributable to the additional training costs.

(e) *Documentation.* The pediatric ESRD facility must provide the following information to support its exception request:

(1) A copy of the facility's training program.

(2) Computation of the facility's cost per treatment for maintenance sessions

and training sessions including an explanation of the cost difference between the two modalities.

(3) Class size and patients' training schedules.

(4) Number of training sessions required, by treatment modality, to train patients.

(5) Number of patients trained for the current year and the prior 2 years on a monthly basis.

(6) Projection for the next 12 months of future training candidates.

(7) The number and qualifications of staff at training sessions.

(f) *Accelerated training exception.* (1) A pediatric ESRD facility may bill Medicare for a dialysis training session only when a patient receives a dialysis treatment (normally 3 times a week for hemodialysis). Continuous cycling peritoneal dialysis (CCPD) and continuous ambulatory peritoneal dialysis (CAPD) are daily treatment modalities; ESRD facilities are paid the equivalent of three hemodialysis treatments for each week that CCPD and CAPD treatments are provided.

(2) If a pediatric ESRD facility elects to train all its patients using a particular treatment modality more often than during each dialysis treatment and, as a result, the number of billable training dialysis sessions is less than the number of actual training sessions, the facility may request a composite rate exception, limited to the lesser of the—

(i) Facility's projected training cost per treatment; or

(ii) Cost per treatment the facility receives in training a patient if it had trained patients only during a dialysis treatment, that is, three times per week.

(3) An ESRD facility may bill a maximum of 25 training sessions per patient for hemodialysis training and 15 sessions for CCPD and CAPD training.

(4) In computing the payment amount under an accelerated training exception, CMS uses a minimum number of training sessions per patient (15 for hemodialysis and 5 for CAPD and CCPD) when the facility actually provides fewer than the minimum number of training sessions.

(5) To justify an accelerated training exception request, an ESRD facility

must document that a significant number of training sessions for a particular modality are provided during a shorter but more condensed period.

(6) The facility must submit with the exception request a list of patients, by modality, trained during the most recent cost report period. The list must include each beneficiary's—

(i) Name;

(ii) Age; and

(iii) Training status (completed, not completed, being retrained, or in the process of being trained).

(7) The total treatments from the patient list must be the same as the total treatments reported on the cost report filed with the request.

[70 FR 70331, Nov. 21, 2005]

§413.194 Appeals.

(a) *Appeals under section 1878 of the Act.* (1) A facility that disputes the amount of its allowable Medicare bad debts reimbursed by CMS under §413.89(h)(3) may request review by the contractor or the Provider Reimbursement Review Board (PRRB) in accordance with subpart R to part 405 of this chapter.

(2) A facility must request and obtain a final agency decision prior to seeking judicial review of a dispute regarding the amount of allowable Medicare bad debts.

(b) *Other appeals.* (1) A facility that has requested higher payment per treatment in accordance with §413.180 may request review from the contractor or the PRRB if CMS has denied the request in whole or in part. In such a case, the procedure in subpart R of part 405 of this chapter is followed to the extent that it is applicable.

(2) The PRRB has the authority to review the action taken by CMS on the facility's requests. However, the PRRB's decision is subject to review by the Administrator under §405.1875 of this chapter.

(3) A facility must request and obtain a final agency decision, in accordance with paragraph (b)(1) of this section, prior to seeking judicial review of the denial, in whole or in part, of the exception request.

(c) *Procedure.* (1) The facility must request review within 180 days of the

date of the decision on which review is sought.

(2) The facility may not submit to the reviewing entity, whether it is the contractor or the PRRB, any additional information or cost data that had not been submitted to CMS at the time CMS evaluated the exception request.

(d) *Determining amount in controversy.* For purposes of determining PRRB jurisdiction under subpart R of part 405 of this chapter for the appeals described in paragraph (b) of this section—

(1) The amount in controversy per treatment is determined by subtracting the amount of program payment from the amount the facility requested under § 413.180; and

(2) The total amount in controversy is calculated by multiplying the amount in controversy per treatment by the projected number of treatments for the exception request period.

[62 FR 43668, Aug. 15, 1997, as amended at 81 FR 77965, Nov. 4, 2016]

§ 413.195 Limitation on Review.

Administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of the following is prohibited: The determination of payment amounts under section 1881(b)(14)(A) of the Act, the establishment of an appropriate unit of payment under section 1881(b)(14)(C) of the Act, the identification of renal dialysis services included in the bundled payment, the adjustments under section 1881(b)(14)(D) of the Act, the application of the phase-in under section 1881(b)(14)(E) of the Act, and the establishment of the market basket percentage increase factors under section 1881(b)(14)(F) of the Act.

[75 FR 49199, Aug. 12, 2010]

§ 413.196 Notification of changes in rate-setting methodologies and payment rates.

(a) CMS or the facility's contractor notifies each facility of changes in its payment rate. This notice includes changes in individual facility payment rates resulting from corrections or revisions of particular geographic labor cost adjustment factors.

(b) Changes in payment rates resulting from incorporation of updated cost data or general revisions of geographic labor cost adjustment factors are announced by notice published in the FEDERAL REGISTER without opportunity for prior comment. Revisions of the rate-setting methodology are published in the FEDERAL REGISTER in accordance with the Department's established rulemaking procedures.

(c) Effective for items and services furnished on or after January 1, 2011 and before January 1, 2012, CMS adjusts the composite rate portion of the basic case-mix adjusted composite payment system described in § 413.220 by the ESRD bundled market basket percentage increase factor.

(d) Effective for items and services furnished on or after January 1, 2012, CMS updates on an annual basis the following:

(1) The per-treatment base rate and the composite rate portion of the basic case-mix adjusted composite payment system described in § 413.220 by the ESRD bundled market basket percentage increase factor minus a productivity adjustment factor.

(2) The wage index using the most current hospital wage data.

(3) The fixed dollar loss amount as defined in § 413.237 of this part to ensure that outlier payments continue to be 1.0 percent of total payments to ESRD facilities.

[62 FR 43668, Aug. 15, 1997, as amended at 75 FR 49199, Aug. 12, 2010]

§ 413.198 Recordkeeping and cost reporting requirements for outpatient maintenance dialysis.

(a) *Purpose and Scope.* This section implements section 1881(b)(2)(B)(i) of the Act by specifying recordkeeping and cost reporting requirements for ESRD facilities under part 494 of this chapter. The records and reports will enable CMS to determine the costs incurred in furnishing outpatient maintenance dialysis as defined in § 413.170(a).

(b) *Recordkeeping and reporting requirements.* (1) Each facility must keep adequate records and submit the appropriate CMS-approved cost report in accordance with §§ 413.20 and 413.24, which

provide rules on financial data and reports, and adequate cost data and cost finding, respectively.

(2) The cost reimbursement principles set forth in this part (beginning with § 413.134, Depreciation, and excluding the principles listed in paragraph (b)(4) of this section), apply in the determination and reporting of the allowable cost incurred in furnishing outpatient maintenance dialysis treatments to patients dialyzing in the facility, or incurred by the facility in furnishing home dialysis service, supplies, and equipment.

(3) Allowable cost is the reasonable cost related to dialysis treatments. Reasonable cost includes all necessary and proper expenses incurred by the facility in furnishing the dialysis treatments, such as administrative costs, maintenance costs, and premium payments for employee health and pension plans. It includes both direct and indirect costs and normal standby costs. Reasonable cost does not include costs that—

- (i) Are not related to patient care for outpatient maintenance dialysis;
- (ii) Are for services or items specifically not reimbursable under the program;
- (iii) Flow from the provision of luxury items or services (items or services substantially in excess of or more expensive than those generally considered necessary for the provision of needed health services); or
- (iv) Are found to be substantially out of line with other institutions in the same area that are similar in size, scope of services, utilization, and other relevant factors.

(4) The following principles of this part do not apply in determining adjustments to allowable costs as reported by ESRD facilities:

- (i) Section 413.157, Return on equity capital of proprietary providers;
- (ii) Section 413.420, Payment to independent organ procurement organizations and to histocompatibility laboratories for kidney acquisition costs;
- (iii) Section 413.9, Cost related to patient care (except for the principles stated in paragraph (b)(3) of this section); and
- (iv) Sections 413.64, Payments to providers, and §§ 413.13, 413.30, 413.35, 413.40,

413.74, and §§ 415.55 through 415.70, § 415.162, and § 415.164 of this chapter, Principles of reimbursement for services by hospital-based physicians.

[62 FR 43668, Aug. 15, 1997, as amended at 73 FR 20474, Apr. 15, 2008; 87 FR 72287, Nov. 23, 2022]

§ 413.200 [Reserved]

§ 413.202 Organ procurement organization (OPO) cost for kidneys sent to foreign countries or transplanted in patients other than Medicare beneficiaries.

An OPO's total costs for all kidneys is reduced by the costs associated with procuring kidneys sent to foreign transplant centers or transplanted in patients other than Medicare beneficiaries. OPOs, as defined in § 486.302 of this chapter, must separate costs for procuring kidneys that are sent to foreign transplant centers and kidneys transplanted in patients other than Medicare beneficiaries from Medicare allowable costs prior to final settlement by the Medicare fiscal contractors. Medicare costs are based on the ratio of the number of usable kidneys transplanted into Medicare beneficiaries to the total number of usable kidneys applied to reasonable costs. Certain long-standing arrangements that existed before March 3, 1988 (for example, an OPO that procures kidneys at a military transplant hospital for transplant at that hospital), will be deemed to be Medicare kidneys for cost reporting statistical purposes. The OPO must submit a request to the contractor for review and approval of these arrangements.

[62 FR 43668, Aug. 15, 1997, as amended at 71 FR 31046, May 31, 2006]

§ 413.203 Transplant center costs for organs sent to foreign countries or transplanted in patients other than Medicare beneficiaries.

(a) A transplant center's total costs for all organs is reduced by the costs associated with procuring organs sent to foreign transplant centers or transplanted in patients other than Medicare beneficiaries. Organs are defined in § 486.302 (only covered organs will be paid for on a reasonable cost basis).

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(b) Transplant center hospitals must separate costs for procuring organs that are sent to foreign transplant centers and organs transplanted in patients other than Medicare beneficiaries from Medicare allowable costs prior to final cost settlement by the Medicare fiscal contractors.

(c) Medicare costs are based on the ratio of the number of usable organs transplanted into Medicare beneficiaries to the total number of usable organs applied to reasonable costs.

§ 413.210 Conditions for payment under the end-stage renal disease (ESRD) prospective payment system.

Except as noted in § 413.174(f), items and services furnished on or after January 1, 2011, under section 1881(b)(14)(A) of the Act and as identified in § 413.217 of this part, are paid under the ESRD prospective payment system described in § 413.215 through § 413.235 of this part.

(a) *Qualifications for payment.* To qualify for payment, ESRD facilities must meet the conditions for coverage in part 494 of this chapter.

(b) *Payment for items and services.* CMS will not pay any entity or supplier other than the ESRD facility for covered items and services furnished to a Medicare beneficiary. The ESRD facility must furnish all covered items and services defined in § 413.217 of this part either directly or under arrangements.

[75 FR 49199, Aug. 12, 2010]

§ 413.215 Basis of payment.

(a) Except as otherwise provided under § 413.235 or § 413.174(f) of this part, effective January 1, 2011, ESRD facilities receive a predetermined per treatment payment amount described in § 413.230 of this part, for renal dialysis services, specified under section 1881(b)(14) of the Act and as defined in § 413.217 of this part, furnished to Medicare Part B fee-for-service beneficiaries.

(b) In addition to the per-treatment payment amount, as described in paragraph (a) of this section, the ESRD facility may receive payment for bad

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debts of Medicare beneficiaries as specified in § 413.89(h)(3).

[75 FR 49200, Aug. 12, 2010, as amended at 81 FR 77965, Nov. 4, 2016]

§ 413.217 Items and services included in the ESRD prospective payment system.

The following items and services are included in the ESRD prospective payment system effective January 1, 2011:

(a) Renal dialysis services as defined in § 413.171; and

(b) Home dialysis services, support, and equipment as identified in § 410.52 of this chapter.

[75 FR 49200, Aug. 12, 2010]

§ 413.220 Methodology for calculating the per-treatment base rate under the ESRD prospective payment system effective January 1, 2011.

(a) *Data sources.* The methodology for determining the per treatment base rate under the ESRD prospective payment system utilized:

(1) Medicare data available to estimate the average cost and payments for renal dialysis services.

(2) ESRD facility cost report data capturing the average cost per treatment.

(3) The lowest per patient utilization calendar year as identified from Medicare claims is calendar year 2007.

(4) Wage index values used to adjust for geographic wage levels described in § 413.231 of this part.

(5) An adjustment factor to account for the most recent estimate of increases in the prices of an appropriate market basket of goods and services provided by ESRD facilities.

(b) *Determining the per treatment base rate for calendar year 2011.* Except as noted in § 413.174(f), the ESRD prospective payment system combines payments for the composite rate items and services as defined in § 413.171 of this part and the items and services that, prior to January 1, 2011, were separately billable items and services, as defined in § 413.171 of this part, into a single per treatment base rate developed from 2007 claims data. The steps to calculating the per-treatment base rate for 2011 are as follows:

(1) *Per patient utilization in CY 2007, 2008, or 2009.* CMS removes the effects

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of enrollment and price growth from total expenditures for 2007, 2008 or 2009 to determine the year with the lowest per patient utilization.

(2) *Update of per treatment base rate to 2011.* CMS updates the per-treatment base rate under the ESRD prospective payment system in order to reflect estimated per treatment costs in 2011.

(3) *Standardization.* CMS applies a reduction factor to the per treatment base rate to reflect estimated increases resulting from the facility-level and patient-level adjustments applicable to the case as described in § 413.231 through § 413.235 of this part.

(4) *Outlier percentage.* CMS reduces the per treatment base rate by 1 percent to account for the proportion of the estimated total payments under the ESRD prospective payment system that are outlier payments as described in § 413.237 of this part.

(5) *Budget neutrality.* CMS adjusts the per treatment base rate so that the aggregate payments in 2011 are estimated to be 98 percent of the amount that would have been made under title XVIII of the Social Security Act if the ESRD prospective payment system described in section 1881(b)(14) of the Act were not implemented.

(6) *First 4 Years of the ESRD prospective payment system.* During the first 4 years of ESRD prospective payment system (January 1, 2011 to December 31, 2013), CMS adjusts the per-treatment base rate in accordance with § 413.239(d).

[75 FR 49200, Aug. 12, 2010]

§ 413.230 Determining the per treatment payment amount.

The per-treatment payment amount is the sum of:

(a) The per treatment base rate established in § 413.220, adjusted for wages as described in § 413.231, and adjusted for facility-level and patient-level characteristics described in §§ 413.232 and 413.235 of this part;

(b) Any outlier payment under § 413.237;

(c) Any training adjustment add-on under § 413.235(c);

(d) Any transitional drug add-on payment adjustment under § 413.234(c); and

(e) Any transitional add-on payment adjustment for new and innovative

equipment and supplies under § 413.236(d).

[75 FR 49200, Aug. 12, 2010, as amended at 84 FR 60803, Nov. 8, 2019]

§ 413.231 Adjustment for wages.

(a) CMS adjusts the labor-related portion of the base rate to account for geographic differences in the area wage levels using an appropriate wage index (established by CMS) which reflects the relative level of hospital wages and wage-related costs in the geographic area in which the ESRD facility is located.

(b) The application of the wage index is made on the basis of the location of the ESRD facility in an urban or rural area as defined in this paragraph (b).

(1) *Urban area* means a Metropolitan Statistical Area or a Metropolitan division (in the case where a Metropolitan Statistical Area is divided into Metropolitan Divisions), as defined by OMB.

(2) *Rural area* means any area outside an urban area.

(c) Beginning January 1, 2023, CMS applies a cap on decreases to the wage index, such that the wage index applied to an ESRD facility is not less than 95 percent of the wage index applied to that ESRD facility in the prior calendar year.

(d) Beginning January 1, 2023, CMS applies a floor of 0.6000 to the wage index, such that the wage index applied to an ESRD facility is not less than 0.6000.

[75 FR 49200, Aug. 12, 2010, as amended at 87 FR 67302, Nov. 7, 2022]

§ 413.232 Low-volume adjustment.

(a) CMS adjusts the base rate for low-volume ESRD facilities, as defined in paragraph (b) of this section.

(b) A low-volume facility is an ESRD facility that, as determined based on the documentation submitted pursuant to paragraph (g) of this section:

(1) Furnished less than 4,000 treatments in each of the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent, except as specified in paragraph (g)(4) of this section) preceding the payment year; and

(2) Has not opened, closed, or received a new provider number due to a change in ownership (except where the change in ownership results in a change in facility type) in the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent) preceding the payment year.

(c) For the purpose of determining the number of treatments under paragraph (b)(1) of this section, the number of treatments considered furnished by the ESRD facility shall equal the aggregate number of treatments furnished by the ESRD facility and the number of treatments furnished by other ESRD facilities that are both:

(1) Under common ownership with, and

(2) Five (5) road miles or less from the ESRD facility in question.

(d) Common ownership means the same individual, individuals, entity, or entities, directly, or indirectly, own 5 percent or more of each ESRD facility.

(e) Except as provided in paragraph (f) of this section and unless extraordinary circumstances justify an exception, to receive the low-volume adjustment an ESRD facility must provide an attestation statement, by November 1st of each year preceding the payment year, to its Medicare Administrative Contractor (MAC) that the facility meets all the criteria established in this section, except that:

(1) For payment year 2012, the attestation must be provided by January 3, 2012;

(2) For payment year 2015, the attestation must be provided by December 31, 2014;

(3) For payment year 2016, the attestation must be provided by December 31, 2015; and

(4) For payment year 2021, the attestation must be provided by December 31, 2020.

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

(g) To receive the low-volume adjustment, an ESRD facility must include in their attestation provided pursuant to paragraph (e) of this section a statement that the ESRD facility meets the definition of a low-volume facility in paragraph (b) of this section. To deter-

mine eligibility for the low-volume adjustment, the MAC on behalf of CMS relies upon as filed or final settled 12-consecutive month cost reports, except as specified in paragraph (g)(4) of this section, for the 3 cost reporting years preceding the payment year to verify the number of treatments, except that:

(1) In the case of a hospital-based ESRD facility as defined in § 413.174(c), the MAC relies upon the attestation submitted pursuant to paragraph (e) of this section and may consider other supporting data in addition to the total treatments reported in each of the 12-consecutive month cost reports for the 3 cost reporting years preceding the payment year to verify the number of treatments that were furnished by the individual hospital-based ESRD facility seeking the adjustment; and

(2) In the case of an ESRD facility that has undergone a change of ownership wherein the ESRD facility's Medicare billing number does not change or changes due to a reclassification of facility type, the MAC relies upon the attestation and if the change results in two non-standard cost reporting periods (less than or greater than 12 consecutive months) does one of the following for the 3 cost reporting years preceding the payment year to verify the number of treatments:

(i) Combines the two non-standard cost reporting periods of less than 12 months to equal a full 12-consecutive month period; and/or

(ii) Combines the two non-standard cost reporting periods that in combination may exceed 12-consecutive months and prorates the data to equal a full 12-consecutive month period.

(3) In the case of an ESRD facility that has changed its cost reporting period, the MAC relies on the attestation and does one or both of the following for the 3-cost reporting years preceding the payment year to verify the number of treatments:

(i) Combines the two non-standard cost reporting periods of less than 12 months to equal a full 12-consecutive month period; and/or

(ii) Combines the two non-standard cost reporting periods that in combination may exceed 12-consecutive months and prorates the data to equal a full 12-consecutive month period.

(4) For payment years 2021, 2022, and 2023, the attestation specified in paragraph (e)(4) of this section must indicate that the ESRD facility meets all the criteria specified in this section, except that, for a facility that would not otherwise meet the number of treatments criterion specified in paragraph (b)(1) of this section because of the COVID-19 PHE, the facility may attest that it furnished less than 2,000 treatments in any six months during the cost-reporting period ending in 2020. For any facility that so attests—

(i) The facility must also attest that it furnished treatments equal to or in excess of 4,000 in the payment year due to temporary patient shifting as a result of the COVID-19 PHE; and

(ii) The MAC relies on the attestation and multiplies the total number of treatments for the 6-month period by 2.

(h) When an ESRD facility provides an attestation in accordance with paragraph (e) of this section, for the third eligibility year, the MAC verifies the as-filed cost report and takes one of the following actions:

(1) If the MAC determines an ESRD facility meets the definition of a low-volume facility as described in paragraph (b) of this section, CMS adjusts the low-volume facility's base rate for the entire payment year; or

(2) If the MAC determines an ESRD facility does not meet the definition of a low-volume facility as described in paragraph (b) of this section, the MAC reprocesses claims and recoups low-volume adjustments paid during the payment year.

[75 FR 49200, Aug. 12, 2010, as amended at 76 FR 70314, Nov. 10, 2011; 79 FR 66262, Nov. 6, 2014; 80 FR 69076, Nov. 6, 2015; 83 FR 57069, Nov. 23, 2018; 85 FR 71485, Nov. 9, 2020]

§ 413.233 Rural facility adjustment.

CMS adjusts the base rate for facilities in rural areas, as defined in § 413.231(b)(2).

[80 FR 69077, Nov. 6, 2015]

§ 413.234 Drug designation process.

(a) *Definitions.* For purposes of this section, the following definitions apply:

ESRD PPS functional category. A distinct grouping of drugs or biological

products, as determined by CMS, whose end action effect is the treatment or management of a condition or conditions associated with ESRD.

New renal dialysis drug or biological product. An injectable, intravenous, oral or other form or route of administration drug or biological product that is used to treat or manage a condition(s) associated with ESRD. It must be approved by the Food and Drug Administration (FDA) on or after January 1, 2020, under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, commercially available, have an HCPCS application submitted in accordance with the official Level II HCPCS coding procedures, and designated by CMS as a renal dialysis service under § 413.171. Oral-only drugs are excluded until January 1, 2025.

Oral-only drug. A drug or biological product with no injectable equivalent or other form of administration other than an oral form.

(b) *Drug designation process.* New renal dialysis drugs or biological products are included in the ESRD PPS bundled payment using the following drug designation process:

(1) If the new renal dialysis drug or biological product is used to treat or manage a condition for which there is an ESRD PPS functional category, the new renal dialysis drug or biological product is considered included in the ESRD PPS bundled payment and the following steps occur:

(i) The new renal dialysis drug or biological product is added to an existing ESRD PPS functional category.

(ii) Except as provided in paragraph (e) of this section, the new renal dialysis drug or biological product is paid for using the transitional drug add-on payment adjustment described in paragraph (c)(1) of this section.

(2) If the new renal dialysis drug or biological product is used to treat or manage a condition for which there is not an ESRD PPS functional category, the new renal dialysis drug or biological product is not considered included in the ESRD PPS bundled payment and the following steps occur:

(i) An existing ESRD PPS functional category is revised or a new ESRD PPS functional category is added for the

condition that the new renal dialysis drug or biological product is used to treat or manage;

(ii) The new renal dialysis drug or biological product is paid for using the transitional drug add-on payment adjustment described in paragraph (c)(2) of this section; and

(iii) The new renal dialysis drug or biological product is added to the ESRD PPS bundled payment following payment of the transitional drug add-on payment adjustment.

(c) *Transitional drug add-on payment adjustment.* A new renal dialysis drug or biological product is paid for using a transitional drug add-on payment adjustment, which is based on 100 percent of average sales price (ASP). If ASP is not available then the transitional drug add-on payment adjustment is based on 100 percent of wholesale acquisition cost (WAC) and, when WAC is not available, the payment is based on the drug manufacturer's invoice. Notwithstanding the provisions in paragraphs (c)(1) and (2) of this section, if CMS does not receive a full calendar quarter of ASP data for a new renal dialysis drug or biological product within 30 days of the last day of the 3rd calendar quarter after we begin applying the transitional drug add-on payment adjustment for the product, CMS will no longer apply the transitional drug add-on payment adjustment for that product beginning no later than 2-calendar quarters after we determine a full calendar quarter of ASP data is not available. If CMS stops receiving the latest full calendar quarter of ASP data for a new renal dialysis drug or biological product during the applicable time period specified in paragraph (c)(1) or (2) of this section, CMS will no longer apply the transitional drug add-on payment adjustment for the product beginning no later than 2-calendar quarters after CMS determines that the latest full calendar quarter of ASP data is not available.

(1) A new renal dialysis drug or biological product that is considered included in the ESRD PPS base rate is paid the transitional drug add-on payment adjustment for 2 years.

(i) Following payment of the transitional drug add-on payment adjust-

ment the ESRD PPS base rate will not be modified.

(ii) [Reserved]

(2) A new renal dialysis drug or biological product that is not considered included in the ESRD PPS base rate is paid the transitional drug add-on payment adjustment until sufficient claims data for rate setting analysis for the new renal dialysis drug or biological product is available, but not for less than 2 years.

(i) Following payment of the transitional drug add-on payment adjustment the ESRD PPS base rate will be modified, if appropriate, to account for the new renal dialysis drug or biological in the ESRD PPS bundled payment.

(ii) [Reserved]

(d) *Oral-only drug determination.* An oral-only drug is no longer considered oral-only if an injectable or other form of administration of the oral-only drug is approved by the Food and Drug Administration.

(e) *Exclusion criteria for the transitional drug add-on payment adjustment.* A new renal dialysis drug used to treat or manage a condition for which there is an ESRD PPS functional category is not eligible for payment using the transitional drug add-on payment adjustment described in paragraph (c)(1) of this section if the drug is approved by FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) or the new drug application (NDA) for the drug is classified by FDA as Type 3, 5, 7, or 8, Type 3 in combination with Type 2 or Type 4, or Type 5 in combination with Type 2, or Type 9 when the parent NDA is a Type 3, 5, 7 or 8 as described in paragraphs (e)(1) through (7) of this section, respectively:

(1) Type 3 NDA—New Dosage Form.

(i) A *Type 3 NDA* is for a new dosage form of an active ingredient that has been approved or marketed in the United States (U.S.) by the same or another applicant but in a different dosage form. The indication for the drug product does not need to be the same as that of the already marketed drug product. Once a new dosage form has been approved for an active ingredient, subsequent applications for the same dosage form and active ingredient should be classified as a *Type 5 NDA*, as

described in paragraph (e)(2) of this section.

(ii) [Reserved]

(2) Type 5 NDA—New Formulation or Other Differences.

(i) A *Type 5 NDA* is for a product, other than a new dosage form, that differs from a product already approved or marketed in the U.S. because of one of the following:

(A) The product involves changes in inactive ingredients that require either bioequivalence studies or clinical studies for approval and is submitted as an original NDA rather than as a supplement by the applicant of the approved product;

(B) The product is a duplicate of a drug product by another applicant (same active ingredient, same dosage form, same or different indication, or same combination), and

(1) Requires bioequivalence testing (including bioequivalence studies with clinical endpoints), but is not eligible for submission as a section 505(j) of the FD&C Act application; or

(2) Requires safety or effectiveness testing because of novel inactive ingredients; or

(3) Requires full safety or effectiveness testing because it is:

(i) Subject to exclusivity held by another applicant, or

(ii) A product of biotechnology and its safety and/or effectiveness are not assessable through bioequivalence testing, or

(iii) A crude natural product, or

(iv) Ineligible for submission under section 505(j) of the FD&C Act because it differs in bioavailability (for example, products with different release patterns); or

(4) The applicant has a right of reference to the application.

(C) The product contains an active ingredient or active moiety that has been previously approved or marketed in the U.S. only as part of a combination. This applies to active ingredients previously approved or marketed as part of a physical or chemical combination, or as part of a mixture derived from recombinant deoxyribonucleic acid technology or natural sources.

(D) The product is a combination product that differs from a previously

marketed combination by the removal of one or more active ingredients or by substitution of a new ester or salt or other noncovalent derivative of an active ingredient for one or more of the active ingredients. In the latter case, the NDA would be classified as a combination of a *Type 2 NDA* as described in paragraph (e)(5)(i) of this section, with a *Type 5 NDA* as described in paragraph (e)(2) of this section.

(E) The product contains a different strength of one or more active ingredients in a previously approved or marketed combination. A *Type 5 NDA*, as described in paragraph (e)(2) of this section, would generally be submitted by an applicant other than the holder of the approved application for the approved product. A similar change in an approved product by the applicant of the approved product would usually be submitted as a supplemental application.

(F) The product differs in bioavailability (for example, superbioavailable or different controlled-release pattern) and, therefore, is ineligible for submission as an abbreviated new drug application (ANDA) under section 505(j) of the FD&C Act.

(G) The product involves a new plastic container that requires safety studies beyond limited confirmatory testing (see 21 CFR 310.509, *Parenteral drug products in plastic containers*).

(ii) [Reserved]

(3) Type 7 NDA—Previously Marketed But Without an Approved NDA.

(i) A *Type 7 NDA* is for a drug product that contains an active moiety that has not been previously approved in an application, but has been marketed in the U.S. This classification applies only to the first NDA approved for a drug product containing this (these) active moiety(ies). *Type 7 NDAs* include, but are not limited to:

(A) The first post-1962 application for an active moiety marketed prior to 1938.

(B) The first application for an active moiety first marketed between 1938 and 1962 that is identical, related or similar (IRS) to a drug covered by a Drug Efficacy Study Implementation notice. Regulation at 21 CFR 310.6(b)(1) states that an identical, related, or similar drug includes other brands, potencies,

dosage forms, salts, and esters of the same drug moiety as well as any of drug moiety related in chemical structure or known pharmacological properties.

(C) The first application for an IRS drug product first marketed after 1962.

(D) The first application for an active moiety that was first marketed without an NDA after 1962.

(ii) [Reserved]

(4) Type 8 NDA—Prescription to Over-the-Counter (OTC).

(i) A *Type 8 NDA* is for a drug product intended for OTC marketing that contains an active ingredient that has been approved previously or marketed in the U.S. only for dispensing by prescription (OTC switch). A *Type 8 NDA* may provide for a different dosing regimen, different strength, different dosage form, or different indication from the product approved previously for prescription sale.

(ii) If the proposed OTC switch will apply to all indications, uses, and strengths of an approved prescription dosage form (leaving no prescription-only products of that particular dosage form on the market), the application holder should submit the change as a supplement to the approved application. If the applicant intends to switch only some indications, uses, or strengths of the dosage form to OTC status (while continuing to market other indications, uses, or strengths of the dosage form for prescription-only sale), the applicant should submit a new NDA for the OTC products, which would be classified as a *Type 8 NDA*.

(5) *Combination of Type 3 NDA*. Type 3 NDA, as described in paragraph (e)(1) of this section, in combination with a Type 2 NDA, as described in paragraph (e)(5)(i) of this section, or in combination with a Type 4 NDA, as described in paragraph (e)(5)(ii) of this section;

(i) Type 2 NDA—New Active Ingredient.

(A) A *Type 2 NDA* is for a drug product that contains a new active ingredient, but not a new molecular entity (NME). A new active ingredient includes those products whose active moiety has been previously approved or marketed in the U.S., but whose particular ester, salt, or noncovalent derivative of the unmodified parent mol-

ecule has not been approved by FDA or marketed in the U.S., either alone, or as part of a combination product. Similarly, if any ester, salt, or noncovalent derivative has been marketed first, the unmodified parent molecule would also be considered a new active ingredient, but not an NME. The indication for the drug product does not need to be the same as that of the already marketed product containing the same active moiety.

(B) If the active ingredient is a single enantiomer and a racemic mixture containing that enantiomer has been previously approved by FDA or marketed in the U.S., or if the active ingredient is a racemic mixture containing an enantiomer that has been previously approved by FDA or marketed in the U.S., the NDA will be classified as a *Type 2 NDA*.

(ii) Type 4 NDA—New Combination.

(A) A *Type 4 NDA* is for a new drug-drug combination of two or more active ingredients. An application for a new drug-drug combination product may have more than one classification code if at least one component of the combination is an NME or a new active ingredient. The new product may be a physical or chemical (for example, covalent ester or noncovalent derivative) combination of two or more active moieties.

(B) A new *physical combination* may be two or more active ingredients combined into a single dosage form, or two or more drugs packaged together with combined labeling. When at least one of the active moieties is classified as an NME, the NDA is classified as a combination of a *Type 1 NDA*, as described in paragraph (e)(5)(ii)(B)(1) of this section, with a *Type 4 NDA*, as described in paragraph (e)(5)(ii) of this section. When none of the active moieties is an NME, but at least one is a new active ingredient, the NDA is classified as a combination of a *Type 2 NDA*, as described in paragraph (e)(5)(i) of this section, with a *Type 4 NDA*, as described in paragraph (e)(5)(ii) of this section.

(1) Type 1 NDA—New Molecular Entity.

(i) A *Type 1 NDA* is for a drug product that contains an NME. An NME is an

active ingredient that contains no active moiety that has been previously approved by FDA in an application submitted under section 505 of the FD&C Act or has been previously marketed as a drug in the U.S. A pure enantiomer or a racemic mixture is an NME only when neither has been previously approved or marketed.

(ii) An NDA for a drug product containing an active moiety that has been marketed as a drug in the U.S., but never approved in an application submitted under section 505 of the FD&C Act, would be considered a *Type 7 NDA* as described in paragraph (e)(3) of this section, not a *Type 1 NDA*.

(iii) An NDA for a drug-drug combination product containing an active moiety that is an NME in combination with another active moiety that had already been approved by FDA would be classified as a new combination containing an NME (that is, *Type 1,4 NDA*, as described in paragraph (e)(5)(ii) of this section). For example, a drug-drug combination can include a fixed-combination drug product or a co-packaged drug product with two or more active moieties.

(iv) An active moiety in a radio-pharmaceutical (or radioactive drug product) which has not been approved by the FDA or marketed in the U.S. is classified as an NME.

(v) In addition, if a change in isotopic form results in an active moiety that has never been approved by the FDA or marketed in the U.S., the active ingredient is classified as an NME.

(C) An NDA for an active ingredient that is a *chemical combination* of two or more previously approved or marketed active moieties that are linked by an ester bond is classified as a combination of a *Type 2 NDA* as described in paragraph (e)(5)(i) of this section, with a *Type 4 NDA* as described in paragraph (e)(5)(ii) of this section, if the active moieties have not been previously marketed or approved as a physical combination. If the physical combination has been previously marketed or approved, however, such a product would no longer be considered a *new* combination and the NDA would thus be classified as a *Type 2 NDA*, as described in paragraph (e)(5)(i) of this section.

(6) *Combination of Type 5 NDA*. *Type 5 NDA*, as described in paragraph (e)(2) of this section, in combination with a *Type 2 NDA*, as described in paragraph (e)(5)(i) of this section.

(7) *Type 9 NDA when the parent NDA is a Type 3, Type 5, Type 7, or a Type 8*. A *Type 9 NDA*, as described in paragraph (e)(7)(i) of this section when the parent NDA is a *Type 3 NDA* as described in paragraph (e)(1) of this section or a *Type 5 NDA* as described in paragraph (e)(2) of this section or *Type 7 NDA* as described in paragraph (e)(3) of this section or a *Type 8 NDA* as described in paragraph (e)(4) of this section.

(i) *Type 9 NDA—New Indication or Claim, Drug Not to be Marketed under Type 9 NDA after Approval*.

(A) A *Type 9 NDA* is for a new indication or claim for a drug product that is currently being reviewed under a different NDA (the “parent NDA”), and the applicant does not intend to market this drug product under the *Type 9 NDA* after approval. Generally, a *Type 9 NDA* is submitted as a separate NDA so as to be in compliance with the guidance for industry on *Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees*.

(B) When the *Type 9 NDA* is submitted, it will be given the same NDA classification as the pending NDA. When one application is approved, the other will be reclassified as *Type 9* regardless of whether it was the first or second NDA actually submitted. After the approval of a *Type 9 NDA*, FDA will “administratively close” the *Type 9 NDA* and thereafter only accept submissions to the “parent” NDA.

(ii) [Reserved]

(f) *Methodology for modifying the ESRD PPS base rate to account for the costs of calcimimetics in the ESRD PPS bundled payment*. Beginning January 1, 2021, payment for calcimimetics is included in the ESRD PPS base rate using the following data sources and methodology:

(1) The methodology specified in paragraph (f)(2) of this section for determining the average per treatment payment amount for calcimimetics that is added to the ESRD PPS base rate uses the following data sources:

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(i) Total units of oral and injectable calcimimetics and total number of paid hemodialysis-equivalent dialysis treatments furnished, as derived from Medicare ESRD facility claims, that is, the 837-institutional form with bill type 072X, for the third and fourth quarters of calendar year 2018 and for the full calendar year 2019.

(ii) The weighted average ASP based on the most recent determinations by CMS.

(2) CMS uses the following methodology to calculate the average per treatment payment amount for calcimimetics that is added to the ESRD PPS base rate:

(i) Determines utilization of oral and injectable calcimimetics by aggregating the total units of oral and injectable calcimimetics in paragraph (f)(1) of this section.

(ii) Determines a price for each form of the drug by calculating 100 percent of the values from the most recent calendar quarter ASP calculations available to the public for the oral and injectable calcimimetic.

(iii) Calculates the total calcimimetic expenditure amount by multiplying the utilization of the oral and injectable calcimimetics determined in paragraph (f)(2)(i) of this section by their respective prices determined in paragraph (f)(2)(ii) of this section and adding the expenditure amount for both forms.

(iv) Calculates the average per treatment payment amount by dividing the total calcimimetic expenditure amount determined in paragraph (f)(2)(iii) of this section by the total number of paid hemodialysis-equivalent dialysis treatments in the third and fourth quarter of calendar year 2018 and the full calendar year 2019.

(v) Calculates the amount added to the ESRD PPS base rate by reducing the average per treatment payment amount determined in paragraph (f)(2)(iv) of this section by 1 percent to account for the outlier policy under § 413.237.

[80 FR 69077, Nov. 6, 2015, as amended at 83 FR 57070, Nov. 14, 2018; 84 FR 60803, Nov. 8, 2019; 85 FR 71485, Nov. 9, 2020]

EFFECTIVE DATE NOTE: At 87 FR 67302, Nov. 7, 2022, § 413.234 paragraph (a) was amended by adding the word “functional” before the

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word “equivalent” in the definition of “Oral-only drug”, effective Jan. 1, 2025.

§ 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]

§ 413.236 Transitional add-on payment adjustment for new and innovative equipment and supplies.

(a) *Basis and definitions.* (1) Effective January 1, 2020, this section establishes an add-on payment adjustment to support ESRD facilities in the uptake of new and innovative renal dialysis equipment and supplies under the ESRD prospective payment system under the authority of section 1881(b)(14)(D)(iv) of the Social Security Act.

(2) For purposes of this section, the following definitions apply:

Capital-related asset. Asset that an ESRD facility has an economic interest in through ownership (regardless of the manner in which it was acquired) and is subject to depreciation. Equipment obtained by the ESRD facility through operating leases are not considered capital-related assets.

Depreciation. The amount that represents a portion of the capital-related asset's cost and that is allocable to a period of operation.

Home dialysis machines. Hemodialysis machines and peritoneal dialysis cyclers in their entirety (meaning that one new part of a machine does not make the entire capital-related asset

new) that receive FDA marketing authorization for home use and when used in the home for a single patient.

Particular calendar year. The year in which the payment adjustment specified in paragraph (d) of this section would take effect.

Straight-line depreciation method. A method in accounting in which the annual allowance is determined by dividing the cost of the capital-related asset by the years of useful life.

Useful life. The estimated useful life of a capital-related asset is its expected useful life to the ESRD facility, not necessarily the inherent useful or physical life.

(b) *Eligibility criteria.* CMS provides for a transitional add-on payment adjustment for new and innovative equipment and supplies (as specified in paragraph (d) of this section) to an ESRD facility for furnishing a covered equipment or supply only if the item:

(1) Has been designated by CMS as a renal dialysis service under §413.171;

(2) Is new, meaning within 3 years beginning on the date of the Food and Drug Administration (FDA) marketing authorization;

(3) Is commercially available by January 1 of the particular calendar year, meaning the year in which the payment adjustment would take effect;

(4) Has a complete Healthcare Common Procedure Coding System (HCPCS) Level II code application submitted, in accordance with the HCPCS Level II coding procedures on the CMS website, by the HCPCS Level II code application deadline for biannual Coding Cycle 2 for durable medical equipment, orthotics, prosthetics and supplies (DMEPOS) items and services as specified in the HCPCS Level II coding guidance on the CMS website prior to the particular calendar year;

(5) Is innovative, meaning it meets the criteria specified in §412.87(b)(1) of this chapter; and

(6) Is not a capital-related asset, except for capital-related assets that are home dialysis machines.

(c) *Announcement of determinations and deadline for consideration of new renal dialysis equipment or supply applications.* CMS will consider whether a new renal dialysis supply or equipment meets the eligibility criteria specified

in paragraph (b) of this section and announce the results in the FEDERAL REGISTER as part of its annual updates and changes to the ESRD prospective payment system. CMS will only consider a complete application received by CMS by February 1 prior to the particular calendar year. FDA marketing authorization for the equipment or supply must occur by the HCPCS Level II code application deadline for biannual Coding Cycle 2 for DMEPOS items and services as specified in the HCPCS Level II coding guidance on the CMS website prior to the particular calendar year.

(d) *Transitional add-on payment adjustment for new and innovative equipment and supplies.* A new and innovative renal dialysis equipment or supply will be paid for using a transitional add-on payment adjustment for new and innovative equipment and supplies based on 65 percent of the MAC-determined price, as specified in paragraph (e) of this section. For capital-related assets that are home dialysis machines, payment is based on 65 percent of the pre-adjusted per treatment amount, as specified in paragraph (f)(1)(ii) of this section.

(1) The transitional add-on payment adjustment for new and innovative equipment and supplies is paid for 2-calendar years.

(2) Following payment of the transitional add-on payment adjustment for new and innovative equipment and supplies, the ESRD PPS base rate will not be modified and the new and innovative renal dialysis equipment or supply will be an eligible outlier service as provided in §413.237, except a capital-related asset that is a home dialysis machine will not be an eligible outlier service as provided in §413.237.

(e) *Pricing of new and innovative renal dialysis equipment and supplies.* (1) The Medicare Administrative Contractors (MACs) on behalf of CMS will establish prices for new and innovative renal dialysis equipment and supplies that meet the eligibility criteria specified in paragraph (b) of this section using verifiable information from the following sources of information, if available:

(i) The invoice amount, facility charges for the item, discounts, allowances, and rebates;

(ii) The price established for the item by other MACs and the sources of information used to establish that price;

(iii) Payment amounts determined by other payers and the information used to establish those payment amounts; and

(iv) Charges and payment amounts required for other equipment and supplies that may be comparable or otherwise relevant.

(2) [Reserved]

(f) *Pricing of new and innovative renal dialysis equipment and supplies that are capital-related assets that are home dialysis machines.* (1) The MACs calculate a pre-adjusted per treatment amount, using the prices they establish under paragraph (e) of this section for a capital-related asset that is a home dialysis machine, as defined in paragraph (a)(2) of this section, as follows:

(i) Calculate an annual allowance to determine the amount that represents the portion of the cost allocable to 1 year, using the straight-line depreciation method, by dividing the MAC-determined price by its useful life of 5 years.

(ii) Calculate a per treatment amount for use in calculating the pre-adjusted per treatment amount by dividing the annual allowance, as determined in paragraph (f)(1)(i) of this section, by the expected number of treatments.

(iii) Calculate a pre-adjusted per treatment amount to determine the amount that is adjusted by the 65 percent under paragraph (d) of this section, by subtracting the average per treatment offset amount (as determined using the data sources and methodology specified in paragraphs (f)(2) and (3) of this section, respectively, of this section) from the per treatment amount (as determined in paragraph (f)(1)(ii) of this section) to account for the costs already paid through the ESRD PPS base rate for current home dialysis machines that ESRD facilities already own.

(2) The methodology specified in paragraph (f)(3) of this section for determining the average per treatment

offset amount uses the following data sources:

(i) Dialysis machine and equipment cost, total cost across all dialysis modalities, the number of hemodialysis-equivalent home dialysis treatment counts, and the number of hemodialysis-equivalent total treatment counts are obtained from renal facility cost reports (CMS form 265–11) and hospital cost reports (CMS form 2552–10) using calendar years 2017–2019 cost reports.

(A) Dialysis machine and equipment costs are obtained by summing lines 8.01 through 17.02 from Worksheet B, Column 4 for renal facility cost reports, and by summing lines 2 through 11 from Worksheet I–2 for hospital cost reports.

(B) Total cost across all dialysis modalities are obtained by summing lines 8.01 through 17.02 from Worksheet C, Column 2 for renal facility cost reports, and by summing lines 1 through 10 from Worksheet I–4, Column 2 for the hospital cost reports.

(C) Hemodialysis-equivalent total treatment counts are obtained by summing lines 8.01 through 17.02 from Worksheet C, Column 1 for renal facility cost reports, and by summing lines 1 through 10 from Worksheet I–4, Column 1 for the hospital cost reports.

(D) Hemodialysis-equivalent home dialysis treatment counts are obtained by summing lines 14.01 through 17.02 from Worksheet C, Column 1 for renal facility cost reports, and by summing lines 7 through 10 from Worksheet I–4, Column 1 for the hospital cost reports. In both renal facility and hospital cost reports, home Continuous Ambulatory Peritoneal Dialysis and home Continuous Cyclic Peritoneal Dialysis are reported as patient weeks, so a conversion factor of 3 is applied to obtain hemodialysis-equivalent treatment counts.

(ii) [Reserved]

(3) CMS uses the following methodology to calculate the average per treatment offset amount for home dialysis machines that is subtracted from the per treatment amount as determined in paragraph (f)(1)(ii) of this section to determine the pre-adjusted per treatment amount specified in paragraph (f)(1)(iii) of this section:

(i) Calculates annualized values for calendar year 2018 at the ESRD facility level for the metrics specified in paragraph (f)(2)(i) of this section by dividing the numbers of days the cost report spanned to compute a per-day metric, then multiplying the resulting value by the number of days in 2018 the cost report covered to compute the metrics attributable to the period covered by the cost report in 2018. Next, for ESRD facilities with multiple cost reports covering 2018 the resulting metrics are aggregated. Finally, each ESRD facility's aggregated metrics are annualized to cover the full calendar year 2018. The annualization factor for an ESRD facility is the total number of days in 2018 divided by the total days in 2018 covered by the ESRD facility's cost report(s).

(ii) Calculates an estimated home dialysis machine and equipment cost for each ESRD facility by multiplying the annualized dialysis machine and equipment cost determined in paragraph (f)(3)(i) of this section by the ESRD facility's hemodialysis-equivalent home dialysis treatment percentage. The hemodialysis-equivalent home dialysis treatment percentage for each facility is calculated by dividing annualized hemodialysis-equivalent home treatment count determined in paragraph (f)(3)(i) of this section by annualized hemodialysis-equivalent treatment count across all modalities determined in paragraph (f)(3)(i) of this section.

(iii) Calculates an average home dialysis machine and equipment cost per home dialysis treatment for calendar year 2018 by dividing the sum of the estimated home dialysis machine and equipment cost in paragraph (f)(3)(ii) of this section across all ESRD facilities by the sum of annualized hemodialysis-equivalent home treatment counts determined in paragraph (f)(3)(i) of this section across all facilities.

(iv) Calculates the amount subtracted from the pre-adjusted treatment amount determined in paragraph (f)(1)(iii) of this section by inflating the average home dialysis machine and equipment cost per home dialysis treatment for calendar year 2018 determined in paragraph (f)(3)(iii) to calendar year 2021. The average home dialysis machine and equipment cost per

home dialysis treatment for calendar year 2018 is inflated to calendar year 2021 by multiplying this value by the payment rate update factor required under section 1881(b)(14)(F)(i) of the Social Security Act for calendar years 2019, 2020, and 2021. This value is then divided by a scaling factor to be converted to the ESRD PPS payment scale. The scaling factor is calculated by dividing the calendar year 2018 total cost per treatment inflated to calendar year 2021 by the average ESRD PPS payment per treatment projected for calendar year 2021.

(v) Effective January 1, 2022, CMS annually updates the amount determined in paragraph (f)(3)(iv) of this section by the ESRD bundled market basket percentage increase factor minus the productivity adjustment factor.

[84 FR 60805, Nov. 8, 2019, as amended at 85 FR 71486, Nov. 9, 2020]

§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) 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.

(vi) As of January 1, 2012, the laboratory tests that comprise the Automated Multi-Channel Chemistry panel are excluded from the definition of outlier services.

(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

for a treatment furnished to a pediatric beneficiary if the ESRD facility's per-treatment imputed MAP amount for ESRD outlier services exceeds the pediatric predicted ESRD outlier services MAP amount plus the pediatric fixed dollar loss amount. To calculate the ESRD facility's per-treatment imputed MAP amount for a pediatric beneficiary, CMS divides the ESRD facility's monthly imputed MAP amount of providing ESRD outlier services to the pediatric beneficiary by the number of dialysis treatments furnished to the pediatric beneficiary in the relevant month. A beneficiary is considered a pediatric beneficiary if the beneficiary is under 18 years old.

(c) *Outlier payment amount*: CMS pays 80 percent of the difference between:

(1) The ESRD facility's per-treatment imputed MAP amount for the ESRD outlier services, and

(2) The adult or pediatric predicted ESRD outlier services MAP amount plus the adult or pediatric fixed dollar loss amount, as applicable.

[75 FR 49201, Aug. 12, 2010, as amended at 76 FR 70314, Nov. 10, 2011; 78 FR 72252, Dec. 2, 2013; 79 FR 66262, Nov. 6, 2014; 80 FR 69077, Nov. 6, 2015; 84 FR 60806, Nov. 8, 2019; 85 FR 71487, Nov. 9, 2020]

§ 413.239 Transition period.

(a) *Duration of transition period and composition of the blended transition payment*. ESRD facilities not electing under paragraph (b) of this section to be paid based on the payment amount determined under § 413.230 of this part, will be paid a per-treatment payment amount for renal dialysis services (as defined in § 413.171 of this part) and home dialysis, provided during the transition as follows—

(1) For services provided on and after January 1, 2011 through December 31, 2011, a blended rate equal to the sum of:

(i) 75 percent of the payment amount determined under the ESRD payment methodology in effect prior to January 1, 2011 in accordance with section 1881(b)(12) of the Act and items and services separately paid under Part B; and

(ii) 25 percent of the payment amount determined in accordance with section 1881(b)(14) of the Act;

(2) For services provided on and after January 1, 2012 through December 31, 2012, a blended rate equal to the sum of:

(i) 50 percent of the payment amount determined under the ESRD payment methodology in effect prior to January 1, 2011 in accordance with section 1881(b)(12) of the Act and items and services separately paid under Part B; and

(ii) 50 percent of the payment rate determined in accordance with section 1881(b)(14) of the Act;

(3) For services provided on and after January 1, 2013 through December 31, 2013, a blended rate equal to the sum of:

(i) 25 percent of the payment amount determined under the ESRD payment methodology in effect prior to January 1, 2011 in accordance with section 1881(b) (12) of the Act and items and services separately paid under Part B; and

(ii) 75 percent of the payment amount determined in accordance with section 1881(b)(14) of the Act;

(4) For services provided on and after January 1, 2014, 100 percent of the payment amount determined in accordance with section 1881(b)(14) of the Act.

(b) *One-time election.* Except as provided in paragraph (b)(2) of this section, ESRD facilities may make a one-time election to be paid for renal dialysis services provided during the transition based on 100 percent of the payment amount determined under §413.215 of this part, rather than based on the payment amount determined under paragraph (a) of this section.

(1) Except as provided in paragraph (b)(3) of this section, the election must be received by each ESRD facility's Medicare administrative contractor (MAC) by November 1, 2010. Requests received by the MAC after November 1, 2010, will not be accepted regardless of postmarks, or delivered dates. MACs will establish the manner in which an ESRD facility will indicate their intention to be excluded from the transition and paid entirely based on payment under the ESRD PPS. Once the election is made, it may not be rescinded.

(2) If the ESRD facility fails to submit an election, or the ESRD facility's election is not received by their MAC

by November 1, 2010, payments to the ESRD facility for items and services provided during the transition will be based on the payment amounts determined under paragraph (a) of this section.

(3) ESRD facilities that become certified for Medicare participation and begin to provide renal dialysis services, as defined in §413.171 of this part, between November 1, 2010 and December 31, 2010, must notify their designated MAC of their election choice at the time of enrollment.

(c) *Treatment of new ESRD facilities.* For renal dialysis services as defined in §413.171, furnished during the transition period, new ESRD facilities as defined in §413.171, are paid based on the per-treatment payment amount determined under §413.215 of this part.

(d) *Transition budget-neutrality adjustment.* During the transition, CMS adjusts all payments, including payments under this section, under the ESRD prospective payment system so that the estimated total amount of payment equals the estimated total amount of payments that would otherwise occur without such a transition.

[75 FR 49201, Aug. 12, 2010]

§413.241 Pharmacy arrangements.

Effective January 1, 2011, an ESRD facility that enters into an arrangement with a pharmacy to furnish renal dialysis service drugs and biologicals must ensure that the pharmacy has the capability to provide all classes of renal dialysis service drugs and biologicals to patients in a timely manner.

[75 FR 49202, Aug. 12, 2010]

Subpart I—Prospectively Determined Payment Rates for Low-Volume Skilled Nursing Facilities, for Cost Reporting Periods Beginning Prior to July 1, 1998

SOURCE: 60 FR 37594, July 21, 1995, unless otherwise noted.