



Service to those affected by chronic kidney disease

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September 16, 2019

The Honorable Alex M. Azar, II
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Secretary Azar and Administrator Verma:

Re: Medicare Program: Specialty Care Models to Improve Quality of Care and Reduce Expenditures directed from the Executive Order on Advancing Kidney Health

I am writing as the Founder and President of the Renal Support Network (RSN), a nonprofit organization founded in 1993 to empower people who have kidney disease to become knowledgeable about their illness and proactive in their care. I have had kidney disease since 1968, have survived 50 plus surgeries and 13 years of dialysis and am now living with my fourth kidney transplant. As an organization focused on the patient perspective, I'd like to give that perspective with regard to the Executive Order on Kidney Disease signed by the President on July 10, 2019.

The Order details ways to improve kidney care, which can be summarized in the three policy points below:

- 1. A focus on earlier diagnosis, more effective treatment and incentives for preventative care, as well as kidney disease education including information about treatment alternatives.**
- 2. An emphasis on higher-value care and development of technological advances including the artificial kidney.**
- 3. Updating and reducing regulations, and streamlining the organ recovery and transplantation process, allowing for more people living with kidney disease to get on the transplant list and receive transplants.**

This order provides a framework for significant positive changes for people living with kidney disease. As a patient-focused organization run by a survivor, we've been hopeful about proposed changes to kidney legislation over the years and been disappointed because when put into action there are often unforeseen obstacles. An important question to ask is what is the measure of failure for these proposed changes? Sometimes it takes time to determine effectiveness and in the interim, patients suffer.

There are millions of people in the US living with some form of Kidney Disease and that number is growing. In the past we have witnessed payment policies that have miscalculated

An illness is too demanding when you don't have hope!
– Lori Hartwell, RSN Founder and President

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the effectiveness of proposed legislation and had unintended consequences. The Executive Order has the possibility of having a significant positive impact on kidney care in the US and we will be pleased to see that result.

Policy Point #1: Earlier Diagnosis, Effective Treatment and Incentives for Preventative Care

The government's plan is to reduce the number of Americans developing end-stage renal disease (ESRD) by 25% by 2030. Americans with ESRD make up 1% of the Medicare population but account for 7% of all Medicare spending. We are focused on the following to reduce these numbers:

Kidney Awareness

Prevention education is as important as educating people already diagnosed with kidney disease. Community awareness to address the Chronic Kidney Disease (CKD) epidemic will go a long way in preventing the need for dialysis and transplant in many people. Because kidney disease is not usually addressed in a regular check-up or physical, the general population needs to be educated about how to notice the signs.

Since hypertension and diabetes are the leading causes of kidney failure, it would behoove the government to take an active role in public awareness and prevention of these conditions. Many people are aware of the link between hypertension, stroke, diabetes and cardiovascular problems, but much of the general public are surprised to learn the connection to kidney failure. For the aging population and the decline of the baby boomer generation who are most vulnerable to these conditions, money spent on prevention and screening programs for these precursors would be well spent and will save money in the long run. Additionally, early awareness of a problem allows patients to become engaged in their own care in order to slow and even prevent the progression of these diseases. The result is an overall healthier population and fewer dollars needed for health care.

Need for More Nephrologists

The kidney community has been dealing with a lack of nephrologists for years. Without enough nephrologists to care for the fast-growing population of CKD and ESRD patients, there will be more patients doing poorly due to inadequate treatment, leading to more hospitalizations and an earlier need for dialysis. On average, people on hemodialysis have two hospitalizations per year and have a 30% chance of another unplanned hospitalization 30 days after discharge. Studies have already shown a direct link between nephrologists with too many ESRD patients and deficient care (even death).

More funding for medical students to go into the kidney field specifically would produce more nephrologists and nurse practitioners, which would be a huge step in improving kidney care. Underserved kidney disease communities could increase kidney care access, which benefits patients, their families and taxpayers and assists in the current goal of increasing preventative treatment.

Increased Access to Medicare Education Benefit

Medicare covers six (6) one-hour sessions of kidney disease education by a doctor or qualified nurse/nurse practitioner/social worker if you have stage 4 CKD or ESRD and qualify based on the criteria established. Education is critical to navigate this disease so there needs to be additional access to all patients at various stages, and increased education covered by Medicare. The majority of people who are in kidney failure don't have access to Medicare until their kidneys fail. There has been a decline in patients using this benefit since its inception in 2012. This may be due to a few factors including: many smaller centers don't have the staff to run the classes, for many it's not cost-effective for them to do so due to limited Medicare reimbursement.

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It's necessary to have patients educated on what to expect and how to care for themselves once they are diagnosed with any stage of kidney disease, but particularly once on dialysis or as they plan for transplant. An increase in funding will improve education and thereby benefit the whole healthcare system in the long run.

Increase Transparency

A way to promote effective treatment and better preventative care is to improve transparency. Transparency in healthcare is paramount in this modern era. Public policy changes and the growing number of health care quality information sources suggest that patient access to information regarding safety, quality, and outcomes is becoming increasingly in demand - patients want to be actively involved in their treatment. When patients are empowered to understand what is happening with their health, including treatment options, possible outcomes and risks and costs, everyone benefits.

Healthcare providers must provide as much information as possible to ensure safe, quality care; so patients, in conjunction with their healthcare team, can make informed decisions. Healthcare providers also need to engage patients with care-planning discussions and ensure patients and their families are vested in decision-making. Additionally, internal transparency leads to improved external transparency, so healthcare providers need to assist each other with it. Using the increasing number of electronic record portals to consolidate information coming from various healthcare sources, taking the time to explain things to patients (this goes back to the need for more nephrologist and kidney nurses) and being reachable through portals or email is extremely useful to keep patients informed. Transparency will directly correlate with improved care.

Position: Prevention/Treatment Education, More Nephrologists and Information Transparency are critical for the success of this policy point.

Policy Point #2: Higher-value care, Treatment Alternatives and Innovation

Higher-value care from a patient perspective is care that improves our overall health and well-being. The following will assist the Executive Order's goal of having the majority of new ESRD patients receiving dialysis at home or do in-center self-care by 2025. We see this being effective through the following:

Self-Care and Home Dialysis

Support and incentives for self-care, home treatment and more remarkable modalities are what everyone should want. Dialysis treatments are a good paradigm for what "home" care can mean, by maintaining the best quality of life for a patient and by helping them stay actively employed. Economically, home modalities have the added benefit of freeing up medical staff time and resources. Creating incentives for home dialysis will not only address the ever-increasing health care staff shortage but will also help alleviate the transportation obstacles. This would further be accomplished by providing incentives for those modalities considered optimal as opposed to adequate: more frequent treatments such as short daily dialysis as well as longer and slower treatments such as nocturnal therapies. These are typically, although not exclusively, done at home.

Studies of patients with access to these treatments have shown to be generally healthier, needing fewer medications and requiring much less frequent hospitalization. All promote a better quality of life for the dialysis patient, again making them more likely to be able to live the life they were meant to live. In addition, new payment models need to be considered, for example whether a patient can be paid a stipend to do their own home treatment, allow a caretaker to be paid to assist them or respite care for caregivers. In the 1990s

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we had higher rates of people on home hemodialysis due to payment structure. I was on home dialysis for 10 years and was able to maintain employment and do dialysis myself. I was younger and had more energy. Today, I'm unsure if I could keep a full-time job outside of the home, care for my family/home and still do the amount of dialysis needed to be healthy with my other conditions I have developed over the course of five decades of living with this illness.

Currently, 12 percent of the population receives home therapy. RSN is concerned about the goals of 80 percent of people by 2025. This aggressive number could have devastating consequences for people. Here is a list of barriers that are real for patients and they need to be addressed so the patient does not go home and feel overwhelmed and give up. Often people crash into dialysis and do not feel well. It can take a while to feel better and for the nephrologist to help you become stable and get your numbers back in acceptable range.

This is a list of home dialysis barriers we received from people who are on dialysis, have received a transplant and family members:

- Home environment not sterile enough, big enough or appropriate for maintenance or storing items.
- Anxiety and stress issues of dialysis process.
- Fear of self-cannulation
- Will have to add wiring or plumbing for home use of machine
- Family not trustworthy and worried about damaging equipment or misplacing dialysis-related items
- Cost of missing work, for either themselves or caregiver, for training
- No one to help – fear of doing it alone
- Lack of family support or fear of family response of having the illness in the home
- Fear of serious medical incident
- Physical issues and unable to lift medical equipment
- Fear of robbery because needles and medical supplies in home
- Fear of burnout and patient's often feels guilty about the time and energy their care givers provide
- Unstable health or cognitive issues
- Homeless or unstable home situation
- Plan of care is to be transplanted and catheter placed in abdomen is not a medical recommendation by transplant team
- Don't trust themselves to be compliant or to sign off dialysis early
- It will be too difficult for them to learn and do properly
- Patient feels isolated at home and the socialization of a dialysis facility reduces anxiety

Self-Care in-center dialysis could provide many of the advantages of home-based dialysis, and remove many of the barriers that prevent patients from choosing to do dialysis at home. Self-care in-center dialysis is a real step to helping people get more comfortable with caring for themselves and every avenue should be explored to incentivize this treatment option.

Getting More People Listed for Kidney Transplant

People who can get a kidney transplant are motivated by the hope that they will someday live their life without the use of a dialysis machine. We know the community is working to refer more people for transplant, and this Executive Order wants this as well. We tell people who contact us so they can self-refer to a transplant center if they wish and do not require their nephrologist to get an evaluation.

There are barriers for people who could be transplant candidates, most notably they need access to a transplant center in their area and socioeconomic issues factor in as well. Transplant centers must be certain the people who are transplanted can easily get to the center for blood work and follow up care, and have the resources to pay for time off, parking, food and travel costs. In addition, there needs to be a plan to help transplant centers increase bandwidth, so patients don't fall through the cracks. Transplant centers are often at capacity and need time to expand bandwidth so they don't fall short of meeting the demand for care.

This is a list of transplant barriers we received from people who are on dialysis, have received a previous transplant and family members.

- Lack of transplant center in geographic area
- Economic concerns of not being able to afford tests/medication, fear of losing existing insurance
- Medicare/State Program/Insurance, fear of losing kidney after 3 years post transplant, fear of previous failed transplant and fear of medication side-effects, fear of loss of wages caregiver/family member unable to go to mandatory tests, etc.
- Physical barriers out of patient's control such as too old to be considered, too sick to be considered, reoccurring illness that will impact graph
- Lack of education about transplant process/eligibility and how to navigate the process and/or how to proceed, accessibility for testing process due to transportation for necessary tests, bloodwork, transplant center, etc.
- Fear/Guilt of accepting a living donor kidney
- List too long and do not feel they will live that long, not worth the hassle
- Non-compliant issues of patient or previous or current substance abuse
- Highly sensitized with antibodies leading to higher rate of rejection
- Lack of health insurance, surgery and risk of dying
- Lack of caregiver for support before, during or after transplant surgery
- Loss of visiting the dialysis center

Information Sharing Between Hospitals and Dialysis Centers

Higher-value care really starts here. Same as with transparency, communication is key when it comes to every patient receiving the best care. For people who have kidney disease, information comes from many sources and often there is a communication breakdown. When a kidney patient is admitted to a hospital as an in-patient, their dialysis center doesn't always receive all the information needed. This is often due to the dialysis center not receiving admitting or discharge information, incompatible electronic records systems, different priorities and lack of standardized content. If everyone is in the know, adverse events like medication mismanagement and readmittance can be greatly reduced and patient care improved. This also speaks to the need for less red tape and regulatory roadblocks. It's not uncommon for a person on dialysis to be hospitalized and the nephrologist or dialysis facility is not notified.

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Incentivizing Innovative Technology

It is encouraging this Executive Order highlights innovation. Statistics continually show that research and technological advancements in critical illness care improve the lives of patients and lower the financial burden for patients and taxpayers. However, innovative devices and technology are not reimbursed at the rate or percentage for kidney disease as they are for other chronic illnesses, so there is a lack of incentive to spend time researching new technology for the kidney world. We have seen firsthand how changes in care, like dialysis machine upgrades and CKD/ESRD drug improvements, have dramatically improved treatment outcome for people who have kidney failure. Advances in biological sciences, coupled with the increasing availability of clinical data from electronic medical records, as well as improved medical imaging, offer many options for medical advances. For KidneyX to work, innovators need to know that there is a market for their product. The ESRD payment system must provide long term payment mechanisms that adjust the bundle when new products come in. If there is never an option for increasing the bundled rate, seed money for research and only a two year promise of reimbursement will lead to KidneyX failing.

In addition to the artificial kidney, technological advances could have a huge impact on diagnosis and treatment if the incentive is there to do it. The Dept of Health and Human Services (HHS) and the American Society of Nephrology is trying to incentivize through KidneyX, an innovation accelerator established in 2018 which holds competitions for new kidney disease products and treatment. RSN was excited to see the creation of KidneyX. There were 165 submissions in their introductory contest and more in 2019, producing some interesting and innovative ideas. More funds allotted for this effort would make a big difference. We are excited to see the outcome and how it improves our lives.

Access to Medigap for all ESRD patients

Though Medicare covers most costs associated with ESRD treatment, the patient is also responsible for a portion. Many people on dialysis have limited incomes and having to pay deductibles and co-pays not covered by Medicare, causes significant financial strain. Medigap is private insurance that fills in the gaps between your Medicare benefits and what patients pay out-of-pocket. Currently, not all states offer Medigap coverage to ESRD patients under the age of 65. Therefore, some ESRD patients under 65 are forced to do what is necessary to become eligible for Medicaid coverage, which can often cripple them financially. It will cost the state and taxpayers more money in the end as well.

There's the belief that covering ESRD patients under 65 will make Medigap coverage too expensive for your average older person getting Medigap, due to high ESRD healthcare expenses. Yet studies have shown in the states offering it to all ESRD patients, Medigap premiums only had a modest increase. A government Medigap mandate would also avoid inequity in coverage by state.

Extend Immunosuppressive Drug Coverage

There is a significant need to protect immunosuppressive medication coverage. Immunosuppressive medications are necessary to maintain the viability of a kidney transplant. Currently, patients who receive a kidney transplant only receive reimbursement for these medications for 36 months following the surgery—despite the fact they must take these medications for the rest of their lives. And that is for the recipients on Medicare; two-thirds of recipients pay through private insurance, Medicaid or other gov't programs according to US Renal Data Systems statistics, none of which are guaranteed. And approximately one-third of those have no other source of drug coverage, which leads to missed doses – data also shows a high percentage of deaths and organ losses are directly related to the high-cost of anti-rejection drugs.

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If transplanted individuals are unable to obtain other insurance coverage after 36 months and cannot afford the cost of these very expensive medications, they often are forced to discontinue the immunosuppressive protocol. This often means losing their transplant and ending up back on dialysis unnecessarily. Not only can this be devastating to the quality of their life and health, but in economic terms, it costs far less to maintain a transplant than to support the cost of dialysis annually. In short, the government will save money and save lives by addressing this issue. In addition, if the person does not have access to affordable quality insurance, it is near impossible for them to have necessary blood work, see a doctor regularly, to have prescriptions written or access to care to maintain their health and the viability of the organ.

Position: There are many ways to improve higher-value care and the basis of making it functional is to improve it for the patient to receive the best care, not for the government or insurance companies to save the most money. However, our definition of higher-value care intrinsically lowers costs for the government, insurance companies and taxpayers. Supporting patients through Self-Care Education, Medical Professional Information Sharing, more people on the transplant list, Medigap Coverage and Extended Immunosuppressive Drug coverage are ways to make that happen.

Policy Point #3: Regulations, organ recovery and transplantation process

Payment Driving Practice

A big part of the problem with patient care is medical and insurance care is focused on payment driving practice which can often be a barrier to optimal care. As it stands now, one big issue is added costs for which dialysis clinics and treatment centers aren't reimbursed. For example, there are many patients who need dialysis more than 3x's per week. But a 4th or 5th session of dialysis often has difficulty in being reimbursed due to the fact that medication is bundled into the payment. There should be a separate payment code allotted that is just for an extra treatment costs and not the medication. Patients don't need additional medication because they have an extra treatment, sometimes the contrary. It has been stated, that dialysis facilities are making more money due to extra treatment. I assure you patients do not want to spend more time on dialysis, but often will if they know their outcome will be improved.

And currently, physicians and ESRD facilities are required to submit additional documentation to justify the medical necessity of an additional treatment of dialysis for each patient. This adds to the already large pile of paperwork required to get people who need dialysis the care that they need, part of the reason for "Patients Over Paperwork" initiative which was proposed by CMS in accordance with the Executive Order. CMS is proposing changes in scoring certain measures in the ESRD Quality Incentive Program (QIP) to streamline policies and encourage the submission of complete and accurate data. These changes will allow facilities to spend less time reviewing policies and more time providing high-quality care. We support minimizing red tape to upgrade processes and directly improve patient care.

Protecting Living Donors

The Order promises to remove financial barriers to living organ donation by expanding the definition of "allowable costs" – this includes increasing the income allowed for eligibility under the Living Organ Donation Program and allowing for reimbursement for expenses ranging from child care to elder care. This is crucial because fear of lost wages is one of the biggest deterrents to donating, but there are other financial burdens. In 2018 Living Donors became covered by FMLA (Family Medical Leave Act) so fear of losing jobs entirely is gone but losing health insurance and unforeseen expenses (donor expenses generally range from \$900-\$3000) still exist and aren't specifically addressed.

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In the past few years, there has been a decline in donation amongst men, younger adults, minorities and low-income adults and a lack of care guarantees for living donors. As it stands now, low-income Americans would already be approved for reimbursement under the living donation program, yet their numbers are still declining – which means incentives must be increased.

Regardless of what motivates us to do something, even if it's because it's the “the right thing to do,” we feel more positive about our choice if there is reward involved. 19 US States currently provide a tax incentive for organ donation ranging from 5-10K; some states have even tried employer tax credits to cover expenses, but donation rates have not increased. More exploration into different types of tax incentives would be useful. Income tax incentives are often successful, so that definitely needs more research.

In order to be a living kidney donor, you must pass an extensive number of tests to ensure you are in peak physical condition. The criteria are structured so both the donor and his/her recipient have the best outcome for living healthy lives with functioning organs. Yet after a living kidney donor is proven to be in excellent physical condition, and it's understood in the medical community you can live with one kidney without issue, a living donor is considered to have a “pre-existing condition” after donating. This means his/her medical care is at risk. The onus should be on the medical community to challenge this label. Everyone in the US knows people with preexisting conditions have difficulty navigating insurance, so of course seeing that your status will change to having a preexisting condition would give donors pause. The mandates in this Executive Order don't mention this specifically, and because they also don't mention any insurance guarantees, there is no protection for Living Donors in this regard.

The Living Donor Protection Act of 2019 aims to help with some of these roadblocks by: ensuring life, disability and long-term care insurers cannot deny/limit coverage or charge a higher premium for living donors; allowing living donors to use family and medical leave for donation surgeries and recovery; and directing Health and Human Services to update materials to reflect these changes to encourage more people to consider giving the gift of life. If we can do a better job of protecting living donors, we can increase the number of transplants, thereby aiding the Executive Order's goal of doubling the number of kidneys available for transplant by 2030. It would also increase the amount of hope among those living with kidney failure.

Increase Viability of Deceased Donor Organs

Changing the way deceased organs are procured, examined and distributed will go a long way to allowing more people with kidney disease to receive transplants. There needs to be a system to effectively use more of the kidneys available, so more people can live. The Executive Order's plan to establish more transparent, standardly accepted and reliable metrics for kidney procurement in order to lower the discard rate and expedite kidney matching will help exponentially. This investment in the organ donation process is necessary.

Position: An emphasis needs to be placed on moving away from the “Payment Driving Practice” system that's been in place for years. There needs to be an emphasis on outcomes based on the efficiency of patient care driven by patient needs. Less stringent regulations will allow for timelier and needed care for patients, and support for Living Donors and a change in the way deceased donations are procured and awarded is essential.

Good policy improves the lives of those living with kidney disease and protects them. Meaning patients receive *optimal*, as opposed to adequate, care. They are given tools to improve their care through better treatment

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and education, and they aren't afraid of losing insurance coverage or access to care. If these policies are implemented effectively, the proper protections will be in place to ensure people who have kidney disease can remain hopeful and secure in their care.

Bad policy promises people living with kidney disease things it cannot deliver. It uses people with kidney disease as guinea pigs without any assurances.

The Dept of HHS, insurance companies and the medical community all have a responsibility to improve the ways patients can access the best care. New kidney disease biologics, equipment and medicine, alternative options for care and improving patient outcomes for transplant with better dialysis methodology and more available kidneys is paramount. As are modernized, quality-approved treatments that will help eliminate ineffective treatment and provide more impactful solutions for people living with kidney disease.

Patient Autonomy is Crucial

People who have kidney failure should be able to make decisions about their medical care without their health care provider trying to influence the decision. Payment drives practice and all policies need to be thought out carefully to ensure patients have a choice. We should all strive for health care providers to educate us. Knowledge is imperative and ultimately we should pick the best treatment after presented with the treatment options for our care.

This Executive Order sounds like what could be a meaningful step towards improving kidney care. The areas of focus RSN suggests are in alignment with the Executive Order on Advancing Kidney Health and are cost-effective and beneficial for everyone. I appreciate your consideration of our input.

I have had kidney disease since 1968 with my first treatment at the age two that required the Kiil dialyzer and a Scribner shunt. I have seen the evolution of kidney care and how Medicare payment has helped us tremendously. I've also see payment policies that have led to subpar care. This is literally a matter of life and death and we welcome a continued dialogue about issues affecting the kidney community.

I founded Renal Support Network because of my struggle to find educational information and peer support to manage my condition. RSN has 18,400 members and more than 30,500 Facebook and 5,800 Twitter followers who seek education and hope. We are increasing our reach via social media to help more people understand how to navigate kidney care and to encourage them to remain hopeful about their future. Our patient-centered programs are resonating with people and families dealing with kidney disease. An illness is too demanding when you do not have hope.

We thank you for working on innovative ways to improve the care we receive.

Sincerely,



Lori Hartwell
President/Founder