

CHAPTER

7

**Improving Medicare's
end-stage renal disease
prospective payment system**

R E C O M M E N D A T I O N S

7-1 The Congress should direct the Secretary to eliminate the end-stage renal disease prospective payment system's transitional drug add-on payment adjustment for new drugs in an existing end-stage renal disease functional category.

COMMISSIONER VOTES: YES 17 • NO 0 • NOT VOTING 0 • ABSENT 0

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7-2 The Secretary should replace the current low-volume and rural payment adjustments in the end-stage renal disease prospective payment system with a single adjustment for dialysis facilities that are isolated and consistently have low volume, where low-volume criteria are empirically derived.

COMMISSIONER VOTES: YES 17 • NO 0 • NOT VOTING 0 • ABSENT 0

Improving Medicare’s end-stage renal disease prospective payment system

Chapter summary

Since 2011, Medicare has paid dialysis facilities under a prospective payment system (PPS) that is based on an expanded bundle of services that includes end-stage renal disease (ESRD) drugs and biologics (hereafter referred to as “drugs”), clinical laboratory tests, and other items and services that were previously paid separately. Drugs included in the bundle are those that can be classified into 1 of 11 ESRD-related functional drug categories, similar to therapeutic classes of drugs. Medicare pays dialysis facilities a case-mix-adjusted base rate for this bundle of services furnished during a dialysis treatment in the facility or in a patient’s home, generally up to three treatments per week. The base payment rate is adjusted for certain patient-level characteristics, including patients’ age, body surface area, and body mass. Base payments are also adjusted for certain facility characteristics, with separate adjustments that increase payments for facilities with low treatment volume and for facilities in rural locations. Dialysis facilities may receive separate add-on payments when furnishing certain new drugs. In this chapter, we address issues related to the expanded transitional drug add-on payment adjustment (TDAPA) for new ESRD drugs and the payment adjustments for low-volume facilities and for facilities located in rural areas.

The Protecting Access to Medicare Act of 2014 (PAMA) required CMS to implement a drug designation process for including new injectable and

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- Background
- Current payment for new ESRD drugs under the ESRD PPS
- Eliminating the TDAPA for new drugs in an existing ESRD functional category
- Current payment for low-volume and rural dialysis facilities
- Improving the adequacy of payments for low-volume and isolated facilities

intravenous products into the ESRD PPS bundled payment. Accordingly, the agency established a process that pays dialysis facilities separately for qualifying products under a TDAPA. The original TDAPA policy for new ESRD drugs that CMS adopted in 2016 applied only to drugs that are *not* in 1 of the 11 ESRD functional categories. As of January 1, 2020, CMS expanded the TDAPA to apply to certain dialysis drugs, including biosimilars, that are in 1 of the 11 ESRD functional categories of drugs included in the ESRD bundle. Under the expanded policy, CMS makes a TDAPA for new ESRD-related injectable and intravenous drugs, unless they are generic equivalents or new dosage forms or formulations of drugs included in an existing ESRD functional category, among others. The process that CMS uses to identify eligible products is based on the pathways that the Food and Drug Administration employs to approve new drugs. The agency pays dialysis facilities the eligible product's average sales price for two years; thereafter, the new product is included in the PPS payment bundle without any increase to the base rate. No products have been paid for under the expanded TDAPA policy in 2020. (Since 2018, CMS pays for calcimimetics under a TDAPA policy that is distinct from the expanded TDAPA policy for new ESRD drugs.)

The Commission has raised concerns about the expanded TDAPA policy, underscoring the importance of maintaining the structure of the ESRD PPS and not creating policies that would unbundle services or encourage high launch prices of new drugs and other technologies (Medicare Payment Advisory Commission 2019a, Medicare Payment Advisory Commission 2018). Further, we have noted that the expanded policy would pay facilities twice for a drug in a functional category by paying separately for the new drug under the TDAPA while also including payment for one or more drugs with a similar purpose or use in the ESRD PPS base rate. The duplicative payment not only is an inappropriate use of Medicare funds but also can create incentives for the excessive provision of ESRD-related products (to the extent clinically possible).

The Commission recommends that the Congress direct the Secretary to eliminate the TDAPA for new drugs that are in an existing ESRD functional category already included in the payment bundle. Doing so would maintain the structure of the ESRD PPS and avoid the introduction of incentives to unbundle services covered under the PPS. In addition, eliminating the TDAPA for these drugs would create pressure for drug manufacturers to constrain the growth of prices for new and existing ESRD drugs. At market entry, such new drugs would be included in the ESRD PPS bundle, with no update to the base payment rate. CMS will need to monitor the alignment of Medicare payments with providers' costs as new products are added to the bundle and diffuse into medical practice. The Commission's annual analysis on payment adequacy, ESRD drug use, and changes in patients' outcomes

can help inform policymakers about the future need for rebasing the ESRD PPS's base payment rate.

The Commission has also raised concerns that neither the low-volume payment adjustment (LVPA) nor the rural adjustment accurately targets facilities that both are critical to beneficiary access and have high costs warranting a payment adjustment (Medicare Payment Advisory Commission 2015, Medicare Payment Advisory Commission 2014). 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 3 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 the facility in question and (2) the treatments furnished by only those facilities under common ownership that were within five road miles from the facility in question. The rural payment adjustment, which increases a facility's base rate by 0.8 percent, applies to all facilities located in rural areas, regardless of treatment volume or proximity to other dialysis facilities. Consequently, 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.

The Commission recommends 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. We found that the facilities that would receive the adjustment would be more appropriately targeted. In 2017, 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. The LVI policy would not have applied to facilities that furnished a high volume of treatments because their 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 since such facilities are not the sole providers of dialysis services in their communities and thus are not critical to maintaining access to care. Under this illustrative LVI policy, payments for LVPA-receiving facilities that are also isolated (more than 5 miles from the nearest facility) would remain

roughly the same, while payments would increase for facilities farther than 5 miles from the nearest facility and with between 4,000 and 6,000 treatments annually in the 3 years before the payment year. 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. We intend this recommendation to be budget neutral with respect to current policy. ■

Background

In 2018, nearly 395,000 beneficiaries with end-stage renal disease (ESRD) receiving dialysis were covered under fee-for-service (FFS) Medicare and obtained dialysis from approximately 7,400 dialysis facilities. ESRD is the last stage of chronic kidney disease and is characterized by permanent, irreversible kidney failure. Patients with ESRD include those who are treated with dialysis—a process that removes wastes and fluid from the body—and those who have a functioning kidney transplant. Because of the limited number of kidneys available for transplantation and variation in patients' suitability for transplantation, about 70 percent of ESRD patients undergo maintenance dialysis. In 2018, total Medicare spending for outpatient dialysis services was \$12.7 billion.

Since 2011, Medicare has paid dialysis facilities under a prospective payment system (PPS) for an expanded bundle of services that includes ESRD-related drugs and biologics, clinical laboratory tests, and other items and services that were previously paid separately.¹ CMS established 11 ESRD-related functional drug categories, similar to therapeutic classes of drugs, that are included in the bundle. The 11 functional categories are (1) access management, (2) anemia management, (3) bone and mineral metabolism, (4) cellular management, (5) antiemetic, (6) anti-infective, (7) antipruritic, (8) anxiolytic, (9) excess fluid management, (10) fluid and electrolyte management, and (11) pain management. Among the drugs falling into the 11 functional categories are Part B ESRD injectable drugs (such as erythropoietin-stimulating agents (ESAs), iron, and vitamin D analogs) and their oral equivalents, and oral calcimimetics (which were covered under Part D before 2018) and their injectable equivalent. Oral-only dialysis drugs (phosphate binders) are currently paid for under Part D. Statutory provisions delayed the inclusion of oral-only Part D ESRD-related drugs into the Part B payment bundle until 2025.

The unit of payment covered by the PPS rate is a single dialysis treatment. Medicare pays facilities furnishing dialysis treatments in the facility or in a patient's home for up to three treatments per week, unless there is documented medical justification showing that the additional dialysis treatments are reasonable and necessary. Medicare payment for adult dialysis beneficiaries does not vary based on dialysis method (hemodialysis vs. peritoneal dialysis) or site of care (in

center vs. a beneficiary's home).² For 2020, the base payment rate is \$239.33 per treatment.

To calculate the case-mix-adjusted payment rate for a dialysis treatment, the base rate is adjusted to reflect patient-level and facility-level characteristics. Each adjustment is applied as a multiplier to the base rate. All adjustment values are greater than one by design and therefore increase the payment for all dialysis treatments above the base rate (with one exception for body surface area, which can increase, decrease, or have no effect on the base payment rate). Table 7-1 (p. 186) shows the value of patient-level and facility-level adjustments as initially implemented in 2011 and revised by CMS in 2016 (the current set of adjustments).

The labor-related portion (52.3 percent) of the base rate is adjusted for differences in area wages using the inpatient hospital wage index (calculated without regard to geographic reclassification).³ In addition to the case-mix-adjusted base rate, CMS may pay facilities:

- an outlier payment when a beneficiary's cost per treatment for outlier services exceeds a threshold. Outlier services include drugs, laboratory services, and other items that facilities separately billed before 2011 (under the old payment method).
- an add-on payment for furnishing self-dialysis training to patients beginning home dialysis. CMS pays for up to 15 training sessions for home peritoneal dialysis and 25 sessions for home hemodialysis.
- a transitional drug add-on payment adjustment (TDAPA), as of 2018, for furnishing oral and intravenous calcimimetics, drugs that are indicated for the treatment of secondary hyperparathyroidism in patients on dialysis. (Before 2018, the oral formulation was covered under Part D.) In 2018, Medicare's TDAPA payment was based on each product's average sales price (ASP), and payments equaled \$1.2 billion. CMS is continuing the TDAPA for calcimimetics in 2020 because the agency is still in the process of collecting sufficient claims data for a rate-setting analysis, at which point the products will be included in the PPS bundle.
- a TDAPA, as of 2020, for certain new ESRD drugs that are in an existing ESRD functional category or are in a new ESRD functional category. To date, no new drugs (either in an ESRD functional category or not) have qualified for an adjustment.

**TABLE
7-1**

ESRD PPS adjustment factors

Payment adjustment	Value 2011-2015	Value beginning 2016
Age		
18-44	1.171	1.257
45-59	1.013	1.068
60-69	1.000	1.070
70-79	1.011	1.000
80+	1.016	1.109
Body surface area (per 0.1 m ²)	1.020	1.032
Underweight (body mass index < 18.5 kg/m ²)	1.025	1.017
Time since onset of dialysis (<4 months)	1.510	1.327
Acute comorbidities		
Pericarditis	1.114	1.040
Gastrointestinal tract bleeding	1.183	1.082
Bacterial pneumonia	1.135	N/A
Chronic comorbidities		
Hereditary hemolytic/sickle cell anemia	1.072	1.192
Myelodysplastic syndrome	1.099	1.095
Monoclonal gammopathy	1.024	N/A
Facility low-volume status	1.189	1.239
Facility rural location	N/A	1.008

Note: ESRD (end-stage renal disease), PPS (prospective payment system), N/A (not applicable). Payment adjustment factors for adults ages 18 and older. Before 2016, CMS did not use a rural payment adjustment in the ESRD PPS. As of 2016, CMS eliminated the payment adjusters for bacterial pneumonia and monoclonal gammopathy.

Source: Centers for Medicare & Medicaid Services 2015.

Current payment for new ESRD drugs under the ESRD PPS

The Protecting Access to Medicare Act of 2014 (PAMA) required CMS to implement a drug designation process for including new injectable and intravenous products into the ESRD PPS bundled payment. Accordingly, the agency established a process that pays dialysis facilities separately for qualifying new products under a TDAPA, which is summarized in Table 7-2. Generally, CMS makes a TDAPA for new ESRD-related injectable and intravenous drugs, unless they are generic equivalents or new dosage forms or formulations of drugs included in an existing ESRD functional category. Beginning in 2020,

the agency lowered the payment for any drug that qualifies for a TDAPA from 106 percent of the drug’s ASP to 100 percent of the drug’s ASP.

TDAPA policy for new ESRD drugs not in an existing ESRD functional category

To comply with PAMA’s mandate for including new ESRD-related injectable and intravenous drugs into the prospective payment bundle, the agency finalized a policy in 2016 that pays a TDAPA for new ESRD-related injectable drugs not in 1 of 11 ESRD-related functional categories of drugs included in the PPS payment bundle. These drugs are eligible for a TDAPA for at least two years, until sufficient rate-setting data are available. When

**TABLE
7-2**

Summary of the ESRD PPS's TDAPA policy for new injectable drugs and biologics in 2020

New ESRD-related drugs and biologics that:

	Are not in an existing ESRD-related functional category	Are in an existing ESRD-related functional category
Year the add-on payment policy began	2016 (no products have been eligible for TDAPA to date)	2020 (no products have been eligible for TDAPA to date)
Is "substantial clinical improvement" standard used?	No	No
Payment rate of add-on	ASP*	ASP*
Length of add-on payment period	At least two years (until sufficient rate-setting data are available)	Two years
Is the new drug included in the PPS payment bundle at the end of the add-on payment period?	Yes	Yes
Is the PPS base rate updated at the end of add-on payment period?	Yes	No

Note: ESRD (end-stage renal disease), PPS (prospective payment system), TDAPA (transitional drug add-on payment adjustment), ASP (average sales price).
*In 2016, CMS set payment based on 106 percent of each drug's ASP. As of 2020, CMS sets payment based on 100 percent of each drug's ASP. To date, no drugs have qualified under either TDAPA policy.

Source: MedPAC analysis of final ESRD payment rules for 2016, 2019, and 2020.

the TDAPA period ends, CMS includes the drug in the PPS payment bundle (by adding a new functional category or modifying an existing one) and adjusts the PPS base rate, if appropriate, to reflect changes to the functional categories.⁴ To date, no new ESRD-related injectable drug has qualified under this TDAPA policy.

TDAPA policy for new ESRD drugs in an existing ESRD functional category

In the 2019 ESRD PPS final rule, CMS made two important changes to the TDAPA policy that expanded the types of drugs that would be eligible for the add-on payment. First, it expanded the TDAPA to allow add-on payments for all new ESRD injectable products (including generic drugs and biosimilars) that are in an existing ESRD-related functional category and approved by the Food and Drug Administration (FDA) on or after January 1, 2020. Second, CMS extended the TDAPA to allow

add-on payments for functional categories of drugs that were, before 2011, paid under the prior ESRD payment system's prospective payment—the composite rate. In other words, the expanded TDAPA policy would make an add-on payment for any new ESRD-related product for two years, even for a new drug with a functional equivalent already included in the payment bundle.⁵ After two years, CMS will include the drug in the PPS payment bundle but will make no modifications to the ESRD PPS base payment rate because there would be no changes to the functional categories. Once included in the ESRD PPS payment bundle, new products considered to be composite rate drugs would not be eligible for an outlier payment, but other new drugs would be eligible for outlier payments. According to CMS, the expanded policy is intended “to promote innovation and bring more high-value drugs to market” (Centers for Medicare & Medicaid Services 2018).

Medicare does not apply substantial clinical improvement criteria to determine a drug's eligibility to receive a TDAPA

CMS explicitly elected not to include substantial clinical improvement criteria to determine whether a new dialysis product receives a transitional drug add-on payment adjustment (TDAPA), stating that (1) its policy will provide an opportunity for new drugs to compete with other similar drugs in the market, which could result in lower prices for all drugs, and (2) the effectiveness of drugs can depend on age, gender, race, genetic predisposition, and comorbidities (Centers for Medicare & Medicaid Services 2018). With respect to paying a TDAPA for biosimilars, the

agency explained that although biosimilar products do not offer a new treatment method, the agency will pay a TDAPA for these products because their exclusion “would disadvantage this sector of biological products in a space where we are trying to support technological innovation.” According to the agency, “While the products [biosimilars] themselves may not be innovative, CMS believes that the technology used to develop the products is sufficiently new and innovative to warrant a TDAPA payment at this time” (Centers for Medicare & Medicaid Services 2019). ■

In response to concerns from stakeholders about the broad nature of the 2019 TDAPA policy expansion, CMS refined the TDAPA eligibility criteria in the rule-making process for the 2020 ESRD PPS, excluding drugs in an ESRD functional category from receiving an add-on payment if the agency considers them to be “not truly innovative,” based on FDA approval pathways (Centers for Medicare & Medicaid Services 2019). Under CMS’s finalized policy, the following new ESRD drugs in an existing functional category are not eligible for a TDAPA:

- generic drugs (i.e., drugs that the FDA approves under section 505(j) of the Federal Food, Drug, and Cosmetic Act) and
- new drugs approved for a new dosage form (e.g., pill size, time-release forms, chewable or effervescent pills); new drugs approved for a new formulation (e.g., new inactive ingredient); new approved drugs that were previously marketed without a new drug application (NDA); new approved drugs that changed from prescription to over the counter, among others. CMS would identify these drugs using the NDA classification code assigned by the FDA.⁶

Under CMS’s finalized policy, new products in an existing ESRD functional category that are eligible for the TDAPA include products that contain a new molecular entity, a

new active ingredient, or a new combination of drugs involving two or more active ingredients (for which one ingredient is a new molecular entity). As described in the text box on TDAPA eligibility criteria, in both the 2019 and 2020 rule-making process, CMS opted not to apply substantial clinical improvement criteria to determine a drug’s eligibility to receive a TDAPA.

Eliminating the TDAPA for new drugs in an existing ESRD functional category

Under current policy, for new ESRD drugs in an existing functional category, CMS does not reduce either the TDAPA payment or the base rate even though the cost of providing all drugs in a given functional category is included in the base rate. CMS elected not to account for the duplicative payment when expanding the TDAPA policy in 2019 and 2020, stating that the policy is temporary and not duplicative because, at the end of the two-year period, there is no additional money added to the base rate for those drugs in an existing functional category.

However, during the two-year period, Medicare effectively pays dialysis facilities twice for a drug in an existing functional category by paying separately for the new drug under the TDAPA while also including payment for

one or more drugs with a similar purpose or use in the ESRD PPS base rate. The TDAPA's ASP-based payment, which Medicare pays according to the number of units administered, creates incentives for potential overuse of drugs. Providers realize greater profits from larger doses than small doses of the TDAPA product (as long as Medicare's payment rate exceeds providers' costs). In addition, ASP-based payments provide no incentive for drug manufacturers to constrain the prices of new ESRD drugs. Further, by paying separately for new drugs in an existing functional category, Medicare misses an opportunity to encourage price competition among therapeutically similar drugs in the payment bundle.

Eliminating the TDAPA for new drugs in an existing ESRD functional category already included in the payment bundle would preserve the structure of the ESRD PPS by not unbundling services already covered under the PPS, create pressure for drug manufacturers to constrain the prices for new and existing ESRD drugs, and maximize price competition among therapeutically similar drugs in the payment bundle (Medicare Payment Advisory Commission 2019a, Medicare Payment Advisory Commission 2018). (The TDAPA for drugs not in an existing ESRD functional category would remain unchanged.)

By eliminating the TDAPA, no additional payments would be made for new drugs in an existing functional category at market entry because payment is already included in the payment bundle. There would be no concurrent update to the base rate after a new drug in an existing ESRD functional category is introduced and included in the PPS payment bundle. This policy would be consistent with the TDAPA policy that CMS implemented between 2016 and 2019.

As new products are added to the bundle and diffused into medical practice, there may be a need for rebasing to keep Medicare payments aligned with providers' costs. For example, the Congress mandated that the Secretary rebase the ESRD PPS base payment rate in 2014 to account for the decline in the use of dialysis drugs covered under the bundle.⁷ The Commission's annual payment adequacy analysis can help inform policymakers about the alignment of Medicare's payments to providers' costs. Our payment adequacy analysis also tracks dialysis drug use and changes in patients' outcomes over time.

Some stakeholders have raised concerns that access to new drugs in an ESRD functional category would be impeded

without a TDAPA and that not updating the base rate to account for new drugs would dampen drug manufacturers' investment in developing new ESRD drugs. However, under the ESRD PPS, beneficiaries appear to have good access to new products that are in an ESRD functional category. For example, in 2015, epoetin beta, an erythropoietin-stimulating biologic, was introduced to the U.S. market. CMS included the biologic in the ESRD PPS payment bundle; facilities did not receive a TDAPA for this product. Nevertheless, by the end of 2015, nearly one-quarter of dialysis beneficiaries had received this new biologic. One of the two large dialysis organizations (Fresenius) switched about 70 percent of its patients to the new biologic within one year after the product's market entry. Thus, including the new biologic in the payment bundle (without any TDAPA) resulted in increased competition and efficiencies. The Commission's analysis of this company's cost reports submitted to CMS showed that its ESA cost per treatment declined between 2015 and 2016. Further, there is no indication that beneficiary quality of care was affected by the treatment change.

There is concern that use of new ESRD drugs may be constrained by long-term contracts that some dialysis organizations have with drug manufacturers.⁸ However, under the ESRD PPS, the use of anemia and vitamin D drugs has shifted over time (Medicare Payment Advisory Commission 2017). Although some dialysis organizations have long-term contracts with particular drug vendors, the Medicare program should not expect the existence of such contracts to be an obstacle to beneficiaries receiving new treatments if those are better for the patient.

Some stakeholders have also asserted that it is not appropriate to assume that the base rate is sufficient to support new drugs that represent a clinical improvement. However, in the Commission's view, paying a TDAPA for new drugs in an existing ESRD functional category—irrespective of whether they meet a substantial clinical improvement standard—would undermine the competitive forces within the PPS payment bundle because the add-on would fail to create pressure on drug manufacturers to constrain prices for new and existing ESRD drugs.

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. This goal is best achieved by relying on the ESRD bundle to the greatest extent possible when determining payment amounts. Bundled payment encourages judicious consideration of

the items and services provided to patients. Paying the TDAPA for two years for new ESRD drugs in an existing functional category is duplicative of the payment already made as part of the ESRD bundle. Instead, including all ESRD drugs in an existing functional category (and thus with a similar function) in the bundle would foster competition for these products and generates pressure to constrain prices.

RECOMMENDATION 7-1

The Congress should direct the Secretary to eliminate the end-stage renal disease prospective payment system’s transitional drug add-on payment adjustment for new drugs in an existing end-stage renal disease functional category.

RATIONALE 7-1

This recommendation would eliminate the TDAPA for new ESRD drugs included in an existing ESRD functional category, which is consistent with CMS’s policy between 2016 and 2019. The recommendation would maintain the structure of the ESRD PPS by continuing to bundle services covered under the PPS and would reduce incentives for high launch prices of new drugs. This recommendation would also prevent duplicative payments for new drugs for which payment is already included in the ESRD bundle.

IMPLICATIONS 7-1

Spending

- This recommendation is estimated to decrease program spending by \$250 million to \$750 million over one year and by \$1 billion to \$5 billion over five years relative to current policy.

Beneficiaries and providers

- We do not anticipate any negative effects on beneficiary access to care. This recommendation would generate savings for beneficiaries through lower cost sharing and would reduce future payments to dialysis facilities without affecting dialysis facilities’ willingness and ability to care for beneficiaries.

Current payment for low-volume and rural dialysis facilities

The ESRD PPS includes a payment adjustment for facilities with low treatment volume and a separate

adjustment for facilities located in rural locations. Facilities with low treatment volume receive a significant upward payment adjustment regardless of their proximity to other providers; some facilities receive a low-volume adjustment even if they are located in close proximity to another dialysis provider and are thus not critical to maintaining access to care. At the same time, Medicare makes an adjustment for rural facilities regardless of the number of treatments they provide. Yet dialysis treatment volume is highly correlated with dialysis facilities’ costs. The greater the facility’s service volume, the lower its costs per treatment. Some rural facilities thus receive an upward adjustment to their payments even when they realize significant economies of scale. Indeed, after controlling for treatment volume, the difference in the cost per treatment between urban and rural facilities narrows considerably.

Current payment adjustment for low-volume facilities

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) required the ESRD PPS to include “a payment adjustment that reflects the extent to which costs incurred by low-volume facilities (as defined by the Secretary) in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing such services.” CMS used regression analyses to empirically determine the magnitude of the adjustment.

Between 2011 and 2015, per regulation, CMS defined a low-volume facility as one that provided 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 was equal to the sum of (1) the treatments furnished by the facility in question and (2) the treatments furnished by other facilities under common ownership that were within 25 road miles of the facility in question. However, the agency exempted facilities that were certified for Medicare participation as of December 31, 2010, from the distance requirement between the facilities that received the low-volume payment adjustment (LVPA) and the next closest facility (the so-called “grandfather” provision).

In our March 2014 report, we stated that only the low-volume ESRD facilities necessary to maintain access—those located in isolated areas—should receive enhanced payment, and recommended that the Congress direct the Secretary to redesign the LVPA to consider a facility’s distance to the nearest facility regardless of ownership

CMS requires facilities to attest to their qualification for the low-volume payment adjustment

CMS requires facilities to attest that they qualify for the low-volume payment adjustment (LVPA), including the total treatment volume in the three preceding years.⁹ At the time of attestation, cost report data is available only for the first two of the three years preceding the payment year. Attestation is necessary because some of the information the Medicare administrative contractors (MACs) need to assess a facility's eligibility—in particular a dialysis facility's cost reports for the year immediately preceding the payment year—may be unavailable to the MACs until several months after the payment year begins.¹⁰

Only after the dialysis facility has submitted its attestation and its designated MAC has verified that the facility meets the eligibility criteria will a facility begin to receive the LVPA. According to the Government Accountability Office (GAO), in cases where the MACs cannot make a final eligibility determination at the beginning of the payment year, they conditionally approve LVPA eligibility. After the necessary information becomes available, the MACs are required

to reassess the dialysis facility's eligibility for the LVPA (Government Accountability Office 2013). If a MAC determines that a facility receiving the LVPA was ineligible, the MAC is expected to recoup all payments to that facility made under the LVPA within six months of that determination.

Determining LVPA eligibility is a passive process for CMS, in which dialysis facility attestations are reviewed by the MACs. Dialysis facilities must assess LVPA eligibility on their own and submit an attestation before CMS or one of the MACs considers a facility's eligibility for the LVPA. Both GAO and the Commission's analysis found that eligible facilities did not receive the LVPA. Under the original LVPA policy (that was in place between 2011 and 2015), GAO determined that 79 eligible facilities in 2011 did not receive the LVPA for any treatments. Under the current LVPA policy (in place as of 2016), the Commission found more than 100 facilities in 2017 that appeared to be eligible but did not receive the LVPA (based on publicly available information on each facility's ownership that is reported in CMS's cost reports and Dialysis Facility Compare file). ■

(Medicare Payment Advisory Commission 2014). In 2016, CMS revised the LVPA definition by:

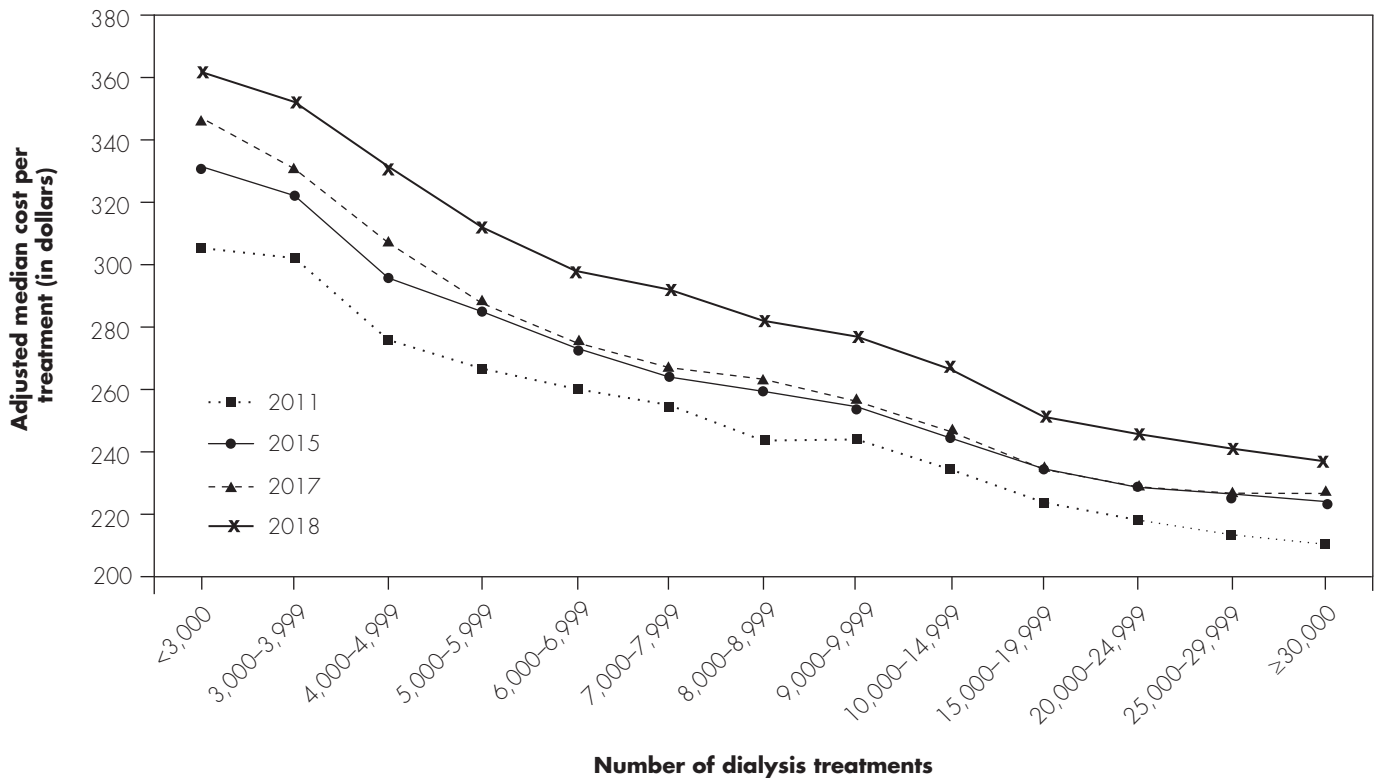
- decreasing the geographic proximity criterion from 25 miles to 5 miles. For the purposes of determining eligibility, a facility's total treatment volume is equal to the sum of (1) the treatments furnished by the facility in question and (2) the treatments furnished by other facilities under common ownership that are within five road miles of the facility in question.
- applying the five-mile distance requirement to all facilities regardless of when a facility was certified for Medicare participation. CMS no longer exempts facilities that were certified before 2011 from the distance requirement.

The 2016 changes did not alter the volume threshold; a low-volume facility is still defined as one that provides fewer than 4,000 treatments (Medicare and non-Medicare) in each of the 3 years before the payment year and has not opened, closed, or received a new provider number due to a change in ownership during the 3-year period.¹¹ As described in the text box on qualification for the LVPA, to establish eligibility, a facility must provide an attestation statement to its designated Medicare administrative contractor (MAC), which is responsible for verifying that the facility has met the eligibility criteria.

Because eligibility for the LVPA requires fewer than 4,000 treatments in each of the 3 years before the payment year, a facility could have an incentive to avoid providing 4,000 treatments or more in a given year

FIGURE 7-1

Higher volume facilities have lower cost per treatment



Note: Cost per treatment is adjusted to remove differences in the cost of labor. Dialysis treatments include those paid for by all sources (not just Medicare-paid treatments).
 Source: MedPAC analysis of cost reports submitted by freestanding dialysis facilities to CMS and the end-stage renal disease wage index files.

(Government Accountability Office 2013). In addition, the 4,000-treatment cut-off for LVPA eligibility leaves many facilities with comparatively low treatment volume without an adjustment for their higher average costs per treatment.¹² As shown in Figure 7-1, facilities providing 4,000 to 5,999 treatments per year also have relatively high average treatment costs, although not as high as facilities furnishing under 4,000 treatments per year.

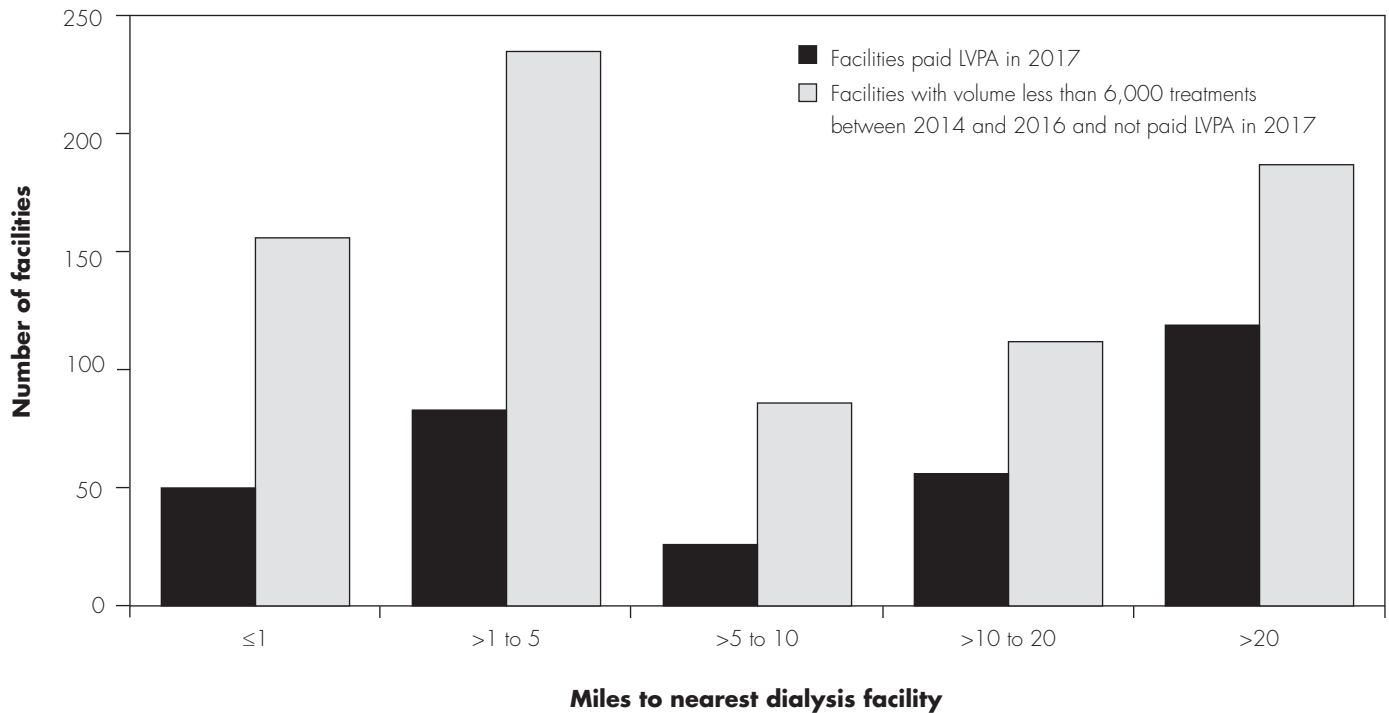
LVPA freestanding facilities incur substantially higher costs per treatment compared with all freestanding facilities.¹³ In 2017, the adjusted cost per treatment of LVPA freestanding facilities was about \$320 per treatment, 28 percent greater than the adjusted cost per treatment of the other freestanding facilities. Among LVPA facilities, costs did not substantially vary based on their proximity to the nearest facility. For example, LVPA freestanding

facilities located within five miles of the next facility incurred a median adjusted cost of \$324 per treatment, while LVPA facilities located more than five miles from the next facility incurred an adjusted cost of \$318 per treatment.

In 2017, 270 freestanding and 66 hospital-based facilities received the LVPA, which increased their base payment rate by 23.9 percent. Figure 7-2 shows that some facilities receiving the LVPA were located near other facilities, suggesting that they may not have been essential for ensuring access to care. For example, in 2017, among facilities receiving the LVPA, 40 percent were located within five miles of the next closest facility and 15 percent were located within one mile of the next closest facility (data not shown). These proximities reflect the LVPA’s design, which, for the purposes of determining a facility’s

FIGURE 7-2

Current design of LVPA includes facilities in close proximity to another facility and excludes some isolated low-volume facilities



Note: LVPA (low-volume payment adjustment).

Source: MedPAC analysis of 2017 claims and 2017 cost reports submitted by dialysis facilities to CMS, Dialysis Facility Survey, and the Dialysis Facility Compare.

total treatments, excludes the treatments from facilities within five miles of the facility in question that are not under the same corporate ownership from the facility in question. In addition, Figure 7-2 shows that the current design of the LVPA does not include roughly 385 facilities that furnished fewer than 6,000 total treatments and were located more than 5 miles from the nearest facility.

Compared with all dialysis facilities, LVPA facilities in 2017 were more likely to be hospital based, rural, and not associated with the two largest dialysis organizations; each of these facility types was more likely to be farther from the next closest facility than its counterparts (freestanding, urban, and affiliated with the two largest dialysis organizations, respectively) (Table 7-3, p. 194). We found similar results when examining the proximity of low-volume facilities to other facilities in 2011 and 2012 (Medicare Payment Advisory Commission 2014).

Current payment adjustment for rural location

MIPPA gave the Secretary the authority to include (but did not require) a payment adjustment for facilities located in rural areas. In the rule-making process that implemented the ESRD PPS in 2011, the agency explained that a rural adjustment was not necessary because the impact of the new ESRD PPS was lower for rural facilities than urban facilities (and other subgroups) (Centers for Medicare & Medicaid Services 2015). Thus, from 2011 through 2015, the ESRD PPS did not include a rural payment adjustment.

Starting in 2016, CMS established a rural payment adjustment that increased the ESRD PPS base rate by 0.8 percent for facilities in rural areas. According to CMS, this change was adopted to address concerns from stakeholders about low-to-negative Medicare margins for rural facilities

**TABLE
7-3**

Dialysis facilities receiving the LVPA were more likely to be hospital based, located in rural areas, and not associated with the two largest dialysis organizations, 2017

	Facilities receiving the LVPA			All facilities		
	Percent of all LVPA facilities	Percent within 5 miles of nearest facility	Median miles to nearest facility	Percent of all facilities	Percent within 5 miles of nearest facility	Median miles to nearest facility
All facilities	100%	40%	11.6	100%	73%	2.2
Freestanding	81	45	7.5	95	74	2.2
Hospital based	19	22	27.0	5	63	2.3
Urban	49	60	3.4	82	82	1.9
Rural	51	20	23.9	18	31	18.7
LDO associated	62	45	7.2	73	72	2.3
Non LDO	38	31	19.9	27	11	1.9

Note: LVPA (low-volume payment adjustment), LDO (large dialysis organization). The number of facilities receiving the LVPA was 336; the number of all facilities was 7,089.

Source: MedPAC analysis of claims and cost reports submitted by dialysis facilities to CMS and the Dialysis Facility Compare file.

(Centers for Medicare & Medicaid Services 2015). For purposes of the rural payment adjustment, a rural area is defined as any area outside of an urban area.¹⁴ The rural adjustment does not impose a distance requirement between a facility that receives this adjustment and the

next closest facility and does not consider a rural facility's treatment volume. In 2017, 1,257 freestanding and hospital-based facilities were located in rural areas and thus received the 0.8 percent rural adjustment.

**TABLE
7-4**

Adjusted cost per treatment is similar between urban and rural facilities with comparable treatment volume, 2017

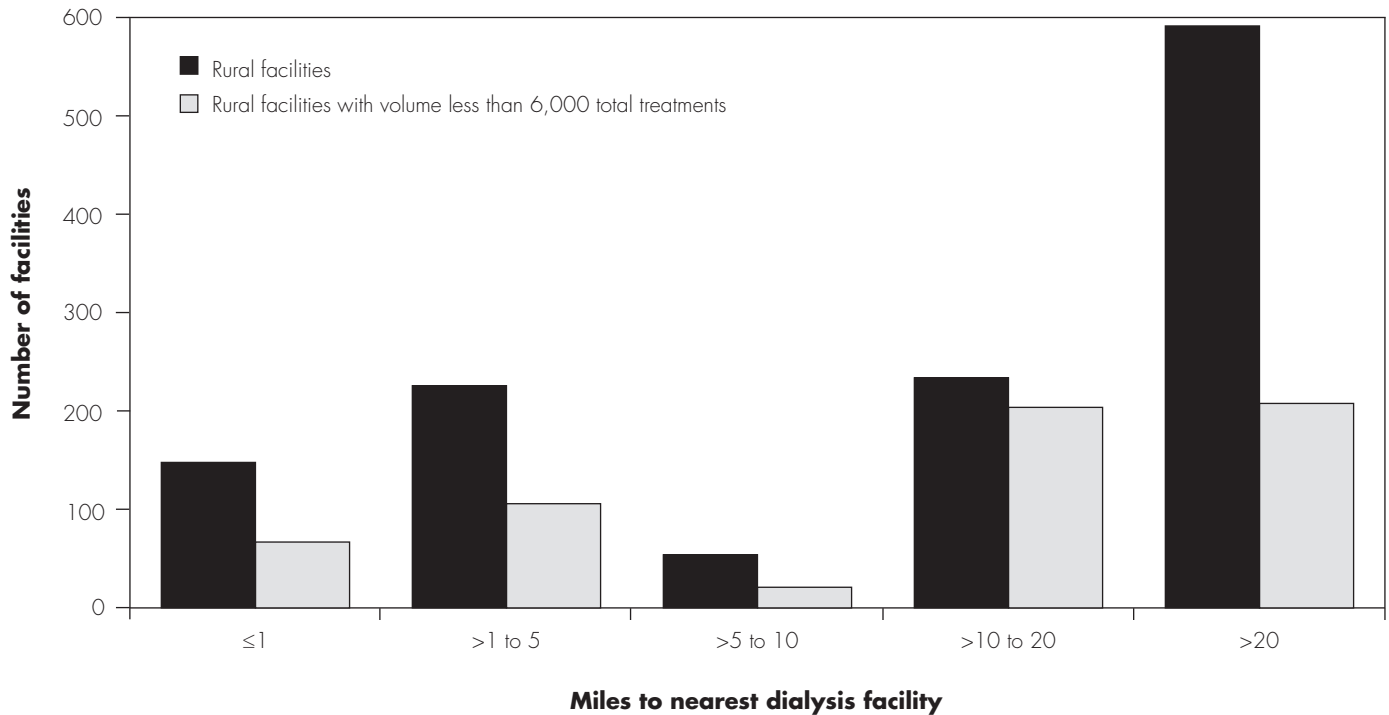
Annual number of dialysis treatments	Urban	Rural	Ratio of adjusted cost per treatment: urban to rural facilities
<4,000	\$337	\$337	1.00
4,000-4,999	310	309	1.00
5,000-5,999	296	289	1.02
6,000-6,999	282	280	1.01
7,000-7,999	271	273	0.99
8,000-8,999	263	270	0.98
9,000-9,999	259	256	1.01
10,000-14,999	248	256	0.97
≥15,000	232	240	0.97

Note: Cost per treatment is adjusted to remove differences in the cost of labor. "Dialysis treatments" includes those paid for by all sources (not just Medicare-paid treatments). Analysis is based on freestanding dialysis facilities.

Source: MedPAC analysis of 2017 cost reports submitted by freestanding dialysis facilities to CMS.

**FIGURE
7-3**

Current design of rural payment adjustment factor includes facilities in close proximity to another facility and facilities that are not low volume



Source: MedPAC analysis of 2017 claims and 2017 cost reports submitted by dialysis facilities to CMS, the Dialysis Facility Survey, and the Dialysis Facility Compare file.

In our comment letter on CMS’s proposal to introduce the separate rural adjustment in 2016, the Commission urged the agency to design a single payment adjustment that targets low-volume isolated providers instead of two separate adjustments for low volume and rural location (Medicare Payment Advisory Commission 2015). The Commission’s analyses have found differences overall in the adjusted cost per treatment for rural and urban facilities (about \$270 per treatment versus nearly \$250 per treatment, respectively, in 2017); however, those differences generally are explained by differences between rural and urban facilities in total treatment volume. As shown in Table 7-4, the adjusted cost per treatment is roughly equivalent in rural and urban facilities with similar treatment volume. The 2017 aggregate Medicare margin follows a similar trend: Urban facilities had higher margins than rural facilities (1.3 percent versus –5.1 percent). However, after controlling for treatment volume,

the gap between urban and rural facilities narrows (data not shown).

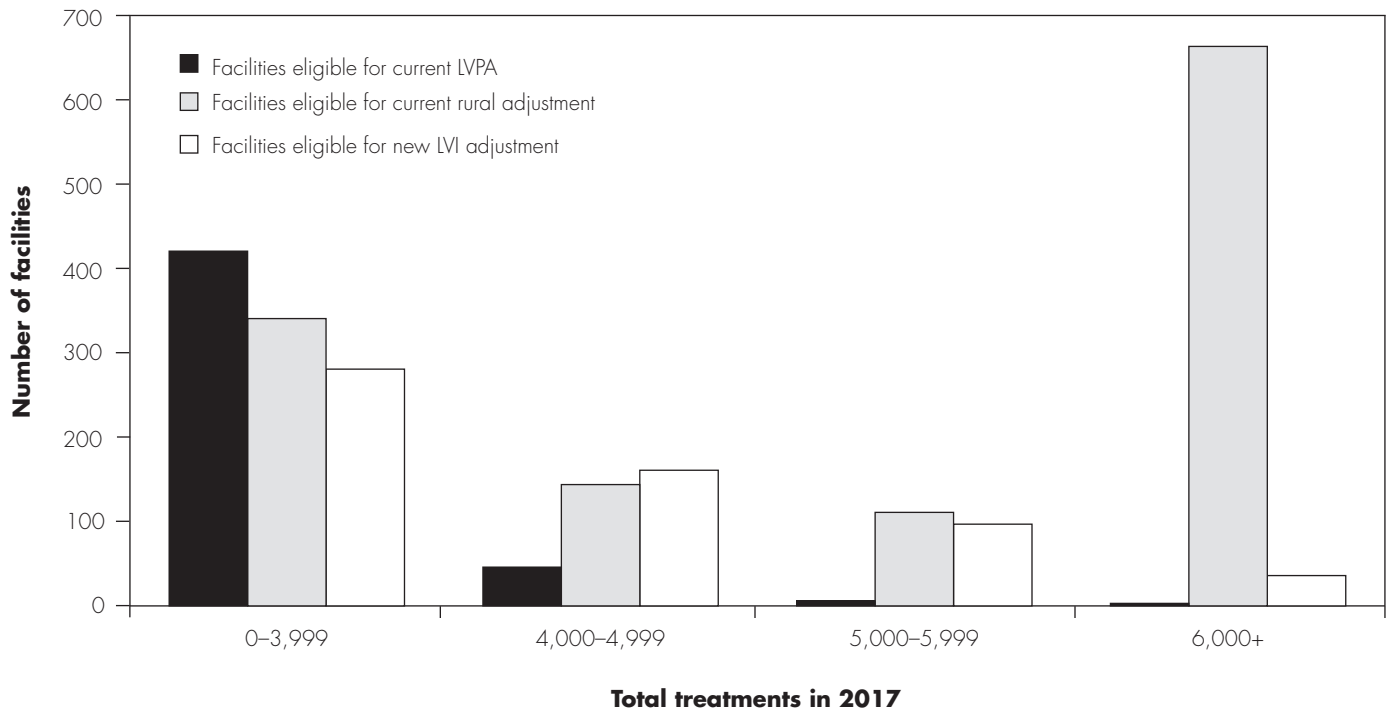
In 2017, high-volume rural facilities (which represent about half of all rural facilities) received the 0.8 percent rural adjustment despite having adjusted costs per treatment that were similar to their high-volume urban counterparts (Table 7-4). In addition, 30 percent of rural facilities were within five miles of the next closest facility (Figure 7-3).

Improving the adequacy of payments for low-volume and isolated facilities

The design of the LVPA and rural payment adjustment are not consistent with the Commission’s principles guiding special payments to rural providers (see text box on

**FIGURE
7-4**

A new LVI adjustment would better target payments to low-volume, isolated dialysis facilities



Note: LVI (low-volume and isolated), LVPA (low-volume payment adjustment). Analysis includes freestanding and hospital-based facilities. Eligibility for the LVPA and the LVI adjustment is based on total treatment volume between 2014 and 2016, the three years before the 2017 payment year in question. In 2017, some LVPA-eligible facilities provided more than 4,000 treatments, and some LVI-eligible facilities provided more than 6,000 treatments.

Source: MedPAC analysis of claims submitted by freestanding and hospital-based dialysis facilities and cost reports submitted by freestanding dialysis facilities to CMS, the ESRD Facility Survey, and the Dialysis Facility Compare file.

evaluating rural payments). The LVPA does not ensure that only isolated facilities receive the payment adjustment. For example, two facilities not under common ownership could be located in close proximity (e.g., within five miles of one another) and receive the 23.9 percent LVPA to their base rate. Further, there is no distance criterion or volume criterion required for a rural facility to receive the 0.8 percent increase to its base payment rate.

Consistent with the Commission’s principles, an adjustment that serves to preserve access to dialysis should focus on isolated *and* low-volume facilities. Neither the LVPA, which increases payment for facilities that are located within five miles of another facility, nor the rural adjustment, which increases payment for high-volume rural facilities, ensures access to dialysis care or spends program funds wisely.

In addition, isolated dialysis facilities, which we define as facilities located more than five miles from the next facility, vary in the number of treatments provided such that isolated facilities exist almost uniformly across all categories of facility treatment volume. For example, in 2017, nearly 30 percent of freestanding and hospital-based dialysis facilities located more than 5 miles from the next facility furnished more than 10,000 treatments.

A single payment adjustment that considers both a facility’s distance to the nearest facility and its treatment volume would eliminate extra payments to low-volume facilities in close proximity to another facility and to high-volume rural facilities and instead would target extra payments to low-volume and isolated facilities. A combined low-volume and isolated (LVI) adjustment would require the facility to be isolated and to have a low treatment volume. For example, CMS could use a distance

Guiding principles to evaluate rural special payments

Under the prospective payment system (PPS) for end-stage renal disease (ESRD), low-volume and rural adjustments are not consistent with the Commission's principles regarding Medicare payment policy for rural providers, nor with expectations regarding rural beneficiaries' access to care and rural providers' quality of care (Medicare Payment Advisory Commission 2012). The Commission stated the following principles in our June 2012 report to the Congress:

- Payments should be targeted toward low-volume, isolated providers—that is, providers that have low patient volume and are at a distance from other providers. Distance is required because supporting

two neighboring providers that both struggle with low volume can discourage mergers that could lead to lower cost and higher quality care.

- The magnitude of special rural payment adjustments should be empirically justified—that is, the payments should increase to the extent that factors beyond the providers' control increase their costs.
- Rural payment adjustments should be designed in ways that encourage cost control on the part of providers. Fixed add-on payments generally provide a greater incentive for cost control than cost-based payments. ■

of five miles to the nearest facility, the mileage threshold used for the LVPA. (Policymakers could consider using a different mileage threshold as long as it did not affect beneficiaries' access to care.) At the same time, to improve on the current cliff effect exhibited by the LVPA (which gives facilities an incentive to limit services to avoid reaching the 4,000-treatment threshold), CMS could apply the low-volume criterion using a few approaches. One method is to use a continuous function to determine the adjustment size. Using another method, the Commission modeled a categorical approach with three levels of low volume. Either approach would reduce the all-or-nothing application of the LVPA and better match the higher cost per treatment for facilities with relatively low volume. We created the following levels of low volume for three mutually exclusive categories:

- **Category 1:** facilities with fewer than 4,000 treatments in each of the 3 years preceding the payment year;
- **Category 2:** facilities that had fewer than 5,000 treatments in each of the preceding 3 years (excluding Category 1); and
- **Category 3:** facilities that had fewer than 6,000 treatments in each of the preceding 3 years (excluding Categories 1 and 2).

Using 2017 data, Figure 7-4 shows how the illustrative LVI adjustment criteria contrast with the current LVPA and rural adjustment criteria by comparing the number of freestanding and hospital-based facilities eligible for either the LVPA or the rural adjustment with the number of facilities eligible for the LVI adjustment.¹⁵

Overall, in 2017, 575 facilities would have been eligible to receive the LVI adjustment, compared with 477 facilities eligible for the LVPA and 1,257 facilities eligible for the rural adjustment. Roughly half of facilities eligible for the LVPA and one-quarter of facilities eligible for the rural adjustment would receive the LVI adjustment. Figure 7-4 shows that the expanded categories under the LVI adjustment increase the number of isolated facilities providing between 4,000 and 5,999 treatments that would receive a low-volume adjustment. As seen earlier in Figure 7-1 (p. 192), facilities with treatment volumes between 4,000 and 5,999 also had relatively high cost per treatment.

Table 7-5 (p. 198) shows the number of eligible facilities (freestanding and hospital based) and the median adjusted cost per treatment (based only on freestanding facilities with cost report data) for each of the three LVI categories. Although the size of the LVI category adjustments would be empirically estimated, the median costs demonstrate

**TABLE
7-5**

Facilities eligible for LVI adjustment have higher costs than all other isolated facilities

	Number of dialysis facilities	Median adjusted cost per treatment
LVI Category 1	255	\$320
LVI Category 2	188	304
LVI Category 3	132	278
Reference group: All isolated facilities not receiving an LVI payment adjustment	1,899	250

Note: LVI (low-volume and isolated). LVI Category 1 comprises facilities with fewer than 4,000 treatments in each of the 3 years preceding the payment year. LVI Category 2 comprises facilities that had fewer than 5,000 treatments in each of the preceding 3 years (excluding LVI Category 1 facilities). LVI Category 3 comprises facilities that had fewer than 6,000 treatments in each of the preceding 3 years (excluding LVI Category 1 and LVI Category 2 facilities). Median cost per treatment is based only on freestanding facilities with cost report data and has been adjusted to account for local wage variation.

Source: MedPAC analysis of claims and cost reports submitted by dialysis facilities to CMS.

that the expanded low-volume categories have higher costs than other isolated facilities.

Effect of a low-volume and isolated adjustment on Medicare payments to dialysis facilities

To assess the effect of replacing the current low-volume and rural location adjustments with a single low-volume and isolated adjustment, we used a regression method based on a model previously developed by CMS to explain variation in treatment costs. Using a single facility-level regression model, we assessed the effect of substituting a single payment adjustment—the LVI adjustment—in place of the two adjustments for low volume and rural location that the ESRD PPS currently uses.

Model specification

Our single facility-level regression model uses freestanding dialysis facilities’ cost reports submitted to CMS, with the dependent variable equal to a facility’s 2017 average cost per treatment, which captures the cost of all services included in the PPS payment bundle, including drugs and laboratory services that were separately billable under the prior payment system. We estimated coefficients for the payment adjustment factors currently included in the ESRD PPS.

We chose a single facility-level regression approach instead of CMS’s two-regression approach out of concerns that multiplying coefficients from the facility-level and

patient-level regressions (with different bases) could diminish the accuracy of the combined coefficients (Medicare Payment Advisory Commission 2015). The text box outlines our concerns with CMS’s two-regression approach.

Our regression model includes freestanding facilities with cost data for 2017 (roughly 400 hospital-based facilities are excluded due to concerns about data validity).¹⁶ To improve the accuracy of regression results, we excluded facilities with outlier values for average cost per treatment (i.e., defined as having logged average treatment cost outside of two standard deviations from the mean). We include the same control variables (i.e., facility size, ownership type, and home dialysis training) as the ESRD PPS-estimating regression, with a few minor differences in definition (i.e., we differentiate between facilities providing 10,000 to 15,000 treatments and more than 15,000 treatments, and we collapsed independent and unknown ownership types). We include the same patient-level variables—age, body mass index, body surface area, comorbid conditions, and time since the onset of ESRD. We specify each set of these variables using the percent of treatment in each category.

The Commission’s model findings

As shown in Table 7-6 (p. 200), the current ESRD PPS adjustment values are 1.239 for the LVPA and 1.008 for rural location. (Payment adjustment values are applied

CMS's model specification may not accurately estimate payment adjustment factors

For the end-stage renal disease (ESRD) prospective payment system (PPS), CMS estimated the payment adjustment factors using a two-equation regression methodology. The agency conducted one regression at the facility level and used cost report data to calculate each facility's average treatment cost for the composite rate set of services, adjusted for differences in wages.¹⁷ CMS conducted the second regression at the patient level and used Medicare claims to calculate the average Medicare-allowable per patient payment amount for items and services that formerly were separately billable. Together, the composite rate services and former separately billable services make up the current ESRD bundle.

Each regression includes the same set of control variables and payment adjustment variables shown in Table 7-1 (p. 186) and estimates a coefficient for each payment adjustment variable.¹⁸ To combine the coefficients from the two regressions, for each adjustment, the coefficient from the composite rate model is multiplied by the share of composite rate service spending, and the coefficient from the former separately billable model is multiplied by the share of former separately billable service spending. The weighted coefficients from each regression are multiplied to derive the final coefficient.

Multiplying coefficients from the facility-level and patient-level regressions (with different bases) can

diminish the accuracy of the combined coefficients. Through various re-estimations of the payment adjustment amounts, the empirically determined lowest cost reference population for the age category variables has shifted from ages 45 to 59 in the proposed rule for the 2011 PPS to ages 60 to 69 in the final rule for the 2011 PPS and to ages 70 to 79 in the final rule for the 2016 PPS (Table 7-1, p. 186). We would expect the relative cost of dialysis treatment across age categories to remain roughly stable over time and are concerned that such shifts indicate that the estimated factors are highly sensitive to the model's specification and that the model lacks robustness. The two-equation approach might contribute to the instability of these results.

The Commission advised CMS to develop payment adjustment factors using a single-equation methodology that accounts for variation in the cost of providing the full PPS payment bundle (Medicare Payment Advisory Commission 2015). Given the availability since 2011 of cost data for the full PPS payment bundle, it is no longer necessary to use pre-2011 service categories when developing the adjustment factors. The distribution of average treatment cost across facilities is quite likely to be different from the distribution of payments for separately billable services across patients, and combining the two factors estimated on unrelated distributions may not accurately reflect cost variation for the payment unit, a dialysis treatment. ■

as multipliers to the ESRD PPS base rate; that is, a 1.239 adjustment value would increase the base rate by 23.9 percent.) The Commission's regression analysis estimated payment adjustment values of 1.319 for the LVPA and 1.010 for rural location.¹⁹

Differences between our results and the current ESRD PPS adjustment values could be due to using different years of data or to differences in the regression specification. As described in the text box on model specifications, CMS

used a two-equation regression methodology to derive the ESRD PPS payment adjustments:

- a facility-level regression model that used 2012 and 2013 cost reports submitted by dialysis facilities to CMS, with the dependent variable equal to the average cost per treatment for composite rate services.
- a patient-level regression model that used 2012 and 2013 dialysis facility claims, with the dependent

**TABLE
7-6**

LVPA and rural location adjustment values in the current ESRD PPS and based on the Commission’s regression analysis

	ESRD PPS values			MedPAC regression values
	Facility-level regression of composite rate services	Patient-level regression of separately billable services	Combined regression results, all ESRD bundle services	Facility-level regression of all ESRD bundle services
LVPA	1.368	0.955	1.239	1.319
Rural location	1.015	0.978	1.008	1.010
Share of treatment cost	80.8%	19.2%	100%	100%

Note: LVPA (low-volume payment adjustment), ESRD (end-stage renal disease), PPS (prospective payment system). CMS derived the ESRD PPS adjustment values by combining the results of (1) a facility-level regression model that used 2012 and 2013 dialysis facility cost reports, with the dependent variable equal to the average cost per treatment for composite rate services, and (2) a patient-level regression model that used 2012 and 2013 dialysis facility claims, with the dependent variable equal to the estimated average payment per patient for dialysis-related drugs and laboratory services. The Commission estimated payment adjustment values based on a single regression that uses 2017 cost report and claims data, with the dependent variable equal to the average cost of ESRD bundle services. The Commission’s regression results are significant at $p < .0001$ level for the LVPA and $p < .05$ level for rural location, are based on a regression including 5,151 freestanding facilities, and have an R^2 of 0.3816. Our estimate of the LVPA adjustment is higher than the ESRD PPS factor in part because the ESRD PPS factor is adjusted by the ratio of low volume to other volume category factors, whereas our estimate incorporates other volume category factors into the base rate.

Source: MedPAC analysis of calendar year 2016 final rule, 2017 cost reports submitted by freestanding dialysis facilities to CMS, and dialysis claims.

variable equal to the estimated average payment per patient for dialysis-related drugs and laboratory services.

To calculate the value of each payment adjustment, CMS combined the facility-level regression results with the patient-level regression results by weighting factors from each regression by the share of treatment cost for each set of services (e.g., composite rate share (1.015×0.808) + separately billable share $(0.978 \times 0.192) = 1.008$ for the rural payment adjustment).

By contrast, the Commission estimated the payment adjustment values using a single-equation regression, with the dependent variable equal to the average cost of all ESRD bundle services and 2017 cost report and claims data.

The rural location variable in our LVPA and rural regression model (Table 7-6) was found to be statistically significant, meaning that accounting for other factors in the model, rural location is associated with higher treatment costs. Despite the statistical significance of this result, an adjustment for all rural facilities, including those that are high volume or near another facility, would

not meet the Commission’s other two rural payment principles: Rural payment adjustment should be targeted to low-volume and isolated facilities and should include a way to encourage cost control. We note that the ESRD PPS regression also includes control variables (e.g., additional facility-size categories and organization of ownership) that serve to accurately specify the size of the payment adjustment factors (i.e., the coefficients for payment adjustment variables are more accurately estimated when controlling for other factors that affect average treatment cost). Regression coefficients for control variables may be statistically significant, yet those control variables do not affect payment.²⁰ For example, facilities associated with large dialysis organizations (LDOs) or other chain organizations were associated with having higher costs than facilities with independent or unknown ownership (statistically significant in our regression results), but LDOs and other chain organizations do not receive a payment increase due to their ownership status.²¹ The goal of this policy is to focus payment adjustments on those facilities most essential to ensure access to care, and thus, in our view, a payment adjustment for rural location is not warranted for facilities that are not low volume and

**TABLE
7-7**

Estimated LVI payment adjustment values decrease as total treatment volume increases

MedPAC regression

Facility level, all ESRD bundle services

LVI Category 1	1.317
LVI Category 2	1.267
LVI Category 3	1.189
Share of treatment cost	100%

Note: ESRD (end-stage renal disease), LVI (low-volume and isolated). LVI Category 1 comprises facilities with fewer than 4,000 treatments in each of the 3 years preceding the payment year. LVI Category 2 comprises facilities that had fewer than 5,000 treatments in each of the preceding 3 years (excluding LVI Category 1 facilities). LVI Category 3 comprises facilities that had fewer than 6,000 treatments in each of the preceding 3 years (excluding LVI Category 1 and LVI Category 2 facilities). MedPAC regression results are significant at $p < .0001$ level, are based on a regression including 5,151 freestanding facilities, and have an R^2 of 0.3840.

Source: MedPAC analysis of cost reports submitted by freestanding dialysis facilities to CMS and dialysis claims.

not isolated. However, given its statistical significance, rural location could be considered as an addition to the control variables in the ESRD PPS regression model.

Table 7-7 shows regression results for the LVI category adjustments. LVI Category 1 facilities, those with fewer than 4,000 treatments in each of the 3 prior years and farther than 5 miles from the nearest facility, would receive an adjustment of 1.317. LVI Category 2 facilities would receive an adjustment of 1.267, and LVI Category 3 facilities would receive an adjustment of 1.189. The relative size of the three LVI coefficients aligns with evidence showing that facilities providing the fewest treatments have higher average costs, and the statistical significance of each coefficient demonstrates the benefit of expanding the definition of low volume above 4,000 treatments for isolated facilities.

To assess the impact on facility payment rates of replacing the LVPA and rural location adjustments with the LVI category adjustments, we estimated the base rate and payment factors from each regression model and calculated the average facility payment rate based on each model. The impact on facilities depends on their eligibility for any LVI adjustment, the LVPA, and the rural location adjustment. Table 7-8 (p. 202) shows that most facilities meeting our low-volume and isolated criteria would have no change in payment or would receive a payment increase

(first three rows of the table), but facilities currently eligible for both the LVPA and rural location adjustment would see a small decrease (fourth row of the table), as the LVI Category 1 factor is smaller than the sum of the estimated the LVPA and rural location adjustment factors. The largest payment increases, 20 percent and 21 percent, would be for facilities that are newly eligible for the low-volume and isolated adjustment based on the expanded definition (i.e., facilities eligible for LVI Category 2 and Category 3 adjustments), depending on whether they are currently eligible for the rural location adjustment.

As shown in Table 7-8 (p. 202), facilities currently eligible for the LVPA, the rural location adjustment, or both but not eligible for the LVI adjustment would see a payment decrease. These facilities are located in a rural area and are not low volume, or they are low volume but located within five miles of another facility. A concern could be that LVPA-eligible facilities that are not isolated (and therefore are not LVI eligible) would receive a 22 percent or 23 percent payment decrease, depending on rural location. However, under the LVPA, Medicare currently subsidizes low-volume facilities that are near other facilities, in contrast to the goal of the LVI adjustment to support only low-volume facilities that are essential to maintain access to dialysis care and thereby improve the value of Medicare’s spending. Overall, we find that the payment changes caused by replacing the LVPA and rural

**TABLE
7-8**

Estimated impact of the Commission’s LVI adjustment on average Medicare payment rate for facilities of varying eligibility

Facilities’ eligibility to receive:

LVI adjustment	LVPA	Rural adjustment	Number of facilities	Estimated average Medicare payment change
Yes	No	No	136	21%
Yes	No	Yes	184	20
Yes	Yes	No	83	0
Yes	Yes	Yes	172	-1
No	No	Yes	867	-1
No	Yes	No	173	-22
No	Yes	Yes	49	-23
No	No	No	5,425	0

Note: LVI (low-volume and isolated), LVPA (low-volume payment adjustment). Estimated impact of LVI adjustment is based on the Commission’s number of facilities affected using data for all 7,089 freestanding and hospital-based facilities in 2017. Average payment change is based on the Commission’s estimates of the LVI adjustment, LVPA, and rural adjustment for 5,823 freestanding facilities.

Source: MedPAC analysis of cost reports and claims submitted by dialysis facilities to CMS.

adjustment with the LVI category adjustments generally align with the Commission’s principles that facilities with greater importance for maintaining access to services (those that are isolated) can receive a higher payment rate if such an increase is empirically justified, as demonstrated by our analysis.

Finally, we estimated the impact of switching from the current LVPA and rural adjustment factors to the LVI adjustment across various facility characteristics (e.g., urban/rural, large dialysis organization/other, for profit/nonprofit, freestanding/hospital based). We found that few facilities would experience a significant payment change under the LVI adjustment. Only 8 percent of facilities are affected, falling into one of three mutually exclusive categories: (1) were LVPA eligible but would not be LVI eligible, (2) were LVPA eligible and would be LVI eligible, or (3) were not LVPA eligible but would be LVI eligible. Moreover, a similar number of facilities would experience a significant payment increase or decrease (i.e., 320 facilities would experience a significant payment increase, 265 facilities would experience a significant payment decrease). Given the low share of facilities affected, we did not find a substantial impact for any of the subgroups of facilities we assessed.

Effects of a low-volume and isolated payment adjustment on beneficiaries’ access to high-quality care

To assess the potential impact of our illustrative LVI policy on quality, we used each facility’s total performance score that CMS calculated under the 2017 ESRD Quality Incentive Program (QIP). Beginning in 2012, outpatient dialysis payments are linked to the quality of care that facilities provide under the ESRD QIP. Under statutory provisions, the maximum payment reduction that CMS can apply to any facility is 2 percent. In 2017, facilities could receive a total performance score ranging from 0 (the lowest) to 100 (the highest) based on the following measures:

- clinical measures that assess vascular access among hemodialysis beneficiaries, dialysis adequacy, bloodstream infections, hospital readmission rates, and presence of hypercalcemia; and
- reporting measures that assess bone mineral metabolism and disease management, anemia management, and the facility’s compliance with administering the in-center hemodialysis Consumer Assessment of Healthcare Providers and Systems® survey on a twice-yearly basis.

Among all dialysis facilities (with 2017 QIP data), the QIP total performance score averaged 68.6. The score of facilities that would no longer receive the LVPA under the illustrative LVI policy was not statistically different from the score of the next closest facility (70.9 versus 69.3, respectively, using a paired t-test).

A separate concern involves the potential for predatory competition with low-volume and isolated providers. That is, would an LVI policy allow an organization with sufficient capital reserves to establish a new facility in close proximity to an LVI-eligible facility, thus rescinding the LVI eligibility and reducing Medicare payments to the existing facility in an attempt to put the facility out of business and capture the facility's patient population? In our view, the incentive to engage in such predatory competition could be limited by the generally negative Medicare margins of low-volume facilities (see March 2019 report findings for evidence that low-volume facilities tend to have lower margins) and the requirement to find a new medical director in an area that is likely to be rural (Medicare Payment Advisory Commission 2019b). Our review of new facility openings in 2017 corroborates this view: Just 7 of 302 new facilities opened within 5 miles of an LVPA-receiving facility and only 1 opened within 5 miles of a rural LVPA-receiving facility.

Under the current LVPA policy, an existing facility would not lose its low-volume payment adjustment (23.9 percent increase) if a competing facility opened within five miles of its location because proximity to another facility is considered only for facilities under common ownership. Under the LVI policy, eligible facilities would need to be located farther than five miles from the nearest facility regardless of ownership. To address predatory competition—a new dialysis facility opening within five miles of an existing LVI facility—policymakers could exempt the existing LVI facility from the five-mile distance criterion for a period of three years as long as it continues to meet the volume criteria (i.e., the existing low-volume facility would continue to receive the LVI adjustment for three years, despite being located within five miles of another facility). A three-year exemption from the distance criterion for the existing facility would ensure beneficiaries' access to care and promote competition between the existing and new facility to provide patient-centered high-quality care. At the end of the three-year "exemption" period, a facility would be required to meet both the distance and volume criteria to receive the LVI adjustment.

Policymakers could consider a continuous low-volume and isolated payment adjustment instead of a categorical approach

As an alternative to a payment adjustment using categorical variables, a continuous adjustment factor could apply the same eligibility criteria for facility isolation (i.e., no other facilities within 5 miles), but would replace the 3 low-volume categories with a single threshold: fewer than 7,000 treatments, for example, in each of the 3 years (2014, 2015, and 2016) preceding the payment year (2017). (We used a 7,000-treatment threshold to approximately align the facilities eligible for the LVI adjustment with those under the 3-category approach used in our model.)

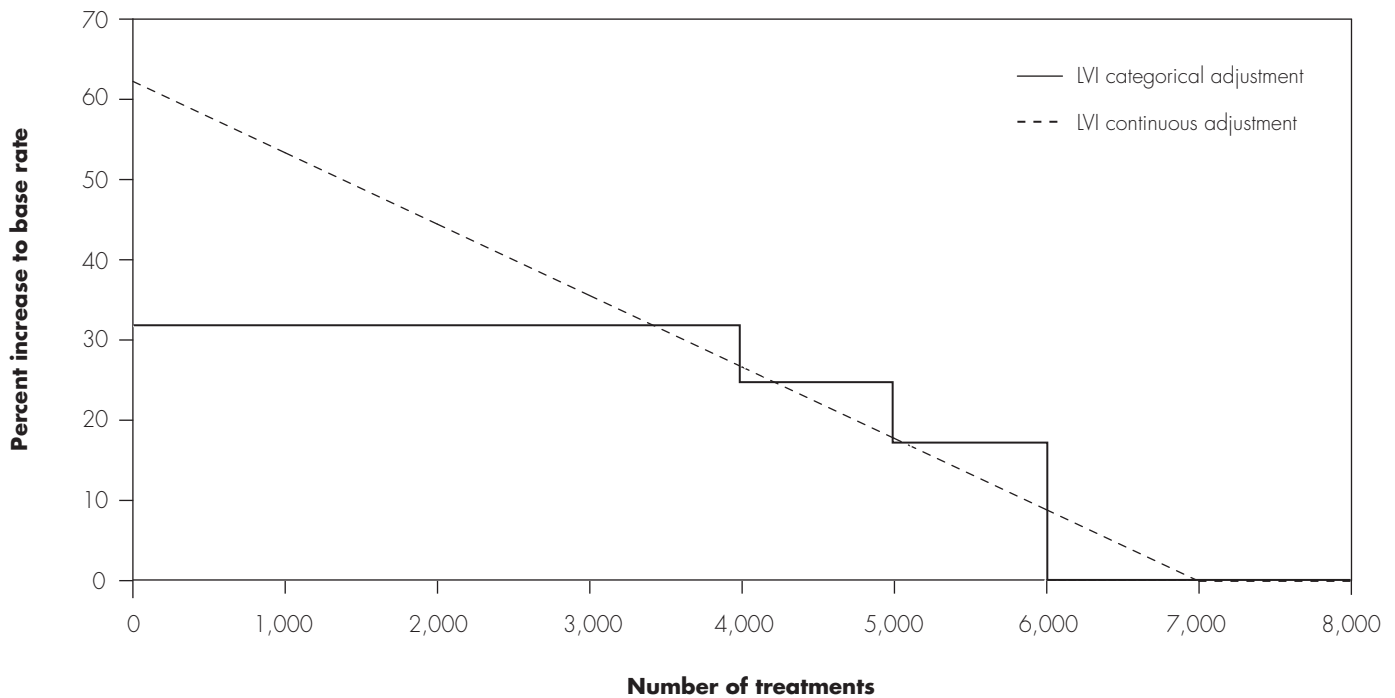
We conducted a preliminary analysis to illustrate the impact of a continuous adjustment factor. For illustrative purposes, we specified a continuous factor by assigning it a value of 7,000 minus the average annual number of treatments across the preceding years for eligible facilities and a value of 0 for all other facilities. To estimate the marginal cost reduction for providing one additional treatment in eligible facilities if a continuous adjustment were in effect, we used the same regression model that was used to determine the LVI adjustment's effect.

Figure 7-5 (p. 204) shows that a continuous adjustment would have the benefit of smoothing the cliffs, or cut points, associated with categorical adjustments, under which an increase from LVI Category 1 (facilities with fewer than 4,000 treatments) to LVI Category 2 (facilities with between 4,000 and 4,999 treatments) decreases the payment adjustment from about 32 percent to 27 percent. Alternatively, adding more categories to the categorical adjustment could also limit the cliff effect.

A continuous adjustment might be more challenging to administer than a categorical approach. To determine the value of a facility's continuous adjustment, the facility would need to attest to whether the number of treatments provided in each of the three preceding years was lower than the 7,000-treatment threshold. Before the payment year, facilities would also need to provide CMS an estimate of the average annual number of treatments provided across the three years preceding the payment year (i.e., average of actual treatment volume for the first two years of this period and the projected treatment volume for the third year still in progress) and multiply that number by the continuous adjustment factor. This

FIGURE 7-5

Illustrative example comparing LVI categorical adjustment to LVI continuous adjustment



Note: LVI (low-volume and isolated).

Source: MedPAC analysis of cost reports submitted by freestanding dialysis facilities to CMS and dialysis claims.

process is slightly more complicated than determining a facility’s categorical LVI adjustment (and current LVPA adjustment), which only requires facilities to check whether the number of treatments provided in each of the three preceding years is lower than a threshold. Because of these differences, providers could calculate and predict Medicare rates more easily under a categorical approach.

A continuous adjustment could provide greater accuracy than a categorical adjustment if it is calculated with the empirically determined number of maximum treatments using accurate dialysis cost report data (our analysis used a 7,000-treatment threshold for illustrative purposes only). One concern about using an adjustment with a complex design is that the quality of the underlying cost data may not be sufficient to support that level of accuracy. For example, facilities do not consistently report peritoneal dialysis treatments according to CMS guidelines. One week of peritoneal dialysis should be reported as three

hemodialysis-standardized (or equivalent) treatments; however, some facilities report according to the guideline and other facilities report seven daily peritoneal dialysis treatments per week. Some stakeholders advocate for fewer and less complicated adjustments in the ESRD PPS over concern that adjustments reduce the base rate, but those adjustments are paid out to facilities to the same extent they are accounted for in estimating the ESRD PPS. Policymakers should consider how to balance the accuracy of adjustments with the accuracy of the underlying data.

RECOMMENDATION 7-2

The Secretary should replace the current low-volume and rural payment adjustments in the end-stage renal disease prospective payment system with a single adjustment for dialysis facilities that are isolated and consistently have low volume, where low-volume criteria are empirically derived.

RATIONALE 7-2

The design of the current low-volume and rural payment adjustments does not align with the Commission's principles on payments to rural providers: Rural payment adjustments should target facilities that are critical for beneficiary access (meaning those that are both low volume and isolated), the magnitude of payment adjustments should be empirically derived, and the adjustments should encourage provider efficiency.

The current low-volume payment adjustment is applied to facilities that are located near another dialysis facility, does not account for the higher cost of facilities with volumes of 4,000 to 5,999 treatments per year, and uses a single all-or-nothing threshold. The rural adjustment applies to all facilities located in rural areas, regardless of their treatment volume or proximity to another facility. The recommendation would apply to facilities that are necessary to preserve access to care (both low volume and isolated), would better account for facilities with higher cost of treatment, and would mitigate the all-or-nothing application of the current low-volume adjustment. The low-volume and isolated adjustment in the recommendation could be implemented with a categorical or continuous approach. In either case, eligibility for the adjustment and size of the adjustment should be empirically derived.

IMPLICATIONS 7-2

Spending

- The recommendation is intended to be budget neutral with respect to current policy.

Beneficiaries and providers

- The recommendation enhances beneficiaries' access to care at isolated, low-volume facilities. It is not expected to affect providers' willingness or ability to serve beneficiaries. Based on our analysis, payments would increase for providers with lower treatment volumes that are not in close proximity to another facility but currently do not receive the low-volume payment adjustment. Payments would decrease for providers currently receiving the low-volume payment adjustment that are in close proximity to another facility and for providers currently receiving the rural adjustment but have higher volume or are in close proximity to another facility. ■

Endnotes

- 1 Before 2011, Medicare paid dialysis facilities a prospective payment, referred to as the composite rate, that covered services routinely required for dialysis treatment, including dialysis equipment and supplies, social services, nursing, dietary counseling and other clinical services, and certain laboratory tests and drugs. The composite rate payment bundle did not include certain commonly furnished Part B drugs, including erythropoietin-stimulating agents, iron, and vitamin D agents.
- 2 A separate method is used to calculate payments for pediatric dialysis beneficiaries (ages 17 and younger), who constitute less than 1 percent of all dialysis beneficiaries.
- 3 Wage index values vary geographically, tied to the Office of Management and Budget's core-based statistical areas. The wage index values used under the ESRD PPS are the inpatient PPS wage index values calculated without regard to geographic reclassifications and utilize pre-floor hospital data that are unadjusted for occupational mix.
- 4 Under the drug designation process that CMS established in 2016, new injectable drugs used to treat or manage a condition that are in an existing ESRD-related functional category are considered part of the PPS payment bundle and thus not eligible for a TDAPA.
- 5 Specifically, for drugs that fall within an existing functional category, the TDAPA ends two years from the effective date of the subregulatory billing guidance that begins the add-on payment.
- 6 Specifically, CMS is excluding from TDAPA eligibility those drugs approved by the FDA under Section 505(c) of the Food, Drug, and Cosmetic Act and new drugs that the FDA assigns an NDA classification code of Type 3, 5, 7, or 8; Type 3 in combination with Type 2 or Type 4; Type 5 in combination with Type 2; or Type 9 when the "parent NDA" is Type 3, 5, 7, or 8.
- 7 The rebasing in 2014 resulted in a reduction of the base payment rate by \$8.16 per treatment.
- 8 The specific terms included in the contracts between dialysis organizations and drug manufacturers are not public. However, we can obtain some information from the annual filings that publicly traded companies submit to the Securities and Exchange Commission. For example, in 2017, DaVita entered into a "Sourcing and Supply Agreement" with Amgen for both the oral and intravenous versions of calcimimetics and Epopen, an agreement that concludes in 2022 (DaVita 2019). According to this public document, the contract requires DaVita to purchase Epopen in amounts necessary to meet no less than 90 percent of the company's requirements for erythropoiesis-stimulating agents through the expiration of the contract.
- 9 This 3-year eligibility period is based on the dialysis facility's as-filed or final settled cost reports for 12 consecutive months. For hospital-based dialysis facilities, when a hospital has multiple locations and treatment counts are aggregated in the hospital's cost report, its MAC may consider other supporting documentation, which may include individual facility treatment counts rather than the hospital's cost report alone.
- 10 Specifically, a facility attests that it was low volume for the first two eligibility years and that it will be for the third eligibility year. In most cases, the MAC will not have received the third eligibility year's cost report and will rely on the attestation to allow the application of the adjustment.
- 11 Facilities are eligible for the LVPA if the change in ownership resulted in a change of facility type. According to CMS, common ownership means the same individual, individuals, entity, or entities directly or indirectly own 5 percent or more of each dialysis facility.
- 12 Across all facilities in 2017, total treatment volume averaged roughly 11,000 treatments.
- 13 The cost analysis uses 2017 cost reports submitted by freestanding dialysis facilities to CMS. This analysis defines total cost as all services in the PPS payment bundle and adjusts total cost per treatment to remove differences in the cost of labor. Cost report data are unaudited, meaning that they do not reflect the audit that PAMA mandated. In the final rule for the 2019 ESRD PPS, the agency said that the audit process is complete and the audit staff are reviewing the findings (Centers for Medicare & Medicaid Services 2018). Historically, facilities' cost reports have included costs that Medicare does not allow.
- 14 Urban areas are metropolitan statistical areas (MSAs) or a metropolitan division (which is a smaller group of counties or equivalent entities defined within an MSA containing a single core with a population of at least 2.5 million).
- 15 We found that more than 100 facilities that were eligible did not receive the LVPA in 2017 (see text box on qualification for the LVPA, p. 191).
- 16 We exclude hospital-based dialysis facilities because 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 of the entire institution and that the expenses of each hospital-based component may be skewed (Centers for Medicare & Medicaid Services 2014).

17 CMS applied a natural log transformation to average treatment costs and used an outer fence methodology to identify average costs that are unusually high or low for exclusion from the regression.

18 The control variables identify facility type as hospital based or freestanding, facility size (4,000 treatments or fewer and ineligible for the low-volume adjustment, 4,000 to 4,999 treatments, 5,000 to 9,999 treatments, and 10,000 or more treatments), ownership type (independent, large dialysis organization, regional chain, unknown), calendar year of data (to combine data from multiple years), and the portion of treatments that included self-dialysis training.

19 Our estimate of the LVPA adjustment is higher than ESRD PPS factor in part because the ESRD PPS factor is adjusted by the ratio of low volume to other volume category factors, whereas our estimate incorporates other volume category factors into the base rate.

20 Instead, the share of costs explained by the intercept and the control variables could be effectively combined into the ESRD base rate (which is the same for all facilities) such that all costs are accounted for in estimating the ESRD PPS base rate and adjustment factors.

21 Similarly, CMS found that facilities associated with large and regional dialysis organizations had higher average dialysis cost per treatment compared with independent freestanding dialysis facilities (Centers for Medicare & Medicaid Services 2009).

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