

Consensus Statement

Medicare End Stage Renal Disease Program: Why We Must Have a Paradigm Shift in Health Care

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We need a paradigm shift in American health care, and this fact is no more evident than in the Medicare End Stage Renal Disease (ESRD) Program. A recent federal report estimated that medical-care-trust reserves will be depleted by 2019.¹ Despite per capita spending about double that of most developed nations, the United States ranks among the lowest in health access and outcomes.² Peter Orszag, director of the Congressional Budget Office, and Philip Ellis recently wrote, “The long-term fiscal balance of the United States will be determined primarily by the future rate of growth of health care costs.”³ They suggest a plan to limit patient and provider choice in the system by eliminating practice variations, creating one-size-fits-all protocols tied to physician reimbursement. Their cautionary words and solutions reflect a mindset that has gained currency among many policy makers and regulators. Their approaches to meeting looming fiscal challenges are finding expression in a wide body of policies and regulations. If fully implemented, these measures could move us closer to a system of health-care rationing and underpower our ability to innovate.

Orszag and Ellis, as well as many other policy makers who share their perspective, assume an almost static technological environment, with infrequent incremental innovations, placing greater emphasis on tighter fiscal constraints that specifically erect barriers to patient and provider choice. They fail to consider that a more productive solution to mounting health-care costs would be encouragement of more investment in human capital. We need to accelerate the introduction of newer therapies and technologies that are simpler to use, more effective, and less costly. The current debate about cost in the Medicare ESRD Program is an excellent example of this creeping willingness to emphasize cost containment and to subordinate patient access to appropriate therapy, ignoring the mounting evidence that old tech-

nologies cannot cope with the demands of the 21st and even the 22nd centuries.

Medicare has played a crucial role in leveling the playing field for the poor and members of racial and ethnic minority groups, ensuring that they have access to health care. The Medicare ESRD Program has been instrumental in providing quality health care for African Americans and other minority populations who have disproportionately high ESRD prevalence. This consensus statement traces the history of Medicare coverage of ESRD and explores current proposals in Congress to deploy an untested payment system that legislators previously disregarded because it would introduce unacceptable risks for beneficiaries.

Findings

Based on a comprehensive review of the literature and existing data, the Association of Minority Nephrologists and the National Minority Quality Forum submit the following findings to inform discussion of legislative proposals:

- Minority populations are disproportionately represented among ESRD patients. Any proposed macro-level change to the ESRD Program must be viewed through this lens to ensure that it does not reduce Medicare’s effectiveness in addressing health disparities.
- Legislation recently passed by the U.S. House of Representatives to reform the ESRD Program is extremely problematic in that it mandates a move to a new payment system without studying the implications of such a change.
- The House proposal is a nationwide, uncontrolled experiment on Medicare beneficiaries who have not consented to accept the risks.
- Previous Congresses, policy makers, and key stakeholders have understood the risks and have required a controlled demonstration project to ensure that Medicare beneficiaries would not be disadvantaged.

- There is a general failure to acknowledge that the Medicare ESRD Program is essentially built on a 1960s technology platform that is costly and ill equipped for the challenges of the 21st century.
- Congress should initiate a program to stimulate the market to make investments in renal therapies that are less expensive and more efficient.

Background

Forty-seven years ago, individuals who received a diagnosis of ESRD faced imminent death. Dialysis and renal transplantation were just emerging as experimental procedures and were available in only a handful of medical centers. Renal transplantation is the surgical procedure by which a healthy kidney is removed from one individual and implanted in an individual with ESRD; the transplanted kidney functions as the individual's own kidney. Demand for donor kidneys exceeds the supply, so dialysis is used to maintain ESRD patients while they await transplants and to maintain patients who are not candidates for transplantation. Dialysis is the process by which metabolic waste products normally cleared by the kidneys through the urinary tract are removed from the bloodstream by an artificial kidney. Both transplantation and dialysis are nonelective procedures for ESRD patients. If these patients do not receive one of these renal replacement therapies, they die.

In the 1960s, when modern dialysis was first developed, the treatments were beyond the financial means of most Americans. With minor exceptions, the federal government did not pay for ESRD care, and a diagnosis of ESRD was essentially a death sentence for many patients unable to pay for dialysis.

The barrier to direct federal support for renal replacement therapy was lifted on October 30, 1972, when President Richard Nixon signed Public Law 92–603, amending the Social Security Act. This legislation dramatically changed the landscape for the treatment of ESRD. It established Medicare coverage for both dialysis and transplantation and included inpatient care, outpatient care from physicians, and care in dialysis units. The implementation of this entitlement

to Medicare for most ESRD patients, regardless of age or disability status, has come to be known as Medicare's ESRD Program. This program is unique within Medicare in that it is the only one under which diagnosis of a disease provides the basis for an entitlement for a person, regardless of age. Medicare is currently the primary payer for 80% of patients with ESRD.⁴

The Medicare ESRD benefit has provided access to care that has extended the lives of ESRD patients, including many who are members of racial or ethnic minority groups. This remarkable success has been purchased at a rising price. Almost from the outset of the program, the continual increase in the population of ESRD patients has prompted efforts to contain the costs. In 1970, three years before the implementation of the ESRD Program, the number of reported dialysis patients was 2,874. By 1972, when the Social Security Act amendments were enacted, the number had climbed to 5,786.⁵ By 1982 the number was 60,000.⁶ Today there are more than 485,000 ESRD patients in the United States: approximately 341,000 are on dialysis, and approximately 144,000 are recipients of kidney transplants.⁷

The costs of the Medicare ESRD benefit have far exceeded projections. Back in 1972, during floor debates on the issue, the Senate considered various estimates of the potential costs of the benefit. The estimated range of \$90 million to \$110 million annually was judged “a minor cost to maintain human life.”⁸ The number of ESRD Program beneficiaries skyrocketed past expectations, as did the costs associated with treating them. In 1982, ESRD expenditures by Medicare approached \$2 billion annually.⁹ By 1991, the program was spending in excess of \$5 billion annually.¹⁰ Currently, Medicare spends about \$20 billion of the nearly \$35 billion spent on ESRD annually.¹¹ If current trends continue, the Medicare ESRD cost will rise to \$53.6 billion in 2020 to cover approximately 785,000 beneficiaries, among whom approximately 526,000 will be dialysis patients.¹²

Shifting its budget priorities and focusing on containing the costs of ESRD, the House of Representatives has included provisions in the

recently passed Children's Health and Medicare Protection Act of 2007 (HR 3162) that, among other things, legislate a dramatic shift in provider reimbursement with no demonstration that this new payment system will not compromise the lives of beneficiaries.¹³

Reimbursement System

Since 1983, Medicare has paid dialysis providers a composite rate: they receive a single payment for each dialysis treatment, generally up to a maximum of three treatments per beneficiary per week. The composite rate was designed to cover the costs of services associated with a single dialysis treatment, including nursing and other clinical services, social services, supplies, equipment, and certain laboratory tests and drugs. Some items that were not common in 1983 and some items whose use varies, including some injectable drugs and certain diagnostic tests, are not included in the composite rate and have separate reimbursements.

Dialysis providers must operate efficiently just to survive, because Congress did not authorize an automatic annual update to the ESRD composite rate and the composite rate has only been updated six times. This is an anomaly, because providers under all other Medicare prospective payment systems receive annual updates in the rates paid for their services. In fact, since 1973, total inflation-adjusted payments for dialysis services have decreased 73%.¹⁴ According to a report issued by the U.S. Department of Health and Human Services (HHS) in 2003, data from dialysis clinics show that during 2000, the overall Medicare margin was only 1.4%, including both the composite rate and separate drug payment.¹⁵ The report did acknowledge, as had other reports by the Medicare Payment Advisory Commission (MedPAC), that the composite-rate payments usually fell below the cost of providing dialysis and that dialysis clinics had to rely on reimbursement from separately billed drugs and laboratory tests to remain solvent. This imbalance in the payment structure may have raised concern that dialysis providers had an incentive to overutilize separately billed injectable drugs to compensate for the low payments received under the composite

rate. Although oversight bodies have found isolated instances of questionable drug administration, they have not found generalized overprescription. The dialysis-drug-reimbursement system was reformed after the HHS 2003 report was issued, and MedPAC notes that this shift "has resulted in Medicare's drug payment no longer being as profitable as it was before 2005."¹⁶

Having operated for so long under these financial constraints, dialysis providers have probably maximized efficiency and minimized costs. It is unlikely that bundling more costs will induce any further increase in efficiency without jeopardizing patients' health. Nevertheless, a drumbeat for a fully bundled composite rate that includes injectables has persisted, even though concerns were raised as early as 1990 that including injectables in the composite rate could create an incentive for providers to withhold or underutilize those products so as to increase profits.

Vitamin D Therapy

Consider the consequences that bundling could have for vitamin D receptor activator (VDRA) hormone therapy for ESRD beneficiaries. Healthy kidneys help maintain the proper level of calcium, phosphorous, and vitamin D in the blood. The loss of kidney function can often lead to dangerously low blood calcium and high levels of phosphorous for ESRD patients. To maintain the balance between phosphorous and calcium, the body releases parathyroid hormone to signal the bones to release calcium into the blood. Untreated, an imbalance between phosphorus and calcium can lead to severe bone loss. ESRD patients suffering from this condition are treated with a VDRA hormone, which regulates parathyroid hormone and enhances the body's ability to absorb and use calcium to reverse the process that causes bone breakdown.

From the early 1990s to the turn of the century, approximately 60% of dialysis patients were treated with injectable vitamin D. Use of oral forms of vitamin D, such as Zemplar and Hecctorol, has increased in recent years: In 2005, 52.2% of patients were treated with Zemplar and 23.8% received Hecctorol.¹⁷ Nearly 80% of dialysis patients received vitamin D in 2005, and some

investigators have suggested that its use may reduce mortality.¹⁸

Injectable forms of VDRA therapy administered to ESRD patients in dialysis units are reimbursed through the Medicare Part B ESRD system, whereas oral formulations are available through Medicare Part D. The bundled-payment system passed by the House of Representatives may, however, limit dialysis patients' access to infused therapy. As payment under the Part B ESRD bundle would be fixed, regardless of the therapy provided, the incentive for providers would be to treat patients with vitamin D deficiency with oral rather than infused therapy. Providers would still receive payment under the Part B ESRD bundle, while shifting the cost for the treatment to the Part D system. This is problematic, because there are extensive data on the effectiveness of infused VDRA agents on dialysis patients, but the same benefits have not yet been demonstrated for oral agents. To avoid this incentive structure, VDRA therapy would have to be made part of the redefined ESRD prospective payment system, with a specific quality measure for infused activated vitamin D that monitors VDRA average dose per patient. This measure would need to be calculated before enactment of a new composite rate and reviewed annually after enactment to ensure that cost shifting does not occur. This legislated safeguard would monitor access to VDRA therapy and avoid any unintended financial incentive for providers to reduce access to this life-saving therapy. In addition, any oral medication with an indication for ESRD patients should be included in any new composite-rate legislation to eliminate the financial incentive to shift patients away from the proven benefits of VDRA therapy to unproven therapies that would potentially remain in Medicare Part D.

Epoetin Alfa and Darbepoetin Alfa

There must be real and meaningful vigilance about access to VDRA therapy, but much of the debate regarding bundling is associated with epoetin alfa and darbepoetin alfa (for simplicity's sake, both are referred to as EPO herein). EPO is at the center of this debate because virtually all

ESRD beneficiaries require the drug and it constitutes a substantial portion of the separately billable items that are paid in addition to the composite rate.

When the U.S. Food and Drug Administration first approved EPO in 1989, it represented an important advance for the treatment of anemia (deficiency of red blood cells) associated with renal disease. Anemia afflicts virtually all dialysis patients. Before the introduction of EPO, the only anemia treatment for most ESRD patients was blood transfusion, which is risky and can interfere with a patient's ability to receive a transplant and anabolic steroids. Anemia is a major cause of morbidity among ESRD patients, particularly among those who undergo dialysis therapy. EPO alleviates patients' anemia and improves their quality of life.¹⁹

Following the introduction of EPO, hematocrit levels (a measure of red blood cells and anemia) have substantially improved, with more and more patients meeting the Centers for Medicare and Medicaid Services (CMS) clinical quality performance measure for hematocrit: above 33%. In 2005, 84% of patients achieved hematocrit levels above 33%, in contrast to only 17% in 1991.²⁰ However, concurrent with this improvement in outcomes, there has been a significant focus on the growth in spending on EPO and on incentives for the drug's use.

Given these concerns, Medicare has had numerous policies for payment for EPO, with the aim of balancing the goals of cost containment with high-quality care. The Erythropoietin Monitoring Policy was implemented in 2006 and replaced predecessor policies. Under this policy, dialysis providers are penalized for maintaining patients at high hematocrit levels. Specifically, if a provider fails to reduce a patient's EPO dosage in response to a hematocrit over 39%, the provider is subject to a 25% payment reduction. Additionally, if a patient's hematocrit remains above 39% for three consecutive months, the provider faces a 50% payment penalty. Lastly, providers are not reimbursed for high doses: above 400,000 units per month for epoetin alfa and 1,200 micrograms per month for darbepoetin alfa.

In addition to CMS, other government agencies keep a close watch on Medicare payment for EPO and EPO utilization. For example, the Office of Inspector General for Health and Human Services (OIG) regularly audits dialysis facilities with regard to EPO use and EPO Medicare billing. Notably, although the occasional dialysis facility has been singled out for improper use or billing of EPO or other injectables, no oversight body has found a generalized practice among providers of using EPO or other injectables medically unnecessarily. It is unclear what benefits, if any, could be gained by bundling the payment for EPO with the composite rate.

Bundling Too Much, Too Tight

As early as 1990, concerns were raised that bundling injectables, and specifically EPO, in the composite rate could create incentives for providers to withhold or underutilize those products so as to increase profits. In May 1990, the Office of Technology Assessment (OTA) issued a report that reviewed the various payment options for EPO, including the bundling of injectables in the composite reimbursement rate.²¹ Its findings are instructive, because they set out the clear limitations of bundling—limitations that subsequent studies have confirmed. OTA found that bundling EPO into the composite rate would eliminate financial incentives to treat more cases or to provide larger doses of this biologic than are clinically appropriate, but it might limit medically appropriate access. Under a bundled payment, providers might have a strong financial incentive to deny EPO to some patients for whom it would be clinically appropriate or to administer doses of EPO that are below clinically appropriate levels in order to increase net revenues or reduce losses. OTA found that besides raising the risks to patients with regard to medically necessary access to the drug, bundled payment could disadvantage providers. The adequacy of compensation would vary with doses provided to patients and the mix of patients at the dialysis center. Inequitable compensation could also result if providers, because of different markets, incur different acquisition costs for EPO, labor, or other inputs.

OIG identified similar concerns in a September 1990 report, based on how EPO was being used under the case-rate reimbursement that was in effect at the time.²² Initially, the Medicare payment policy for EPO under the case rate was \$40 per treatment for doses below 10,000 units and \$70 for doses of 10,000 units and above. OIG found that EPO doses under this payment system were about half of what Medicare had anticipated. Patients also had concomitantly low hematocrit levels relative to the hematocrits achieved in the EPO clinical trials. The OIG report recommended eliminating the case rate, and Congress subsequently modified the EPO-payment policy away from a case rate to a fee per each 1,000 units administered.

After Congress eliminated the case rate and set reimbursement for EPO based on the units administered, policy makers and Congress continued to explore how the composite rate might be updated to bundle items that the ESRD Program was reimbursing separately. Generally, these studies reinforced the basic points made in the OTA report.²³ Nevertheless, concerns about growth in spending for ESRD have resulted in continued discussion of bundling as a possible solution.

Since 2001, a number of policy makers have come out in support of a broader payment bundle in ESRD, despite the acknowledged potential for undertreatment, cherry-picking patients, and inadequate payment leading to facility closure or other access issues. MedPAC and the U.S. Government Accountability Office support a broader payment bundle, and as early as 2003 CMS issued a report suggesting that a broader payment bundle would be feasible.

Ultimately, the policy debate on a broader payment bundle for ESRD led Congress to require under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) that CMS develop a demonstration program to test a fully bundled payment system. Specifically, the MMA required CMS to consider how a fully bundled payment system could be developed, submit a report to Congress outlining this analysis in 2005, and launch a three-year demonstration project in 2006 to test the payment sys-

tem to make sure that the changes would not put at risk beneficiaries' safety, quality of care, or access to services.²⁴

CMS has yet to meet the ESRD bundling requirements in the MMA and has neither submitted its report on a fully bundled ESRD payment system to Congress nor initiated the ESRD bundling demonstration project. A key challenge facing CMS is to design an accurate and adequate bundled-payment system. For example, a CMS 2005 analysis shows that under the bundled-payment system that the agency had developed and was considering for the ESRD bundling demonstration, 44% of facilities would experience payment gains or losses of 10% or more.²⁵ Payment variations with such significant ranges could be extremely disruptive to the delivery of ESRD services and could make it difficult for facilities to stay in business, possibly forcing them to operate at a loss, given that many small dialysis facilities operate on razor-thin margins. In addition, if the payment under bundling is inadequate, facilities might undertreat patients or cherry-pick patients for treatment. Each of the aforementioned potential implications of inadequate payments could seriously limit patients' access to and quality of care.

The inaction by CMS on the bundling report and demonstration, coupled with cost-containment concerns and shifting budget priorities, appears to have motivated some policy makers in Congress to support moving forward with untested bundling. The House Ways and Means Committee and its Subcommittee on Health, in particular, have been very active on this issue, holding hearings in December 2006 and June 2007, respectively. Despite CMS's own research demonstrating the complexities and difficulties associated with developing an adequate fully bundled payment system and despite CMS's inability, to date, to conduct the related demonstration project to test bundling, the agency testified in June 2007 before the House Ways and Means Subcommittee on Health that it could implement an untested fully bundled payment in ESRD, systemwide, within two to three years of the passage of authorizing legislation and that it

could monitor and analyze patients' and providers' experiences during implementation.²⁶

At the June 2007 hearing, CMS's acting administrator, Leslie Norwalk, noted that "CMS is generally supportive of such reform," but once again raised the same cautionary points that OTA raised in 1990 about incentives under bundling.²⁷ Testifying in December 2006, she had noted that a bundled-payment system "should guard against incentives to under-treat patients or to 'cherry-pick' patients in order to maximize facility profits. Accomplishing these goals will require (1) research to support the development of an adequate case mix adjustment for a fully bundled system, and (2) mechanisms to ensure beneficiary protections and promote quality care."²⁸

Others also testified at these hearings about the risks of increased bundling. For example, Congresswoman Donna Christen-Christensen, physician and member of the Congressional Black Caucus, testified before the House Ways and Means Committee, focusing on the disproportionate incidence of ESRD among minorities and emphasizing the need to be cautious and judicious when considering any changes to Medicare ESRD reimbursement. She was particularly concerned that bundling separately billable services into the composite rate as a cost-containment mechanism could have a disproportionate negative impact on minority patients, given their overrepresentation among ESRD patients. She also reminded committee members of the devastating effects that payment changes in ESRD had on patients in 1997, when CMS issued the original EPO-monitoring policy (Hematocrit Measurement Audit Program Memorandum), which limited the ability of physicians to treat anemia and resulted in poor outcomes until it was changed in 1998. She also highlighted the need for prevention of ESRD in the face of the growing incidence of the disease.

Despite the cautionary testimonies, the OTA 1990 report and other reports that raised concerns about bundling, and the inability of CMS to conduct a bundled-payment demonstration, the House passed HR 3162 on August 1, 2007, which requires a shift to an untested bundled-payment system, in concert with a 4% cut in ESRD

spending.²⁹ At present the Senate is considering these House proposals.

A Need for Innovation

The implementation of bundled payment without a test is tantamount to a nationwide uncontrolled human experiment. CMS must conduct a controlled demonstration of bundling to ensure that it does not compromise the health care and health status of vulnerable ESRD beneficiaries. We are disappointed that the House has passed legislation (HR 3162) requiring a shift to a fully bundled payment system for ESRD without requiring a demonstration project to study its impact on patients' access to and quality of care. In supporting implementation of a fully bundled payment system for ESRD under these conditions, the House and CMS appear to be focused on cost containment at the expense of patient well-being. We believe that such a major change in payment policy, without proper testing and research, will result in limitations on access to and quality of care for ESRD patients—a vulnerable population that comprises disproportionately large numbers of minority patients.

On average, African American patients require higher weekly dosages of EPO than white patients and other minority patients to maintain appropriate hemoglobin levels.³⁰ Any payment system, such as the proposed fully bundled payment system, that may lead to undertreatment with EPO will have a proportionally greater negative impact on patients who require larger doses of the drug, including, generally speaking, African Americans.

Instead of focusing on only short-term containment of ESRD costs, Congress, CMS, and other stakeholders must adopt a long-term perspective on effective ESRD treatment and prevention. Doing so would help to curb federal spending by eliminating unnecessary expenses and curtailing the growth of the population in need of dialysis and transplants. The specific issues that must be addressed are growth in the number of patients with kidney disease, growth in the number of kidney-disease patients who progressing to ESRD (stage IV of chronic kidney disease), and the disproportionate impact of ESRD on minority

populations. Congress, CMS, and other federal policy makers must develop and support policies that stimulate innovation to stem the growing tidal wave of patients with ESRD and improve the lives of patients already living with ESRD. Government is afforded a unique and crucial role in stimulating the market to address these needs. To protect the advances that we have made and the special benefits that the ESRD Program has provided the minority community, we need novel approaches to renal-replacement therapy and disease prevention that are effective and efficient. It is our recommendation that Congress play a more direct role to encourage investments and innovations that will more constructively reduce costs in the ESRD Program rather than continue blunt-force approaches, such as forcing a move to bundling without testing it first to understand the risks and benefits for patient care.

We recognize that the escalating costs of ESRD treatment must be reined in, but short-sighted expenditure limits would necessitate a retreat toward the treatment gap that patients faced before 1972. A significant consequence of the Medicare ESRD benefit is the growth of the ESRD-patient population. This growth is driven by both incidence (new cases) and prevalence (growing number of patients surviving with the disease), which together are contributing to a longevity revolution that fuels our modern-day conundrum: We have the capacity to keep people alive longer with impaired health, but we cannot cure them and the need for constant intervention is driving medical expenditures. This pattern is manifest in the ESRD benefit, which has led to the diffusion of a lifesaving therapy to those who were previously unable to access needed therapies. This remarkable success has come with a significant price tag, as the patient population and use of therapies grow. Financial realities have sparked discussions about how government might adjust payment policies to encourage efficiency while maintaining patients' access to quality care. The proposed restructuring to a fully bundled payment system would only have marginal financial benefit, if any, and if it is not done carefully and thoughtfully, it would jeopardize patients' quality of life and survival.

African Americans, especially those who live in rural regions, may be disproportionately harmed by the implementation of an untested fully bundled payment. If the untested fully bundled payment system fails to compensate dialysis organizations adequately, such organizations may be forced to consolidate to remain solvent, or they may go out of business altogether. Dialysis-facility closures are already affecting African Americans disproportionately with respect to access to care: According to MedPAC, when comparing characteristics of dialysis facilities that closed in 2004 with characteristics of facilities that opened in 2005, closed facilities were more likely to be less profitable as measured by the Medicare margin (-13.7% versus 3.9%) and to treat a greater proportion of African American patients (48% versus 29%).³¹ As stated above, on average, African Americans require higher doses of EPO than do other patients to treat anemia. If there are flaws in the untested Medicare payment system that would render facilities vulnerable to financial loss when treating patients who require high doses of EPO, they could exacerbate the troubling closing trend observed among dialysis facilities whose patient bases are largely African American. Moreover, if facility closures result, patients who live in rural regions will likely face an additional burden of traveling farther to receive renal care at other dialysis facilities.

To make real progress in grappling with ESRD, the government should encourage innovation and investment. The economically, politically, and medically sound approach to the growing burden of ESRD is to devote resources and energy to preventing ESRD and to finding more cost-efficient technologies and therapies to treat ESRD. Government has a crucial role in stimulating the market to address these needs. Government has promoted diffusion of and access to renal-replacement therapy, and it should now create an imperative to innovate.

Looking Forward

Some policy makers look into the future and postulate a static medical world in which health-care costs rise to the point that they undermine our economy. They pooh-pooh incremental tech-

nological advances as unwarranted costs that are fueling medical expenditures with little return on investment. They propose a system in which physicians' and patients' choices are constrained by artificial financial barriers. They have fundamentally lost faith in our ability to stimulate our economy to innovate and create medical technologies that are simpler to use, more effective, and less costly. This school of thought has seduced legislators into believing that cost-containment strategies are the proper answers to the challenges that we face in the 21st century. Their proposals must be vigorously debated. If they have sway, our health-care system will be powered by old technologies that lack the capacity to improve patient outcomes or to reduce costs, except in an artificially contrived world.

This consensus statement has focused on the Medicare ESRD Program and the remarkable achievements that it has made. We have seen how government policy has molded medical practice within the boundaries of 1960s technology to the benefit of many patients. The success has occasioned an unsustainable cost structure, prompting some to promote excursions down corridors that were previously marked as hazardous.

It is important that we understand and respond to present realities and trends, but we must not map a course that bypasses opportunities to reverse the continual growth in incidence and prevalence of ESRD or to ease the burdens on patients, providers, and payers. The government has the power and thus the responsibility to open doors to innovations in prevention and technology. If government were to search aggressively for solutions beyond existing therapies, what innovations might emerge?

The rise in the incidence and prevalence of ESRD is largely the result of innovations in treating other diseases, allowing patients to survive other life-threatening illnesses, but not without confronting kidney failure. The government is rightly concerned about the consequent growth in health-care costs from kidney-replacement therapy. If one rejects a policy of abandoning ESRD patients, the most obvious candidates for mitigating ESRD are primary and secondary (after the onset of kidney disease) prevention. Experience

with technological innovation tells us that there must also be room for improvement in dialysis and transplantation after the onset of ESRD.

As significant as ESRD's rising costs are for a developed country, such as the United States, they present an even greater challenge to less-developed countries, which are also experiencing the worldwide surge in ESRD. The United States has the capacity to conduct pioneering work in preventing and managing ESRD—a capacity that most other countries cannot approach. The benefits of innovations that mitigate or reverse current trends in ESRD would extend well beyond our borders, to people whose financial and medical resources are far more limited than ours.

For all these reasons, we need a paradigm shift in how we approach health care in the 21st century.

Notes

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² *OECD Health Data 2007: How Does the United States Compare*, (Organization for Economic Cooperation and Development, 2007), <http://www.oecd.org/dataoecd/46/2/38980580.pdf> (accessed December 9, 2007); Karen Davis et al., *Mirror, Mirror on the Wall: An International Update on the Comparative Performance of American Health Care* (The Commonwealth Fund, 2007), http://www.commonwealthfund.org/usr_doc/1027_Davis_mirror_mirror_international_update_final.pdf?section=4039 (accessed December 9, 2007).

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⁴ *Kidney Disease by the Numbers* (Congressional Kidney Caucus) <http://www.house.gov/mcdermott/kidneycaucus/numbers.html> (accessed December 3, 2007).

⁵ Richard A. Rettig, “The Policy Debate on Patient Care Financing for Victims of End-Stage Renal Disease,” *Law and Contemporary Problems* 40, no. 4 (1976): p. 200.

⁶ U.S. Renal Data System, “Prevalence and Cost of ESRD Therapy,” <http://www.usrds.org/download/1994/ch03.pdf> (accessed December 3, 2007), p. 26, chapter III in *USRDS 1994 Annual Data Report* (Bethesda, MD: National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, 1994).

⁷ U.S. Renal Data System, “Précis,” http://www.usrds.org/2007/pdf/00a_precis_07.pdf (accessed December 3, 2007), p. 20, in *USRDS 2007 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States* (Bethesda, MD: National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, 2007).

⁸ Rettig, “The Policy Debate,” pp. 224–225.

⁹ Drummond Rennie, R. A. Rettig, and A. J. Wing, “Limited Resources and the Treatment of End-Stage Renal Failure in Britain and the United States,” *Quarterly Journal of Medicine* 56, no. 1 (July 1985): 327, <http://qjmed.oxfordjournals.org/cgi/content/citation/56/1/321> (accessed December 5, 2007).

¹⁰ U.S. Renal Data System, “Précis,” http://www.usrds.org/2007/pdf/00a_precis_07.pdf (accessed December 3, 2007), p. 29, in *USRDS 2007 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States* (Bethesda, MD: National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, 2007).

¹¹ *Kidney Disease by the Numbers* (Congressional Kidney Caucus), <http://www.house.gov/mcdermott/kidneycaucus/numbers.html> (accessed December 3, 2007).

¹² U.S. Renal Data System, “ESRD Incidence and Prevalence,” http://www.usrds.org/2007/pdf/02_incid_prev_07.pdf (accessed December 3, 2007), p. 92, chapter 2 in *USRDS 2007 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States* (Bethesda, MD: National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, 2007).

¹³ Title VI, Subtitle C, “End Stage Renal Disease Program,” of the *Children’s Health and Medicare Protection Act of 2007* (HR 3162), section 637.

¹⁴ Matt Gitlin, Mahesh Krishnan, and Tracy J. Mayne, “Inflation-Adjusted Cost Trends in End Stage Renal Disease (ESRD) Patients Undergoing Dialysis: Medicare 1991–2004,” presented at Renal Week 2007, San Francisco, November 4, 2007, http://www.abstracts2view.com/asn/view.php?nu=ASN07L1_4645a (accessed December 3, 2007).

¹⁵ Tommy G. Thompson, “Report to Congress: Toward a Bundled Outpatient Medicare End Stage Renal Disease Prospective Payment System” (2003).

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