

End Stage Renal Disease and Kidney Transplantation in the Era of Healthcare Reform

Katie Gu

Over the course of the last half century, a significant array of legislative initiatives has been launched to reform America's healthcare system. Successful reforms, the most significant of which include Medicare's End Stage Renal Disease Program Amendments, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the Health Care and Education Reconciliation Act of 2010, and the Patient Protection and Affordable Care Act of 2010, have been taken to streamline coverage and delivery systems of health care programs. Collectively, these initiatives have helped improve access to kidney transplantation, alleviate costs of dialysis and medications, increase coverage for uninsured patients in the post-transplant stage, and introduce novel healthcare delivery systems for end stage renal disease patients. However, these reforms may also impose potential challenges for organ transplantation (by exacerbating the organ shortage crisis or placing significant financial pressure on transplant centers). The following paper analyzes both the advantages and setbacks of recent healthcare reforms in Medicare, Medicaid, and Accountable Care Organizations in the context of end stage renal disease.

Medicare Reforms

I. A history of payment policies and reforms in Medicare's dialysis program

Medicare was formally enacted in July 1965 under President Lyndon Johnson, as a national social insurance program for Americans aged 65 or older. Dialysis was developed in the 1960s, but because of its high costs, was unavailable to most kidney failure patients in need of the treatment. Thus, in 1972, Congress passed the End Stage Renal Disease (ESRD) Program into law, setting Medicare as the nation's primary provider and payer for dialysis treatment in patients with end-stage renal disease. The ESRD program expanded the original Medicare coverage to include all patients (regardless of age) diagnosed with chronic renal failure and insured under Social Security. ESRD

patients, who constitute about 0.5% of Medicare's beneficiary population, contribute to 5% of all Medicare expenditures (Nissenson and Rettig, 1999).

Due mostly to the discovery and increasing use of erythropoietin stimulating agents (ESA's), Medicare spending on dialysis treatment skyrocketed over the last twenty years (Swaminathan et al., 2012). According to Swaminathan et al., "by the beginning of 2005, erythropoietin stimulating agents had become the single largest drug expenditure within the entire Medicare program, with total annual expenditures on the drug for dialysis patients approaching \$2 billion." Healthy kidneys produce normal levels of the erythropoietin hormone, which prompt bone marrow to make red blood cells that carry oxygen throughout the body. However, individuals with kidney failure or chronic kidney disease will often have lower-than-normal levels of erythropoietin, which consequently lead to lowered red blood cell count and extremely elevated risks of developing anemia. ESA's, though effective at treating anemia in ESRD patients, have stretched Medicare spending to alarming heights.

End-Stage Renal Disease (ESRD) Medicare Beneficiaries And Program Expenditures, Millions Of Dollars, Fiscal Years 1974-1999

Fiscal year	Expenditures, Parts A and B	Number of beneficiaries, Part A only	Expenditures per person
1974	\$229	15,993	\$14,319
1975	361	22,674	15,921
1976	512	28,941	17,691
1977	641	35,889	17,861
1978	800	43,482	18,398
1979	1,010	52,636	19,188
1980	1,250	55,509	22,519
1981	1,472	61,930	23,769
1982	1,651	69,552	29,738
1983	1,994	78,642	25,355
1984	2,336	87,929	26,567
1985	2,824	97,200	29,053
1986	3,159	106,633	29,625
1987	3,475	116,937	29,717
1988	3,909	127,487	30,662
1989	4,601	139,132	33,069
1990	5,093	152,541	33,388
1991	5,654	164,354	34,401
1992	6,124	174,454	35,104
1993	6,662	184,257	36,156
1994	7,266	194,201	37,415
1995	7,960	204,310	38,960
1996	8,754	214,564	40,799
1997	9,617	224,926	42,756
1998	10,580	235,351	44,954
1999	11,657	245,806	47,424

SOURCE: Office of the Actuary, Health Care Financing Administration, Department of Health and Human Services, for fiscal years 1979-1999. Reprinted from 1994 Green Book, Committee on Ways and Means, U.S. House of Representatives.

(A.R. Nissenson and R.A. Rettig. Medicare's end-stage renal disease program: current status and future prospects. Health Affairs 18, no. 1 (1999): 161-179)

As the data table from Nissenson et al. indicates, Medicare expenditures increased at an annual rate of about 30.5% from 1974 to 1981. As a result of these costs, Medicare's end-stage renal disease program has undergone several payment policy reforms since its inception.

Initially, Medicare's ESRD program paid dialysis providers using the traditional fee-for-service cost-based reimbursement method (Nissenson and Rettig, 1999). This method paid providers for each provision of dialysis, billable medication, lab test and dialysis-related service, thus providing a powerful incentive to increase volume and intensity of dialysis services (Swaminathan et al., 2012). Medicare first attempted to lower dialysis treatment costs by controlling only the frequency of dialysis, limiting providers to no more than three dialysis sessions per week. However, this reform proved ineffective because it provided no clear monetary cap on reimbursement rates. The Omnibus Budget Reconciliation Act was then introduced in 1981, which added the idea of a composite rate: a fixed rate paid to providers for each dialysis session (\$131 per treatment in hospital facilities and \$127 per treatment in freestanding facilities), in addition to the previous frequency reform. For the first time, payments for home dialysis treatments, where the equipment, supplies, and support services are provided through a facility, would be made at the same rate as in-facility treatments (\$131 or \$127) (Laaser et al., 1990). Since home dialysis is less costly than in-facility treatments, the composite rates estimated lower-cost, higher profit home dialysis. However, contrary to predictions, the prevalence of home dialysis didn't increase substantially (Laaser et al., 1990). Further, these composite rates did not include separately injectable medications (ESA's, Vitamin D, Iron) or separately billable services (laboratory tests), which accounted for 40% of cost for outpatient dialysis services. Thus, Medicare's spending on dialysis continued to surpass projected costs.

Then, in 2003, the Medicare Prescription Drug, Improvement, and Modernization Act (MMA), called for a report by the Secretary of Health and Human Services on a bundled dialysis prospective payment system (PPS) for dialysis treatments. By 2006, sufficient evidence had accumulated on the potential for bundled payments to reduce Medicare dialysis spending.

Medicare launched the system of bundling dialysis payments with dialysis-associated diagnostic and treatment care in 2011 (Swaminathan et al., 2012). Bundled payments included costs of dialysis-related oral drugs, injectable medication, and laboratory tests (previously paid for separately) into a single composite rate for ESRD services. In 2015, Medicare paid a base rate of \$239.43 per treatment for up to three hemodialysis treatments per week, adjusting the base rate to account for certain factors that affect the cost of a treatment, including costs to stabilize patients and to provide training during the first 4 months of dialysis treatments. Whether this bundled payment system can ultimately help cap the increasing rates of dialysis costs, while also ensuring quality of care, remains to be determined. Centers for Medicare & Medicaid Services implemented its Quality Incentive Program in 2012, which can reduce Medicare payments for dialysis treatments to facilities by up to 2% based on the quality of care provided. Policy makers should continue to work with researchers, and renal provider and patient communities, to ensure that costs of dialysis, health care spending, and legislative regulations are all balanced with patient's quality of care.

II. End Stage Renal Disease Program Amendment of 1978

The ESRD Program Amendments of 1978 also included several provisions to encourage home dialysis and eliminate existing financial disincentives to transplantation. Home dialysis was not only shown to be more cost-efficient, but studies also suggested that patients performing home dialysis may have increased autonomy and health-related quality of life. Reacting to a decrease in the percent of patients dialyzing at home, the Amendments offered full coverage for home dialysis supplies and 100% reimbursement for home dialysis equipment (the Omnibus Budget Reconciliation Act mentioned previously replaced full coverage with composite rates in 1981) (Eggers, 2000). Further, the Amendments eliminated financial disadvantages to transplantation by providing for immediate Medicare entitlement, without the previous three-month waiting period, for patients choosing self-dialysis or transplants from living donors as their initial treatment modality. Further, while the original 1972 ESRD Program limited Medicare entitlement provisions to one year following a successful trans-

plant, these amendments extended Medicare coverage to three years post-transplant (Eggers, 2000). Cumulatively, the 1978 amendments provided for more complete coverage of home dialysis costs, increased coverage of kidney acquisition costs, and implemented incentive reimbursement rates that would assure the most cost-effective delivery of dialysis services.

III. Health Care and Education Reconciliation Act

The Health Care and Education Reconciliation Act, passed in 2010, has significant effects on kidney transplantation: it closed the Medicare Part D (Prescription Drug Coverage) “donut hole,” extended the ban on lifetime limits for insurance, (Title I, Section 2711), prevented rescission of coverage to existing health plans (Title I, Section 2712), and provided a 50% discount on brand-name drugs for Medicare patients beginning in 2011 (Subtitle D, Section 3301). The Medicare “donut hole” refers to a coverage gap—the period of consumer payment for prescription medication costs in-between the initial coverage limit and the catastrophic-coverage threshold. Over a quarter of Medicare Part D participants stop following prescribed drug regimens when they hit the donut hole, according to the U.S. Department of Health (Claffey, 2010). By 2020, the Reconciliation Act states that the federal government will provide up to a 75% discount on brand-name and generic drugs. By creating discounts on medication purchased within the gap range, the Health Care and Education Reconciliation Act has the potential to close the coverage gap until it is eventually eliminated. Kidney transplant patients would thus be able to better afford costs of medication and experience decreased rates of non-compliance due to increased drug affordability.

Medicaid Reforms

Medicaid, the second major health care coverage program in the United States, is a joint federal and state healthcare insurance program for American citizens of all ages with incomes up to 133% of the Federal Poverty Level. Unlike Medicare, Medicaid is financed by a combination of federal, state, and local funds, and is administered primarily by the states. Medicaid has been significantly impacted by the recent Patient Protection and Affordable Care Act reform, as well as by the introduction of an exciting new health care delivery system, Accountable Care Organizations.

I. Patient Protection and Affordable Care Act

The Patient Protection and Affordable Care Act, signed into law on March 23, 2010, introduced a series of changes to the organization and financing of the American healthcare system. By 2023, the Act is estimated to provide health insurance to 24 million previously uninsured Americans. About half of these individuals are projected to receive coverage through expansion of Medicaid, and the other half through new insurance exchanges and expanded employer-based coverage (Axelrod et al., 2010). Medicaid eligibility will be expanded to individuals under 65 years old with income below 133% of the federal poverty level (Axelrod et al., 2010). With the expansion of Medicaid eligibility, the number of patients with access to transplant care will likely increase. According to Axelrod et al.’s paper “US Health Care Reform and Transplantation,” patients with end-stage renal disease often experience difficulties in accessing private insurance coverage, resulting in suboptimal care for progressive end-stage renal failure, “delayed referral for nephrology and transplant care, [and ultimately] reduced access to transplantation and poor post-transplant outcomes (Axelrod et al., 2010). Axelrod et al. note that Medicare coverage for ESRD patients previously only became “effective at the time of kidney transplantation or after a defined period of dialysis for Medicare-eligible individuals under 65 years old. The expanded legislation through the Affordable Care Act (ACA) will offer coverage to patients prior to meeting those previous criteria” (Axelrod et al., 2010). Under this reform, insurers are also prohibited from establishing lifetime limits on coverage, rescinding coverage when recipients become ill, or setting preexisting condition exclusions. Thus, the ACA will improve access for ESRD patients to transplant services earlier in the course of their illness, leading to better care and more equitable transplantation access. Further, as lack of private health insurance has often been cited as a barrier to living donation, the ACA can also increase rates of living organ donation (Gibney et al., 2010).

It is important to note that these Medicaid reforms may also present potentially adverse effects on transplant waitlists. An increase in the number of insured patients with earlier access to transplantation could further exacerbate the nation’s alarming organ short-

age. While the Affordable Care Act may help increase living donations, it is likely that the expansion of insured patients in need of a transplant will exceed the increase of insured living organ donations. As a result, waiting-list mortality rates may increase. And, as Meier-Kriesche et al. have demonstrated in their paper "Effect of waiting time on renal transplant outcome," a longer time on dialysis is a significant risk factor for death-censored graft survival and patient death with functioning graft after renal transplantation" (Meier-Kriesche, 2000). Thus, the potential increase in waiting-list times associated with the Affordable Care Act's expansion of transplantation access may induce worsened post-transplant outcomes in patients subjected to longer dialysis sessions and extended waiting-list times. A significant pressure will also be placed on private insurance companies and transplant centers, who may experience significant revenue shortfalls as more Medicaid-only patients seek care and transplant services. According to Axelrod et al., current Medicaid reimbursement "is generally inadequate, often providing insufficient funding to even reimburse centers for the standard acquisition cost to obtain a deceased donor organ ... [thus,] transplant centers will be increasingly forced to accept patients who are guaranteed to result in significant financial losses" (Axelrod, 2010). Medicaid accountable care organizations are becoming increasingly prevalent in state Medicaid delivery systems, and may serve as a potential solution to this problem of inadequate federal reimbursement.

II. Affordable Care Organizations

Medicaid Accountable care organizations (ACOs) are voluntary groups of physicians, hospitals, and health care providers that create organized delivery systems for a defined patient population (Berwick, 2011). According to the Center for Health Strategies, ACOs "align provider and payer incentives to focus on value instead of volume, with the goal of keeping patients healthy and costs manageable." By fostering highly coordinated, data-driven, and evidence-based practices, ACOs are thus an effective means of controlling costs and improving patient outcomes. If an ACO succeeds in both delivering high-quality care and reducing the cost of that care below a baseline amount, it will receive a portion of the savings it achieves. The three key facets of ACOs that help to ensure account-

ability are a value-based payment structure, quality improvement metrics, and consistent data collection and analysis. As of March 2016, nine states have launched ACO programs and many have already shown promising results; Colorado's Regional Care Collaborative Organizations reported a net savings between \$29-33 million for Colorado Medicaid in its first three years, while Vermont reported \$14.6 million in savings due to its Medicaid ACO program in its first year. Thus, ACOs present an exciting new pathway towards financial sustainability and patient-centered, coordinated healthcare. For Medicare and Medicaid, the organizations may serve as a promising alternative to plans that place the burden of costs onto patients, providers, and private purchasers.

Although many believe ACOs will provide a promising future direction for renal healthcare delivery reform, concerns have been raised that ACOs surrounding patient privacy. With increased information exchange and more eyes on a patient's health chart, data security and patient privacy may be at increased risk for being compromised. Thus, it will be important for ACOs to ensure strict HIPAA protocols.

Conclusion

A history of payment reforms in Medicare's End Stage Renal Disease Program and the Affordable Care Act's expansion of Medicaid funding and eligibility have reduced dialysis costs and decreased barriers to kidney transplantation for ESRD patients. The two treatment options for ESRD individuals, dialysis and kidney transplant, are expensive and require continual legislative initiatives to balance quality of care with cost containment. Significant progress has been made in the health care delivery of ESRD treatment: the Medicare Prescription Drug, Improvement, and Modernization Act created an efficient, bundled payment system for dialysis treatments, the ESRD Program Amendments eliminated financial barriers to kidney transplantation, and the Health Care and Education Reconciliation Act increased affordability of renal disease medications. Rates of home dialysis, associated with equal levels of quality of care and higher levels of patient comfort than in-facility treatments, are finally beginning to rise, and Medicare reforms have saved a total of \$6.1 billion dollars for Americans on prescription drugs through Medicare

coverage. Though the 2010 Affordable Care Act has expanded healthcare coverage, eliminated limits and pre-existing conditions exclusions on insurance plans, increased transplant access, and encouraged living organ donations, the reform also has the potential to further exacerbate the nation's organ shortage crisis and may place an enormous financial burden on transplant centers and dialysis providers.

Novel healthcare delivery systems, including Accountable Care Organizations, have been developed to regulate the interplay between financial and regulatory changes, health care spending, and quality of care. Although the model is still evolving, Medicaid ACOs offer significant potential for positive change at the provider level to support a healthier population at lower cost, but must follow strict HIPAA protocols so that patient privacy is protected during the collection of ACO quality-assurance data metrics. Moving forward, it is crucial that funding and support are continually given to support ESRD research, and that policy makers communicate with leading researchers in the dialysis and kidney transplant industries, as well as renal patient and professional communities, in considering further health care reform.

The Trump administration and Congress are now

beginning to draft negotiations and legislations that are predicted to introduce substantial changes to the United States' health policy. If Trump follows through on his campaign to dismantle the Affordable Care Act, millions of ESRD patients will receive later access to care, rates of living organ donation will decrease, and insurers may again be allowed to set preexisting condition exclusions or establish lifetime limits on ESRD coverage. Propositions to change Medicaid in the form of block grants will dramatically decrease the ability of states to pay for low-income citizens' health insurance coverage. Previously, the federal government would match state spending in the program dollar-for-dollar, with additional money given to states with a larger number of low-income citizens. But with block grants, a single lump sum of money would be delivered to states, without adjustment for low-income populations. Thus, in addition to overall rollbacks in healthcare coverage, the new administrations' changes in healthcare policy may also create a socioeconomic disparity in treatment and provision of care. With respect to ESRD patients in particular, this decrease in coverage paired with decreased access to early-stage care has the potential to setback federal policy over the past half-century that has worked to improve ESRD patient outcomes.

References

Axelrod, D. A., Millman, D. and Abecassis, M. M. (2010). US Health Care Reform and Transplantation. Part I: Overview and Impact on Access and Reimbursement in the Private Sector. *American Journal of Transplantation*, 10(10), 2197–2202. doi: 10.1111/j.1600-6143.2010.03246.x

Axelrod, D. A., Millman, D. and Abecassis, M. M. (2010). US Health Care Reform and Transplantation, Part II: Impact on the Public Sector and Novel Health Care Delivery Systems. *American Journal of Transplantation*, 10(10), 2203–2207. doi: 10.1111/j.1600-6143.2010.03247.x

Berwick DM. (2011). Making good on ACOs' promise—the final rule for the Medicare shared savings program. *N Engl J Med*. 10(19), 1753–6. doi: 10.1056/NEJMp1111671

Claffey, Jason (2010). "Medicare 'Doughnut Hole' Checks in the Mail". *Foster's Daily Democrat*. Retrieved May 20, 2016.

Eggers, P. W. (2000). Medicare's End Stage Renal Disease Program. *Health Care Financing Review*, 22(1), 55–60.

Gibney, E. M., Doshi, M. D., Hartmann, E. L., Parikh, C. R., & Garg, A. X. (2010). Health Insurance Status of US Living Kidney Donors. *Clinical Journal of the American Society of Nephrology*. 5(5), 912–916. doi:10.2215/CJN.07121009

Meier-Kriesche H., Port F., Ojo A., Rudich S., Hanson J., Cibrik D., Leichtman A., Kaplan B. (2000). Effect of waiting time on renal transplant outcome. *Kidney International*. 58(3), 1311–17.

Nissenson AR, Rettig RA. (1999). "Medicare's end-stage renal disease program: current status and future prospects." *Health Aff (Millwood)*. 18(1), 161–79.

Swaminathan, Shailender. (2010) "Medicare's payment strategy for end-stage renal disease now embraces bundled payment and pay-for-performance to cut costs." *Health Affairs*. 31(9), 2051–2058.

U. Laaser, E. J. Roccella, J. B. Rosenfeld and H. Wenzel. (1990). Costs and Benefits in Health Care and Prevention. doi:10.1007/978-3-642-75781-5_12