Centers for Medicare & Medicaid Services Calendar Year 2019 ESRD Prospective Payment System and Quality Incentive Program Final Rule Summary

CY 2019 Payment

2019 Base Rate

The base rate paid to dialysis facilities will be \$235.27.

Transitional Drug Add on Payment

CMS finalized its policy to pay for all new drugs and biologics including newly approved generics and biosimilars separately for a period of at least two years. If the drug fits into one of the existing functional categories, the TDAPA is limited to only 2 years. If the drug falls outside of an existing functional category the TDAPA could be extended beyond 2 years.

CMS will reimburse dialysis facilities for drugs and biologics under TDAPA the average sales price (ASP +0%) without any add-on beginning in 2020. If a new drug is approved in 2019 that falls outside of the functional categories, the current policy is to pay for that drug at ASP plus a 6% add on (ASP +6%). Patients will be responsible for paying the coinsurance for new medications during the TDAPA period and states that CMS does not have the authority to waive cost-sharing for patient adjusters.

Beyond 2020 once TDAPA ends for a new drug or biologic that falls into an existing functional category no new dollars will be added to the dialysis facilities base rate and it will be the responsibility of dialysis facilities to cover the costs. CMS appears to state that dialysis facilities can determine the worthiness of a drug and whether it will provide it to patients or not. This appears to be a departure from current policy where it's the responsibility of the dialysis facility to provide any renal dialysis drug within the functional categories that is prescribed to patients.

CMS states the outlier payments will allow facilities to receive reimbursement for patients who are using higher costing drugs (as long as it is not a composite rate drug). CMS states it will monitor beneficiary use of new drugs after the TDAPA period ends to ensure patients aren't losing access.

Other adjusters

NKF reiterated past year requests for CMS

- to eliminate the rural payment adjuster and instead revisit additional policies related to the Low Volume Facility Adjuster (LVPA) to ensure the adjuster adequately provides funds to support facilities that serve a critical access need and
- to revisit the patient case-mix adjusters of age body mass index (BMI) and body surface area (BSA) to ensure they are achieving their stated purpose of accounting for higher costing patients.

CMS finalized its proposed policy to allow dialysis facilities that experience a change in ownership to continue to qualify for the LVPA without a new three-year waiting period if it meets the other requirements and to allow dialysis facilities that miss the attestation deadline due to an extraordinary circumstance to receive an exception at the discretion of the Medicare Administrative Contractor. CMS

characterized NKF's comments on modifying the LVPA and patient case-mix adjusters as "out of scope." but did say it is launching a new research effort on this topic and plans to engage with stakeholders.

Solicitation for Information on Transplant and Modality Requirements

CMS does not address comments it solicited on home dialysis and transplant changes to the conditions for coverage, but thanked commenters and noted it would consider them for the future. NKF did not recommend changed to the conditions for coverage but did make substantial comments about the need for an earlier CKD payment model, improved education and to measure shared-decision making between patients and clinicians about their renal replacement therapy options.

Quality Incentive Program 2021-2024

Social Risk Factors

CMS restated its desire to expand on current efforts to address how patients with social risk factors influence performance on quality measures in the ESRD QIP. CMS responded that it shares our concern about adjusting measures for fear of masking disparities and also agreed with our recommendation to use the ESRD Networks to aid in quality improvement in disparities. NKF also recommended stratifying reporting on quality measures to illuminate any disparities in care. CMS referred commenters to the long-term care hospital and inpatient prospective payment system final rule for how it plans to stratify measures for social risk factors in hospitals. Separate from the ESRD PPS and QIP final rule, CMS also released a new request for information on how to account for social risk factors in healthcare settings. The National Quality Forum has also extended its trial on risk adjustment in quality measures.

Removal of Measures

CMS finalized its proposal to remove 4 measures from the QIP:

- 1. pain assessment and follow up;
- 2. healthcare personnel influenza vaccination;
- 3. anemia reporting measures.
- 4. Serum phosphorus

CMS agreed with NKF that removing pain assessment did not indicate that there weren't gaps in addressing pain in patients, but still proceeded with removal of the pain assessment measure due to high performance and high clinician burden of the measure.

Measure Weights

In response to comments, including those from NKF, CMS changed the weighting for the 2021 payment year. NKF had highlighted concerns with the high weighting of the standardized transfusion ratio (proposed at 22% and changed to 10% in the final rule) in particular. NKF recommended that one measure should not be given such a high weight unless there is a significant performance gap, the measure has met National Quality Forum (NQF) standards for reliability and validity, and there is agreement among clinicians and patients that the measure addresses a critical opportunity to advance quality improvement. The final 2021 measure weights are included in a Table 15 of the final rule pasted below.

Table 15: Finalized Performance Standards for the PY 2021 ESRD QIP C Measures Using the Most Recently Available Data²⁸

Measure	Achievement Threshold	Benchmark	Performance Standard
Vascular Access Type			
Standardized Fistula Rate	51.79%	75.22%	62.80%
Catheter Rate	19.20%	5.47%	12.01%
Kt/V Composite	92.98%	99.14%	96.88%
Hypercalcemia	1.86%	0.00%	0.58%
Standardized Transfusion Ratio	1.684	0.200	0.847
Standardized Readmission Ratio	1.268	0.629	0.998
NHSN Bloodstream Infection	1.479	0	0.694
SHR measure	1.249	0.670	0.967
ICH CAHPS: Nephrologists' Communication and Caring	58.09%	78.52%	67.81%
ICH CAHPS: Quality of Dialysis Center Care and Operations	54.16%	72.03%	62.34%
ICH CAHPS: Providing Information to Patients	73.90%	87.07%	80.38%
ICH CAHPS: Overall Rating of Nephrologists	49.33%	76.57%	62.22%
ICH CAHPS: Overall Rating of Dialysis Center Staff	49.12%	77.46%	63.04%
ICH CAHPS: Overall Rating of the Dialysis Facility	53.98%	82.48%	67.93%

Data sources: VAT measures: 2016 CROWNWeb; STrR, SHR: 2016 Medicare claims; SRR: 2017 Medicare claims; Kt/V: 2017 CROWNWeb and Medicare claims; Hypercalcemia: 2017 CROWNWeb; NHSN: 2017 CDC, ICH CAHPS: CMS 2017.

Percent of Patients Prevalent on the Transplant Waitlist (PPPW)

CMS disagreed with commenters, including the NKF, that dialysis facilities should not be accountable for driving performance on the waitlist. CMS acknowledged that there are other measures like the standardized readmission ratio that hold dialysis facilities accountable for care that is beyond their walls and requires coordination with other providers. CMS also acknowledged the variation in waitlist criteria and mentioned it would discuss with HRSA opportunities to address it. CMS finalized PPPW for payment year 2024.

Medication Reconciliation

CMS finalized its proposal to add the Kidney Care Quality Alliance Medication Reconciliation Measure to the QIP in 2022. NKF supported this addition in our comments on the proposed rule.

Modifications to measures

CMS noted our comments as out of scope of the proposed rule regarding the need for changes to many of the QIP measure specifications, including eliminating the pooled adequacy Kt/V measure and returning to separate measures or developing a true composite measure.