

1972-2012: Forty Years of Federally-funded Dialysis

A “Renal Debilitation” Program That Is Failing Patients and Taxpayers

“In order to continually improve outcomes and technology that are important to patients and taxpayers, renal replacement therapy must be synonymous with long-term patient employment and re/habilitation.”

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ABSTRACT / SUMMARY

In 1972, Congress added a provision to Medicare¹ to pay for life-saving dialysis treatments for any U.S. citizen of any age who was suffering from kidney failure. Forty year later, dialysis has become a \$20 billion a year industry that will treat over 400,000 Americans this year. Over 5700 dialysis centers across the country now routinely offer treatments that have prolonged the lives of a small percentage of patients for decades.

Today, very few realize that kidney failure patients enter a government / corporate system of care that has become highly dysfunctional. Most patients endure a very low quality of life that would be unacceptable to the industry's medical professionals and corporate leaders. Despite having regulatory and medical professionals overseeing patient care, extensive medical databases, quality improvement programs built into the system, and corporate leaders that are highly regarded, this system of care has been failing patients and taxpayers — spectacularly:

- Unlike every other field of medicine, dialysis patients have seen little improvement in their mortality rates over the last 25 years.
- Standard dialysis care has become minimal, debilitating, and offers little psychosocial support to vulnerable and overwhelmed patients.
- Virtually no renal medical professional² or corporate officer involved in dialysis care today would accept the treatment modality that more than 90% of their patients receive
- Few advances in technology have been developed that improves patients' quality-of-life and allows them to lead normal lives.
- A far smaller percentage of patients dialyze at home today than in the 1960s.
- A far smaller percentage of working-age patients are employed today than in the early 1970s. It is estimated only 10% of working-age patients remain employed after three years on dialysis.
- Two dominating corporations, which care for over 70% of U.S. dialysis patients, have no programs for patient employment or rehabilitation. "Renal debilitation" has become the norm because of low expectations.
- Patients are increasingly viewed as short-term corporate revenue streams that only provide profits during their first three years on dialysis. The median survival time for U.S. dialysis patients is 36-38 months, not much longer than when the Medicare Secondary Payer period expires.
- Taxpayers pay for additional federal and state social services that must be provided due to the unnecessary debilitation of hundreds of thousands of U.S citizens.
- Almost no data has been collected on patient experiences, positive or negative, during the last 40 years.

¹ As stated clearly at §1881 (II) (2) (H) of the Social Security Act, "It is the intent of the Congress that the maximum practical number of patients who are medically, socially, and psychologically suitable candidates for home dialysis or transplantation should be so treated and that the maximum practical number of patients who are suitable candidates for vocational rehabilitation services be given access to such services and encouraged to return to gainful employment".

² Healthcare Research Consulting Group. *NxStage Report. July 28, 2009. p. 1-64*

- To deflect criticism, patients are routinely characterized as unmotivated, non-compliant, medically disabled, unemployable, and elderly.
- Patients seldom complain and those who do may find themselves dialyzing in hospital emergency departments on a non-routine basis which places their lives at much greater risk.

This system, best described as a medical-industrial complex, is made up of an intertwining web of entities and influences from the corporate, financial, government, medical, political, and academic worlds. Unfortunately, this system no longer serves patients' best interests and insufficient motivations exist for significant change to occur. Realizing the futility of trying to change this system from within, patient advocates and activists are now working with the media to educate the taxpaying public and Congress about the failures of this federally-funded program.

Despite decades of directionless and non-improving care, a common sense solution exists to greatly improve dialysis care. There is no better public example of excellence in dialysis care than an employed patient. Towards this end, the entire medical-industrial complex can be set on a corrective course with a simple, common-sense philosophy:

“In order to continually improve outcomes and technology that are important to patients and taxpayers, renal replacement therapy must be synonymous with long-term patient employment and re/habilitation.”

This basic philosophy of care will improve multiple quality-of-life outcomes for patients, drive the development of smaller and easier-to-use technology, promote home and self-care dialysis, greatly increase patient participation in the system, and change the financial incentives for corporations. Publicizing patient employment data would provide patients with a tremendous tool in identifying dialysis providers that provide the best overall dialysis care.

Considering the hundreds of billions of taxpayer dollars that will be spent on dialysis care this decade, we strongly urge Congress to hold hearings to correct this federal program's failures, problems, purpose, and direction. We believe Congress should insist on a coordinated, five-year effort from corporations, medical professionals, and government agencies to greatly increase patient employment. After forty years of ever-worsening missteps, this federal program must return to serving patients and taxpayers — and a truly patient-centered model of care.

BIGGEST PROBLEMS

- Dysfunctional government / corporate system of care with no effective sense of direction or purpose.
- The vast majority of patients endure a very low quality of life standard that is non-improving.
- Little or no patient feedback built into system of care.

- Little improvement in mortality in the last 25 years. By focusing on biochemical markers and statistics, nephrology is “stuck” and cannot adopt the therapies that physicians/professionals would choose for themselves.
- The original intent of our national taxpayer-funded dialysis program, to support working patients, has been forgotten and ignored. Employment rates among working-age patients are now lower than 40 years ago. Fastest growing segment of incoming dialysis patients are now working-age patients.
- Despite having tens of millions of dollars of databases on dialysis patients, patient-specific employment data is not tracked anywhere: USRDS, DOPPS, CMS, Forum of ESRD Networks, LDOs.
- US taxpayers now pay over \$20 billion a year for a major-organ replacement industry that has no holistic model of care, no well-patient model, no rehabilitation, few psychosocial services, and no incentives to keep patients working. This system of care also adds tens of thousands of people to welfare rolls yearly.
- "If the treatment of chronic uremia cannot fully rehabilitate the patient, the treatment is inadequate." – Dr. Belding Scribner, pioneer of dialysis therapy.
- Programs to sustain or increase patient employment and/or rehabilitation DO NOT EXIST.
- Few facilities offer shifts starting after 5 pm. The system of care is shaped to serve corporations’ needs and for the convenience and ease of nephrologists and dialysis staff, not working patients.
- Original social contract was not for taxpayers to pay for dialysis treatments AND disability payments.
- Depression is common and widespread. When patients self-report depression, they have a 48% higher risk of death. Disability and debilitation have been reported, but are not widely acknowledged in the renal community as causes of depression.
- Virtually no medical professionals or corporate officers would accept the treatment modality that 90% of their patients receive. In order to stay healthy, they know they must dialyze at home. Standard, in-center hemodialysis treatments do not provide enough therapy.
- Government funded ESRD Networks, which are supposed to direct quality improvement, are not effectively addressing the issues of employment, rehabilitation or quality-of-life (QOL) nationwide.
- Dialysis care is dominated by two corporations that have no professional expertise in patient employment and rehabilitation. Free market “choices” do not exist for most dialysis patients.
- Patients are easily intimidated and threatened. Due to lack of choice, patients must often dialyze in the same corporation’s facilities that they criticize.
- Little technological advancement has occurred in the last 20 years.
- Poor patient fluid management has led to cardiovascular disease, the leading cause of death in dialysis patients. The traditional hemodialysis schedule is a major source of problem (3-times a week with 2-day weekends off dialysis).

- Numerous financial disincentives exist that discourage long-term survival and patient well-being (MSP, Part A/B separation, “acute dialysis” contracts, medical director salaries, low utilization of home therapies and reliance on high-cost brick and mortar facilities)

AFTER 40 YEARS, HOW DIALYSIS CARE SHOULD BE (OR “TODAY’S GOALS”)

- Greatly improving mortality rates — like every other field of medicine
- Should offer survival outcomes similar to transplants for many patients —more frequent dialysis does
- Employment and re/habilitation seen as integral components of overall patient health and successful renal replacement therapy (or any major organ replacement therapy)
- Hundreds of thousands of employed patients on renal replacement therapy who remain working and paying taxes after their diagnosis. Many patients are integrated into the system of care and employed by large dialysis providers and renal organizations. Large dialysis provider corporations leading the movement for dialysis patient employment.
- A system that considers all societal costs of renal replacement. Incentivizes long-term patient employment and rehabilitation.
- High health-related quality of life for patients, near normal diets, highly individualized approaches to care, minimal dialysis recovery times. Patient choose optimal dialysis schedule to fit and maximize their lives. System of care shaped to meet the individualized needs of patients.
- New medical specialty (renal replacement therapy specialist or renal rehabilitation counselor) created that focuses on optimizing employment/rehabilitation with major organ replacement. This field has unique expertise in educating and motivating patients.
- Small, portable, convenient, easy-to-use dialysis machines are the norm. There is a wide diversity of equipment choices.
- Many people are able to combine hemodialysis with restorative sleep. Nocturnal hemodialysis is a widely used treatment modality.
- Dialysis schedules and technology effectively address patient fluid management (no 2-day weekend gap with every-other-day dialysis). Excellent left ventricle health and few hospitalizations for fluid overload/heart failure.
- Diversity of whole-patient and well-patient approaches to renal replacement therapy FOR ALL AGES.
- High quality patient feedback integrated into the formation of federal legislation, systems of care, and technology design. Government-funded Network 19 (not dependent on corporations) provides independent patient perspective.
- Far more home dialysis and self-care dialysis
- Minimal renal-related medication use

FOLLOW THE MONEY — HISTORY

(Reimbursement history: <http://www.atlanticdialysis.com/Downloads/1%20-%20Dr.%20J.G.%20Bhat.pdf>)

1960s

In 1962, Northwest Kidney Centers in Seattle founded. Throughout the decade, most patients were employed and many dialyzed at home.

1970s

In 1972, federal government begins reimbursement for dialysis treatments through Medicare. Hospitals and clinics submit bills for treatment expenses. Nephrologists receive fee, monthly capitated payment (MCP), for overseeing patients' care. Government initially estimates treatment costs at \$140.

For next 30 years, many large, medium, and small dialysis providers come into existence, most of which are for-profit. Many physicians also build and own their own dialysis facilities.

Gradually over the next four decades, all U.S. dialysis providers replace most RNs with technicians and increase patient/staff ratios.

1980s

Dialysis treatments: OBRA 81 established a Medicare cost savings mechanism called the Medicare Secondary Payer (MSP) period. Originally it was a 12-month period when Medicare coverage would be secondary to a patient or spouse's employer group insurance for any ESRD patient who qualified for Medicare due to ESRD only. Simply put, commercial insurance paid for the first 12-months of dialysis treatments for many patients.

In 1983, the prospective payment system (PPS – also sometimes called the “composite rate” or the “first bundle”) is instituted by Medicare to control costs. It sets a limit on reimbursement for treatment costs of \$128 (Medicare pays 80% of it), which is a bundled payment for treatment labor/supplies and routine labs, but excludes injectable EPO, iron, vitamin D, antibiotics and non-routine labs).

For next thirty years, Medicare reimbursement essentially stagnates and dialysis providers begin charging commercial insurance plans higher rates than Medicare during the 18-month MSP period to compensate.

In the 1980s and 1990s, the “dialysis adequacy” formula was developed and “quality” dialysis care usually meant reducing the amount of time patients spent connected to the dialysis machines. This approach was embraced by for-profit dialysis providers, as shortening dialysis treatment times reduced their operating costs. Providers were paid the same whether they provided a 2.5-hour treatment or a 6-hour treatment. This practice resulted in higher patient mortality and has been reversing in the last few years.

For next thirty years, physicians and small providers sell their dialysis facilities to large and medium-sized dialysis provider corporations at enormous profits. Some physicians and small dialysis corporations sell their operations at a price tag of \$40,000-\$75,000 or more per patient (per head).

EPO/Meds: In 1989, EPO (erythropoietin or later known as an “ESA”) introduced to treat anemia and reduce blood transfusions. EPO reimbursed at \$40/treatment for doses under 10,000 units and \$70/treatment for over 10,000 units.

1990s

Dialysis treatments: Stagnant Medicare reimbursement, but Medicare patients can be profitable with EPO/IV drug revenues. In 1990, OBRA 90 extended the Medicare Secondary Payer period to 18 months (and expanded those affected to patients dually entitled to Medicare due to age or disability as well as ESRD). In 1997, BBA 1997 extended the MSP period to 30 months. MSP-period patients are now routinely used to subsidize Medicare patients. Dialysis providers begin charging commercial insurers an even higher rate than previously charged to those payers, significantly higher than Medicare. Fresenius Medical Care becomes vertically integrated, owning facilities and manufacturing equipment and supplies. Large dialysis-providers begin use junk bonds to finance acquisitions.

EPO/Meds: In Dec. 1990, EPO reimbursed at \$11 per 1000 units, and then reduced to \$10 in 1994. EPO and separately billable drugs becomes profit centers and their use increases throughout decade.

2000s

Dialysis treatments: Stagnant Medicare reimbursement rates. MSP-period patients increasingly subsidize Medicare patients. Dialysis providers charge commercial insurers 2-10 times Medicare rate. Physician-owned and small dialysis providers increasingly unable to make significant profits and are purchased by medium and large-sized dialysis providers. Large providers now own private laboratories to capture more reimbursement.

EPO/Meds: Greater use of EPO and IV drugs in for-profit centers. In 2006, EPO use peaks in U.S. at mean of 7,507 units per treatment, as Medicare costs for EPO exceed \$2 billion. In 2006/2007, CHOIR, CREATE, and TREAT studies are published, which result in FDA Alerts. Some dialysis providers establish pharmacies and buy pharmaceutical companies.

Chronic kidney disease patients become highly sought after commodities as large dialysis organizations establish brief education programs to market their brand to them.

2010s

Dialysis treatments: Medicare reimbursement no longer profitable. All providers must rely on MSP-period patients, charging private insurance 5-20 times Medicare rate, to subsidize Medicare patients. In 2011, Medicare creates second “bundle” as EPO, IV iron and vitamin D and dialysis-specific labs are bundled into per treatment reimbursement of approximately \$230. Largest dialysis providers are thriving (with economies of scale). Large dialysis-providers use

billions in junk bonds to finance more acquisitions. The only high-margin/profit “products” remaining are MSP-period patient treatments (first 33 months of Medicare eligibility) and some acute in-hospital treatment contracts.

EPO/Meds: Second Medicare bundle is instituted to control EPO, IV drugs and lab costs. No longer are sources of profits, IV drugs and most lab tests for Medicare patients now cost-centers to be controlled and limited. EPO and IV drug dosages decline significantly. Transfusions increase placing patients at higher risk of blood borne infections and jeopardizing potential transplants, making patients longer-term captives of dialysis providers.

THE DYSFUNCTIONAL SYSTEM AND ITS MAJOR PLAYERS

- Corporations – Fresenius Medical Care, DaVita, DCI (large dialysis organizations (LDOs))
- Nephrologists – Renal Physicians Association (RPA) and American Society of Nephrology (ASN)
- Centers for Medicare & Medicaid Services (CMS)
- Congress
- Lobbying Groups: Kidney Care Partners, Kidney Care Council
- Amgen/Pharma
- Individual Patients
- Patient Groups
- Academic medical institutions

A well-constructed system of care that continually improves outcomes that are important to patients must balance corporate, government, medical, and patient concerns. The current system’s most obviously dysfunction is that the collective patient experiences have been lost and no effective patient advocacy system exists. The system has failed patients and continues to fail patients. At this time, this system of care best serves the interests of corporations and nephrologists at the risk to patients. The system must begin collecting patient experiences (good and bad), valuing patient input and feedback, as well as aid the development of effective, independent patient voices, both individual and collective.

- Corporations – Two for-profit corporations, Fresenius Medical Care and DaVita, now dominate dialysis care with their sheer size, market share, financial power, political power, purchasing power, economies-of-scale, and clinical/medical influence. They capture as many dollars associated with dialysis patient care with dialysis facilities, pharmacies, large laboratory businesses (blood analyses), and acute dialysis hospital contracts. Fresenius is vertically integrated, manufacturing equipment, supplies, and pharmaceuticals as well as owning dialysis facilities. Both are growing internationally and Warren Buffet (Berkshire) recently invested in DaVita.

Dialysis providers have two high profit margin services: MPS-period dialysis treatments and some acute, in-hospital dialysis treatments. The large profits earned on these services allow Fresenius and DaVita to exist as Fortune 500-level companies. Fresenius and DaVita currently have business strategies that now function to increase their market shares under the new “Medicare” bundle. They can operate at lower costs than independents and are purchasing competitors, increasing their power and influence. If they have the “acute dialysis” contract at the local hospital, they make more profit when patients are hospitalized, giving little incentive to improve care in their centers.

They employ nephrologists as medical directors of dialysis clinics, creating a conflict of interest in terms of patient advocacy. Many top nephrologists also have financial ties and arrangements with them, including clinic ownership, research, consulting, and corporate stock ownership/options. Fresenius and DaVita not only employ most nephrologists and nephrology nurses, but also provide much of the funding for the physicians’ and nurses’ professional organizations and most patient organizations.

Fresenius and DaVita have succeeded by cutting operating and supply costs and psychosocial services to a minimum. They have won the “race to the bottom” in terms of providing minimal patient support/convenience/education/training, yet still “technically” comply with federal/state regulations for rehabilitation on paper, and thus maximize profits. Patients are simply given packets of information. Although social workers and dietitians are required to provide care, their case loads are now often over 125 patients. Social workers spend nearly all their time on insurance and transportation issues and few have time to attempt any kind of patient employment/rehabilitation advocacy.

These corporations spend heavily on lobbying, political influence, and campaign contributions.

Fresenius and DaVita have no patient focus groups to improve care. The typical, new, in-center patient quickly discovers that that they are expected to conform to the existing system of care, regardless of their employment or life activities. The existing culture is one that routinely “infantilizes” patients, with little support or expectation of patient employment or rehabilitation. Considering this environment, behavioral scientists would likely find frequent displays of patient non-compliance not unexpected.

DaVita emphasizes the experience of the employees, not the patients.

- The next largest provider is DCI, a non-profit, which has had better outcomes (mortality and morbidity) since the United States Renal Data System (USRDS) began comparing the large dialysis organizations (LDOs) several years ago. No one asks why. This may be because DCI offers more psychosocial services and patient support than the for-profits.

- Nephrologists, RPA, ASN – In general, nephrologists see dialysis care as managing medical problems, not as a part of a chronic illness that should be managed to provide the patients with the highest possible quality of life. Comprehensive, holistic approaches to patient care are almost unknown and are not presented at their professional conferences. Over the last four decades, the field of nephrology has shown little interest in patients’ health-related quality of life, employment, or rehabilitation.

Nephrology, as a medical specialty, appears ill-suited for overseeing the quality of chronic disease patients’ lives. Nephrologists receive no training in patient employment or rehabilitation or home dialysis therapies. They see rehabilitation as the responsibility of the dialysis providers or other professionals. Forty years after the start of the federal ESRD program, there should be medical journals dedicated to CKD5 patient employment, rehabilitation, and health-related quality of life. There are none.

Simply put, instead of asking “What's the matter?” nephrologists need to ask “What matters to you?”

For the 1980s and 1990s, nephrologists focused on how short dialysis treatment times could possibly be. In the 2000s to the present, they have been debating on whether patient mortality can be reduced by increasing dialysis frequency or treatment times. Nephrology has become stuck in an endless argument over what data, studies, statistics, and databases are correct. Nephrologists keep insisting on sufficiently-powered, randomized controlled trials with statistically significant results to change patient care policies. As medical scientists, they are unable to recommend the therapy to their patients that they would choose for themselves.

Nephrologists would never accept the treatment regimen that over 90% of their patients receive. They know that in order to stay healthy, they would almost always have to dialyze at home in order to get the amount of therapy they felt they needed.

Thousands of nephrologists are facility medical directors for corporations. Few independent voices remain. Numerous financial conflicts of interest exist. The system of care has become shaped to maximize the ease, convenience, and profits of the nephrologists and corporations.

Many nephrologists see transplants as both rehabilitation and a “cure” for dialysis. Even if a nephrologist wanted to emphasize patient employment and rehabilitation for dialysis patients, the LDOs have no tools for them use.

Nephrologists (Brent Miller Talk at ADC) have a financial disincentive to have home patients. According to Dr. Miller, he can see three times as many in-center patients as home patients for the same amount of money.

- To rise in power and influence within this system, up and coming nephrologists must “go along” to “get along”.
- AMGEN – In the 1990s-2010’s, received 20-30% of all federal reimbursement for dialysis care. Original 1989 patent extended through 2013. Amgen provided a “magic pill” for anemia correction. The term “quality of life” in dialysis care became attached to anemia correction for decades. Fatal/dangerous side effects of Amgen’s products and high dosages were denied for years. With its 90% margins, profits, hiring, grants, and sales incentives, few questioned Amgen’s motives and a slow, insidious corruption of many professionals in this medical field occurred.

DaVita administered more IV drugs than other providers. DaVita justified this by saying nephrologists signed the orders. Often, nephrologists were medical directors and stockholders in DaVita. DaVita and Fresenius recently signed contracts with Amgen that effectively locks out other anemia drug makers of the ESA/EPO market, discouraging competition and patient choices.

- CMS – Policies are out-of-touch with patient needs. Receives little feedback and information from patients. Never collected patient experiences, positive or negative. Does not promote patient employment or rehabilitation. Existing “quality” programs (QIP) are ineffective. CMS has created an extremely convoluted reimbursement/quality improvement system that has nothing to do with patient life outcomes. ESRD Networks ineffective in improving care.

CMS has spent millions of dollars implementing the CROWNWeb system to track enormous amounts of treatment and lab data that are entered by facility personnel and, although values are validated within a range of expected, there is no way to verify the accuracy of the data entered. With the potential to lose money under the current the QIP, there is an incentive for facilities to game the CROWNWeb system. It can be argued that far better patient outcomes could be achieved by simply tracking and publicizing patient employment data.

Only 14% of current morbidity and mortality can be accounted for by assessing the CMS mandated clinical performance measures that dialysis facilities report (albumin, Ca, P, Kt/V, PTH, hemoglobin, etc). The system of care must instead address the issues that make the greatest difference in outcomes, not continue outmoded measurements that do not reflect quality of care (Boston 2009 conference).

- Congress – Receives a great deal of lobbying from the two largest corporations through many influences. Receives little valid feedback and information from patients.

Congress has enacted legislation that directs CMS to set the wrong financial incentives for improving dialysis care. Congress should set financial incentives that improve outcomes

important to patients and taxpayers. Congress has an extremely powerful tool to improve dialysis care, in that it can control the MSP period length and the conditions for which it applies.

- Kidney Care Partners – Lobbying group that, in theory, represents all stakeholders, but it is controlled by corporate interests. It includes one seat for patient groups that rotates, so there is no continuity in the patient voice. Dues are charged to pay lobbyists and admission of nonprofits is intended to establish credibility of this organization with legislators.
- Individual patients – extremely vulnerable, lives are highly medicalized, often feel overwhelmed. Most are provided very limited psychosocial services.

Patient who do want to remain employed and/or maintain a high quality of life quickly are often shocked to find that there is no system of care to advocate for them. These patients either quickly or eventually figure out that they must do it on their own.

More often than not, most patients resign themselves to a much lower health-related quality of life. They accept their place in a system of care that “infantilizes” them and shows little interest in trying to improve the situation.

Once patients stop working, it is nearly impossible to have them return to the workforce for a variety of reasons. Many feel they are unemployable if they require dialysis and their doctors and other dialysis staff do little to change this perception.

Some patients will choose not to pursue any sort of rehabilitation. Renal rehabilitation requires a high degree of compliance with prescribed medical care and is not for everyone. Some patients will always choose the minimal treatment possible. In those cases, dialysis providers and caregivers must be non-judgmental, evaluate each patient’s reasons, and provide education to separate myth from fact about work expectations, benefits loss, and work incentive programs.

- Patient groups – Never developed a collective patient voice. Most are dependent on corporate funding. Some accept corporate money to develop and provide minimal psychosocial services for patients, something the providers should do themselves. In doing so, many patient groups have become de facto divisions of the major corporations. Some offer programs that funnel prospective patients to the corporations.

American Association of Kidney Patients routinely gives awards to the medical directors of the largest for-profit corporations.

American Kidney Fund (AKF) describes itself as a “patient” organization. However, it acts as an incredible profit-generating instrument for the large dialysis providers. As it is illegal for

Fresenius and DaVita to pay the private insurance premiums of their patients, they and other dialysis providers instead donate money to the AKF³. AKF pays the premiums which results in returns of 10-60 times their “donations.”⁴

- Academic medical centers – Harvard and other leading academic centers have had nephrologists and medical staff with financial ties to Amgen, Fresenius Medical Care, and DaVita.

WHAT WENT WRONG

- Patient employment HAS NEVER BEEN A TARGET of treatment or care.
- General, long-term belief that as technology improved, dialysis treatments could be done quickly and infrequently.
- Kt/V (and its derivative urea reduction ratio (URR)) – Medical measurement of dialysis treatment adequacy that became standard of care starting in the 1980s. Uses urea removal as a marker for dialysis adequacy. Focused only on two outcomes: hospitalization and death. Value is only a point-in-time result and is essentially meaningless.
- 1983 bundle (composite rate) not balanced with patient-centered outcomes. To hold down growing costs, Medicare decided to pay a fixed rate of \$128/treatment... regardless of the patients’ employment status.
- Separate reimbursement for Medicare Part A and B for dialysis patients. Little incentive for dialysis providers (Part B) to provide preventative care and keep patients healthy and out of hospital (Part A). Today, if the dialysis provider (or physician group) also has the “acute dialysis” contract at the local hospital, the provider (or physician group) can make more money when the patient is hospitalized.
- Stagnant CMS reimbursement rates were offset with increased MSP charges to commercial insurance. Patients are only profitable for providers when their commercial insurance is paying. Since the MSP period is 30 months, there is a disincentive for long-term survival. Today, the ideal patient is one that either dies, transfers, gets a transplant, or is discharged shortly after their MSP period expires.
- No separate care goals for working-age patients. The medical field never has seen the importance of being gainfully employed in overall patient health, well-being, and survival. All patients have been treated as disabled and/or retired by Medicare.
- Lack of quality patient feedback, lack of data collection of patient experiences, no effective collective voice, patient intimidation inherent in system. No one, not CMS, providers, or patient groups has accumulated patient feedback and their experiences
- Financial disincentives for nephrologists to improve patient outcomes. Being on corporate payrolls, adding services means they reduce their own pay and corporate standing.

³ Advisory Opinion, No. 97-1, Office of the Inspector General

⁴ OregonLive, Oregon officials grill dialysis companies and the American Kidney Fund, January 4, 2012

- No incentives to create better dialysis machines, equipment, services, and supplies that improve quality of patients' lives.
- Replaced too many RNs with minimally educated and trained technical staff.
- Stopped feeding patients on dialysis. Many are malnourished.

OTHER PROBLEMS

- Mortality rate in US is worse than in Europe, much worse than in Japan
- Home dialysis in the US is utilized far less often than possible
- No common language for patient experiences. Very different definitions of patient-centered care, rehabilitation, and quality of life.
- No record of what made has working patients successful.
- Inspections / Enforcement of existing rehabilitation regulations ineffective and infrequent. Requires minimal compliance (simple chart notation) for patient rehabilitation. Inspections of dialysis providers are not frequent enough due to insufficient funding from Congress.
- Fastest growing segment of new patients are working age patients.

TOPICS NEEDING MEDIA and/or CONGRESSIONAL INVESTIGATION (ANALYSIS / CONCLUSIONS)

- Patient employment HAS NEVER BEEN A TARGET of treatment or care.
- Why isn't patient-specific employment data tracked over time and published in any of these databases: USRDS, DOPPS, CMS, and Forum of ESRD Networks?
- Dialysis patients are provided far too limited psychosocial services for a major organ replacement therapy. Virtually no noteworthy programs exist.
- Very little or no professional expertise exists in dialysis patient employment and re/habilitation. Does not exist in two dominating corporations. Has minimal to no importance at national professional conferences of nephrologists and nurses.
- System fails to capture meaningful accounts of the patients' experiences, as well as their feedback, ideas, and criticisms. CMS and patient organizations have completely failed to represent the collective patient experience of the last forty years. There is no debate or varied points of view about what is best for patients. Major corporations have no patient focus groups. CMS often gives patients very short notice to comment on complex issues, so only sophisticated corporate sources reply effectively.
- Patient groups are dominated and intimidated by corporate money, influence and power. Patient groups cannot exist without corporate funding.
- Total societal costs of debilitating hundreds of thousands of dialysis patients are unknown (disability payments, family assistance, food stamps, lost tax revenues, lost opportunity costs,

increased hospitalizations). Economically unsustainable for the U.S. and state economies to keep increasing the number of non-working patients.

- Corporations can increase profits by providing minimal psychosocial services and allowing increasing patient disability and debilitation to occur. These additional unpublicized societal costs are simply passed on to taxpayers. No effort to reduce it. Companies now profit by creating disabled and debilitated (and non-complaining) dialysis patients.
- LDOs and CMS consider their products (quality indicators) to be biochemical markers and fistula placement rates, instead of patients that are well, employed and re/habilitated.
- Spokespersons for the medical-industrial complex avoid public discussion of patient employment and rehabilitation as it only leads to embarrassing answers (or non-answers). The entire medical-industrial complex has a collective blind spot for the importance of patient employment and rehabilitation. (The emperor has no clothes.)
- DCI, a large non-profit dialysis provider, has better outcomes (morbidity and mortality) than Fresenius or DaVita. (Why? No one address this. Is it because Fresenius and DaVita have reduced psychosocial services far more?)
- Many nephrologists have been focused only on reducing mortality rates and dialysis complications and have not taken a wider approach in caring for these patients. They tend to see transplants as a cure. They have not addressed increased disability/debilitation and the greatly increased societal costs of dialysis.
- Minimal dialysis treatments regimen ignores common sense that longer and/or more frequent dialysis is better for patients. Nephrology care professionals are routinely asked at professional conferences if they would accept the treatment modality that over 90% of their patients receive. No hands go up and the question is often met with open laughter. The entire field of medicine remains committed to a 3-times-a-week, short-time hemodialysis treatment regimen, despite the scientific studies on cardiovascular disease/water volume control.
- Medicare patients are no longer a source of needed profits for corporations. Providers must depend on two high-margin products: commercial insurance rates that are 5-20 times the Medicare rate during the first 30 months of Medicare eligibility (MSP period) and some acute, in-hospital dialysis treatment contracts for hospitalized patients.
- Financial disincentives of MSP and the separation of Part A and B. The highest profit margin services in the industry both work against long-term patient survival and well-being.
- EPO and injectable use dropping since implementation of “new bundle” and transfusions increasing placing patients at risk of infections and jeopardizing transplant status.
- Corporate goals, rather than patient goals, are lobbied to Congress via LDOs, Kidney Care Partners and the Kidney Care Council, as well as patient organizations that have been co-opted to believe the corporate message.
- Free market forces do not work. If patient is not a source of significant profit, they have little power. Patients have few, if any, practical choices and can be easily intimidated. No patient group has their back. CMS Networks, which are supposed to resolve disputes, are made up of peers of the nephrology professionals and are perceived by patients who have complained as taking the side of the facility.

- Technology has stagnated around the equipment used for in-center, 3x/week hemodialysis treatments, and the most cost-effective for large dialysis providers. There have been few advances seen in last twenty years. Why so little miniaturization?
- We built the wrong dialysis machines, the wrong dialysis facilities, the wrong healthcare corporations, have the wrong financial incentives, the wrong government policies, the wrong etc... all because we didn't keep our eye on the "ball" or "prize" of employment.
- Due to their corporate size and the fact that they are publically traded, Fresenius and DaVita must remain significantly profitable and operate as efficiently as possible. They are unlikely to invest in new technology that does not offer high-margin (profit) products. Few financial incentives exist to change.
- New bundle is driving out all but a few corporations, which increases their financial and political power. Very little choice and few options for patients, which is even more dangerous if facilities choose to black-ball a patient.
- Fresenius Medical Care is vertically integrated (producing its own machines, supplies, and drugs), which discourages outside entrepreneurs, competition, and new technology.
- Industry is too inbred. Numerous financial conflicts of interest exist for nephrologists, nurses, patient groups. Often one/same person represents different/conflicting perspectives to Congress.

OVERALL LONG-TERM GOALS (results in five years):

- A new, well-patient model of care is established as the norm.
- Patient input and feedback are integral, essential components of the dialysis care system.
- Any employed patient entering this system of care is educated, empowered, and incentivized to remain working. Greatly increased employment rates.
- New markers for excellence in dialysis care established for all age groups and comorbidities.
- 30-40% of population on home or self-care dialysis.
- Dramatically improved survival rates and dialysis technology FOR ALL.

POSSIBLE SOLUTIONS:

- Agree on an overarching philosophical statement on employment/rehabilitation that will change the activities and direction of all involved parties.
- A coordinated, national-level agenda is necessary, involving a collective effort from CMS, Congress, providers, nephrologists, and patient groups to increase employment/rehab. With so many "players" and diverse agendas, only a unifying "target" set for all by Congress could improve patient employment and rehabilitation.
- 5-year focus and thrust on increasing patient employment
- Congress needs to provide financial incentives to increase employment, technology development, and a diversity of approaches. The most obvious incentives are to extend the MSP period for employed patients and to provide tax breaks to employers of dialysis patients. Consider other criteria for extending the MSP period.

- Establish a balanced, 4-quadrant patient-centered care model (patients, government, corporate, medical professionals).
- Redefine the function of the ESRD program as a renal rehabilitation program.

REQUESTS TO CONGRESS: WHAT SHOULD BE DONE TO BEGIN IMPROVING DIALYSIS CARE

Hold congressional hearings as soon as possible to set a new, corrective direction for the entire system of dialysis care.

- Expose the dysfunctional system, the parties involved, and the system’s problems
 - Begin by asking all involved parties why the original intent of the federal program, patient employment and re/habilitation, has been ignored.
 - Ask why patient-specific employment data isn’t tracked over time and published in any of these databases: USRDS, DOPPS, CMS, and Forum of ESRD Networks?
 - Ask the leaders of this medical/industrial complex what therapy they would choose for themselves
 - Ask if CMS’s quality improvement programs are playing a role in improving patients’ health-related quality of life
 - Hear testimony from the most frustrated patients and medical professionals, as well as the most successful patients. Have patients and professionals testify on the benefits of employment and re/habilitation.
- Instead of calling for more medical studies, embrace a “common sense” solution based on patient employment and re/habilitation
- Recognize that only Congress can change the direction and activities of all involved parties in the system of care
- As a starting point, Congress should insist on a 5-year coordinated push by all involved parties to increase patient employment. Possible actions:
 - Extend the Medicare Secondary Payer (MSP) period when patients are kept employed. (This will REDUCE Medicare costs.)
 - Provide tax breaks/credits to companies that employ dialysis patients and provide health insurance
 - Dialysis patients and other collecting disability insurance income based upon being 100% disabled should be able to attempt to return to the workforce without the fear of losing their disability insurance income if their employment gets interrupted due to their disability.
 - Provide incentives for dialysis facilities to offer treatment shifts starting after 5 pm.
 - Require large dialysis providers to hire some dialysis patients.

- Have CMS begin measuring and publishing dialysis patient employment. Identify and publically acknowledge which facilities keep patients healthy and working over extended periods of time.
- Develop a bigger economic picture of renal replacement therapy. Establish all societal costs of failing to target employment and rehabilitation as part of major organ replacement therapy, including disability payments, food stamps, transportation, social services provided to families, as well as lost tax revenues and lost opportunity costs.
- Realign corporate financial incentives to deliver positive outcomes for taxpayers and patients and improve patient survival
- Have analysis/reviews of the system of care by outsiders (industry is too in-bred).
- Require that ACOs must be focused on patient employment and rehabilitation.
- Have CMS develop the collective patient voice and accumulate patient experiences.
- Consider psychosocial issues as important as medical issues for long-term survival.
- Consider that it is time to develop a new medical specialty for a comprehensive, holistic approach to renal replacement therapy. It will specialize in a body of medical knowledge, coordinate multi-faceted care with personal priorities, keep patients at their highest level of functioning, and develop modern tools for effective patient education and motivation.
- Demand new quality markers for OVERALL quality dialysis care to be developed.
- Hold yearly hearings to determine progress on increasing patient employment.

QUESTIONS TO ASK

To nephrologists and corporate officer: “What treatment modality would you choose for yourself and why? Why aren’t you recommending that to your patients? Could you work if you were on conventional 3x/wk hemodialysis?”

To clinic administrators and nephrologists: How much emphasis do you place on working-age patients remaining employed or returning to work by the policies and procedures you have established?

With such a multi-factored therapy, don’t you have to target an increased patient employment rate to achieve it?

Headlines: Are dialysis clinics “disability factories”? (that enrich a few corporations... while increasing state and federal social services budgets?)

To working-age patients: When you entered the dialysis care system, did it seem it was a priority of the healthcare team to keep you employed? Has anyone asked you what they could do to help you stay employed or get a job... or to make your life easier?

To social workers: If you had a caseload of 100 patients or less and non-clinical tasks (admissions, forms, transportation, insurance, AKF HIPP, etc.) were performed by someone else, what could you do to help patients keep their jobs, find new jobs, and have improved health-related quality of life?

Journalists should contact the local ESRD Network offices for patient employment data in their area.
Which clinics keep patients employed over a period of several years?

Why does DCI have lower morbidity/mortality?

Ask patients if they have the level of quality of life they had hoped for when they started dialysis? Is this what they expected after 40 years of a federally-funded medical program?