

August 30, 2021

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Re: File code CMS-1749-P

Dear Ms. Brooks-LaSure:

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, and End-Stage Renal Disease Treatment Choices Model" in the *Federal Register*, vol. 86, no. 129, pp. 36322–36437 (July 9, 2021). This proposed rule includes provisions that update the end-stage renal disease (ESRD) prospective payment system (PPS) for 2022, update the payment rate for services provided to individuals with acute kidney injury (AKI) when those services are furnished in dialysis facilities, address the ESRD Quality Incentive Program (QIP), and address the ESRD Treatment Choices (ETC) Model. 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:

- Updating the ESRD PPS base rate for calendar year (CY) 2022;
- Under the ETC Model, including nocturnal in-center dialysis in the home dialysis rate calculation for managing clinicians and for ESRD facilities not owned (in whole or in part) by a large dialysis organization (LDO);
- Request for information on estimating case-mix adjustments, including patient-level adjustments;
- Request for information on calculating the low-volume payment adjustment (LVPA) and the rural adjustment;
- Request for information on calculating the outlier payment adjustment; and
- Ensuring the accuracy of cost reports submitted by dialysis facilities.

Updating the ESRD PPS base rate for CY 2022

Per statutory requirements, CMS proposes to update the ESRD PPS base rate for CY 2022 by 1.0 percent. This update is based on the ESRD market basket increase factor (of 1.6 percent) reduced by a multifactor productivity adjustment (of 0.6 percent). The proposed CY 2022 ESRD PPS base rate is \$255.55, which is an increase of \$2.42 to the current base rate of \$253.13.

Comment

The Commission recognizes that CMS must provide the statutorily mandated payment update of the market basket minus the productivity adjustment; however, we note that the Commission has concluded that this increase is not warranted based on our analysis of payment adequacy. In our March 2021 report to the Congress, the Commission’s assessment of the adequacy of Medicare’s payments to freestanding dialysis facilities was generally positive. (Our payment adequacy assessment includes beneficiary access, supply of providers, providers’ access to capital, quality, and financial indicators for the sector.) The Medicare margin for freestanding dialysis facilities was 8.8 percent in CY 2019, and we project it will be 4 percent in CY 2021. Based on this assessment, the Commission recommended that, for 2022, the Congress eliminate the update to the 2021 ESRD PPS base rate.

The ESRD Treatment Choices Model: Calculating home dialysis rates

The ETC Model—which began January 1, 2021, and is currently scheduled to end June 30, 2027—is a mandatory Center for Medicare & Medicaid Innovation payment model that tests whether financial incentives result in increased home dialysis use and kidney transplantation among adult ESRD beneficiaries. The model adjusts certain Medicare payments to ESRD facilities and managing clinicians (who receive a monthly capitated payment established in the Part B physician fee schedule for outpatient dialysis-related management services) that are required to participate in the model, through positive or negative payment adjustments based on their home dialysis and kidney transplant rates. In 2020, when CMS finalized the model, it stated that:

“This value-based payment model will encourage participating care providers to invest in and build their home dialysis programs, allowing patients to receive care in the comfort and safety of their home.”¹

The ETC Model is intended to counter the short-term financial incentives under the ESRD PPS that may lead dialysis facilities and their clinician partners to encourage in-center hemodialysis to justify their investment in dialysis facilities. These incentives may be driven by marginal costs of treating an additional patient that are likely lower for a new hemodialysis patient than for a new

¹ Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2020. CMS announces transformative new model of care for Medicare beneficiaries with chronic kidney disease. <https://www.cms.gov/newsroom/press-releases/cms-announces-transformative-new-model-care-medicare-beneficiaries-chronic-kidney-disease>.

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.²

To measure facilities' performance under the ETC, CMS first calculates the rate of (or share of patients receiving) home dialysis for each facility, irrespective of ownership (i.e., whether or not the facility is owned by one of the LDOs). In this rule, CMS now proposes to include nocturnal in-center dialysis in the numerator of the home dialysis rate calculation for dialysis facilities not owned (in whole or in part) by one of the two LDOs and for managing clinicians.³ The agency contends that:

“this modality [in-center nocturnal dialysis] allows beneficiaries to continue to receive maintenance dialysis in an ESRD facility under medical supervision, but at a time of day that is more convenient for them, and in a manner that is associated with improved health outcomes. In particular, we believe that including nocturnal in-center dialysis in the home dialysis rate may improve access to alternative renal replacement modalities for beneficiaries who are unable to dialyze at home.”

CMS posits that this proposed change offers an additional pathway to success for ETC participants with more limited resources. According to the proposed rule, CMS received comments that some providers, particularly independent facilities or facilities owned by small dialysis organizations, may be unable to develop and maintain a home dialysis program. According to CMS: (1) operating a home dialysis program requires specialized staff, as well as upfront investment in additional equipment and certification and (2) establishing a nocturnal in-center dialysis program does not require additional equipment or certification, and may be more feasible for independent ESRD facilities or ESRD facilities owned by small dialysis organizations. The agency further states that facilities owned in whole or in part by LDOs do not incur the same resource constraints in establishing a home dialysis program as independent facilities or facilities owned by small dialysis organizations.

Comment

CMS should not proceed with the proposal to include nocturnal in-center dialysis in the numerator of the home dialysis rate calculation for dialysis facilities not owned in whole or in part by one of the two LDOs or for managing clinicians. As CMS acknowledges, this proposal runs counter to the ETC Model's goal of encouraging providers to invest in home dialysis and may result in non-LDO

² Government Accountability Office. 2015. *End-stage renal disease: Medicare payment refinements could promote increased use of home dialysis*. Washington, DC: GAO. The Government Accountability Office 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.

³ Specifically, CMS proposes to include nocturnal in-center in the numerator of the home dialysis rate calculation for facilities not owned in whole or in part by an LDO as well as for managing clinicians. In the numerator, CMS proposes to include one half of the total number of dialysis treatment beneficiary years during the measurement year in which the attributed beneficiaries received nocturnal in-center dialysis. For the ETC, CMS proposes to define an LDO as a legal entity that owns, in whole or in part, 500 or more dialysis facilities. There are currently two companies, Fresenius Medical Care and DaVita, that meet that definition.

model participants deciding to not develop or expand their home dialysis programs.⁴ We also find this proposal contrary to CMS’s statement that home dialysis “...gives patients the freedom to choose the therapy that works best with their lifestyles, without being tied to the dialysis facility’s schedule.”⁵ Compared with in-center dialysis, home dialysis offers patients greater flexibility, independence, and autonomy, as well as fewer transportation challenges. By contrast, patients on in-center dialysis are bound to the dialysis facility’s schedule.

The proposed rule lacks any analysis demonstrating that non-LDO facilities are unable to invest in home dialysis. Publicly available data suggest that non-LDO facilities do invest in home dialysis infrastructure. As shown in the table below, the share of in-center dialysis, peritoneal dialysis, and home hemodialysis in 2019 is comparable across the top 10 dialysis organizations.⁶ MedPAC analysis shows that the two largest dialysis organizations (Fresenius Medical Care and DaVita Inc.) in the table below accounted for 75 percent of all treatments furnished to dialysis beneficiaries in 2019. According to older data from the U.S. Renal Data System (not in the table), the prevalence of peritoneal and home hemodialysis was actually *lower* for the large and small freestanding chain dialysis organizations than for independent freestanding and hospital-based facilities.⁷

Table 1. The share of in-center dialysis, peritoneal dialysis, and home hemodialysis is comparable across the top 10 dialysis organizations, 2019

Facility type	In 2019, percent of patients furnished:		
	In-center hemodialysis	Peritoneal dialysis	Home hemodialysis
Two largest dialysis organizations	88%	10%	2%
Other top eight chain providers	88	10	1

Note: The “two largest dialysis organizations” include Fresenius Medicare Care and DaVita Inc. “Other top eight chain providers” include: U.S. Renal Care, American Renal Associates, Dialysis Clinic Inc., Satellite Healthcare, Atlantic Dialysis Management, Northwest Kidney Centers, Rogosin Institute, and Centers for Dialysis Care. Under the ETC model, “large dialysis organizations” are defined as a legal entities that own, in whole or in part, 500 or more dialysis facilities. There are currently two companies, Fresenius Medical Care and DaVita Inc., that meet that definition.

Source: Neumann, M. 2019. Large providers continue strong growth in home dialysis. *Nephrology News and Issues*. August.

⁴ Centers for Medicare & Medicaid Services. 2021. 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, and End-Stage Renal Disease Treatment Choices Model. *Federal Register* 26, no. 89 (July 9): 36322–36437.

⁵ Centers for Medicare & Medicaid Services. 2020. CMS announces transformative new model of care for Medicare beneficiaries with chronic kidney disease. <https://www.cms.gov/newsroom/press-releases/cms-announces-transformative-new-model-care-medicare-beneficiaries-chronic-kidney-disease>. September 18.

⁶ Neumann, M. 2019. Large providers continue strong growth in home dialysis. *Nephrology News and Issues*. August.

⁷ U.S. Renal Data System, National Institute of Diabetes and Digestive and Kidney Diseases. 2015. USRDS 2015 annual data report. Bethesda, MD: NIDDK.

The ETC should focus on patients' needs and improving patients' access to dialysis rather than on facilities' finances. If additional incentives for certain types of dialysis facilities to invest in home dialysis are needed, then CMS should develop policies that can identify and target such facilities. As we discuss later in the section on the ESRD PPS's LVPA, the Commission believes that Medicare should develop policies that target facilities that are both critical to beneficiary access and have high costs warranting a payment adjustment.

Though we do not support the inclusion of nocturnal in-center dialysis in the numerator of the home dialysis rate calculation, if CMS decides to finalize this proposal then such a change should apply to all managing clinicians and to all dialysis facilities, not just those facilities not owned, in whole or in part, by one of the two LDOs. Including nocturnal in-center dialysis in the numerator for the home dialysis rate calculation for all facilities—across all ownership types—is consistent with CMS's method that includes the use of in-center self-dialysis for all facilities in the calculation of the ETC Model's home dialysis rate that was established in the final rule dated September 29, 2020.⁸

Request for information on estimating case-mix adjustments, including patient-level adjustments

Under the ESRD PPS, the base payment rate for adults is adjusted for patient-level characteristics (age, two body measurement variables (body surface area and body mass index), four specific acute and chronic comorbidities, and onset of dialysis (for the first four months a patient receives dialysis), and for facility-level factors (low volume, rural location, and local input prices).⁹ To estimate the case-mix adjustments, CMS uses a two-equation regression methodology that includes:

- A facility-level regression model that uses 2012 and 2013 ESRD cost reports. For independent (i.e., freestanding) and hospital-based facilities, the dependent variable is equal to the average dialysis cost per treatment for composite rate services that before 2011 were paid under a PPS.
- A patient-level regression model that uses 2012 and 2013 dialysis facility claims. For both freestanding and hospital-based facilities, the dependent variable is equal to the estimated average payment per patient for ESRD-related drugs and laboratory services.

CMS is seeking comments about potential changes to the modeling used to develop the case-mix payment adjustments under the ESRD PPS, in order to inform future model refinements.

⁸ Centers for Medicare & Medicaid Services. 2020. Medicare program; Specialty care models to improve quality of care and reduce expenditures. *Federal Register* 85, no. 189 (September 29): 61114–61381.

⁹ For children (under the age of 18), CMS adjusts the base rate by age and dialysis modality.

Comment

Developing a single regression model to estimate adjustment factors

In our comment letter to CMS dated August 6, 2015, the Commission raised the following concerns about using a two-equation model to estimate the ESRD PPS adjustment factors:¹⁰

- It is not clear whether costs associated with separately billable services are also included in the cost centers that are used to derive the dependent variable—composite rate cost per treatment—for the facility-level regression.¹¹ If separately billable services are included in the dependent variable for both regressions, the weights applied to combine the factors from the two regressions will not accurately distinguish the relative cost or payment addressed by each regression.
- Multiplying factors from the facility-level regression (with average cost per treatment for composite rate services as the dependent variable) and the patient-level regression (with average payment per treatment for separately billable services as the dependent variable) may diminish the accuracy of the combined factors. The distribution of average cost for composite rate services across facilities is likely quite different than the distribution of payments for separately billable services across patients. Combining the two factors estimated from unrelated distributions may not accurately reflect cost variation for the payment unit, a dialysis treatment. Of particular concern are factors based only on one regression model because the factor was only found to have a significant association with the dependent variable of one regression model.
- Through various revisions of the model, the reference category for the age category variables, which is empirically-determined as the lowest-cost category, has shifted. We would expect the relative cost of dialysis treatment across age categories to remain relatively stable over time, and we are concerned that such shifts indicate that the estimated factors are highly sensitive to the model's specification. Estimates having a high sensitivity to model specification diminish confidence that the model factors produce Medicare payments that reflect providers' underlying costs.

According to CMS, the agency has not implemented a single equation approach because dialysis treatment costs (formerly composite rate services) do not vary across patients. However, for the reasons listed above, we continue to assert that CMS should develop payment adjustment factors

¹⁰ Medicare Payment Advisory Commission. <http://medpac.gov/docs/default-source/comment-letters/medpac-comment-on-cms-s-proposed-rule-on-the-end-stage-renal-disease-prospective-payment-system-and-.pdf?sfvrsn=0>. August 6.

¹¹ For example, the cost report instructions in CMS's *Provider Reimbursement Manual* for independent facilities state that the cost center for dialysis supplies includes supplies covered under the composite rate payment and separately billable supplies.

using a single-equation methodology that accounts for variation in the cost of providing the full PPS payment bundle.¹²

CMS should explore using *time on a dialysis machine per treatment*, which was discussed at CMS's Technical Evaluation Panel (TEP), to apportion composite rate costs (such as labor and capital-related costs) that are currently only observable at the facility level to the patient or treatment level for use in the case-mix adjustment. We agree with CMS that such data have the potential to allow for a proportionately higher amount of composite rate costs to be allocated to patients with longer dialysis treatment times. Some researchers have found that longer dialysis treatment time is linked with higher treatment costs.¹³ If the time data are robust, such an approach might permit CMS to develop a single-regression approach to estimate the payment adjustments to the ESRD PPS. If the agency elects to use time on dialysis machine per treatment to develop the payment adjustments, then the agency should collect such information using claims to permit researchers to gain access to the data.

Estimating patient-level comorbidity adjustment factors

The Commission agreed with a prior CMS proposal to drop two of the six comorbidity adjustments (bacterial pneumonia and monoclonal gammopathy) used at the time because: (1) patients had to undergo undue burden for clinical testing to meet CMS's documentation requirements, (2) CMS's requirements did not correspond with the diagnostic practices of Medicare providers, and (3) the diagnoses were poorly identified on dialysis claims.¹⁴ The Commission also stated that CMS should consider removing the four remaining comorbidity adjustment factors from the case-mix model, as these concerns are relevant to those factors as well. Specifically, diagnostic requirements for the remaining comorbidity factors include invasive imaging and bone marrow aspiration or biopsy, and our analysis of 2013 claims data showed that dialysis facility claims do not accurately identify the presence of any of the six comorbidities.

The two comorbidities that CMS removed were identified on dialysis facility claims only 11 percent (bacterial pneumonia) and 44 percent (monoclonal gammopathy) of the time they were identified on physician, inpatient, and outpatient hospital claims. The other four comorbidities were identified on dialysis facility claims 19 percent (pericarditis), 25 percent (gastrointestinal tract bleeding with hemorrhage), 36 percent (myelodysplastic syndrome), and 47 percent (hereditary hemolytic/sickle cell anemias) of the time they were reported on physician, inpatient, and outpatient hospital claims.

The poor identification of each comorbidity on dialysis facility claims can cause comorbidity adjustment factors to be inaccurate, as costs associated with unreported comorbid conditions are not incorporated into the factors and are instead incorporated into the base payment rate. In addition, CMS used claims submitted by other providers (e.g., hospital inpatient and outpatient

¹² Medicare Payment Advisory Commission. 2015. MedPAC comment letter regarding Medicare end-stage renal disease prospective payment system and quality incentive program proposed rules for 2016. <http://medpac-comment-on-cms-s-proposed-rule-on-the-end-stage-renal-disease-prospective-payment-system-and-.pdf>. August 6.

¹³ Hirth, R. A., P. J. Held, S. M. Orzol, et al. 1999. Practice patterns, case mix, Medicare payment policy, and dialysis facility costs. *Health Affairs* 33, no. 6: 1567–1592.

¹⁴ Medicare Payment Advisory Commission 2015, op cit.

hospital departments, physician offices) to estimate the size of the comorbidity adjustment factors, resulting in Medicare payments that were too low when the comorbidity was present (according to physician and hospital claims), but payment for the dialysis treatment did not include a comorbidity adjustment because the comorbidity was not identified on a dialysis claim.

For these reasons, CMS should again consider removing the remaining comorbidity adjustment factors from the case-mix model; however, if CMS continues to retain the current comorbidity adjustment factors, the agency should:

- Ensure that case-mix adjustments do not result in undue burden on patients or the provision of unnecessary diagnostic procedures for the facility to be eligible for the payment adjustment.
- Align the claims used to estimate the comorbidity adjustment factors with the claims used to identify eligibility for the adjustment. CMS could use only claims submitted by dialysis facilities both to estimate the comorbidity coefficients and to identify treatments eligible for a comorbidity adjustment, or use claims submitted by all providers both to estimate the comorbidity coefficients and to identify treatments eligible for a comorbidity adjustment.

Estimating patient-level adjustment factors for body size

Regarding adjusting payment for body size, CMS should address the inherent correlation between body surface area (BSA) and body mass index (BMI) by jointly estimating the association of BSA and BMI with treatment cost. Both BSA and BMI are calculated based on patient height and weight. The Commission's analyses have found that their values are correlated such that patients with low BMI also tend to have low BSA, and that these variables have a joint effect on treatment costs that is different from the sum of independent effects as currently implemented.¹⁵

In the ESRD PPS, the BSA factor is based solely on composite rate services, while the BMI factor is based solely on separately billable services, thus treating the effects of these variables on treatment cost independently. The Commission has raised concerns about the current adjustment factors, which increase payment by 2.5 percent for patients with low BMI, but also decrease payment for those same patients because they tend to have BSA values that are less than the average.

Request for information on calculating the low-volume payment adjustment (LVPA) and rural adjustment

The LVPA, which increases a facility's base rate by 23.9 percent, applies to facilities with fewer than 4,000 total treatments in each of the three years before the payment year. For these years, a facility's total treatment volume is equal to the sum of (1) the treatments furnished by that facility and (2) the treatments furnished by facilities under common ownership and within five road miles of that facility. The rural payment adjustment, which increases a facility's base rate by 0.8 percent,

¹⁵ Medicare Payment Advisory Commission 2015, op cit.

applies to all facilities located in rural areas, regardless of treatment volume or proximity to other dialysis facilities.

As an alternative to the LVPA, participants of the ESRD TEP discussed an approach that would identify facilities eligible for the LVPA by estimating latent demand for dialysis services in a specified geographic area (census tract) rather than by using facility treatment counts. This alternative approach would support dialysis organizations operating facilities in otherwise nonviable locations. The process of calculating latent demand would involve dividing the U.S. into geographic areas based on an assessment of ESRD beneficiaries' ability or willingness to travel, counting the number of ESRD beneficiaries near each facility ("near" is defined by driving time to a facility), then multiplying the number of beneficiaries near an ESRD facility by the average number of treatments per beneficiary. The LVPA threshold is then applied by determining the threshold of adjusted latent demand. That is, those facilities, which fall below the threshold are LVPA eligible.¹⁶

CMS is seeking comments to inform potential future modifications to the methodology to adjust payments for low treatment volume.

Comment

The Commission has raised concerns that neither the LVPA nor the rural adjustment accurately targets facilities that both are critical to beneficiary access and have high costs warranting a payment adjustment.¹⁷ In 2017, about 40 percent of LVPA facilities were located within five miles of the next closest facility, while some 385 facilities that did not receive the LVPA were isolated (and therefore necessary for beneficiary access to care) and incurred substantially higher-than-average costs per treatment. In addition, in 2017, about half of all rural facilities were high volume, and 30 percent of rural facilities were within five miles of the next closest facility.

In June 2020, the Commission recommended that the Secretary replace the LVPA and rural adjustment with a single payment adjustment—a low-volume and isolated (LVI) adjustment—to better protect isolated, low-volume dialysis facilities that are critical to ensure beneficiary access. Facilities that are low volume and isolated are defined based on both a facility's distance from the nearest facility and its total treatment volume. An illustrative LVI policy would have applied to 575 freestanding and hospital-based dialysis facilities, compared with the 336 facilities receiving the current LVPA and the 1,257 facilities receiving the rural adjustment in 2017. The LVI policy would not have applied to facilities that furnished a high volume of treatments because their

¹⁶ This model calculates latent demand using the following steps: (1) divide the U.S. into market areas based on dialysis patients' willingness or ability to travel, (2) predict the size of facilities by calculating the number of treatments that each facility would be expected to furnish given the number of patients near the facility (based on actual driving time by dialysis patients), (3) estimate facility demand using actual driving time of dialysis patients, (4) draw a circle around each beneficiary and count the number of times each beneficiary circle overlaps with a given facility, and (5) multiply the number of overlaps by the average number of beneficiaries. The resulting estimate of latent demand is adjusted using a statistical model to account for patients who do not seek treatment at the nearest dialysis facility.

¹⁷ Medicare Payment Advisory Commission. 2020. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

economies of scale generally result in lower costs per treatment, on average, than low-volume facilities. Nor would the LVI policy have applied to facilities near another dialysis facility because such facilities are not the sole providers of dialysis services in their communities and thus are not critical to maintaining access to care.

The Commission evaluated the impact of changing from the LVPA to the LVI policy (using illustrative parameters). Under the illustrative LVI policy, payments for facilities that receive the LVPA and are also isolated (more than five miles from the nearest facility) would remain roughly the same. Payments would increase for facilities with between 4,000 and 6,000 treatments annually that are farther than five miles from the nearest facility (facilities eligible for the LVI, but not the LVPA). Payments would be reduced for facilities currently receiving a rural payment adjustment that have larger treatment volumes and for those currently receiving a LVPA that are within five miles of another facility.

When recommending the LVI, MedPAC modeled an illustrative LVI policy with three adjustment categories or tiers. As an alternative, CMS could explore a continuous adjustment factor that would apply the same eligibility criteria for facility isolation (i.e., no other facilities within five miles), but would replace the three low-volume categories with a single factor multiplied by facility treatment volume below a threshold (e.g., factor \times [6,000 – facility volume]).

CMS has requested comments about concerns that the LVI methodology could generate inappropriate provider responses to the policy, such as limiting the number of dialysis treatments they provide in order to maintain eligibility for the higher payments. Compared to the LVPA, the LVI, with multiple tiers, reduces the incentive for providers to limit dialysis services. According to GAO, the payment problems associated with the LVPA were not related to provider behavior per se, but rather occurred primarily because the guidance issued by CMS on facility eligibility was sometimes not clear or timely and because CMS's monitoring of the LVPA was limited.¹⁸ As a result, some facilities that were eligible for the LVPA did not receive the adjustment, while other facilities that were not eligible received it.

If CMS decides to pursue the latent demand approach discussed by its TEP, then the agency should:

- Ensure that the methods used to determine the LVPA are transparent. For example, CMS's TEP discussed that a regression model would be used to adjust for differences between hypothetical and actual demand.¹⁹ The specification of such a model and its results should be available on CMS's website and published in the *Federal Register*. In addition, CMS should discuss how frequently the model would be updated.

¹⁸ Government Accountability Office. 2013. *CMS should improve design and strengthen monitoring of low-volume adjustment*. <https://www.gao.gov/assets/gao-13-287.pdf>. Washington DC: GAO.

¹⁹ Patient (latent) demand is adjusted using a statistical model to account for patients who do not seek care at the nearest dialysis facility.

- Discuss how census tracts changing over time would impact the accuracy of the LVPA, how this approach would respond to rapid increases in population growth in a given census area, and how the approach would address the anticipated increase in home dialysis use.

Request for information on calculating the outlier payment adjustment

The outlier policy in the ESRD PPS partially reimburses facilities' costs for certain patients that incur very high costs for items and services that were separately billable prior to the implementation of the ESRD PPS.²⁰ The policy aims to distribute 1 percent of total spending to the highest-cost months of treatment by reimbursing 80 percent of costs above a specified threshold. Each year, CMS estimates the outlier threshold based on two values: (1) the average spending on separately billable services (referred to as the Medicare Allowable Payment (MAP) amount) and (2) the amount of spending above the MAP that is necessary to meet the 1 percent of total spending target for the outlier policy (referred to as the 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.²¹ 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). Since 2011 when the ESRD PPS was established, CMS has set the outlier threshold too high. Over the last three years, CMS has paid out between 0.5 percent and 0.6 percent of the outlier pool in each year. In each year, the outlier threshold has generally declined, except when CMS included calcimimetics in determining outlier payments.²² Based on drug utilization patterns in 2020, CMS proposes to set the 2022 outlier threshold (i.e., the sum of the MAP and FDL amounts) at \$159.05, a decline of 8 percent compared to 2021.

CMS is seeking comments on improving the outlier payment, including alternative approaches that could be used to estimate the retrospective FDL trend by using historical utilization data.

Comment

We recognize the difficulty in estimating an outlier threshold such that the target of 1 percent of ESRD PPS spending will be met by the outlier policy. However, 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 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

²⁰ 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.

²¹ 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.

²² *Outlier threshold* refers to the threshold that CMS sets for adult beneficiaries. CMS sets different outlier thresholds for pediatric beneficiaries. In 2021, with the addition of calcimimetics to the ESRD bundle, CMS made calcimimetics eligible for outlier payments, resulting in a large increase to the outlier threshold.

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 Commission suggests that CMS consider modeling alternative approaches to establishing the outlier threshold and use an approach that reflects the *trend* over time in spending for items in the ESRD bundle that were separately billable prior to 2011. Other CMS payment systems use trend information when establishing similar payment policies. 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. Such an approach could produce a more reliable outlier threshold estimate and may result in outlier payment amounts that, on average, are closer to the target.

Consequently, the Commission reiterates our suggestion from our September 20, 2019, comment letter that CMS model alternative approaches to establish the outlier threshold and use an approach that reflects the trend in separately billable spending over time.²³ Such an approach could produce a more reliable outlier threshold estimate and may result in outlier payment amounts that, on average, are closer to the target. Analysis presented during CMS’s technical expert panel meeting supports the use of multiple years of data. An analysis that used the three most recent years to estimate outlier payments for 2020 would have resulted in CMS paying out 0.8 percent of payments. By contrast, the actual outlier payment percentage made for 2020 claims was 0.6 percent.

Ensuring the accuracy of cost reports submitted by dialysis facilities

The Protecting Access to Medicare Act of 2014 (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.

In this proposed rule, CMS publishes the results of their audit. CMS’s Office of the Actuary (OACT) selected a sample of 1,479 freestanding ESRD facilities from five large dialysis organizations (as defined by OACT) for the cost audit.²⁴ A contractor performed cost audits of these ESRD facilities in September of 2015. All audits were completed by September of 2018.

²³ Medicare Payment Advisory Commission. 2019. Comment letter on ESRD PPS proposed rule for 2020. http://medpac.gov/docs/default-source/comment-letters/09202019_esrd_cy2020_medpac_comment_v2_sec.pdf?sfvrsn=0. September 20.

²⁴ “Five large dialysis organizations” as defined by OACT to select facilities for the audit differs from how CMMI’s ETC Model defined “large dialysis organizations.” CMMI’s definition included only two organizations (Fresenius Medical Care and DaVita).

A key finding of the audit was that, of the 1,395 ESRD freestanding facilities analyzed, a total of \$147.5 million of unallowable costs were removed from the total costs reported on Worksheet A.²⁵ According to the proposed rule, noteworthy adjustments included the removal of \$136.5 million of unallowable costs initially reported in the administrative and general cost center on Worksheet A. Non-allowable items included: advertising, legal fees, interest expense and financing fees, corporate travel/lodging/relocation, various consulting fees, business development expenses, insurance settlement payments, and insurance expenses. CMS concluded that, based on this audit, cost report data were corrected.

CMS is also requesting comments on suggested changes to the cost reports submitted by freestanding facilities.

Comment

It is basic fiscal management to ensure that facilities' cost reports 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. Finally, prior audits of facilities' cost reports have included costs that Medicare does not allow.

The primary goal of the cost report audit is to assess whether dialysis companies are accurately reporting their facility costs; however, the information published in the proposed rule about the audit findings is insufficient to make this assessment. In the final rule, CMS should report the share of total reported costs that were non-allowable. Specifically, the agency should provide the total reported costs and total non-allowable costs. The Commission would like to compare the results of this audit to prior audits that found that providers' allowable costs were about 90 percent to 96 percent of reported costs. CMS should also publish the same statistics by cost report category (i.e., for capital, labor, supply, laboratory, general and administrative, composite rate drugs, ESA, and other drug costs) as well as background information about the number, types, and size of facilities included in the audit.

Regarding the application of these audit results to CMS's refinement of the ESRD payment adjustment factors:

- When developing a regression equation to estimate the patient-level and facility-level adjustment factors of the ESRD PPS, CMS should consider applying an adjustment to facilities' cost per treatment using the results of this audit (i.e., the share of total costs that were non-allowable).

²⁵ Worksheet A provides for recording the trial balance of expense accounts from facilities' accounting books and records. It also provides for the necessary reclassifications and adjustments to certain accounts.

- CMS should not use cost reports from hospital-based dialysis facilities to develop patient- and facility-level payment adjustment factors. First, the recent audit of cost reports did not include hospital-based facilities; thus, we lack knowledge about the extent to which non-allowable costs are reported. Second, there is no guarantee of consistency in the methods used to allocate hospital costs to dialysis departments and to dialysis cost categories. CMS has said that expense data for hospital-based cost reports reflect the allocation of overhead over the entire institution, and that the expenses of each hospital-based component may be skewed.²⁶ The inclusion of hospital-based cost reports likely increases statistical noise in the regression model.

Regarding future changes to dialysis facilities' cost reports, we would ask CMS to consider including categories to permit the reporting of costs associated with the drugs and devices that were paid under the transitional drug add-on payment adjustment and the transitional add-on payment adjustment for new and innovative equipment and supplies.

Furthermore, the Commission urges CMS to collect cost data from ETC participants. The ETC model provides a unique opportunity for CMS to gather data on the cost of developing and expanding home dialysis programs. Data could be analyzed by type of modality (home hemodialysis vs. peritoneal dialysis), size of the home dialysis program, and ownership type.

Conclusion

MedPAC appreciates the opportunity to comment on this proposed rule. The Commission values the ongoing collaboration between CMS and MedPAC staff on technical policy issues, and 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.
Chair

²⁶ Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2014. Medicare program; End-stage renal disease prospective payment system, quality incentive program, and durable medical equipment, prosthetics, orthotics, and supplies. Proposed rule. *Federal Register* 79, no. 133 (July 11): 40207–40315.