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September 2, 2020

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Re: File code CMS-1732-P

Dear Ms. Verma:

The Medicare Payment Advisory Commission (MedPAC) welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS's) proposed rule entitled "Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program" in the *Federal Register*, vol. 85, no. 134, p. 42132–42208 (July 13, 2020). This proposed rule includes provisions that update the end-stage renal disease (ESRD) prospective payment system (PPS) for 2021, update the payment rate for services provided to individuals with acute kidney injury (AKI) when furnished in dialysis facilities, and address the ESRD Quality Incentive Program (QIP). We appreciate your staff's ongoing efforts to administer and improve payment systems for ESRD, particularly considering the competing demands on the agency.

Our comments address the following provisions in the proposed rule:

- Including oral and non-oral calcimimetics, which treat secondary hyperparathyroidism in dialysis patients, into the ESRD PPS bundled payment in calendar year (CY) 2021,
- Modifying the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) to include new and innovative capital-related assets that are home dialysis machines when used in the home for a single patient in CY 2021,
- Adopting the Office of Management and Budget's (OMB's) changes to geographic area delineations in the ESRD PPS wage index in CY 2021,
- Proposed CY 2021 update to the outlier policy, and
- Review of two applications for the TPNIES for CY 2021.

In addition, we reiterate prior comments about the accuracy of the cost reports that dialysis facilities submit to CMS and the ongoing CMS audit.

Including oral and non-oral calcimimetics into the ESRD PPS bundled payment

To improve provider efficiency, in 2011 Medicare began a PPS for outpatient dialysis services that expanded the prospective payment bundle to add (1) Part B dialysis drugs, laboratory tests, and other ESRD items and services that were previously billable separately and (2) Part D ESRD oral drugs—calcimimetics and phosphate binders. CMS delayed including ESRD oral-only drugs into the Part B ESRD PPS to give facilities additional time to make operational changes and logistical arrangements to furnish these products to their patients. In addition, several statutory changes precluded CMS from including ESRD oral-only drugs prior to January 1, 2025.

In 2016, CMS established a drug designation process (as mandated by the Protecting Access to Medicare Act of 2014) for determining when ESRD oral-only drugs are no longer oral only and therefore must be paid under the ESRD PPS. Under the process, once the Food and Drug Administration (FDA) approves an equivalent injectable product (or other non-oral forms), CMS pays facilities for the oral and non-oral products under the ESRD PPS through a transitional drug add-on payment adjustment (TDAPA) until sufficient claims data (at least two years of data) for rate-setting analysis are available; thereafter, the oral and non-oral products will be added to the ESRD PPS bundle, and the base rate will be updated to reflect their costs.¹

With the 2017 approval by the FDA of an injectable calcimimetic, CMS has paid, as of 2018, for cinacalcet (the oral product) and etelcalcetide (the injectable product) under the ESRD PPS using a TDAPA based on each product's average sales price (ASP).

The agency is proposing to add the oral and non-oral calcimimetics to the PPS bundle in 2021 because there are now sufficient claims data to conduct a rate-setting analysis. To account for the calcimimetics' cost, CMS calculated the calcimimetic addition to the ESRD PPS's base rate of \$12.18 per treatment (in 2020 dollars) by:

- Determining total calcimimetic utilization for oral and injectable drugs using both 2018 and 2019 claims submitted by dialysis facilities to CMS.
- Using the most recent calendar quarter of ASP data to price each calcimimetic according to its ASP, which is how the agency paid for the products under the TDAPA policy in 2020.
- Calculating total calcimimetic expenditures (in 2020 dollars) by multiplying total utilization of oral and injectable drugs by their respective ASPs.

¹ According to CMS, these products qualify for a TDAPA because the base ESRD payment rate has not yet accounted for their costs.

- Calculating an average per treatment cost (in 2020 dollars) by dividing total calcimimetic expenditures (\$1,096,200,947) by the total number of hemodialysis-equivalent treatments in 2018 and 2019 (90,014,098 treatments).²

Comment

Calcimimetics should be included in the ESRD PPS bundle, and the agency should increase the base rate to account for the drugs' costs. To determine the one-time addition to the ESRD PPS's base rate, CMS should use data on utilization and pricing that results in the *lowest average payment amount per treatment for these drugs*. Such an approach would be consistent with the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), which required that CMS establish the 2011 ESRD PPS using the lowest utilization of ESRD services (including drugs that were previously separately billable) per patient utilization year.³ Therefore, CMS should:

- Use the single year of claims data that would result in the lowest per treatment use of these products.
- Set the price for calcimimetics using values from the calendar quarter of ASP data that would result in the lowest total expenditures for these drugs, at 100 percent of ASP.
- Spread the cost of calcimimetics across all dialysis treatments, rather than the treatments of patients receiving the drugs.

Bundled payment encourages judicious consideration of the items and services provided to dialysis patients and cost-conscious decision making. Historically, the implementation of PPSs in Medicare has been characterized by providers quickly reducing use of services in the payment bundle. Because payments rates are not immediately adjusted, periods of "overpayment" allow providers to benefit from the change in practice patterns; however, the Medicare program does not realize savings until the payment rate is adjusted.⁴ We saw this pattern in the ESRD PPS when the ESRD bundle was introduced in 2011. Because of the decline in the use of ESRD drugs during the initial years of the ESRD PPS, the Congress required that CMS rebase (lower) the outpatient dialysis payment rate effective 2014. Consequently, when calculating the addition to the base rate to account for calcimimetics, we strongly believe that CMS should use the year that results in the lowest average payment amount per treatment for these drugs to minimize overestimates of use under the bundle.

² When adding the average per treatment cost to the ESRD base payment rate, CMS will reduce the estimated cost by 1 percent to fund the outlier pool, which is funded with 1 percent of total ESRD PPS payments. To cover the cost of calcimimetics, CMS proposes to add \$12.06 (in 2020 dollars) to the 2020 base rate, and then update the 2020 payment rate by a productivity-adjusted market basket increase for CY 2021.

³ To establish the 2011 ESRD PPS base rate (as mandated by MIPPA), the agency evaluated data from several years (2007, 2008, and 2009) and determined that utilization from a single year (2007) resulted in the lowest average payment amount per treatment, which reflected the lowest utilization of ESRD services.

⁴ Medicare Payment Advisory Commission. 2013. Comment letter on CMS's proposed notice entitled "Medicare Program: End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies." August 30.

To calculate the one-time addition to the base rate, CMS should use 2020 ASP pricing data from the most recent calendar quarter available because such data best reflect: (1) the increasing use of oral generic calcimimetics,⁵ which entered the market in late December 2018, and (2) how ESRD facilities are likely to purchase and furnish the oral calcimimetics in the future.

We support CMS's proposal to calculate total calcimimetic expenditures by multiplying each products' utilization by 100 percent of their ASP, since this is how CMS paid for these products in 2020. As we said in a previous comment letter, it is appropriate for CMS to pay for ESRD drugs under the TDAPA at 100 percent of their ASP.⁶

CMS should not use the alternative method discussed in the proposed rule, under which total calcimimetic expenditures would be based on utilization and pricing data from 2018 and 2019 because this method: (1) does not factor in the impact of oral generic calcimimetics, which entered the market beginning in late 2018, and (2) does not reflect the 2020 policy of paying ASP + 0, since in 2018 and 2019 calcimimetics were paid ASP + 6 percent.⁷ Under the alternative method, we estimate that the modification to the base rate for calcimimetics would likely be more than twice the amount compared to CMS's proposed approach.⁸ The alternative approach is not consistent with the method of using the lowest per patient utilization that MIPPA required when CMS established the ESRD PPS base rate in 2011.

Modifying the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) to include new and innovative capital-related assets that are home dialysis machines when used in the home for a single patient

As of 2020, CMS established an add-on payment for new and innovative ESRD-related equipment and supplies that are not capital-related assets under a "transitional add-on payment adjustment for new and innovative equipment and supplies" (TPNIES). CMS is proposing to utilize a similar determination process that the agency established for the TPNIES to expand eligibility to include capital-related assets that are home dialysis machines that receive FDA marketing authorization for home use and are used in the home for a single patient. CMS intends that this TPNIES proposal will "provide a transition period to support ESRD facility use of these machines when they are new and innovative to the market." Home dialysis machines would be eligible if the item:

⁵ There is a two-quarter lag in the data used to set Medicare's payment rates to allow manufacturers to submit ASP data and CMS to calculate and implement the new payment rates.

⁶ Medicare Payment Advisory Commission. 2019. Comment letter on CMS's proposed notice entitled "Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule Amounts, and DMEPOS Competitive Bidding (CBP) Proposed Amendments, Standard Elements for a DMEPOS Order, and Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements." September 20.

⁷ According to CMS, total calcimimetic expenditures in 2018 and 2019 were \$2.3 billion.

⁸ Based on aggregate 2018 and 2019 treatment and utilization included in the proposed rule and MedPAC data on 2018 treatment and utilization, we estimate that the one-time addition under the alternative approach would be roughly \$26 per treatment (in 2020 dollars).

- is new, meaning within three years beginning on the date of the FDA marketing,
- has a complete, submitted application for a Healthcare Common Procedure Coding System (HCPCS) billing code, and
- is innovative, defined as meeting the substantial clinical improvement (SCI) criteria that is based on the criteria used to determine a new technology's eligibility for the new technology add-on payment (NTAP) under the inpatient prospective payment system (IPPS) in section 412.87(b)(1).

Eligible home dialysis machines would be paid an add-on for two years. Thereafter, the item would be included in the ESRD PPS payment bundle without any increase to the base rate.

To price qualifying home dialysis machines, CMS is proposing to adopt a similar invoice-based approach that the agency established in 2020 for non-capital-related items paid under the TPNIES. Under this approach, due to the absence of data indicating a market price, Medicare Administrative Contractors (MACs) determine the payment of new equipment and supplies paid under the add-on adjustment taking into account: invoice amounts; facilities' charges for the item reported on its claims and their discounts, allowances, and rebates; the price established for the item by other MACs and the sources of information used to establish the price; payment amounts determined by other payers and the information used to establish those payment amounts; and charges and payment amounts required for other equipment and supplies that may be comparable or otherwise relevant. To mitigate Medicare spending resulting from the TPNIES, CMS sets the new item's payment rate at 65 percent of the price that the MACs establish.⁹ Because home dialysis machines are capital-related, depreciable assets, CMS is proposing to: (1) apply a five-year straight-line depreciation method to determine an annual allowance, by dividing the MAC-determined price by its useful life of five years and (2) divide the annual allowance by the number of treatments expected to be furnished in a year.

Comment

The Commission applauds the agency's commitment to increasing use of home dialysis among ESRD beneficiaries. Compared with in-center dialysis, home-based dialysis offers ESRD patients greater autonomy, fewer transportation challenges, improved quality of life, and enhanced satisfaction. The Commission also recognizes the need to promote beneficiary access to new technologies that improve outcomes while preserving the incentives within a prospective payment system for efficiency.¹⁰ However, we also believe that it is important to maintain the structure of the ESRD PPS and not create policies that will unbundle services covered under the ESRD PPS or create incentives that encourage high launch prices of capital-related technologies such as home dialysis machines as well as non-capital related ESRD-related equipment and supplies. For the reasons detailed in the following paragraphs, the Commission does not support CMS's proposal to

⁹ The percentage amount (65 percent) that the MACs apply to calculate the TPNIES payment is derived from the percentage amount that Medicare uses in the IPPS to pay for new technology (specified in section 412.88).

¹⁰ Medicare Payment Advisory Commission. 2019. Comment letter on CMS's proposed notice entitled "Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Hospital Prospective Payment System, and Proposed Policy Changes and Fiscal Year 2020 Rates; Proposed Quality Reporting Requirements for Specific Providers; Medicare and Medicaid promoting Interoperability Programs Proposed Requirements for Eligible Hospitals and Critical Access Hospitals; Proposed Rule." June 21.

pay a TPNIES for new home dialysis machines. Instead, CMS should address the clinical and nonclinical factors known to affect home dialysis use.

CMS's proposal would unbundle the ESRD PPS bundle

The ESRD bundle defines the set of ESRD-related services that are commonly provided during dialysis treatment. The ESRD PPS establishes a single payment amount for services commonly provided during dialysis treatments, and additional payments for cases in which home dialysis training is provided or certain costs are extremely high. In the Commission's view, an important goal of the ESRD PPS is to give dialysis facilities an incentive to provide ESRD-related items and services as efficiently as possible. We think this goal is best achieved by relying on the ESRD bundle to the greatest extent possible when determining payment amounts. Including all items and services with a similar function in the bundle fosters competition for ESRD-related items and services and generates pressure to reduce prices. For example, both MedPAC and CMS analysis of erythropoietin-stimulating agents (ESAs) has shown that price competition increased and ESA costs decreased after the market entry of a new ESA in 2015.^{11,12}

CMS's proposal to expand the TPNIES to include home dialysis equipment when used in the home by a single patient would undermine the integrity of the bundle and limit the competitive forces that generate price reductions. We also reiterate our comments from our September 20, 2019, comment letter, in which we acknowledged that the Secretary has the authority to make adjustments to the ESRD PPS but asserted (without weighing in on the applicability of statutory language) that the Secretary should maintain a single payment for items and services in the ESRD bundle. We note that the examples of such adjustments identified in statute (i.e., adjustments for providers of pediatric services, providers in rural areas, and geography) were introduced to the ESRD PPS in a budget-neutral manner (i.e., without establishing non-budget-neutral, separate payments). The Secretary now proposes to use the same authority to make add-on payments that are not budget neutral and could result in duplicative payments for home dialysis machines.

Home dialysis is increasing under the ESRD PPS

According to CMS, this proposal is in response to the 2019 Advancing American Kidney Health Initiative, an Executive Order that intends to transform kidney care, and CMS's goal of promoting home dialysis under the mandatory payment model—ESRD Treatment Choices Model (that would be implemented under the authority of the Center for Medicare & Medicaid Innovation). The agency states that expanding TPNIES would address stakeholders who contend that there is a need to promote dialysis device innovation, that current payment policy does not provide a pathway for adding new devices to the bundled payment, and that investors and industry need incentives to invest in the development of new devices.

¹¹ Medicare Payment Advisory Commission. 2019. *Report to the Congress: Medicare payment policy*. Washington, DC, MedPAC.

¹² Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2017. Medicare program; end-stage renal disease prospective payment system, payment for renal dialysis services furnished to individuals with acute kidney injury, and End-Stage Renal Disease Quality Incentive Program. Proposed rule. *Federal Register* 82, no. 127 (July 5): 31199.

The ESRD PPS provides a financial incentive over the long term for dialysis providers to furnish home dialysis, which is associated with less-intensive use of expensive injectable medications than in-center hemodialysis.¹³ Home dialysis use has been increasing since 2009, and researchers have shown that since 2011, the ESRD PPS is associated with its overall increase.¹⁴ Our research shows that between 2011 (when the ESRD PPS began) and 2018, the number of fee-for-service (FFS) beneficiaries dialyzing at home grew by about 45 percent, while the number of all FFS dialysis beneficiaries grew by about 8 percent.

The current payment structure provides support for the development of new home dialysis technologies and investment in home treatment. Stakeholders' concerns that the ESRD PPS does not incentivize home dialysis are not supported by past and current investment in this technology. For example, one manufacturer, which first received FDA approval for its home dialysis machine in 2005, subsequently received approval for additional new items in 2014 and 2017.¹⁵ In one of its financial filings, this manufacturer stated that "...There is also an increasing interest in the home hemodialysis market from other competitors."¹⁶ In 2019, another manufacturer of home dialysis equipment announced that it anticipates an investment of \$500 million to support the Advancing American Kidney Health Initiative.¹⁷

If CMS proceeds with proposal, eligible equipment should be innovative and payment should not be duplicative

The Commission does not support expanding the TPNIES to include home dialysis equipment, but if CMS proceeds with this proposal, the agency should:

- Require that the new product be an advance in medical technology that substantially improves beneficiaries' outcomes relative to technologies in the PPS payment bundle. We support the agency's proposal to use the IPPS substantial clinical improvement standard for new IPPS technology that is set forth in section 412.87(b)(1) for the ESRD PPS TPNIES.
- Remove the portion of payment attributable to home dialysis machines from the base rate for those cases receiving a TPNIES. Paying for new home dialysis machines under the TPNIES for two years is duplicative of payment for items with a similar purpose or use that are already paid under the ESRD PPS base rate. We support the agency's proposal to subtract the amount for capital-related machines that are already included in the ESRD PPS base rate for those cases receiving a TPNIES. Under this proposal, when facilities use a new home dialysis machine, the TPNIES would cover some of the cost of the new machine per

¹³ Shen, J. I., K. F. Erickson, L. Chen, et al. 2019. Expanded prospective payment system and use of outcomes with home dialysis by race and ethnicity in the United States. *Clinical Journal of the American Society of Nephrology* 14 (August): 1200–1212.

¹⁴ Lin, E., X. S. Cheng, K. K. Chin, et al. 2017. Home dialysis in the prospective payment system era. *Journal of the American Society of Nephrology* 28, no. 10 (October): 2993–3004.

¹⁵ <https://www.prnewswire.com/news-releases/nxstage-medical-announces-fda-clearance-for-solo-home-hemodialysis-using-nxstage-system-one-300509804.html>.

¹⁶ <https://www.sec.gov/Archives/edgar/data/0001333170/000095012311015749/b84122e10vk.htm>.

¹⁷ <https://www.baxter.com/baxter-newsroom/baxter-reports-second-quarter-2019-results>.

treatment minus a per treatment payment amount that the agency determines to be included in the base rate for current home machines, which CMS estimates to be \$9.23 per treatment.

Eliminating duplicative payments under the TPNIES is consistent with the Commission's prior comments, in which we said: (1) payments under the TDAPA for new dialysis drugs in an existing functional category and TPNIES for non-capital items are duplicative of the payment that is already made as part of the ESRD bundle and (2) the agency should reduce the add-on amount to reflect the amount already included in the base rate.¹⁸

- Base TPNIES payment on the price established by the MACs (using information from invoices and other relevant sources of information) but only for the first two calendar quarters after CMS begins applying the TPNIES. Thereafter, CMS should set the price of new equipment and supplies using a method based on pricing data collected directly from each manufacturer, similar to how the agency establishes the ASP for Part B drugs. The ASP for a Part B drug reflects the average price realized by the manufacturer for its sales broadly across different types of purchasers and for patients with different types of insurance coverage. It is based on the manufacturer's sales to all purchasers (with certain exceptions) net of manufacturer rebates, discounts, and price concessions. There is a two-quarter lag in the data used to set ASP-based payment rates. An approach similar to how CMS collects ASP data would increase the consistency of pricing data and should lead to more accurate payment rates for items paid under the TPNIES. Similar to the TDAPA for ESRD drugs and biologics, CMS should link payment of the TPNIES to a requirement that equipment and supply manufacturers submit ASP-like data to the agency.
- Publish in the final rule an estimate of the increase in beneficiaries' and taxpayers' spending due to the proposed policy change and the method used to develop the estimate.

CMS should consider other approaches to increase home dialysis use before adopting TPNIES

The TPNIES policy is designed to increase home dialysis use by providing manufacturers a financial incentive to invest in home dialysis equipment. However, this proposed policy does not address other factors that affect the use of home dialysis, including both clinical (patients' other health problems and prior nephrology care) and nonclinical (e.g., patients' social circumstances and knowledge about treatment options and physicians' training and preference). Facility factors, such as unused in-center capacity or additional in-center shifts and each dialysis facility's staff experience, can also affect use of home dialysis. Some dialysis patients report that clinical staff did not provide them with information about their options.

Some clinical and nonclinical factors affecting home dialysis use are not immutable. For example, between 2008 and 2018, under an integrated care delivery system (Kaiser Permanente Northern

¹⁸ Medicare Payment Advisory Commission. 2018. Comment letter on CMS's proposed notice entitled "Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments to Correct Existing Regulations Related to the CBP for Certain DMEPOS." August 31.

California), peritoneal dialysis (PD) use among new dialysis patients more than doubled, from 15 percent to 34 percent. To augment the use of home dialysis, the health care system implemented a multidisciplinary, system-wide approach that increased patient and family education, educated health care professionals about the importance of PD, adopted operational improvements, monitored outcomes, and shared best practices with staff.¹⁹

Medicare's FFS payment policies may also affect use of home dialysis. As discussed in the Commission's March 2020 report, addressing these policies, with or without the implementation of the TPNIES, could encourage home dialysis use. For example:

- Medicare physician payments for dialysis care do not consistently result in incentives for physicians to prescribe home dialysis. Based on 2013 Medicare fee schedule data, the Government Accountability Office (GAO) found that the payment rate for managing adult home patients was lower than the average payment and maximum payment for managing adult in-center patients.²⁰ The Commission's analysis of 2018 data confirm GAO's finding.
- Under the ESRD PPS, short-term financial incentives may lead dialysis facilities and their clinician partners to encourage in-center hemodialysis because once substantial investment in a facility has been made, the marginal costs of treating an additional patient are likely lower for a new hemodialysis patient than for a new home patient. That is, a dialysis facility with an in-center hemodialysis unit incurs fixed costs whether its in-center capacity is utilized at half capacity or full capacity. GAO found that, in the short term, expanding the provision of in-center hemodialysis within existing facility space generally tends to increase that facility's Medicare margin and that the estimated increase is more than would result if the facility instead expanded the provision of home dialysis.²¹ For adult patients, Medicare pays dialysis facilities the same base payment amount whether a patient uses in-center hemodialysis or home dialysis.

To improve the care of ESRD patients and incentivize home dialysis and kidney transplantation, the Commission believes that CMS should modify CMMI's Comprehensive End-Stage Renal Disease Care Model. As we said in our comment letter of September 3, 2019, such an approach could: (1) provide a holistic approach to the care of beneficiaries with chronic kidney disease (prior to and after the start of dialysis), who often have multiple comorbidities in addition to kidney disease and (2) hold both dialysis facilities and managing clinicians jointly accountable for the outcomes (quality, utilization, and financial) of beneficiaries with chronic kidney disease, including rates of home dialysis and transplantation.²² Kidney transplant centers, a key participant in the transplant process, should also be considered to participate in such a model.

According to CMS, the proposed TPNIES for home dialysis equipment is intended to support the agency's efforts to encourage home dialysis, including its the proposed mandatory payment

¹⁹ Pravoverov, L. V., S. Zheng, R. Parikh, et al. 2019. Trends associated with large-scale expansion of peritoneal dialysis within an integrated care delivery model. *JAMA Internal Medicine* (September 9).

²⁰ Government Accountability Office. 2015. *End-stage renal disease: Medicare payment refinements could promote increased use of home dialysis*. Washington, DC: GAO.

²¹ GAO 2015.

²² Medicare Payment Advisory Commission. 2019. Comment letter on CMS's proposed notice entitled "Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures," September 3.

model—the ESRD Treatment Choices (ETC) Model—that aims to increase home dialysis and kidney transplantation among ESRD beneficiaries. In our comment letter of September 3, 2019, we raised significant methodological concerns such that we believe CMS should not implement the proposed ETC Model. We believe the proposed measurement of home dialysis and kidney transplantation rates lack sufficient validity to serve as the basis for the payment incentives. For both the home dialysis and transplant measures, we have specific concerns about the reliability of the measurement; the comparison-to-control-group benchmarks and scoring method; the risk-adjustment method; and, in certain instances, the alignment of incentives for participants.

Adopting the OMB’s changes to geographic area delineations in the ESRD PPS wage index

The wage index used for the ESRD PPS is calculated using the most recent pre-floor, pre-reclassified hospital wage data collected annually under the inpatient PPS and is assigned to a dialysis facility on the basis of the labor market area in which the facility is located. Dialysis facility labor market areas are delineated based on the core-based statistical areas (CBSAs) established by OMB. Periodically, OMB revises the delineations and CMS adopts them in establishing the wage index values. In 2018 OMB published an updated set of delineations that included the creation of new CBSAs, the splitting of some existing CBSAs, and changes in the designation of some areas from rural to urban and from urban to rural.

For 2021, CMS proposes to adopt the 2018 OMB delineations of geographic areas. CMS proposes a 5 percent limit on wage index reductions in a single year, thus mitigating the impact on dialysis facilities whose wage index values will decrease. The adoption of the new wage index values would be done in a budget-neutral manner.

Comment

The Commission supports the adoption of the new delineations of the geographic areas and the use of transition policies to mitigate the impact of changes to the wage index values. Regarding the limit on decreases to the wage index values, the Commission supports limiting wage index changes to 5 percent in one year. However, the Commission believes the limit should apply to both increases and decreases in the wage index, not just decreases. As a result, no provider would have its wage index value increase or decrease by more than 5 percent for 2021. Consistent with CMS’s proposed approach, the implementation of the revised relative wage index values (where changes are limited to plus or minus 5 percent per year) should be done in a budget-neutral manner.

Proposed CY 2021 update to the outlier policy

The outlier policy in the ESRD PPS reimburses some of a facility’s cost for patients with very high costs for items and services that were separately billable prior to the implementation of the ESRD PPS.²³ The goal of the outlier policy is to help compensate facilities for patients with extremely

²³ The remainder of the ESRD bundle is made up of items and services that were included in the composite rate, used for dialysis payments prior to 2011. Items and services that were formerly separately billable are generally drugs, labs, and related services.

high dialysis treatment costs. The policy intends to distribute 1 percent of total spending to the highest-cost months of treatment by reimbursing 80 percent of costs above a certain threshold. Each year, CMS estimates the outlier threshold based on two values, the average spending on separately billable services (or Medicare Allowable Payment (MAP) amount) and the amount of spending above the MAP that is necessary to meet the 1 percent of total spending target for the outlier policy (Fixed Dollar Loss (FDL) amount). The outlier threshold is the sum of the MAP and the FDL dollar amounts. CMS uses the most recently available claims data (from two calendar years prior to the payment year) to project MAP and FDL amounts for the following payment year.

CMS funds the outlier policy by withholding 1 percent of total expected spending.²⁴ If the outlier threshold is too high, less than 1 percent of total expected spending will be paid through the outlier policy and total ESRD PPS payments will be lower than intended (and vice versa if the outlier threshold is set too low).

For CY 2021, CMS proposes to update the outlier services MAP amounts and FDL amounts using 2019 claims data, which CMS believes will bring outlier payments closer to the 1 percent target. Also for CY 2021, CMS is proposing to make calcimimetics (which are added to the ESRD bundle for the first time in 2022) eligible for outlier payments, resulting in a 124 percent increase to the outlier threshold from \$84 in 2020 to \$188 in 2021.²⁵

Comment

We recognize the great difficulty in estimating an outlier threshold such that the 1 percent of the ESRD PPS spending target is met by the outlier policy. We also note that in every year since the ESRD PPS was implemented in 2011, the outlier threshold has been reduced and yet still turns out to have been set too high. This phenomenon suggests a declining trend in the use of outlier-eligible services (i.e., drugs and laboratory services that were separately billable under the prior payment system) for dialysis patients with very high estimated spending on those services. Each year, CMS states that updating the base year of data used to calculate the outlier threshold should bring the outlier payments closer to the targeted 1 percent, but this strategy alone has not been effective.

The ongoing issue of outlier payments being too low may be exacerbated with calcimimetics becoming eligible in 2021 for outlier payments. The two problems are additive, meaning that the outlier payments may be too low because (1) the outlier threshold calculation does not account for the trend of decreasing spending for services previously eligible for an outlier payment; and (2) in making calcimimetics eligible for outlier payments in 2021, the outlier threshold calculation does not account for the likelihood that calcimimetic use will be lower after calcimimetics are added to the ESRD bundle. Specifically:

²⁴ When implementing the ESRD PPS in CY 2011, CMS funded the outlier pool by reducing the per treatment base rate by 1 percent to account for the proportion of the estimated total payments that are outlier payments.

²⁵ With the addition of calcimimetics to the ESRD bundle, CMS is proposing to add the cost of calcimimetics to the base rate and withhold 1 percent of that cost to fund its share of the outlier pool.

- The fact that CMS is proposing to increase the outlier threshold by 126 percent in 2021, rather than decrease the threshold as the agency has done in every other year, corroborates the reliance on high calcimimetic use for receiving an outlier payment in 2021.
- If calcimimetic use decreases between 2019 (when the products were paid under a TDAPA) and 2021 (when the products will be paid under the PPS bundle), the outlier threshold will be set too high and outlier payments will be lower than the 1 percent of total 2021 payments.

Consequently, the Commission reiterates our suggestion from our September 20, 2019, comment letter that CMS consider modeling alternative approaches to establishing the outlier threshold and use an approach that reflects the trend in separately billable spending over time. Other CMS payment systems use trend information when establishing similar payment policies.²⁶ Such an approach could produce a more reliable outlier threshold estimate and may result in the outlier payment amounts that, on average, are closer to the target.

Review of two applications for the TPNIES

As discussed above, in 2020, CMS established a TPNIES for new and innovative ESRD equipment and supplies. Baxter and Outset Medical each submitted applications for the TPNIES for 2021.²⁷ CMS concluded that there is insufficient evidence for Baxter's technology at this time to demonstrate a clear clinical benefit for Medicare dialysis patients. Within the larger policy context of FDA approval and that TPNIES does not cover capital-related assets, CMS concluded that there are some irregularities in the application submitted by Outset Medical, and the agency is concerned that the technology cannot be evaluated for meeting the SCI criteria.

Comment

We applaud CMS's thorough evaluation of whether each technology represents an advance in medical technology that substantially improves beneficiaries' outcomes relative to technologies in the PPS payment bundle. In our comment letter of September 20, 2019, we said that if CMS proceeds with its proposal to establish the TPNIES policy to new ESRD-related equipment and supplies, we believe that CMS should require that the new product be an advance in medical technology that substantially improves beneficiaries' outcomes relative to technologies in the PPS payment bundle. We support the agency's proposal to use the IPPS substantial clinical improvement standard for new IPPS technology that is set forth in section 412.87(b)(1) for the ESRD PPS TPNIES.

²⁶ For example, in establishing county benchmark rates, the Medicare Advantage program uses a prediction method that accounts for utilization trends for specific services combined with the most recent available prices.

²⁷ Baxter submitted an application for the Teranova 400 Dialyzer/Theranova 500 Dialyzer and Outset Medical submitted an application for the TPNIES for the Tablo® Cartridge for use with the Tablo® Hemodialysis System.

Auditing dialysis facilities' cost reports

PAMA required that the Secretary of Health and Human Services conduct audits of Medicare cost reports beginning in 2012 for a representative sample of freestanding and hospital-based facilities furnishing dialysis services, consistent with a prior MedPAC recommendation. To support this effort, the law authorized the Secretary to transfer \$18 million (in fiscal year 2014) from the Federal Supplementary Medical Insurance Trust Fund to CMS's program management. In September 2015, CMS awarded a contract to conduct the audit.

Comment

CMS should release the final results of the audit. In the final rule for the CY 2020 ESRD PPS (issued October 31, 2019), CMS said that the audit process is complete. CMS is conducting follow-up activities related to the audit to obtain summary results and investigating what adjustments were made on the cost reports of specific ESRD facilities. CMS will discuss the results when these follow-up activities are available in a future rule.

The Commission has repeatedly discussed the importance of auditing the cost reports that dialysis facilities submit to CMS to ensure that they are accurate. First, inaccurate cost report data could affect the ESRD PPS's payment adjustment factors and ESRD market basket index, which are derived from this data source. Second, accurate accounting of costs is essential for assessing facilities' financial performance under Medicare. The Medicare margin is calculated from this data source, and policymakers consider the margin (and other factors) when assessing the adequacy of Medicare's payments for dialysis services. If costs are overstated, then the Medicare margin is understated. Third, it has been more than 15 years since cost reports were audited, and in 2011, the outpatient dialysis payment system underwent a significant change, which might have affected how facilities report their costs. Finally, prior audits of facilities' cost reports have included costs that Medicare does not allow.

Conclusion

MedPAC appreciates the opportunity to comment on this proposed rule. The Commission also values the ongoing cooperation and collaboration between CMS and MedPAC staff on technical policy issues. We look forward to continuing this productive relationship.

If you have any questions, or require clarification of our comments, please feel free to contact James E. Mathews, MedPAC's Executive Director at (202) 220-3700.

Sincerely,



Michael E. Chernew, Ph.D.
Chairman