Kidney failure?

Dialysis is the only medical service without automatic inflation updates from Medicare. Some people are trying to change that.

Three days a week, 55-year-old Shirley Nealy waits for a van to transport her to the Lincoln Park Dialysis clinic in Chicago, where she spends four hours each visit receiving treatments for end-stage renal disease. A former respiratory therapist, Nealy has followed this routine since June 2005, when she learned in an emergency room that her kidneys were failing.

Nealy has spent much of her time at the clinic—owned by the dialysis provider DaVita—learning about what led to her diagnosis, how other patients are affected, and what actions can be taken to ensure that patients living with this debilitating disease receive the proper care and treatment.

“My whole life has changed,” Nealy said. “I didn’t know that if I didn’t control my hypertension, it would come to this. I want doctors to tell patients the possibilities.”

In addition to educating patients about the disease, Nealy also is working hard to bring about change at the highest levels of the industry. She is one of many doing her part to ensure a more reliable and regular inflation increase in renal-care providers’ Medicare reimbursement, known as an automatic update. Currently, they must lobby Congress each year for an increase.

Advocates for a change in this direction said the lack of an annual update in the composite rate of services for dialysis providers is the renal-care industry’s greatest problem.

At stake is the well-being of millions of patients and billions of dollars for providers. About 20 million Americans, or one in nine U.S. adults, suffer from chronic kidney disease, according to the National Kidney Foundation. Conditions such as diabetes, heart disease and hypertension often lead to chronic kidney failure, and the foundation reports that blacks, Hispanics, American Indians and seniors are at increased risk. And the problem is worsening: The number of new patients with kidney failure has grown from about 51,000 in 1990 to more than 104,000 in 2004.

The National Institutes of Health reports that it currently spends $425 million per year on kidney disease research, and that expenditures for care of the 450,000 patients with end-stage renal disease represent about 6% of Medicare spending. A U.S. Renal Data System’s annual report said the Medicare program spent about $20 billion annually on care in 2004 for patients with end-stage kidney disease.

The two biggest providers—Fresenius Medical Care, headquartered in Bad
Homburg, Germany; and DaVita, based in El Segundo, Calif.—last week reported strong earnings growth from renal care or renal-care-related device sales. Together they account for about 65% of dialysis services nationwide, according to LeAnne Zumwalt, a vice president with DaVita and treasurer of Kidney Care Partners, a coalition group of providers, manufacturers, physicians and nurses. But strong profits do not erase the need for an automatic update in reimbursement, according to Robert Provenzano, president of the Renal Physicians Association and chief of the division of nephrology, hypertension and transplantation at 607-bed St. John Hospital and Medical Center in Detroit.

“Why would a publicly traded company have to justify their profit margin?” Provenzano asked rhetorically. “Whether it is HealthSouth, GM or anybody else, these companies’ profits are predicated on their ability to stay competitive. The government shouldn’t hold any special right (of) what their profit margins should be. They have set the standard with hospitals and every other payer except for dialysis.”

Automatic update
Others in the industry voiced support for an automatic update. “It is true that it is a historic anomaly that reimbursement for dialysis services is not adjusted for inflation on an annual basis with a market update the way other services that CMS pays for is,” said Jonathan Himmelfarb, director of the division of nephrology and transplantation at 557-bed Maine Medical Center in Portland. “I think it is a very legitimate concern in the dialysis industry.”

As a comparison, the U.S. Medical Care Services Consumer Price Index increased by 107% from 1990 to 2006, while the Medicare payment to dialysis providers increased by 6.8% during that period, according to Rob Foreman, president of the newly renamed Kidney Care Council (formerly the Renal Leadership Council), a coalition group of eight dialysis companies.

Lori Hartwell, founder and president of the patient advocacy group Renal Support Network, and a kidney patient for 38 years, said reimbursement is inadequate and affects patients directly. “I saw a lot of smaller providers going out of business, and, as a patient, I want there to be choice,” Hartwell said, adding that it will be difficult for the industry to provide advancements and technologies without an increase in the composite rate.

Provenzano has the same concern, and said underfunding could cause access issues for patients. But even more important, the ability to conduct research could be compromised, he said. “The question always becomes one of how do you focus on patient care when you’re underfunded?” Provenzano said. “My response would be that it’s an unknown.”

An increase in diabetes may be one of the drivers behind the growing need for dialysis. About 50% of diabetic patients have chronic kidney disease, which could lead to end-stage renal disease, or ESRD as it is commonly known, said Melvin Roseman, medical director and one of the founders of the Lincoln Park clinic. Dialysis removes waste, salt and extra water to prevent these substances from
building up in the body. The treatment also keeps a safe level of chemicals in the blood and helps to control blood pressure. There are two types of dialysis: hemodialysis and peritoneal. In hemodialysis, a physician makes an access point into a patient’s blood vessels, while peritoneal requires a catheter to be inserted in a patient’s abdomen.

The March Medicare Payment Advisory Commission report shows that Medicare covered 309,300 dialysis patients, nearly 93% of all such U.S. patients in 2004. The Medicare ESRD program is the only Medicare program that does not receive an annual automatic update from the CMS.

The reason why can be traced back decades. The late journalist Shana Alexander wrote about dialysis in a 1962 article, “They decide who lives, who dies,” for Life magazine. In it, Alexander described selection committees that determined which patients would be eligible for dialysis—at the time, a costly, elaborate and new procedure.

The Omnibus Budget Reconciliation Act of 1981 established a composite rate of services for dialysis providers, which was implemented two years later—the same year Medicare established the prospective payment system. By 1972, the Social Security Amendment established federally financed healthcare coverage for dialysis and renal transplantation, which became effective in July 1973. An automatic inflation update was not included, as it was for the PPS, because a composite payment rate was established for renal care before the prospective payment system was created.

"Because we were ahead of DRGs, our payment system doesn't have" automatic updates, said Kathleen Smith, vice president of government affairs for Fresenius.

Nealy’s advocacy efforts caught the attention of U.S. Sen. Barack Obama (D-Ill.) earlier this year when she sent a letter urging him to support the Kidney Care Quality and Improvement Act, a current bill. Obama aides visited the Lincoln Park clinic, and Obama pledged to support the bill, according to a spokesman for him. Along with an identical bill in the House, the Senate bill supports patient and public education programs about chronic kidney disease and self-management skills. The bill would also extend the Medicare Secondary Payer system to 33 months, meaning private insurers would have to assume renal-care coverage three months longer than the current system before Medicare takes over. But it is the composite rate that seems to be the most important part of the legislation.

The bill likely faces long odds in the last session of this Congress—set to begin later this month after the elections and to end in December. If the bill does not pass in the current Congress, industry leaders will continue to advocate its passage next year, Foreman said. Provenzano said he thinks the bill has less than a 50% chance of passing in the current Congress.

Foreman said uncertainty about reimbursement has taken its toll on providers. “In any field of healthcare, the technology is changing. There is a great deal of competition for doctors, quality and clinicians,” Foreman said. “We’re having a
hard time keeping people working at these clinics. We need some more predictability in our Medicare payment system. If Congress can pass the establishment of an automatic review by CMS, that would do so much to provide stability in the industry with respect to reimbursement from Medicare.”

Poor federal reimbursement rates offer some insight into recent consolidation in the industry, as rising healthcare costs make it increasingly difficult for smaller companies to stay viable without an automatic update for inflation.

Consolidation in this industry began in the mid-’90s and it is now “down to two behemoth players” and about six midsize companies, said Steve Everett, president and chief executive officer of the Dialysis Corporation of America, which trades shares on the Nasdaq system, opened a new facility in Calhoun, Ga., in August and now owns or manages 32 free-standing hemodialysis centers in seven states.

“I don’t know that it (consolidation) is significant as it relates to patients,” Everett said. “From a business perspective, it gives buying and contracting strength with managed-care providers, especially in large metropolitan areas. With the contracting side, specific to managed-care companies, that is critically important to our industry.”

The March report by MedPAC, which advises Congress on Medicare issues, confirms there is an increasing proportion of dialysis providers that are free-standing, bigger, for-profit and owned by publicly traded companies. “These trends in the profit status, size, type and consolidation of dialysis providers suggest that the dialysis industry is attractive to for-profit providers, and providing dialysis care in larger facilities leads to efficiencies and economies of scale,” according to the report.

In the past year, DaVita completed its $3.05 billion purchase of renal dialysis services company Gambro Healthcare, making it the second-largest dialysis provider in North America. It follows Fresenius Medical Care, which acquired Nashville-based Renal Care Group for $3.5 billion earlier this year.

Both companies reported strong results recently. Last week, DaVita reported a 72% increase in third-quarter net income to $94.9 million, compared with net income of $55.2 million in the year-ago period. Revenue rose 92% to $1.24 billion as the number of treatments increased. Fresenius, meanwhile, reported a 20% increase in third-quarter net income to $139 million from $115.9 million in the year-ago quarter. Net revenue rose 29% to $2.2 billion. In addition to providing dialysis treatments to more than 160,000 patients worldwide, Fresenius also provides dialysis products, such as hemodialysis machines, dialyzers and other disposable products, according to the company’s Web site.

The industry is advocating changes in areas other than reimbursement, such as pay-for-performance, also mentioned in the bill. Another part of the Kidney Care Quality and Improvement Act would require HHS to establish a demonstration project in which the department would provide financial incentives to kidney-care providers and renal-dialysis facilities that show improved quality of care.
This year, Kidney Care Partners formed the Kidney Care Quality Alliance to develop a pay-for-performance program that seeks to meet the needs of patients, federal policymakers and other members of the renal-care community. Alliance members include dialysis service providers such as Fresenius Medical Care North America, DaVita and Renal Care Group; manufacturers Abbott Laboratories, Baxter Healthcare Corp. and Amgen; and organizations such as the National Kidney Foundation, American Society of Nephrology, American Health Care Association and America’s Health Insurance Plans.

The project’s first phase, which a Kidney Care Partners spokeswoman said is nearly finished, seeks to develop a legislative and regulatory proposal for a set of clinical and quality-of-life measures to incorporate into a pay-for-performance program. Simply put, it creates a “starter set” of measures for quality. The second phase will develop what the alliance calls the “next generation” of clinical and quality-of-life measures. Members of the alliance have received ballots to vote on the measures for phase one by Nov. 6.

Barry Straube, a nephrologist and transplant physician who is chief medical officer and director of the office of clinical standards and quality at the CMS, serves as a liaison to the Kidney Care Quality Alliance. He said the alliance wanted to “be in alignment” with the other quality alliances in terms of its interaction with the CMS. Straube has recommended that the alliance submit its quality measures, once developed, to the National Quality Forum.

“I am especially interested in this area, and I think the Kidney Care Quality Alliance has done a very nice job in setting itself up in getting to this phase,” he said. “I have very high hopes in what they will be able to do in improving the quality of care of patients with kidney disease.”