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Report to Congressional Committees

March 2013

END-STAGE RENAL DISEASE

CMS Should Improve Design and Strengthen Monitoring of Low-Volume Adjustment

GAO-13-287

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GAO Highlights

Accountability * Integrity * Reliability

Highlights of GAO-13-287, a report to congressional committees

Why GAO Did This Study

Medicare spent about $10.1 billion in 2011 on dialysis treatments and related items and services for about 365,000 beneficiaries with end-stage renal disease (ESRD). Most individuals with ESRD are eligible for Medicare. As required by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), CMS implemented the LVPA to compensate dialysis facilities that provided a low volume of dialysis treatments for the higher costs they incurred. MIPPA required GAO to study the LVPA; GAO examined (1) the extent to which the LVPA targeted low-volume, high-cost facilities that appeared necessary for ensuring access to care and (2) CMS's implementation of the LVPA, including the extent to which CMS paid the 2011 LVPA to facilities eligible to receive it. To do this work, GAO reviewed Medicare claims, facilities' annual reports of their costs, and data on dialysis facilities' location to identify and compare facilities that were eligible for the LVPA with those that received it.

What GAO Recommends

To more effectively target the LVPA and ensure LVPA payment accuracy, GAO recommends that the Administrator of CMS consider restricting payments to low-volume facilities that are isolated; consider changing the LVPA to a tiered adjustment; recoup 2011 LVPA payments that the Medicare contractors made in error; improve monitoring of those contractors; and improve the clarity and timeliness of guidance. The Department of Health and Human Services, which oversees CMS, agreed with GAO's recommendations.

View GAO-13-287. For more information, contact James C. Cosgrove at (202) 512-7114 or cosgrovej@gao.gov.

What GAO Found

The low-volume payment adjustment (LVPA) did not effectively target low-volume facilities that had high costs and appeared necessary for ensuring access to care. Nearly 30 percent of LVPA-eligible facilities were located within 1 mile of another facility in 2011, and about 54 percent were within 5 miles, indicating these facilities might not have been necessary for ensuring access to care. Furthermore, in many cases, LVPA-eligible facilities were located near high-volume facilities. Among the freestanding facilities in GAO's analysis, LVPA-eligible facilities had substantially higher costs per dialysis treatment than the average facility ($272 compared with $235); however, so did other facilities that provided a relatively low volume of treatments (and were isolated) but were ineligible for the LVPA. The design of the LVPA gives facilities an adverse incentive to restrict service provision because facilities could lose a substantial amount of Medicare revenue over 3 years if they reach the treatment threshold. In another payment system, the Centers for Medicare & Medicaid Services (CMS) implemented a tiered adjustment that decreases as facility volume increases. Such an adjustment could diminish the incentive for dialysis facilities to limit service provision and also more closely align the LVPA with the decline in costs per treatment that occurs as volume increases.

Medicare overpaid an estimated $5.3 million in 2011 to dialysis facilities that were ineligible for the LVPA and did not pay an estimated $6.7 million that same year to facilities that were eligible. The payment problems occurred primarily because the guidance issued by CMS on facility eligibility was sometimes not clear or timely and CMS's monitoring of the LVPA was limited. For example, the majority of the ineligible facilities that received the LVPA were hospital-affiliated facilities that failed the volume requirement. Although CMS gave the Medicare contractors guidance for determining how to count treatments when facilities are affiliated with hospitals, the agency did not issue that guidance until July 2012. CMS has conducted limited monitoring of the LVPA, which has left CMS with incomplete information about LVPA administration and payments. For example, CMS was unaware as of January 2013 whether its contractors had recouped erroneous 2011 LVPA payments. In addition, CMS had requested information from its contractors about the implementation of the 2011 LVPA, such as which facilities were eligible for or had received the LVPA, but had not yet verified whether the information it received was complete or in a usable form. Without complete information about the administration of this payment adjustment, CMS is not in a position to ensure that the LVPA is reaching low-volume facilities as intended or that erroneous payments to ineligible facilities are recouped.

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Abbreviations

CMS	Centers for Medicare & Medicaid Services
ESRD	end-stage renal disease
DFC	Dialysis Facility Compare
HHS	Department of Health and Human Services
KCC	Kidney Care Council
LVPA	low-volume payment adjustment
MIPPA	Medicare Improvements for Patients and Providers Act of 2008
NRAA	National Renal Administrators Association

GAO
Accountability * Integrity * Reliability

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Congressional Committees

In 2011, Medicare spent about $10.1 billion on dialysis care—including dialysis treatments and related items and services—for about 365,000 beneficiaries.[1] Dialysis removes excess fluids and toxins from the bloodstream and is the most common treatment for end-stage renal disease (ESRD)—a condition of permanent kidney failure. Most individuals with ESRD are eligible for Medicare regardless of their age.[2]

As required by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), the Department of Health and Human Services' (HHS) Centers for Medicare & Medicaid Services (CMS) recently implemented several changes to the way Medicare pays for dialysis care, including the introduction of a low-volume payment adjustment (LVPA) for services furnished on or after January 1, 2011, to increase the payment rate for facilities that provide a low volume of dialysis treatments.[3] MIPPA required that the adjustment reflect the extent to which costs incurred by low-volume facilities exceed the costs incurred by other facilities and authorized CMS to define the level at which a facility's treatments are

[1]Medicare expenditure amounts throughout this report include beneficiary cost sharing.

[2]Medicare coverage generally begins in the 4th month after patients start dialysis. For individuals who have employer group coverage, Medicare is the secondary payer for the first 30 months of Medicare entitlement, after which Medicare becomes the primary payer. 42 U.S.C. § 1395y(b)(1)(C). Most individuals diagnosed with ESRD are eligible to receive Medicare benefits under Medicare Part A, Part B, and Part D. 42 U.S.C. §§ 426-1, 1395w-101(a)(3)(A). Medicare Part A covers inpatient hospital, skilled nursing facility, and hospice care, as well as some home health care, and generally does not require a monthly premium. Medicare Part B covers outpatient dialysis treatment, injectable ESRD drugs, certain oral ESRD drugs, physician services, hospital outpatient services, and certain other services, such as physical therapy. Beneficiaries enrolled in Part B are required to pay a monthly premium. To receive most Part B-covered services, beneficiaries are required to meet an annual deductible and typically pay 20 percent coinsurance. Medicare Part D covers outpatient prescription drugs and generally requires payment of a monthly premium, meeting an annual deductible, and paying part of the cost associated with each prescription.

[3]Pub. L. No. 110-275, §153, 122 Stat. 2494, 2553-59 (codified at 42 U.S.C. § 1395rr). Medicare pays dialysis facilities a single, bundled rate for providing dialysis. Beginning in 2011, this bundled rate includes payment for a dialysis treatment and dialysis-related items and services, such as injectable ESRD drugs.

considered low volume and to determine the amount of the adjustment. CMS defined the criteria for identifying a facility eligible for the 2011 LVPA as a facility that, during each of the 3 previous years, (1) provided fewer than 4,000 total dialysis treatments—including treatments covered by Medicare and those that were not—and (2) had not opened, closed, or changed ownership.[4] CMS set the magnitude of the adjustment at 18.9 percent and indicated that the LVPA was designed to encourage small ESRD facilities to continue operating in areas where beneficiary access might be jeopardized if such facilities closed.[5]

Medicare's payment adjustment for low-volume dialysis facilities is one of several modifications in Medicare's various payment systems designed to help maintain beneficiaries' access to care. These payment modifications include those that were developed to target small and geographically isolated providers.[6] Providers that furnish a low volume of services may incur higher costs of care because they cannot achieve the economies of scale that are possible for larger providers. Low-volume providers in areas where other care options are limited may warrant higher payments because, if Medicare's payment methods did not account for these providers' higher costs of care, beneficiary access to care could be reduced if these providers were unable to continue operating. In contrast, low-volume providers that are in close proximity to other providers may not warrant an adjustment because beneficiaries have other care options nearby.

[4]*See* 42 C.F.R. § 413.232(b) (2011). CMS subsequently amended the requirement related to change of ownership to read "or received a new provider number due to a change in ownership" to correct an inadvertent omission in the 2011 final rule and provided clarification that the 3 years for purposes of determining eligibility are cost-reporting years, as opposed to calendar (or payment) years. *See* 76 Fed. Reg. 70228, 70236-37, 70314 (Nov. 10, 2011) (codified at 42 C.F.R. § 413.232(b) (2012)).

[5]*See* 75 Fed. Reg. 49,030, 49,118, 49,125) (Aug. 12, 2010).

[6]The Medicare Payment Advisory Commission has recently developed three principles that should guide Medicare's special payment adjustments for rural providers. In order for beneficiaries' needs to be met most efficiently, such payment adjustments should (1) be targeted toward low-volume isolated providers, (2) increase to the extent that factors beyond the provider's control increase their costs, and (3) be designed in such a way that encourages cost control on the part of providers. See Medicare Payment Advisory Commission, *Report to the Congress: Medicare and the Health Care Delivery System* (Washington, D.C.: June 2012).

MIPPA required us to conduct a study of the LVPA.[7] As discussed with the committees of jurisdiction, this report: (1) examines the design of the adjustment and the extent to which it targeted low-volume facilities that appeared necessary for ensuring access to care and had high costs; and (2) examines how CMS implemented the LVPA, including the extent to which CMS paid the 2011 adjustment to facilities that were eligible to receive it.

To examine the extent to which the 2011 LVPA targeted low-volume facilities that appeared necessary for ensuring access to care and had high costs, we used three different Medicare data sources—claims data, cost reports, and the Dialysis Facility Compare (DFC) database.[8] We first identified facilities that were available to beneficiaries at the beginning of 2011 using Medicare claims data from 2010 and 2011.[9] Using the methods specified by CMS in applicable guidance[10] and clarified through our interviews with the agency, we used Medicare cost reports for 2008, 2009, and 2010 to identify facilities that were eligible for the 2011 LVPA. We determined the extent to which a facility appeared necessary for ensuring access to care by evaluating whether it was isolated from other facilities, which we measured using the facility's address obtained from Medicare's DFC database to calculate the distance to the nearest facility.[11] To compare the average cost per dialysis treatment of LVPA-

[7]Pub. L. No. 110-275, § 153(d), 122 Stat. 2559. This provision also required us to report on trends in the utilization of ESRD drugs. See GAO, *End-Stage Renal Disease: Reduction in Drug Utilization Suggests Bundled Payment Is Too High*, GAO-13-190R (Washington, D.C.: Dec. 7, 2012).

[8]DFC is a database on Medicare's website that allows users to compare dialysis facilities nationwide based on factors such as the types of services and quality of care provided. Medicare-certified providers are required to submit an annual cost report to Medicare contractors. Dialysis facilities' cost reports contain provider information, such as the total number of dialysis treatments and the number covered by Medicare, and the providers' costs associated with those services. Providers are allowed to define their own cost-reporting year; for example, cost reports may span from January 1 through December 31 or July 1 through June 30.

[9]We defined facilities available at the beginning of 2011 as those for which Medicare paid at least one dialysis claim in both 2010 and 2011.

[10]As used in this report, the term "guidance" refers to information provided by CMS to explain and supplement the regulatory criteria for identifying a facility eligible for the LVPA and includes but is not limited to information found in preambles to pertinent proposed and final CMS rules.

[11]If an address for a facility could not be found through DFC, we used a facility's zip code or the address of a facility's parent hospital, depending on the type of facility.

eligible facilities with the average cost per treatment for facilities overall, we analyzed data from 2010 Medicare cost reports for freestanding facilities and adjusted those costs for differences in wages and beneficiaries' health status.[12] We excluded from our analysis certain freestanding facilities that had an extremely high or low average cost per treatment or failed other validity checks, such as reporting more Medicare treatments than total treatments.[13] Beyond these exclusions, we did not independently verify whether the information reported in 2010 cost reports for freestanding facilities represented an accurate or complete picture of dialysis facilities' costs.

To examine how CMS implemented the LVPA, including the extent to which CMS paid the 2011 LVPA to facilities that were eligible to receive the adjustment, we compared the set of facilities that received the adjustment with those that were eligible to receive it, and interviewed CMS officials and representatives of dialysis organizations about the potential sources of any discrepancies. We identified dialysis facilities that received the LVPA in 2011 using Medicare claims for dialysis treatments provided in that year and compared these facilities with those that were eligible. To estimate the amount that Medicare overpaid to ineligible facilities, we used payment information from Medicare claims. We also used Medicare claims data to estimate the amount that LVPA-eligible facilities did not receive—that is, the additional amount that Medicare would have paid if all eligible facilities had received the adjustment for all treatments provided to adult beneficiaries in 2011.[14] To examine other aspects of CMS's implementation of the LVPA, we reviewed CMS regulations and guidance, interviewed CMS officials, and interviewed groups representing large and small dialysis organizations.

[12]When adjusting freestanding facilities' costs for the health status of their patients, we used the basic case-mix adjustment CMS used in 2010 and, like CMS, applied it to costs that were paid under a single bundled rate in 2010. Because we only had information on the health status of Medicare beneficiaries, we assumed that the average health status of the facility's non-Medicare patients was the same as that of its Medicare patients. To adjust for wages, we used CMS's 2010 wage index file. We did not analyze costs for facilities affiliated with a hospital, primarily because these facilities' costs may be driven in part by hospitals' methods for allocating overhead costs within hospitals rather than by the costs of the dialysis facility itself.

[13]To identify extreme values, we used a standard statistical distribution (the lognormal) and excluded facilities whose average cost per treatment was three or more standard deviations above or below the mean.

[14]The LVPA applies only to dialysis treatments provided to adults (age 18 years or older).

We took several steps to ensure that the data used to produce this report were sufficiently reliable. Specifically, we assessed the reliability of the CMS data we used by interviewing officials responsible for overseeing these data sources, reviewing relevant documentation, and examining the data for obvious errors. We determined that the data were sufficiently reliable for the purposes of our study.

We conducted this performance audit from May 2012 through January 2013 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

End-Stage Renal Disease (ESRD)

Treatment options for individuals with ESRD include kidney transplants or maintenance dialysis. Kidney transplants are not a practical option on a wide scale, as suitable donated organs are scarce. Consequently, dialysis is the treatment used by most individuals with ESRD. Hemodialysis, the most common form of dialysis, is generally administered three times a week at facilities that provide these services. During hemodialysis, a machine pumps blood through an artificial kidney and returns the cleansed blood to the body. Other dialysis options include receiving hemodialysis at home and peritoneal dialysis.[15]

[15]Peritoneal dialysis, which usually occurs in an individual's home, utilizes the peritoneal membrane, which surrounds the patient's abdomen, as a natural blood filter. Patients remove wastes and excess fluids from their abdomen manually throughout the day, or a machine automates the process while patients sleep at night. As of December 31, 2010, the percentage of all dialysis patients receiving hemodialysis at a facility, peritoneal dialysis, and home hemodialysis was approximately 91 percent, 7 percent, and 1 percent, respectively.

Low-Volume Payment Adjustment (LVPA)

To have been eligible to receive the LVPA in 2011, a facility must have established that it met the CMS regulatory criteria that, during each of the 3 previous years, it (1) provided fewer than 4,000 total dialysis treatments and (2) had not opened, closed, or changed ownership.[16] CMS guidance provided additional detail on the application of these criteria.[17]

To establish eligibility, a facility must provide an attestation statement to its designated Medicare contractor, which is responsible for verifying that the facility has met the eligibility criteria.[18] Only after the facility has submitted its attestation and its designated Medicare contractor has verified that the facility meets the eligibility criteria will a facility begin to receive the LVPA for its Medicare-covered dialysis treatments provided to adult beneficiaries. CMS requires facilities to provide an attestation because some of the information the Medicare contractors need to assess a facility's eligibility—in particular, facilities' cost reports for the year preceding the payment year—may be unavailable to the Medicare contractors until several months after the payment year begins. In cases where the Medicare contractors could not make a final eligibility determination at the beginning of the payment year, they were to conditionally approve LVPA payments; then, once the necessary information becomes available, the Medicare contractors are required to reassess the facility's eligibility for the LVPA. If a Medicare contractor determines that a facility that received the LVPA was actually ineligible, the contractor is expected to recoup all LVPA payments made to that facility within 6 months of that determination.

[16]42 C.F.R. § 413.232 (2011). For facilities certified on or after January 1, 2011, the regulations state that the number of treatments determined to have been provided by a facility be equal to the aggregate number of treatments provided by the facility and all other facilities that are under common ownership and located within 25 miles. Because the regulations also require that a facility be in operation for at least 3 years in order to be eligible for the LVPA, the earliest this additional requirement would affect eligibility would be 2014.

[17]*See, e.g.,* 74 Fed. Reg. 49,922 (Sept. 29, 2009); 75 Fed. Reg. 49,030 (Aug. 12, 2010); CMS, JSM/TDL-10444 (Oct. 8, 2010); 76 Fed. Reg. 40,498 (July 8, 2011).

[18]See 42 C.F.R. § 413.232(f) (2012). In 2011, the designated Medicare contractors—Fiscal Intermediaries and Medicare Administrative Contractors—were expected to verify a facility's eligibility within 60 days of receiving the facility's attestation.

LVPA Did Not Effectively Target Low-Volume Facilities That Appeared Necessary for Ensuring Access to Care and Had High Costs

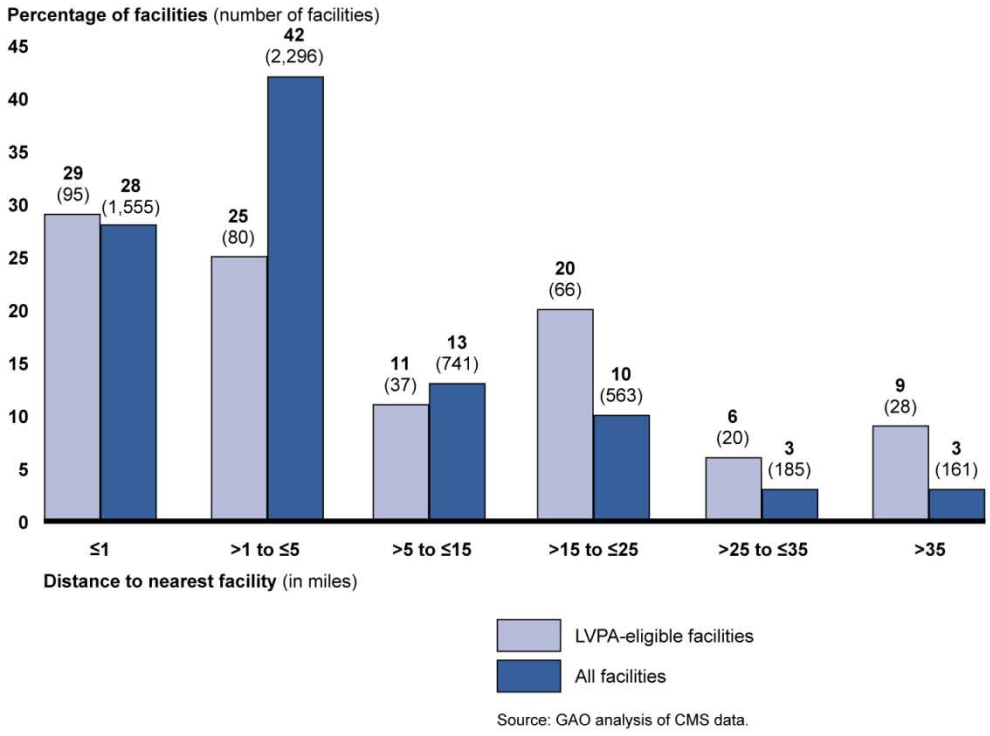
Many of the 326 facilities eligible for the 2011 LVPA were located near other facilities, indicating that they might not have been necessary for ensuring access to care. Certain facilities with relatively low volume that were not eligible for the LVPA had above-average costs and appeared to have been necessary for ensuring access to care. Moreover, the design of the LVPA provides facilities with an adverse incentive to restrict their service provision to avoid reaching the 4,000 treatment threshold.

Many LVPA-Eligible Facilities Appeared Unnecessary for Ensuring Access to Care—Nearly 30 Percent Were Located within 1 Mile of Another Facility

Many LVPA-eligible facilities in 2011 were located near other dialysis facilities, indicating that they might not have been necessary for ensuring access to care. While LVPA-eligible facilities were more isolated compared with all dialysis facilities (see fig. 1), nearly 30 percent of LVPA-eligible facilities were located within a mile of another facility, and more than 3 percent of LVPA-eligible facilities shared an address with another facility that was not eligible and was owned by the same company.[19] In addition, more than half—approximately 54 percent—of LVPA-eligible facilities were 5 miles or less from another facility. These results indicate that the patients using many LVPA-eligible facilities may have had access to multiple facilities for receiving dialysis care, which suggests that the LVPA does not effectively target facilities that appear necessary for ensuring access to dialysis care.

[19]For instance, we found several examples of a company having two facilities located at the same address, one providing in-center hemodialysis and the second providing other services, such as training services.

Figure 1: Distance to Nearest Dialysis Facility, Facilities Eligible for 2011 LVPA Compared with All Facilities



Source: GAO analysis of CMS data.

Notes: CMS data sources examined include cost reports, claims, and the Dialysis Facility Compare database. Percentages may not sum to 100 due to rounding.

Many LVPA-eligible facilities were located near high-volume facilities, suggesting that these LVPA-eligible facilities may not have warranted a payment adjustment because they were located in areas with a population base sufficient to support high-volume facilities. Approximately 35 percent of the 326 LVPA-eligible facilities were located within 5 miles of a high-volume facility.[20] Further, of these facilities, approximately 94 percent were located in urban areas, compared with 51 percent of all LVPA-eligible facilities.

[20]The average number of Medicare dialysis treatments per facility was 7,462 in 2011. We defined a facility as high-volume if it provided more than that number of Medicare dialysis treatments in 2011. The average number of Medicare dialysis treatments provided by high-volume facilities in 2011 was 12,027.

Certain Ineligible Facilities Had Above-Average Costs and Appeared Necessary for Ensuring Access to Care; LVPA Design May Introduce Adverse Incentives

Compared with all freestanding facilities in our cost analysis, freestanding LVPA-eligible facilities had substantially higher costs per dialysis treatment in 2011, but other freestanding facilities that provided a relatively low volume of treatments were ineligible for the LVPA, even though they were isolated and incurred above-average costs, because they exceeded the treatment threshold.[21] The average cost per treatment for the 216 freestanding facilities that were LVPA-eligible was $272, compared with $235 for all freestanding facilities—a difference of approximately 16 percent.[22] However, the 2011 LVPA did not target other freestanding facilities that provided a relatively low volume of treatments, were isolated, and incurred above-average costs. For example, if the volume threshold was raised to 5,000 dialysis treatments, 203 additional freestanding facilities would have been eligible for the 2011 LVPA. Of these 203 facilities, 68 and 25 were located more than 15 miles and 25 miles, respectively, from another facility, indicating that these facilities likely were important for ensuring access to care. On average, costs per dialysis treatment for these two groups of isolated facilities exceeded the average for all freestanding facilities by approximately 9 percent each—$21 and $22, respectively.

The design of the LVPA also raises concerns because it provides facilities with an adverse incentive to restrict their service provision to avoid reaching the 4,000 treatment threshold. Facilities that reach this threshold lose eligibility for the next 3 calendar years.[23] For example, for a facility that provided 3,999 total treatments in 2010 and met all other eligibility

[21]For our cost analysis, hospital-affiliated facilities and certain freestanding facilities were excluded. In total, we analyzed cost information for 4,429 facilities, approximately 81 percent of the 5,501 dialysis facilities open as of January 1, 2011.

[22]The payment increase for the 2011 LVPA was 18.9 percent. While we found the actual cost difference to be slightly lower at 16 percent, this report does not comment on the appropriateness of the size of the adjustment because the methodology we used was not directly comparable to the one used by CMS. For instance, CMS included hospital-affiliated facilities, which we did not because of our concerns regarding the reliability of the cost data from these facilities, and CMS used a regression-based methodology, while we averaged the cost per treatment across different groups of facilities. In our comparison of costs between low-volume and all freestanding facilities, we were only able to adjust a portion of a facility's costs—those that were part of the set of services paid under a single rate in 2010—for differences in wage levels and patients' health status; however, we found that the variation in facilities' total costs per treatment was due almost entirely to services for which we were able to apply these adjustments.

[23]A facility may also lose eligibility for the remainder of the current year, if the facility was receiving the LVPA in the year in which it reached the threshold.

criteria for the LVPA, providing an additional treatment would have caused the facility to lose eligibility for the LVPA for the next 3 calendar years, resulting in an estimated $390,000 in lost revenue from Medicare for 2011 through 2013.[24]

CMS has implemented an adjustment in another payment system that decreases as facility volume increases—an approach which, if applied to the LVPA, could diminish the incentive for providers to limit service provision by making the loss of potential revenue smaller for supplying additional services.[25] In addition, such an adjustment—referred to as a tiered or phased-out adjustment—could more closely align the LVPA with the decline in cost per treatment that occurs as volume increases. For example, among freestanding facilities that met the other LVPA eligibility criteria, the average cost per treatment for facilities that would have qualified under a 3,000 treatment threshold was $290; the average cost per treatment for facilities that would have failed a 3,000 treatment threshold but qualified under a 4,000 treatment threshold was $263, and the average cost per treatment for facilities that would have failed a 4,000 treatment threshold but qualified under a 5,000 treatment threshold was $256.

[24]We assumed that the proportion of this facility's total services that are paid by Medicare is equal to the average proportion for LVPA-eligible facilities in our cost analysis—73 percent. We did not analyze 2011 cost-report data for evidence of facilities restricting their service provision to obtain or maintain eligibility for the LVPA because such data were not available at the time of our analysis. However, numerous facilities could be affected by the incentive to restrict service provision, based on the total volume of treatments the facilities recorded in their 2010 cost reports. For instance, 284 facilities—over 6 percent of all freestanding facilities in our analysis—provided from 3,500 to 4,499 total treatments in 2010.

[25]Under the adjustment, hospitals received increased payments per discharge if the hospital provided fewer than 1,600 discharges a year. The amount of the adjustment was as much as 25 percent for hospitals with fewer than 200 discharges and decreased linearly until it was phased out for hospitals with 1,600 or more discharges.

Medicare Overpaid Facilities Ineligible for the 2011 LVPA and Did Not Pay Some Eligible Facilities; Primary Causes Were Unclear Guidance and Insufficient Monitoring

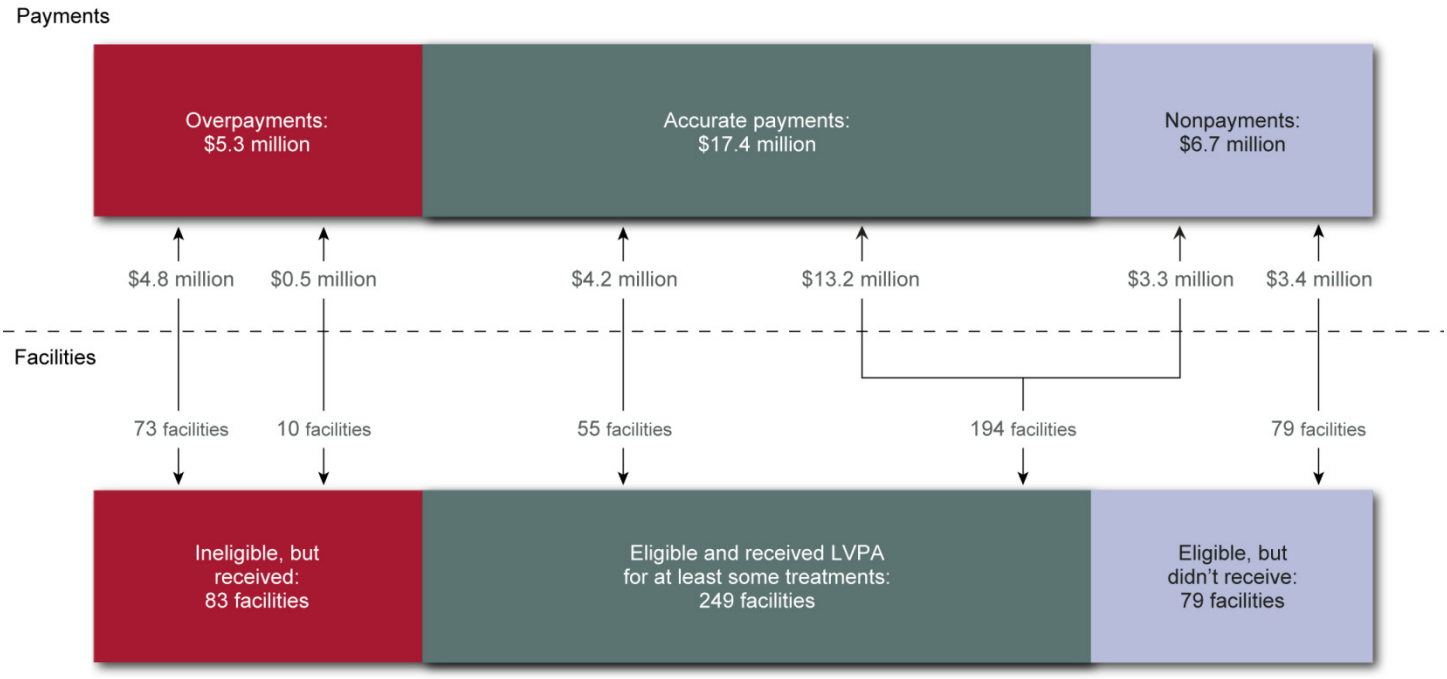
Medicare overpaid an estimated $5.3 million for the LVPA to dialysis facilities that did not meet the eligibility requirements established by CMS and did not pay about $6.7 million to facilities eligible for the LVPA. The guidance that CMS issued for implementation of the regulatory requirements was sometimes unclear and not always available when needed, and the misunderstanding of LVPA eligibility likely was exacerbated because CMS conducted limited monitoring of the Medicare contractors' administration of LVPA payments.

Medicare Overpaid Facilities Ineligible for the 2011 LVPA by an Estimated $5.3 Million and Did Not Pay an Estimated $6.7 Million to Some Eligible Facilities, including Those That Did Not Request Payments

Medicare overpaid 83 dialysis facilities that were ineligible for the LVPA in 2011 by an estimated $5.3 million, which was nearly one-quarter of the approximately $22.7 million in LVPA payments made that year. (See fig. 2.) These facilities were ineligible because, on the basis of applicable data and methods specified by CMS in its guidance (and clarified through our interviews with CMS), they did not meet the regulatory requirements of having (1) provided under 4,000 dialysis treatments in each of the 3 years preceding the payment year and (2) not opened, closed, or had a change of ownership in the 3 years preceding the payment year. Medicare contractors are expected to recoup payments made in error within 6 months of detecting the error,[26] but as of January 2013, CMS did not know whether any of these overpayments had been recouped.

[26]CMS, TDL-12034 (Oct. 21, 2011).

Figure 2: Analysis of Payments Associated with the 2011 LVPA



Source: GAO analysis of CMS data.

Note: The overpayments were made to 73 dialysis facilities that were ineligible at the beginning of 2011 and to 10 facilities that were potentially eligible at the beginning of 2011 but failed one or more criteria when all pertinent information became available. Seventy-nine eligible facilities did not receive any LVPA payments and an additional 194 facilities received payments for only some treatments. These nonpayments may have occurred because facilities did not promptly—or ever—attest to their eligibility or because Medicare contractors did not pay correctly. Accurate payments were made to 249 facilities, including 55 facilities that received accurate payments for all their treatments. Eligible facilities include those that met the eligibility criteria for 2008 and 2009 but for which the data to assess the criteria in 2010 were not yet publicly available.

These overpayments were of two types: payments to dialysis facilities that were ineligible at the beginning of 2011 and payments to facilities that were potentially eligible given the data available at the beginning of 2011 but proved ineligible when all pertinent information became available.[27] Most of these payments—about $4.8 million—were to 73 facilities that were clearly ineligible at the beginning of the year

[27]Because cost reports—the data source CMS specified Medicare contractors should use to assess eligibility for the LVPA—can be submitted up to 5 months after the end of the cost-reporting year, facilities' cost reports for the prior year may not be available until part way through the payment year.

because data available prior to 2011 showed that the facility did not meet one or more of the eligibility criteria. The remaining $0.5 million was paid to 10 facilities that met the eligibility criteria for 2008 and 2009, but when data on 2010 activity became available were shown not to have met the eligibility criteria for that year. In cases where Medicare contractors could not make a final eligibility determination at the beginning of the payment year, they were to conditionally approve LVPA payments, reassess eligibility when facilities' 2010 data became available, and, for facilities determined to be ineligible, recoup payments within 6 months of determining ineligibility.

Furthermore, many eligible dialysis facilities did not receive any LVPA payments in 2011 and others received payments for only part of the year. These nonpayments amounted to about $6.7 million and affected 273 facilities. Seventy-nine eligible facilities did not receive payments for any treatments; these payments would have amounted to about $3.4 million. It is probable that these facilities did not claim the LVPA—that is, they did not attest to their eligibility, as required in regulations—although it is also possible that some attested to their eligibility and were incorrectly denied by their Medicare contractor. Another 194 facilities received some but not all payments for which they were eligible—in total accounting for another estimated $3.3 million in nonpayments. Thirty-two facilities did not start receiving LVPA payments until part way through the year, but then consistently received payments for all treatments for the remainder of the year. These are likely facilities that were late in attesting to their eligibility, resulting in LVPA nonpayments of about $0.9 million. For the remaining estimated $2.4 million in nonpayments to 162 facilities, the reason is less clear because there is no discernible pattern. For example, some facilities received payments for several months, did not receive payments for 1 or more subsequent months, and then started receiving payments again. Other facilities received payments for some but not all treatments within a given month for multiple months in a row. We cannot explain the cause of these payment inconsistencies, but the inconsistencies could suggest problems with the claims payment system. Many of the overpayments to ineligible facilities showed a similar lack of pattern, which also could suggest problems with the claims payment system.

In 2011, CMS correctly paid the LVPA to 249 facilities for at least some of their treatments; these payments totaled an estimated $17.4 million. Fifty-five of these facilities received about $4.2 million in payments for all their treatments. CMS paid the remaining estimated $13.2 million to the 194 eligible facilities that received the LVPA for only some treatments.

Unclear and Late Guidance and Insufficient Monitoring Were Primary Contributors to Payment Problems

Although CMS provided opportunities for Medicare contractors and facilities to ask clarifying questions regarding its implementation of the requirements for LVPA eligibility,[28] the guidance for implementing these requirements was sometimes unclear and not always available when needed. For example, the majority of the facilities that incorrectly received the LVPA—54 of 83—were hospital-affiliated facilities that failed the volume threshold. Eventually, CMS specified that Medicare contractors should combine the treatments of a hospital's affiliated dialysis facilities in determining whether the LVPA requirement for fewer than 4,000 treatments had been met. While this method of applying the regulatory requirement is logical because hospital-affiliated facilities do not file individual cost reports,[29] CMS did not issue explicit guidance on this topic until July 2012.[30]

CMS guidance to Medicare contractors for determining whether a facility had met the LVPA requirement of not having opened, closed, or changed ownership during the 3 years preceding the payment year was neither clear nor timely. According to our interviews with CMS officials, the agency's intention was for contractors to verify that each of the facility's cost reports for the previous 3 years covered exactly 12 months; however the connection between the regulatory requirement and the duration of the cost-reporting periods has not been explicitly made in CMS guidance. (For example, an October 2010 internal technical direction letter stated that, in order to meet the LVPA eligibility verification requirements, Medicare contractors needed to confirm that fewer than 4,000 total treatments were provided for each of the 12-month cost-reporting periods—however, it was not clear which regulatory verification

[28]CMS officials told us that the agency provided several opportunities for Medicare contractors and facilities to ask about the ESRD payment changes implemented in 2011, but that the agency received very few questions on the LVPA. Opportunities to ask questions included a 2010 conference call with all the Medicare contractors, a 2010 town hall open to the public, and a frequently asked questions section on CMS's website.

[29]Hospital-affiliated facilities do not file individual cost reports, rather, their treatments are included in their parent hospital's cost report as part of the total treatments provided by all facilities affiliated with the hospital. According to CMS officials, cost reports are the only source of the total dialysis treatments provided by ESRD facilities.

[30]CMS, TDL-12419 (July 18, 2012). Previous guidance had specified that the volume criterion should be assessed using cost reports, and CMS officials told us they had believed that using the total number of treatments reported on a hospital's cost report as a method to assess the eligibility of hospital-affiliated facilities did not need specific clarification.

requirement(s) the sentence was implementing.[31]) CMS officials explained that three cost-reporting periods of exactly 12 months (which need to be consecutive) are a time frame that would exhibit business practice patterns that demonstrate a facility is consistently low-volume and that, because cost reports correspond with the facility's fiscal year, using them provides a snapshot of a facility's financial ability to incur costs for furnishing renal dialysis. Furthermore, CMS officials noted that having three cost-reporting periods of exactly 12 months each was a reasonable method of assessing the regulatory requirement because, generally, if a facility opened, closed, or had a change in ownership (in which case the facility may receive a new provider number), this would cause a break in the cost-reporting period and thus lead a facility to have one or more cost reports that spanned fewer than 12 months. In July 2011, CMS issued public guidance clarifying that the relevant periods during which a facility had not opened, closed, or had a change in ownership were the three cost-reporting periods before the payment year and not the 3 calendar years before the payment year.[32] While this likely helped clarify that the 12-month rule was sufficient for assessing that a facility had not opened, closed, or had a change in ownership, as of January 2013, no CMS guidance has been explicit on this topic, and no guidance has stated that each cost-reporting period must be exactly 12 months.

Unclear and late guidance for determining whether a facility had opened, closed, or changed ownership led to misunderstanding about which facilities were eligible, and at least some of the misunderstanding persisted as of September 2012. For example, when we questioned a representative of a large dialysis organization in September 2012 about some of the organization's facilities that we found to have not received the 2011 LVPA despite being eligible, the representative still believed those facilities were ineligible because they had a change in ownership during the previous 3 calendar years. In fact, these facilities were still eligible for the 2011 LVPA because the change in ownership occurred

[31]CMS, JSM/TDL-10444 (Oct. 8, 2010), pp. 2-4. Subsequent guidance only partially addressed this issue. For example, TDL-12419 in July 2012 stated that the cost-reporting years must report costs for 12 consecutive months and Medicare contractors shall not accept two short cost-reporting periods and add them together to create a 12-consecutive-month cost report. In addition, this guidance was provided more than 17 months after the beginning of the 2011 payment year.

[32]76 Fed. Reg. 40,506.

after the end of the facilities' 2010 cost-reporting period and they therefore had 2008, 2009, and 2010 cost reports that each covered exactly 12 months. In addition, when we questioned the representative about some of the organization's facilities that we found to have incorrectly received the 2011 LVPA, the representative still believed those facilities met all the regulatory requirements and therefore had been eligible. However, because these facilities opened in December 2007 and complied with CMS's general requirement that cost reports not span less than a month, they had a 2008 cost report that spanned slightly more than 12 months. This made these facilities ineligible for the 2011 LVPA. When we shared this example with CMS, a CMS official stated that the agency had not considered the possibility that a facility could have a cost report spanning more than 12 months. Additionally, when we questioned a representative from a different large dialysis organization in September 2012 about some of that organization's facilities that we found to have incorrectly received the 2011 LVPA, the representative still believed that those facilities had been eligible because the changes in ownership for those facilities did not result in new provider numbers. However, these facilities were ineligible because the changes in ownership caused a break in the cost-reporting period and thus the facilities had at least one cost report that spanned fewer than 12 months.

While CMS has continued to issue clarifying guidance and provide Medicare contractors and facilities with opportunities to ask clarifying questions, evidence shows that CMS's guidance for determining LVPA eligibility was not fully and correctly implemented. In particular, none of the estimated $5.3 million in 2011 overpayments had been recouped by June 2012, based on an analysis of claims, and CMS was not aware of any overpayments that had been recouped by January 2013. This suggests that many Medicare contractors either had not yet discovered the payments made in error or were not aware of their obligation to reassess facilities' eligibility once the cost report for the previous year became available and to recoup overpayments within 6 months of discovery. Another possible reason for overpayment or nonpayment of the LVPA is that some of the guidance was sent only to Medicare contractors and was not publicly available. Medicare contractors are responsible for ensuring that facilities receive any required information based on this guidance, and that function is particularly important for the LVPA because in order to receive the LVPA a facility must first attest to its eligibility, which it will do only if it believes it is eligible. We do not know the extent to which continued misunderstanding of LVPA eligibility stems from Medicare contractors' failure to share the relevant portions of this

nonpublic guidance or from facilities' not understanding the guidance that they received.

Much of the misunderstanding and resulting payment problems related to eligibility were exacerbated by CMS's limited monitoring of the Medicare contractors and its consequent limited knowledge about implementation of the LVPA. While CMS requested information about the 2011 LVPA from Medicare contractors in October 2011 and again in July 2012, as of January 2013, it had not yet verified whether the information it received was complete or in a usable form. In particular, CMS still did not know which facilities were eligible for the 2011 LVPA, which facilities had attested to being eligible for the adjustment, nor which facilities received the 2011 LVPA.

Conclusions

CMS intended the LVPA to encourage small ESRD facilities to continue operating in areas where beneficiary access might be jeopardized if such facilities closed. However, as designed, the LVPA does not effectively achieve this goal because it does not target all relatively low-volume, high-cost facilities that are in areas where beneficiaries may lack other dialysis care options, and it targets some facilities that appeared unnecessary for ensuring access to dialysis, such as dialysis facilities located in close proximity to other facilities. In addition, facilities currently face a large loss in potential revenue if they reach the LVPA treatment threshold. This creates an adverse incentive for facilities to restrict their service provision to avoid reaching the treatment threshold.

In addition to these concerns about more appropriately targeting the LVPA, we also found significant issues associated with its implementation, including frequent LVPA overpayments. These overpayments primarily stemmed from unclear and untimely CMS guidance and persisted because of CMS's insufficient monitoring of Medicare contractors. Without clear, timely guidance and stronger monitoring of Medicare contractors' implementation of the guidance, Medicare may continue to pay facilities that are not eligible for the LVPA and to not pay many facilities that are eligible. Although the amount of money involved was small—overpayments and nonpayments totaling about $12 million in 2011 for the $10.1 billion ESRD program—payment problems with the adjustment undermined its purpose, which is to encourage small ESRD facilities to continue operating in areas where beneficiary access might be jeopardized without them.

Recommendations for Executive Action

To more effectively target facilities necessary for ensuring access to care, we recommend that the Administrator of CMS consider restricting the LVPA to low-volume facilities that are isolated.

To reduce the incentive for facilities to restrict their service provision to avoid reaching the LVPA treatment threshold, we recommend that the Administrator of CMS consider revisions such as changing the LVPA to a tiered adjustment.

To ensure that future LVPA payments are made only to eligible facilities and to rectify past overpayments, we recommend that the Administrator of CMS take the following four actions:

- require Medicare contractors to promptly recoup 2011 LVPA payments that were made in error;
- investigate any errors that contributed to eligible facilities not consistently receiving the 2011 LVPA and ensure that such errors are corrected;
- take steps to ensure that CMS regulations and guidance regarding the LVPA are clear, timely, and effectively disseminated to both dialysis facilities and Medicare contractors; and
- improve the timeliness and efficacy of CMS's monitoring regarding the extent to which Medicare contractors are determining LVPA eligibility correctly and promptly redetermining eligibility when all necessary data become available.

Agency and Industry Comments and Our Evaluation

We received written comments on a draft of this report from HHS, which are reprinted in appendix I. HHS agreed with our recommendations and stated it would explore refinements to the design of the LVPA and take actions to improve its implementation. HHS also provided technical comments, which we incorporated as appropriate.

With regard to our recommendation that CMS consider restricting the LVPA to low-volume facilities that are isolated, HHS stated that CMS will explore potential refinements. HHS stated that other factors, in addition to geographic isolation, may contribute to an ESRD facility being low-volume and that the department had studied the costs of both rural and nonrural facilities and decided not to implement an adjustment on the basis of rural location. We did not analyze all the reasons facilities were low-volume,

nor did we recommend a payment adjustment for rural facilities. However, we believe that providing increased payments to facilities in close proximity to one another may not be warranted. We also note that, while facilities certified on or after January 1, 2011, that apply for the LVPA must combine all of the treatments provided by facilities under common ownership within 25 miles to determine eligibility, this restriction does not ensure that only isolated facilities receive the LVPA. For example, two facilities not under common ownership could be located in close proximity and still receive the LVPA.

In response to our recommendation to consider revisions such as changing the LVPA to a tiered adjustment, HHS stated that it would explore whether refinements to the LVPA are necessary. HHS stated that the incentive for facilities to limit dialysis services would exist regardless of where the decrease in payment occurred. We agree that such a change would not eliminate the incentive to limit dialysis services, but we believe it would reduce the incentive.

HHS concurred with our recommendation about ensuring proper payments and rectifying past overpayments. HHS also listed specific actions it plans to take to implement the recommendation, including using multiple methods to communicate with Medicare contractors and ESRD facilities to deliver clear and timely guidance.

We invited two organizations to provide oral comments on our draft report: the Kidney Care Council (KCC), which represents dialysis facility companies, and the National Renal Administrators Association (NRAA), which represents independent dialysis facilities. Representatives from these organizations expressed their appreciation for the opportunity to review the draft.

Both KCC and NRAA noted that facilities within close proximity to another facility may still be necessary for ensuring access to dialysis care (for example, if the other facility is operating at capacity) or access to choice of dialysis modality (for example, if the other facility does not offer the same dialysis options). While these situations may occur, if CMS determines a single larger facility could provide appropriate services where two or more smaller facilities exist now, paying the LVPA to the existing smaller facilities may not be warranted.

NRAA agreed with our finding that CMS guidance on LVPA eligibility was unclear and not transparent to facilities. Additionally, NRAA noted that CMS's guidance requiring that hospitals—but not large dialysis organizations—sum the treatments across all of their affiliated facilities when determining eligibility for the LVPA was inconsistent. We agree there is some inconsistency; however, it will be somewhat reduced starting in 2014 as CMS requires that facilities certified after January 1, 2011, sum their treatments across all facilities that are under common ownership and within 25 miles. NRAA also disagreed with the statement that hospital cost reports are the only source of information on total treatments provided by hospital-affiliated facilities. As we note in the report, CMS officials told us that cost reports are the only source of total treatments.

Both KCC and NRAA requested more details on GAO's recommendations related to improving the design of the LVPA. Our recommendations—that CMS should (1) more effectively target facilities necessary for ensuring access to care by considering restricting the LVPA to low-volume facilities that are isolated and (2) reduce the incentive for facilities to restrict their service provision by considering revisions such as changing the LVPA to a tiered adjustment—outlined the factors CMS should consider in improving the LVPA. We did not specify details of the design because we believe CMS should have flexibility in how to more effectively target facilities necessary for ensuring access to care and reduce their incentive to restrict service provision.

KCC urged GAO to recommend that CMS pay out LVPA payments that CMS failed to make. We believe facilities are best positioned to determine and pursue their own rights to appeal Medicare claims determinations.

Technical comments from KCC and NRAA were incorporated in the draft as appropriate.

We are sending copies of this report to the Secretary of Health and Human Services. The report will also be available at no charge on our website at http://www.gao.gov.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or cosgrovej@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report.

James C. Cosgrove
Director, Health Care

List of Committees

The Honorable Max Baucus
Chairman
The Honorable Orrin G. Hatch
Ranking Member
Committee on Finance
United States Senate

The Honorable Fred Upton
Chairman
The Honorable Henry A. Waxman
Ranking Member
Committee on Energy and Commerce
House of Representatives

The Honorable Dave Camp
Chairman
The Honorable Sander Levin
Ranking Member
Committee on Ways and Means
House of Representatives

Appendix I: Comments from the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

FEB 21 2013

James Cosgrove
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Mr. Cosgrove:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "END-STAGE RENAL DISEASE: CMS Should Improve Design and Strengthen Monitoring of Low-Volume Adjustment" (GAO-13-287).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Jim R. Esquea
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "END STAGE RENAL DISEASE: CMS SHOULD IMPROVE DESIGN AND STRENGTHEN MONITORING OF LOW-VOLUME ADJUSTMENT" (GAO-13-287)

The Department appreciates the opportunity to review and comment on this draft report.

GAO Recommendation

To more effectively target facilities necessary for ensuring access to care, we recommend that the Administrator of CMS restrict the Low Volume Payment Adjustment (LVPA) to low-volume facilities that are isolated.

HHS Response

HHS concurs with the need to ensure that the LVPA is targeted effectively at low-volume, high cost facilities that are in areas where beneficiaries may lack other dialysis care options. However, we do believe that there may be other factors, in addition to geographic isolation, that may contribute to an end stage renal disease (ESRD) facility being low-volume and CMS will explore whether or not refinements to the methodology are appropriate.

During the development of the LVPA methodology, we did analyze if ESRD facilities located in rural areas experienced a higher cost in furnishing renal dialysis services when compared to non-rural ESRD facilities. In the calendar year (CY) 2011 ESRD Prospective Payment System (PPS) final rule (75 Fed. Reg. 49030, 49125-49126 (Aug. 12, 2010)), HHS explained that our analysis indicated that rural facilities as a group were projected to receive less of a reduction than urban facilities. Therefore, we did not implement a facility-level adjustment based on rural location. The results of the implementation of the LVPA have suggested that low-volume facilities are more likely to be located in rural areas.

GAO Recommendation

To reduce the incentive for facilities to restrict their service provision to avoid reaching the LVPA treatment threshold, we recommend that the Administrator of CMS consider revisions such as changing the LVPA to a tiered adjustment.

HHS Response

HHS concurs with the need to ensure that the LVPA is targeted effectively at low-volume, high cost facilities that are in areas where beneficiaries may lack other dialysis care options. HHS would like to note that during the development of the LVPA methodology, we considered a gradual "phase out" of the adjustment so that there were no size thresholds that would lead to a sharp decrease in payment. However, HHS believes that an incentive for facilities to limit renal dialysis services would still exist regardless of where the decrease in payment occurred. HHS provided the findings of our analyses in the CY 2011 ESRD PPS proposed rule with a specific discussion about treatment thresholds at (74 Fed. Reg. 49922, 49973-49974 (Sept. 29, 2009)). However, given the concerns raised by this review, HHS will explore whether or not refinements to the methodology are appropriate.

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GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "END STAGE RENAL DISEASE: CMS SHOULD IMPROVE DESIGN AND STRENGTHEN MONITORING OF LOW-VOLUME ADJUSTMENT" (GAO-13-287)

GAO Recommendation

To ensure that future LVPA payments are made only to eligible facilities and to rectify past overpayments, we recommend that the Administrator of CMS take the following four actions:

- require Medicare contractors to promptly recoup 2011 LVPA payments that were made in error;
- investigate any errors that contributed to eligible facilities not consistently receiving the 2011 LVPA and ensure that such errors are corrected;
- take steps to ensure that CMS regulations and guidance regarding the LVPA are clear, timely, and effectively disseminated to both dialysis facilities and Medicare contractors; and
- improve the timeliness and efficacy of CMS's monitoring regarding the extent to which Medicare contractors are determining LVPA eligibility correctly and promptly re-determining eligibility when all necessary data become available.

HHS Response

HHS concurs with this recommendation and will take action to ensure appropriate payment in the following ways:

- We will evaluate our policy guidance and contractor instructions to ensure appropriate application of the LVPA.
- We will use multiple methods of communication to Medicare administrative contractors (MACs) and ESRD facilities to deliver clear and timely guidance of the LVPA.
- We will better monitor Medicare administrative contractors and consider measures that can provide specific expectations.

In addition, we issued Technical Direction Letter-12419, entitled, "The Low-Volume Payment Adjustment Under the End-Stage Renal Disease Prospective Payment System" on July 18, 2012, which instructed Medicare Administrative Contractors (MACs) to reconcile any errors made in payment in CY 2011 and CY 2012.

Appendix II: GAO Contact and Staff Acknowledgments

GAO Contact

James Cosgrove, (202) 512-7114 or cosgrovej@gao.gov

Staff Acknowledgments

In addition to the individual named above, Phyllis Thorburn, Assistant Director; Todd D. Anderson; Alison Binkowski; William Black; George Bogart; Elizabeth T. Morrison; Brian O'Donnell; and Jennifer Whitworth made key contributions to this report.