



June 22, 2015

The Honorable Johnny Isakson
The Honorable Mark R. Warner
Co-Chairs, Senate Finance Committee Chronic Care Working Group
United States Senate
Washington, DC 20510-6200

Subject: Request for Input on Impact of Chronic Disease on the Medicare Program

Dear Senators Isakson and Warner:

The Renal Physicians Association (RPA) is the professional organization of nephrologists whose goals are to ensure optimal care under the highest standards of medical practice for patients with kidney disease and related disorders. RPA acts as the national representative for physicians engaged in the study and management of patients with kidney disease.

RPA believes that the kidney care community and nephrology in general, and RPA specifically, have a unique perspective to offer the Finance Committee's Chronic Care Working Group (CCWG) with regard to improving disease management, streamlining chronic care coordination, improving quality, and reducing Medicare expenditures. The first disease management demonstration project in end-stage renal disease (ESRD) began almost ten years ago, nephrologists have been reimbursed for their services using a capitated payment model (the 'original' alternate payment model in Medicare) for almost 40 years, dialysis facilities have been reimbursed for the services provided in that setting of care using a bundled payment system since 1983, and the United States Renal Data System (USRDS) was established in 1988 to perform research and analysis on ESRD care in this country.

This long term experience with disease management, unique payment structures, and extensive data gathering informs RPA's responses regarding many of the issues raised in the Finance Subcommittee's request. It is worth noting that typically adult ESRD patients suffer from a series of chronic illnesses in addition to their kidney disease, including Type II diabetes mellitus, cardiovascular and peripheral vascular disease, and hypertension. There is an approximate 19% annual mortality rate among adult ESRD patients, and without question the death rate is higher for those hospitalized ESRD patients. The typical adult ESRD patient has 2.0 hospital admissions per year, or on average 12 hospitalization days per year, and an approximate readmission rate of 36%. Thus, ESRD patients are among the sickest and most vulnerable patient sub-populations

in the Medicare beneficiary universe. RPA's input draws on our organizational expertise in the treatment of kidney disease, although the recommendations may apply to the treatment of other chronic diseases. A summary of our recommendations is appended to this letter.

In addition to the thoughts outlined below, RPA would be happy to serve as a resource to the Finance Committee and the CCWG specifically as it seeks to improve chronic care management in the Medicare program.

Improvements to Medicare Advantage for Patients Living with Multiple Chronic Conditions

RPA believes that one opportunity available to improve Medicare Advantage (MA) is to expand existing integrated care models, specifically by promoting Special Needs Plans (SNPs) for ESRD. The SNP is a way of taking advantage of the time a patient is in the dialysis clinic to coordinate the patient's care across several settings of care. It aligns the goals of all the participants in the patient care continuum such as insurers, dialysis providers, hospitals, nephrologists and other physicians, and incents them to partner together to improve outcomes that also result in reduced costs (and thus higher value). SNPs also allow the risk taking entity to provide additional benefits to the patient to improve their outcomes. For example, patients who receive necessary dental care would improve their likelihood to receive a kidney transplant, a transportation benefit would allow patients to easily get to an access center to have their dialysis access declotted in an outpatient setting rather than the hospital setting, and the availability of a care manager would facilitate smooth transitions of care, educate the patient and offer recommendations on how to improve their quality of life. The SNP model also enables full transparency into total cost and utilization data via claims analysis, provides the opportunity to develop networks to better manage patient care, and utilizes risk adjusted capitated payment that appropriately accounts for patient demographics and medical conditions. The public-private partnerships that form the basis of these SNPs cut Medicare costs and incentivize care coordination that reduces hospitalizations, improves quality, and enhances patient satisfaction.

In addition, RPA recommends that new ESRD patients be permitted to enroll in Medicare Advantage plans; currently, ESRD patients only have access to MA plans if they were already in one when they were certified as having ESRD. To be clear, ESRD patients should not be compelled to enter an MA plan, however, they should have the option to do so if they desire.

Transformative Policies Affecting Chronic Disease Care Implemented Via Medicare Shared Savings Programs and Other Alternate Payment Models

Given nephrology's longitudinal experience in reimbursement through payment models unique in the Medicare system, RPA along with other stakeholders in the kidney community long ago championed the use of coordinated care models in the treatment of kidney disease. These advocacy efforts resulted in the release by CMS' Center for

Medicare and Medicaid Innovation of a request for application (RFA) to create “ESRD Seamless Care Organizations” or ESCOs, ACO-like organizations specific to renal care. The ESCO model would serve as a test for efforts to improve care for beneficiaries with ESRD while reducing costs to the Medicare program.

While the ESCO proposal has progressed incrementally since its announcement over two years ago, as this document is being written the selected ESCO proposals and other key details of the project have yet to be finalized. This delay is particularly frustrating to potential participants, given the experience of the community in ESRD disease management demonstration projects over the past decade.

Additionally, we believe there is a design flaw in one significant area with regard to the ESCO project and a lack of clarity in two others that CMMI should address. First, the RFA states that “to be eligible for matching to an ESCO (a beneficiary) must NOT have already been matched to a Medicare ACO or another Medicare program/demonstration/model involving shared savings at the date of initial matching for the CEC Model.” RPA believes that this specific criterion is not in the best interests of ESRD patients and should be removed from the list of beneficiary criteria. We recognize the complexities with attribution that arise from implementation of care delivery models such as ACOs and ESCOs across large patient populations. However, we are concerned that the unique needs of ESRD patients may not be addressed in non-kidney disease specific ACOs, and that these patients will be exposed to a care delivery model lacking the unique degree of nephrology expertise that would exist in an ESCO. While we are not advocating that ESRD patients already enrolled in a general ACO be required to leave that model, we believe that they should have that option. Thus, RPA urges the CCWG to compel CMMI to allow that option.

Second, there is an absence of clarity regarding the quality metrics by which participants in the project will be evaluated, and the availability of waivers from, for example, illegal inducement provisions of the Stark law that will affect the scope of services ESCOs can provide to enrolled patients. On quality, it is of paramount importance that the measures selected are appropriate for use with the ESRD patient population (as noted in the RFA), and we suggest that the numerous ESRD-specific measures that have been endorsed through the National Quality Forum (NQF) process be considered in the search for appropriate measures.

Regarding waivers, in the RFA CMMI noted the legal requirements and considerations that the Agency must account for in issuing waivers from existing regulation, and we also appreciate that in their interactions with other federal agencies CMS and CMMI must navigate the course of allowing waivers carefully. However, we also believe that the availability of waivers is the design feature that distinguishes innovative payment models like ESCOs from existing models such as fee for service. Further, the use of waivers is critically important to the care improvements and cost savings that are the goal of ESCOs. For these reasons, RPA believes that the CCWG should strongly urge CMMI to provide greater clarity on the type and scope of waivers that may be available to ESCO applicants.

Finally, in response to a request for information (RFI) promulgated by CMMI in 2014 that focused on outpatient care provided by specialty practitioners for a specific patient population (based on a chronic condition), the Coalition for Vascular Care, of which RPA is a member, submitted a proposal pertaining to vascular access care in kidney disease. The proposal would focus on vascular access care as a key and distinct aspect of ESRD patient care instead of the full continuum of ESRD care, and would include Medicare patients with advanced chronic kidney disease (CKD--not only ESRD patients) who receive vascular access anticipating the need for dialysis. The general concept is that advanced planning for this aspect of kidney care would result in higher rates of fistula placement and lower rates of catheter placement, and both ease the transition of the patient into dialysis and save Medicare program costs resulting from the elimination of the 'crash' into dialysis over the first three months of care, which is typically the most expensive period of a dialysis patient's care. RPA urges the CCWG to review the status of the Coalition's proposal with senior CMMI staff.

Reforms to Medicare's Current Fee-for-Service Model to Incentivize Coordinated Care

In recent years CMS has made the laudable decision to increase its commitment to education and care planning services as part of the Medicare Fee Schedule (MFS) as evidenced by implementation of the kidney disease education (KDE) codes in 2010, the transitional care management codes in 2014, and the chronic care management codes in 2015. Whether specific to kidney disease or not, all of these services have the potential to offer staggering savings to the Medicare program by promoting informed and efficient healthcare, and preventing occurrences such as infections and unnecessary hospital admissions and readmissions more likely to occur in the absence of these services.

However, if the expense incurred when providing these services is close to or exceeds the reimbursement, the small businesses that are medical practices are simply unlikely to provide them. This is especially true when one considers the administrative burden of providing the services in a way that is compliant with associated CMS regulatory requirements. Additionally, since none of these services fall under the Medicare Preventive Care Benefit, the physician practices are obligated to charge and bill patients for their Medicare Part B 20% coinsurance amount resulting from the care.

Further, it is also RPA's understanding that large nephrology practices have chosen not to utilize the CCM codes in caring for their pre-ESRD CKD patients because the monthly reimbursement (about \$42.00) does not cover the cost and administrative burden of providing the care. RPA recognizes the self-serving appearance of medical specialty societies and practices contending that Medicare reimbursement rates for particular codes are too low, but for those services with tremendous potential to create downstream savings, we would urge the CCWG to examine the factors involved in determining regulatory requirements for these codes.

RPA also strongly urges the CCWG to explore Medicare reimbursement of advance care planning (ACP) services. As of the 2015 MFS, there are no relative value units (RVUs) assigned to the ACP codes currently in the MFS (CPT codes 99497 and 99498), and thus there is no Medicare reimbursement for these services. There is published, peer-reviewed research that shows that ACP leads to better care, higher patient and family satisfaction, fewer unwanted hospitalizations, and lower rates of caregiver distress, depression and lost productivity. ACP is particularly important for Medicare beneficiaries because many have multiple chronic illnesses, receive care at home from family and other caregivers, and their children and other family members are often involved in making medical decisions. Further, it is worth noting that costs of care are highest near the end of life (this is particularly true in ESRD). Appropriate use of ACP optimizes that chance that patients won't receive costly unwanted care by default (such as dialysis).

Lastly, the KDE benefit has been woefully underused since its inception, due in part to the fact that it can only be provided to Stage 4 CKD patients. Unfortunately, Medicare will not reimburse the KDE benefit for Stage 5 CKD patients who are closer to kidney failure but not yet on renal replacement therapy. Elimination of this regulatory barrier would improve patient education about options and preparation for treatment while increasing the opportunity for better care coordination.

Effective Use, Coordination, and Cost of Prescription Drugs

One prescription drug issue specific to kidney disease care relates to the immunosuppressive drugs prescribed to post-kidney transplant patients. Kidney transplants are safe, cost-effective procedures that can extend and significantly improve the lives of patients suffering from ESRD, allowing them the freedom to forgo time-consuming and costly dialysis treatments three to four times per week. Accordingly, kidney patient return-to-work and resumption of other normal life activities is greatly enhanced post-transplant.

However, if an individual has Medicare coverage only because of kidney failure, Medicare will pay for immunosuppressive drug therapy for only 36 months, leaving the patient to pay for expensive drugs out-of-pocket after that time period. If the patient cannot afford the drugs after the 36 month time period, the transplanted kidney will stop working and the patient will either return to more costly dialysis treatment, or will die. In these scenarios, not only does the patient have to go through the heartbreaking transition from being post-transplant to back on dialysis (in most cases), but the Medicare expenditure associated with the transplant and the organ itself is in essence wasted, and the Medicare program reverts to paying for monthly dialysis for the patient (roughly eight times the expense of the immunosuppressive drugs). We therefore strongly urge the CCWG to examine Medicare's coverage policy for post-kidney transplant immunosuppressive drugs.

RPA also believes that early identification of CKD is critically important, and would allow for earlier initiation of relatively inexpensive prescription drugs which may lead to improved outcomes and delayed progression of CKD. From a population health point of

view, the identification of microalbumin in the urine and initiation of ACE-inhibitors or ARB agents with statins would likely impact the most people and prevent or delay progression to ESRD in patients with CKD. Earlier identification and referral to a nephrologist would allow these patients the opportunity to slow the progression to and delay the onset of ESRD and ease their transition to renal replacement therapy once indicated, with considerable cost-savings.

Effective and Improved Use of Telehealth and Remote Monitoring Technology

Over the last ten years CMS has made efforts to promote the use of telehealth in nephrology. First, in 2005 the Agency added the multi-visit monthly capitated payment (MCP) codes to the list of approved MFS telehealth services, indicating that if the complete assessment of the patient was performed in person, the additional visits within the month could be achieved using approved telehealth technology, subject to all applicable telehealth criteria. Further, in 2011 CMS also added the previously discussed kidney disease education benefit to the list of approved services that can be provided via telehealth.

However, neither the patient's home nor the dialysis facility are on the list of approved 'originating sites' (where the patient is) for telehealth services, a policy feature which in effect eliminates the vast majority of locations from which kidney disease-related telehealth services may originate. Further, Medicare only reimburses for telehealth services when the originating site is in a Health Professional Shortage Area (HPSA) or in a county that is outside of any Metropolitan Statistical Area (MSA), defined by HRSA and the Census Bureau, respectively. Acknowledging the need for these services to clearly be available in remote areas of geographic hardship, RPA also believes that limiting the use of telehealth in Medicare to HPSAs and non-MSAs removes a significant part of the opportunity to maximize their positive impact on Medicare beneficiaries with chronic disease. We urge the CCWG to evaluate the applicability of telehealth in non-rural areas and consider adding the dialysis facility and dialysis patient's home to the list of approved "originating sites" for telehealth services.

Increasing Chronic Care Coordination in Rural and Frontier Areas

In addition to the concepts expressed above on telehealth which would clearly affect rural and frontier areas, RPA recommends that the CCWG consider expansion of graduate medical education (GME) and National Health Service Corps (NHSC) loan forgiveness programs for specialists and subspecialists such as nephrologists that practice in rural and frontier areas. For the purposes of the NHSC, eligibility would require nephrologists to be able to be defined as primary care physicians, which is perfectly appropriate considering that in rural areas the nephrologist often is the primary care physician for their CKD and ESRD patients. Appended to this document is the *RPA Position Paper on Nephrology Scope of Practice*, which addresses primary care provided by the nephrologist in detail. While we recognize that loan forgiveness is not a novel concept, many medical school graduates are carrying hundreds of thousands of dollars of medical school debt (this is especially true for subspecialists like nephrologists), and loan

forgiveness programs would heavily incent these physicians to practice in rural and frontier areas. Specific to kidney disease, no other specialty is better suited to take charge of chronic disease management than nephrology, and facilitating the ability of nephrologists to practice in rural and frontier areas would broaden the scope of patients benefitting from their care coordination skills.

Empowering Medicare Patients to Play a Greater Role in Managing Their Health

RPA strongly believes that patient involvement is a key element in effective chronic disease management, and this commitment lead the organization to develop and publish the *RPA Clinical Practice Guideline on Shared Decision Making in the Appropriate Initiation of and Withdrawal from Dialysis* (<http://www.renalmd.org/catalogue-item.aspx?id=682>). The catalyst for RPA's efforts in this area is the realization that while dialysis is a life sustaining therapy, it can also be a difficult and challenging journey that is not necessarily appropriate for or desired by all patients, and that decisions on whether or not to embark on this journey should be fully informed and carefully considered. This guideline provides 19 recommendations for initiating, withholding and withdrawing dialysis in adult and pediatric patients with acute kidney injury (AKI), CKD, or ESRD. The guideline represents consensus expert opinion informed by ethical principles, case and statutory law, and systematic review of research evidence. The guideline also includes performance measures and implementation tools.

Further, resulting from RPA's efforts to promote patient safety, the Association created the *Keeping Kidney Patients Safe* website, <http://www.kidneypatientsafety.org/>, which houses materials such as *Dialysis Safety: What Patients Need to Know*, a take-home resource for dialysis patients, and an educational video created by The ESRD Network of New England, Inc. Featuring patient perspectives, the video seeks to empower hemodialysis patients and to teach the importance of hand hygiene, proper equipment, and careful technique in preventing infection.

Utilization of shared decision making techniques and educational materials such as those described above promote patient involvement in managing their health and meaningfully engaging with their health care providers, and we urge the CCWG to explore ways to facilitate the dissemination of techniques and materials such as these.

Enhanced Use of Primary Care Providers and Care Coordination Teams

RPA has long recognized the opportunity for improvement in patient care through the enhanced collaboration between primary care physicians (PCP) and nephrologists, and the use of care coordination teams. We believe that the importance of good communication between PCP and nephrologist cannot be underemphasized in that successful care coordination as well as the potential for prevention of complications of comorbid disease hinge on it. Toward this end, in 2009 RPA launched the Improved Identification and Co-Management of Advanced CKD Patients project in Philadelphia and Chicago. The pilot project focused on two nephrology practices and their eight referring primary care practices. During the pilot project, select tools from RPA's

Advanced CKD Patient Management Toolkit

(<http://www.renalmd.org/page.aspx?id=749&terms=CKD+Toolkit>) were modified for use by PCPs in collaboration with nephrologists. These tools were utilized in an effort to achieve better patient outcomes through improved identification, communication and co-management.

In the course of the project, several key themes emerged, including:

- Enhanced awareness and identification of CKD as compared with practices prior to completion of the study;
- Increased and enhanced communication between the practices among PCPs, nephrologists, and respective staff;
- Improved co-management practices between PCP and nephrology practices;
- Increased awareness, through the project process and the use of toolkit materials, of recommended clinical guidelines, with resulting changes in care and referral patterns; and
- Individual variations in office practice, acceptance, modification and use of communication tools, including barriers to optimal tool use.

The changes reported by the PCPs, nephrologists, and their respective site champions were directly relevant to the project goals of improving communication between PCPs and nephrologists, improving the referral process, improving co-management and CKD patient care, and enhanced satisfaction of all parties. The process of project participation heightened the awareness of participating PCPs and PCP site champions in their role in the identification and early management of CKD. After the final interviews, virtually all of the participating PCPs noted increased awareness of the risk factors for renal disease, discussing tracking patients with previous renal disease, diabetes, hypertensive, lipid disorders, and/or rising creatinine levels. We believe that this project can be replicated in other specialties and disease states. The findings, which were published in the American Journal of Kidney Disease in 2014, are appended to this document.

As always, RPA welcomes the opportunity to work collaboratively with the Senate Finance Committee and the Chronic Care Working Group specifically in its efforts to improve the quality of care provided to the nation's kidney patients, and we stand ready as a resource to the Subcommittee in its future endeavors. Any questions or comments regarding this correspondence should be directed to RPA's Director of Public Policy, Rob Blaser, at 301-468-3515, or by email at rblaser@renalmd.org.

Sincerely,



Rebecca Schmidt, DO
President

Enclosures: 1) RPA Position Paper on Nephrology Scope of Practice
2) Improving Care Coordination Between Nephrology and Primary Care:
A Quality Improvement Initiative Using the Renal Physicians Association
Toolkit

Summary of RPA Recommendations

- Improve Medicare Advantage (MA) by promoting Special Needs Plans (SNPs) for ESRD patients.
- New ESRD patients should be permitted to enroll in Medicare Advantage plans.
- ESRD patients should have the option to leave a general ACO to participate in an ESCO.
- The ESRD-specific measures that have been endorsed through the National Quality Forum (NQF) process should be considered for use in the ESCOs.
- The CCWG should strongly urge CMMI to provide greater clarity on the type and scope of waivers that may be available to ESCO applicants.
- The CCWG should review the status of the Coalition for Vascular Care’s proposal pertaining to vascular access care in kidney disease with senior CMMI staff.
- Provide Medicare reimbursement for the KDE benefit for Stage 5 CKD patients not yet on renal replacement therapy.
- For those services with tremendous potential to create downstream savings, the CCWG should examine the factors involved in determining regulatory requirements for these codes.
- Explore Medicare reimbursement for advance care planning (ACP) services.
- Examine Medicare’s coverage policy for post-kidney transplant immunosuppressive drugs.
- Evaluate the applicability of telehealth in non-rural areas and consider adding the dialysis facility and dialysis patient’s home to the list of approved “originating sites” for telehealth services.
- Expand graduate medical education (GME) and National Health Service Corps (NHSC) loan forgiveness programs for specialists and subspecialists such as nephrologists that practice in rural and frontier areas.
- The CCWG should promote the use of shared decision making guidelines and disease-specific educational tools to support patient empowerment.
- The CCWG should promote the promulgation of available resources to foster communication between primary care providers, specialists, and subspecialists such as nephrologists.