Wynne Health Group

Memorandum

November 3, 2020

CMS FINALIZES CY 2021 ESRD PPS; PAYMENTS EXPECTED TO INCREASE BY 2.0 PERCENT

The Centers for Medicare & Medicaid Services (CMS) **released the final calendar year (CY) 2021 prospective payment system (PPS) for end stage renal disease (ESRD) facilities** (proposed rule; fact sheet; press release).

- **What it is.** The final rule outlines ESRD PPS payment policies applying to dialysis facilities beginning on or after Jan. 1, 2020. The rule also includes final changes to the acute kidney injury (AKI) dialysis payment rate, as well as changes to the ESRD Quality Incentive Program (QIP).

- **Why it is important for you.** Under this final rule, CMS expects to pay $10.3 billion to approximately 7,400 facilities for furnishing dialysis services. Pursuant to the Trump administration's executive order last year (WHG summary), this final rule establishes policies to encourage greater uptake of home dialysis technology by implementing add-on payments for the use of such services. In response to the COVID-19 pandemic, CMS is also finalizing a provision that will allow low-volume facilities to continue receiving low-volume facility payment adjustments if a facility's case load increases to such a level that would normally disqualify it from receiving such adjustments, if the increase in services is attributable to COVID-19.

- **Potential next steps.** The finalized provisions go into effect on January 1, 2021.

CMS estimates that in CY 2021, **net payments to ESRD facilities will increase by 2.0 percent ($250 million) to all ESRD facilities compared with CY 2020.** Hospital-based ESRD facilities, however, will have an estimated 0.2 percent decrease in payments compared with freestanding facilities, which will experience the full estimated 2.0 percent increase. Specifically, the components of the ESRD rate update are:

- +1.6 percent market basket update (consisting of a 1.9 percent ESRD Bundled market basket percentage increase factor for CY 2020, reduced by a 0.3 percent multifactor productivity adjustment);
- +0.4 percent from outlier payment policies;
- -0.1 percent from bundling calcimimetics into the base rate;
- +0.0 percent from overall budget neutral wage indices and wage floor changes.

The full table expressing the impact on all ESRD facilities begins on p. 280. **Details on the CY 2021 final rule follow**.

- **Update to the ESRD PPS base rate** – The CY 2021 finalized ESRD PPS base rate is $253.13, up from the current base rate of $239.99. This amount reflects a reduced market basket increase (1.6 percent); application of the wage index budget-neutrality adjustment factor (0.999485); and the addition of $9.93 to the base rate for the inclusion of calcimimetics (discussed in more detail below).

- **Inclusion of Calcimimetics in the ESRD PPS Base Rate –** Beginning on p. 47, CMS finalizes a methodology for including the provision of calcimimetics into the ESRD PPS base rate. CMS is doing so because it will cease payment for calcimimetics using the transitional drug add-on payment adjustment (TDAPA) beginning in CY 2021. The agency states it will use claims data from the third quarter of calendar year (CY) 2018 through the fourth quarter of CY 2019 to determine the utilization of calcimimetics for calculating the base rate add-on. This differs from its proposed methodology, wherein CMS said it would use claims data from all of CY 2018 and 2019 to calculate the add-on amount.

  CMS will then take the most recent calendar quarter value for 2020 average sales price (ASP) of calcimimetics and multiply that across the utilization period described above to calculate the calcimimetics expenditure amount for an 18-month period. The agency is doing this for both oral and injectable forms of calcimimetics. This expenditure amount equals $683,246,041, which CMS then divides by the total number of dialysis treatments for Medicare beneficiaries during this same time period (68,148,651). This results in an average per-treatment payment amount of $10.03, which CMS further reduced by 1 percent to account for outlier policy, ultimately resulting in an add-on amount of $9.93.

- **Annual update to the wage index** – Wage indices are updated annual to reflect the most recent hospital wage index data and newest core-based statistical area (CBSA) delineations. CMS finalized its proposal to update the wage index values using the latest available data. CMS further notes the wage index is only applied to the labor-related share of the payment rate, and that the CY 2021 labor-related share is currently at 52.3 percent (same as proposed). CMS finalizes its proposal regarding wage index budget neutrality. The final CY 2021 ESRD PPS wage index is available in Addendum A, available here.

- **OMB delineations and 2-year transition** – As outlined in a 2018 bulletin, the Office of Management and Budget revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas. These delineations impact how CMS calculates the wage index used for the ESRD PPS. CMS finalized its proposal to adopt these new delineations for the CY 2021 ESRD PPS, codifying its proposal to include a 2-year transition policy that would temporarily shield an ESRD facility from substantial decreases in the wage index from the prior year. The final policy caps any wage index reductions at five percent in CY 2021, followed by no cap for CY 2022.

- **Outlier Policy Update –** CMS updates the outlier policy using the most recent data and to update the outlier services fixed-dollar loss (FDL) amounts for adult and pediatric patients as well as the Medicare Allowable Payment (MAP) amounts for adult and pediatric patients for CY 2021 using CY 2019 claims data (utilization of renal dialysis items and services). CMS notes that outlier payments represented approximately 0.5 percent of total payments in CY 2019 and fell short of the 1.0 percent target. CMS says that the CY 2021 updates to the outlier policy (predicated on CY 2019 claims data) are expected to increase payment for ESRD beneficiaries requiring higher resource utilization pursuant to the 1 percent outlier percentage. See Table 5 on p. 146 for further details.

- **Changes to the Eligibility Criteria and Determination Process Deadlines for the TPNIES –** CMS finalized its proposed definition for what is considered "new" for the purposes of applying the transition add-on payment adjustment for new and innovative equipment and supplies (TPNIES). Under the final rule, an item will be considered new for a three-year period beginning

on the date the FDA market authorization is granted rather than the TPNIES policy effective date of January 1, 2020.

CMS also finalized its proposal to align TPNIES regulations regarding eligibility with the HCPCS Level II coding guidelines by requiring applicants submit documentation of FDA marketing authorization to CMS by the deadline for biannual Coding Cycle 2 for DMEPOS items and items. CMS reiterates its rationale that the alignment would provide "consistency across CMS processes and transparency on deadlines for applicants for the TPNIES." The agency also finalized other technical changes on p. 59.

- **Expansion of the TPNIES for New and Innovative Capital-Related Assets** – Beginning on p. 65, CMS finalizes the expansion of the traditional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) to include certain capital-related assets that are home dialysis machines when used in the home for a single patient. The agency will pay 65 percent of the pre-adjusted per treatment amount for 2 years and TPNIES would apply for 3 years. To codify this proposal, the agency also finalizes the amened definition of "capital-related asset" as an 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. CMS will continue to exclude water purification systems and dialysis machines when they are used in-centers from TPNIES. The agency asserts that this new policy aligns with the President's Executive Order on Advancing American Kidney Health and will facilitate greater use of in-home dialysis.

- **Low-Volume Payment Adjustment (LVPA)** – For the duration of the COVID-19 public health emergency (PHE), CMS is finalizing its proposal to hold ESRD facilities that would otherwise qualify for the LPVA harmless if they experience an increase in treatment amounts in 2020 due to COVID-19 (p. 159). Facilities would be required to attest that the increase in treatments was due to COVID-19. Specifically, CMS finalizes that, to determine LVPA eligibility for payment years 2021, 2022, and 2023, it would only consider total dialysis treatments furnished for a six-month period of a facility's 2020 cost-reporting period, which a facility would choose. The six-month period could be consecutive or non-consecutive. A facility would therefore be able to demonstrate that its furnishing of over 4,000 treatments for the cost-reporting period ending in 2020 was due to temporary patient shifting resulting from COVID-19, and that its total dialysis treatments for any six-month period during that time is less than 2,000.

- **Calendar Year (CY) 2021 Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury (AKI)** – CMS finalizes a CY 2021 per treatment payment rate of $253.13 for renal dialysis services furnished by ESRD facilities to individuals with AKI. This update reflects the CY 2021 ESRD PPS base rate and the CY 2021 wage index. See p. 242 for more.

- **End-Stage Renal Disease Quality Incentive Program (ESRD QIP)** – Beginning on p. 246, CMS finalizes its proposed changes to the ESRD QIP for PY 2023 and 2024:

    - Replaces the current Ultrafiltration Rate reporting measure with a new equation that scores facilities based on eligible patient months, as opposed to facility-months. CMS asserts that the change better supports the goal of assessing performance on whether the facility is documenting UFR for its eligible patients, which will lead to better patient outcomes.

    - Updates the National Healthcare Safety Network (NHSN) validation study to allow facilities to submit patient records from any two quarters during the year and reduces the

sample size from 40 records to 20 records. CMS believes this approach will allow more flexibility and reduce facility burden by decreasing the required number of patient records.