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November 20, 2017

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Room 314G
Hubert H. Humphrey Building,
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Verma,

The National Kidney Foundation is pleased to comment on the Request for Information (RFI): Innovation Center New Direction. The National Kidney Foundation is the largest, most comprehensive and longstanding, patient centric organization dedicated to the awareness, prevention and treatment of kidney disease in the US. In addition, the National Kidney Foundation has provided evidence-based clinical practice guidelines for all stages of chronic kidney disease (CKD), including transplantation since 1997 through the National Kidney Foundation Kidney Disease Outcomes Quality Initiative (KDOQI).

The National Kidney Foundation agrees that an affordable, accessible healthcare system that puts patients first is the most important goal that the Centers for Medicare & Medicaid Services (CMS) and particularly the Innovation Center can realize. Therefore, we are pleased to share with you our proposed model for improvements in earlier detection and treatment of chronic kidney disease (CKD), which align with many of the guiding principles outlined in this RFI. CKD is a progressive disease in which 90 percent of the 30 million American adults with the condition don't realize they have it and for which Medicare spends \$103 billion on the care of beneficiaries who have received a diagnosis, including \$33 billion caring for end-stage renal disease (ESRD) patients who qualify for Medicare, regardless of their age. The National Kidney Foundation strongly believes that CMS can take a leading role to substantially improve outcomes for people with CKD and reduce spending by promoting earlier, improved care that is supported by changes in reimbursement and economic incentives. The National Kidney Foundation hopes to work with CMS and additional provider and patient stakeholders to fully

develop the methodology needed to support the model and deploy voluntary, five-year pilot testing that will provide the opportunity for patients to receive earlier, cost-effective care that empowers them to make informed decisions about their health and treatment options.

Sincerely,

Jeffrey Berns

Jeffrey Berns, MD
Chair, CKD Innovation Model Workgroup
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CKDintercept: Comprehensive Chronic Kidney Disease Care Model



November 20, 2017

Background and Model Overview

Chronic Kidney Disease (CKD) affects 30 million adults in the United States. CKD is a progressive disease, yet many with CKD did not know they had it prior to their kidneys failing. This is true even among those at the highest risk due to diabetes or hypertension. In fact, 96% of those with early kidney disease (stages 1 and 2) don't even know they have CKD. Of those with severely reduced kidney function, (stage 4) but not on dialysis, only about half are aware of having the disease. Another 1 in 3 (73 million) American adults are at risk for kidney disease.¹

Impact: Medicare incurs tremendous expense on CKD patients as the primary payer for most Americans with end-stage renal disease (ESRD). ESRD is treated primarily with dialysis or a kidney transplant. **Total Medicare expenditures for all stages of kidney disease were nearly \$103 billion in 2014, not including prescription medications.** Approximately \$70 billion of the total expenditures were spent on the care of those with diagnosed CKD who did not have kidney failure, but ESRD patients account for \$33 billion was spent on care for ESRD patients who account for about one percent of Medicare beneficiaries, but over six percent of Medicare spending².

The impact of CKD is further amplified as the disease burden is growing. A recent study published by researchers leading the Centers for Disease Control and Prevention's (CDC) CKD surveillance program shows that over half of U.S. adults age 30-64 are likely to develop CKD.³ Furthermore, many with CKD also have cardiovascular disease, bone disease, and other chronic conditions; contributing to poor health outcomes and increased health spending for this population. In fact, CKD is an independent risk predictor for heart attack and stroke. The presence of CKD using both eGFR and ACR has outperformed individual, traditional, modifiable cardiovascular risk factors like smoking, high blood pressure, and cholesterol. CKD is the 9th leading cause of death in the U.S. and roughly half of people with CKD will die because of its complications than will progress to ESRD.⁴ Yet, the economic incentives instilled in our health care reimbursements promote only a concerted focus on this disease once it has progressed to ESRD requiring dialysis or a kidney transplant to survive. No quality measures exist for practitioners who care for the patients at highest risk of CKD, those with diabetes and hypertension, to properly test for it or manage it early when it is identified. While nephrologists receive a monthly capitated payment (MCP) to manage the care of dialysis patients and interdisciplinary care team support provided through dialysis

¹Centers for Disease Control and Prevention, National Center for Disease Prevention and Health Promotion, Division of Diabetes Translation, CKD Surveillance Project, data from the 2011–2014 National Health and Nutrition Examination Survey and the CKD Epidemiology Collaboration (CKD-EPI) equation. Published online June 2017 at https://www.cdc.gov/diabetes/pubs/pdf/kidney_factsheet.pdf.

² United States Renal Data System. 2016 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2016.

³ Hoeger, Thomas, et al. The Future Burden of CKD in the United States: A Simulation Model for the CDC CKD Initiative *American Journal of Kidney Disease* (2015); 65(3):403-411.

⁴ Matsushita K, Estimated glomerular filtration rate and albuminuria for prediction of cardiovascular outcomes: a collaborative meta-analysis of individual participant data *Lancet Diabetes Endocrinology*; (2015) Published online

facilities no similar payment or support team exists to manage advanced CKD patients who need management of their CKD and other comorbid conditions to preserve kidney function and proper preparation for ESRD treatment options should they progress.

Comprehensive CKD Care: Earlier detection allows the introduction of low-cost medical and patient safety interventions, patient education, and care management that can, reduce associated co-morbidities, limit cardiovascular events, and reduce or delay progression of kidney disease and the need for dialysis or kidney transplantation. Given the impact that earlier recognition can have on prevention of CKD and its progression, the primary care setting is the ideal environment for CKD diagnosis and early management. However, PCPs often do not properly test for CKD even in their high-risk patients, and therefore miss opportunities to manage the potential causes and associated co-morbidities of CKD. Among Medicare beneficiaries, data indicate that most individuals at risk do not receive recommended testing. In a recent analysis, only 39% of beneficiaries with diabetes and 6% of beneficiaries with hypertension had urine albumin testing and only 40% of those with diabetes and hypertension had urine albumin testing in 2014.⁵

The direct oversight and management of 30 million adults in the U.S. with CKD is impossible by nephrologists alone. Providing this population with optimal care will require the education of and involvement of the primary care network. Thus, CKD care management would allow PCPs to feel more competent managing CKD patients until advanced CKD when nephrology referral is recommended by the evidence-based clinical practice guidelines for all stages of chronic kidney disease: Kidney Disease Improving Global Outcomes (KDIGO) and Kidney Disease Outcomes Quality Initiative (KDOQI).⁶

The CKDintercept model will enhance coordination of care (*see figure 1*) between PCPs and nephrologists, improve health outcomes, lower costs of caring for kidney patients, and address gaps in care for patients who often are not engaged in self-management and shared decision making prior to kidney failure.

CKDintercept is aligned with Centers for Medicare and Medicaid Services (CMS) Quality Strategy goals of strengthening patient engagement so that patients are partners in their care, promoting effective communication and coordination of care, making care safer by reducing the harm caused in the delivery of care, as well as effective prevention and treatment of chronic disease⁷. It also aligns with the Innovation Center's guiding principles to promote competition based on quality, outcomes and cost, offer provider choice and incentives for participation, deliver patient-centered care, use data-driven insights to ensure cost-effective care that also leads to improvements in

⁵ Ibid 2

⁶ Inker, Lesley, et al. KDOQI US Commentary on the 2012 KDIGO Clinical Practice Guideline for the Evaluation and Management of CKD, *AJKD*, 63:5, 713–735, May 2014.

⁷ Centers for Medicare and Medicaid Services (CMS) Quality Strategy (2016) Retrieved from <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-instruments/QualityInitativesGenInfo/Downloads/CMS-Quality-Strategy.pdf>

beneficiary outcomes. The model was designed by a workgroup comprised of a broad range of multidisciplinary health care professionals including primary care practitioners, nephrologists, a social worker, a dietitian, and patients from across country. Given that payment changes recommended in this model are untested, this model is being recommended initially for limited scale testing to ensure it produces on the intended improvements in outcomes without increasing health care costs.

Figure 1. Comprehensive Chronic Kidney Disease (CKD) Care Strategy		
Primary Care	Nephrology Care	ESRD Care
<ul style="list-style-type: none"> • Assessment of at Risk Individuals • Monitoring of CKD progression • Treatment of stage 3a/b patients • Education on self-management • Patient Awareness/Activation • Medicare Nutritional Therapy • Referral/co-management of stage 4 or more complex patients 	<ul style="list-style-type: none"> • Treatment advanced CKD • CKD Medicare Education Benefit • Patient informed decision making/selection of modality • Placement of access if dialysis selected • Assessment and management or care coordination for comorbidities • Co-management or coordination with PCP • Support transition to preferred modality 	<ul style="list-style-type: none"> • Dialysis facility • Transplant Center • Nephrologist • Primary Care • Palliative Care • Hospice

Earlier detection and management of CKD by PCPs is a critical gap in care that must be addressed. Ultimately, the goal of management in CKD patients is to prevent or delay progression and to lower risk of adverse events. If CKD is identified early, PCPs could properly dose adjust medications, avoid prescribing and counsel patients about avoidance of non-steroidal anti-inflammatory drugs (NSAIDs), contrast induced media, and other medications that are eliminated by the kidneys to ensure patients are protected from toxic side effects and acute kidney injury (AKI) – which can result in temporary kidney failure requiring dialysis and faster progression to permanent kidney failure. The use of blood pressure medications such as angiotensin-converting enzyme (ACEi) inhibitors or angiotensin II receptor blockers (ARB) for CKD with albuminuria and hypertension is supported with high-level evidence to slow or prevent progression. KDIGO and KDOQI guidelines recommend patients receive a nutritional education program tailored to the stage and severity of the CKD. Receipt of nutritional education from a dietitian is a key component of providing patients with actionable strategies to help self-manage their CKD. Yet, only 10% of patients receive proper nutritional counseling even though medical nutritional therapy for CKD patients is a benefit covered by Medicare.⁸

⁸ Ibid 2

CKD assessment and management should be part of an overall strategy to improve population health and longitudinal care, but unfortunately there is no mechanism currently to drive an accelerated focus on early CKD care. Current Innovation Center models do not incorporate care goals related to CKD in the same way they do for diabetes or blood pressure control. A CKD specific payment and quality measures is necessary to help facilitate change, but to also ensure that at the end of five years CMS has detailed data on costs related to CKD stage and level of ACR. This data would allow CMS to better integrate CKD into population health models in the future.

Collaboration between PCPs and nephrology practitioners for patients with advanced CKD is crucial. Over 100 observational studies and one prospective trial demonstrate that outcomes improve when patients with progressive CKD are referred to a nephrologist in a timely fashion.^(9,10,11,12,13) Other studies have also shown that referral to a nephrologist prior to dialysis initiation leads to lower mortality and hospitalization. Furthermore, Medicare data suggests lower spending results for patients with CKD stage 4 when they visit a nephrologist 1-2 times in the year prior to starting dialysis¹⁴. **However, a 2012 CMS data report suggests that 41% of ESRD patients did not see a nephrologist before initiating dialysis, despite the referral recommendations in the clinical practice guidelines^{15,16}.** The CKDintercept model aims to improve timely referral to nephrology care for late stage (CKD stages 4-5) patients, which would allow nephrologists to act in time to preserve kidney function, manage comorbidities, and improve care transitions for those that do progress to ESRD.

From the patient perspective, a late diagnosis of CKD leaves little opportunity for patients to learn about their disease or engage in self-management and shared decision making of treatment options. Across the spectrum of CKD care appropriate diagnosis as well as patient education and preparation for ESRD, for those that are likely to progress, can reduce hospitalizations, medication errors, and improve transitions through advance care planning.

⁹ Chan MR, Dall AT, Fletcher KE, Lu N, Trivedi H. Outcomes in patients with chronic kidney disease referred late to nephrologists: a meta-analysis. *American Journal of Medicine* (2007); 120(12):1063-1070.

¹⁰ Jungers P, Massy ZA, Nguyen-Khoa T, et al. Longer duration of predialysis nephrological care is associated with improved long-term survival of dialysis patients. *Nephrology Dialysis Transplantation*. (2001); 16(12):2357-2364.

¹¹ Kinchen KS, Sadler J, Fink N, et al. The timing of specialist evaluation in chronic kidney disease and mortality. *Annals of Internal Medicine* (2002); 137(6):479-486.

¹² Lin CL, Chuang FR, Wu CF, Yang CT. Early referral as an independent predictor of clinical outcome in end-stage renal disease on hemodialysis and continuous ambulatory peritoneal dialysis. *Renal Failure* (2004); 26(5):531-537.

¹³ Roderick P, Jones C, Drey N, et al. Late referral for end-stage renal disease: a region-wide survey in the south west of England *Nephrology Dialysis Transplantation* (2002) ; 17(7):1252-1259.

¹⁴ Avalere Health analysis of 2013 Medicare 5% claims data. Spending represents total payments in all settings for patients enrolled in fee-for-service.

¹⁵ Ibid 10

¹⁶ United States Renal Data System. 2015 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2014.

Scope of the CKDintercept Model

CKDintercept is a two-part patient-focused physician led payment model. Eligible practitioners are those who accept Medicare fee for service payments, but we also believe this model can and should be deployed by private payers, Medicaid organizations and Medicare Advantage plans for maximum impact.

Part 1 provides a monthly or quarterly payment for the management of CKD stages 3a and 3b. Payment is contingent on an appropriate percentage of the attributed diabetic and hypertension population receiving an estimated Glomerular Filtration Rate (eGFR) and Albumin Creatine Ratio (ACR) in alignment with the KDIGO/KDOQI guidelines. To the extent practicable, practitioners should ensure that all of their attributed patients with diabetes, hypertension, or a diagnosis of CKD have laboratory results conducted within the past 12 months or receive screening for eGFR and ACR. Part 1 of this model is targeted to family and internal medicine practitioners, but any clinician serving as the primary care provider for a patient, including nephrologists, should be considered eligible to participate. PCPs can also receive a bonus for lowering health care costs in comparison with a peer group if satisfactory performance on quality measures is achieved.

Payment is contingent on performance of select measures specific to CKD care for the detection, diagnosis, and risk stratification of the at-risk patient with diagnosed CKD – reductions in the monthly or quarterly payment amounts would occur if satisfactory performance on quality measures is not met.

Part 2, of the model provides a tiered per-member per month payment (PMPM) for the management of advanced CKD patients, which includes CKD 3b patients who have an ACR greater than 300mg/g and all patients stages 4-5 who are not on renal replacement therapy.

Part 2 of the model is targeted for nephrologists, but PCPs could continue to lead and serve in this care management role, if they desired, with an agreement from a nephrologist to provide consultation as needed and the agreement of the patient. Nephrology practitioners should form a care team that includes a care/case manager and a dietitian, who has experience caring for CKD patients. The dietitian could serve in a virtual capacity given the limited number of dietitians with CKD expertise. Practitioners must also include a role for pharmacists as their role in medication management is key to protecting kidney health.¹⁷

The CKDintercept model is intended to allow PCPs and nephrologists, regardless of practice size or experience with alternative payment models to for participate. For PCPs and nephrologists who are participating in other APMs, the model can be tailored to allow for cross participation. We also encourage the participation of community health

¹⁷ St Peter, W. L., Wazny, L. D., & Patel, U. D. New Models of CKD Care Including Pharmacists: Improving Medication Reconciliation and Medication Management. *Current Opinion in Nephrology and Hypertension*, 22:6, 656–662, 2013, <http://doi.org/10.1097/MNH.0b013e328365b364>.

centers and their practitioners as CKD has a disproportionate impact on individuals with social risk factors.

Practitioners participating in Part 1 of the model would not be required to take on risk as the model is intended to incorporate CKD detection and management into existing efforts to manage diabetes and hypertension. We also want to encourage broad PCP participation – not just practices that are structured to take on risk. In addition, since many models for PCPs are currently operating we wanted to ensure PCPs participating in those models could also participate in the CKDintercept model. For Part 2 of the model, we have included an upside only track and a voluntary track for downside risk.

The flexibility in risk tracks will facilitate greater participation by individual physicians and small practices and will also allow practitioners to qualify for credit in MIPS for participating in alternative payment models (APM) and an option for nephrologists to participate in advanced alternative payment models (AAPM). The model's monthly/quarterly payment structure also encourages participation by all practice types by providing for the upfront resources needed to meet the model's criteria. The bonus payments and peer comparison groups will encourage quality improvement including improvement in care transitions among participants.

The model also promotes collaborative care between PCPs and nephrologists and allows for flexibility in how those collaborations can be structured. Both nephrologists and PCPs wanting to participate in the model must have agreements in place for how they will work with one another – regardless of whether both are participating in the model. Only one practitioner leading care management for a particular patient at a point in time can receive payment under this model. This will ensure there is accountability in who is leading care management for the patient and avoid overpayments.

CKDintercept: Payment Methodology

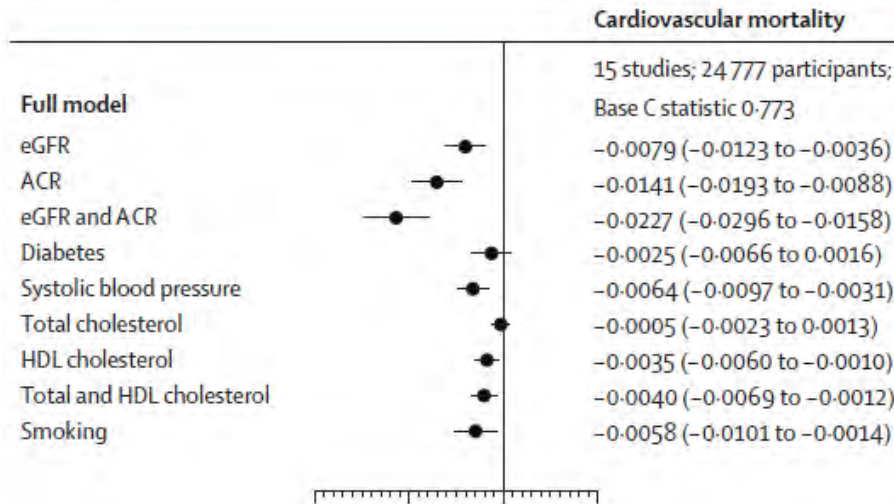
Part 1, Payment to PCPs for proper detection, diagnosis, and risk stratification. To qualify for this payment, participants will need to ensure that they report an eGFR/ACR, to the extent practicable and measured against a practical benchmark, for every person with diabetes, hypertension, or a diagnosis of CKD who is attributed to the practitioner.

Payment under this model is contingent on completion of a second test within a 12-month period, but greater than 90 days from original test indicating that the patient has CKD stage 3 or greater. Appropriate ICD-10 codes should be assigned to beneficiaries who have detected stages of CKD. In CKD patients, the combination of eGFR and ACR is the strongest predictor of cardiovascular related mortality (*see figure 2*). Risk stratification of patients using eGFR and ACR will provide practitioners with the data they need to target and deliver evidence based and patient-centered care according to risk of progression and cardiovascular events.

There are limitations in the current ICD-10 codes that could be addressed using temporary G-codes to support this model. The KDIGO/KDOQI guidelines for staging of CKD have divided stage 3 into 3a and 3b to allow practitioners to better target

interventions for a large population that has varying needs. The distinction between stage 3a and 3b is not reflected in the ICD-10 codes. Additionally, ACR is key to risk stratifying the CKD population and targeting treatment strategies, but the three categories of ACR are also not part of the ICD 10 code set.

Figure 2.



*Figure 1. Matsushita, Kunihiro et al. Estimated glomerular filtration rate and albuminuria for prediction of cardiovascular outcomes: a collaborative meta-analysis of individual participant data. *The Lancet Diabetes & Endocrinology*, Vol3; Issue 7: 514 – 525, May 2015.

Creating temporary G-codes to distinguish between stages 3a and 3b and between the three ranges of ACR would allow for CMS and other payers aligning with this model to have claims data information to support and oversee risk stratification and monitoring of CKD progression (see figure 3). We recognize this is a novel use of CPT codes, but would be helpful to providing administrative data that could be used by payers in oversight of this model and in providing technical assistance to model participants since CMS and many payers do not have automatic access to laboratory test results.

To develop the proper monthly/quarterly payment amounts additional research is needed to produce a methodology that drives incentives for participation while also not increasing health care costs. The National Kidney Foundation is interested in working with CMS further to determine the appropriate methodology. In determining payment amounts for the CPC+ initiative and OCM, an increase of 10% in total reimbursement above current fee-for-service was noted as necessary to incentivize participation. However, many PCPs are now participating in models in which they can increase their reimbursements and as we highlighted early CKD management is a component of population health management, just one that is acutely missed and requires additional work on behalf of the PCP. For those reasons we suggest a potential starting place for evaluating a payment methodology that begins with two approaches that build on the current fee for service structure and the existing CPC+ payment structure.

For practitioners participating only in Medicare fee-for-service or in shared savings models with no upfront payment structure CMS could consider using the baseline

amount of the Chronic Care Management Codes adjusted by a risk factor that is specific to CKD 3 – and indicative of their higher cost of care.

Figure 3

Albuminuria Categories		
A1 <30mg/g	A2 30mg/g – 299mg/g	A3 ≥ 300mg/g
G-XXXX	G-XXXX	G-XXXX

CKD Stage	ICD-10 Codes	Accompanied by G Code
Stage 1	N18.1	ACR 1-3: G-XXXX
Stage 2	N18.2	ACR 1-3: G-XXXX
Stage 3a	N18.3	3a: G-XXXX + ACR 1-3 G-XXXX
Stage 3b		3b: G-XXXX + ACR 1-3 G-XXXX
Stage 4	N18.4	ACR 1-3: G-XXXX
Stage 5	N18.5	ACR 1-3: G-XXXX
CKD unspecified	N18.9	ACR 1-3: G-XXXX

*G-XXXX illustrates placeholder for CPT code assignment.

For practices in CPC + we recommend evaluating adjusting the Care Management Fee by this CKD risk factor as well – CPC+ practices already have payment amounts adjusted by HCC, a model for which CKD 3 is no longer included. This would make up the monthly/quarterly payment amounts to participants and would be downward adjusted in future years if satisfactory performance on quality measures specific to CKD care was not achieved.

Participants who are not in a shared savings model or in CPC+ would be able to receive a bonus if costs are lower than a peer group (not participating in the mode) as long as satisfactory performance on quality measures were met.

Part 2, Payment for Nephrology Management of Advanced CKD: Is a tiered PMPM based on level of kidney function would be provided to nephrologists to lead a care team and conduct close management of patients. A PMPM would be higher for managing patients who have an eGFR less than 20 (Stage 4-5) than it would be for managing patients with an eGFR of less than 45 (Stage 3b) with ACR >300 or all patients with an eGFR between 30 and 20 (Stage 4) because additional effort is needed to prepare those who are progressing towards ESRD for renal replacement therapy.

In year 3 and beyond, bonus payments for quality and cost would be effective. Downside risk would also be delayed until year 3. This allows adequate time for nephrologists to implement care management strategies and achieve lower costs of care.

In addition, to working to determine proper payment and bonus amounts for both parts of the model. Additional methodology work is needed to determine how to evaluate whether the model resulted in reduced spending. One recommended approach is using peer based groups, not participating in the model, to identify whether lower costs resulted. This methodology is preferred over using historic data to show reduced spending because it allows for more current comparisons on costs and it doesn't necessarily result in diminished returns over the long run making it more sustainable. It also has the benefit of creating market competition among primary care practitioners and nephrologists.

We hypothesize that lower costs will result from reductions in hospitalizations, avoidance of comorbidities including acute kidney injury, and delaying progression, including delaying dialysis. For patients that do progress to ESRD, expected cost reductions will come from proper renal replacement therapy preparation such as advanced vascular access or Peritoneal Dialysis (PD) access placement, greater use of PD, and preemptive transplant. Earlier preparation for dialysis is expected to achieve reduced costs for those patients within the first 6 months of dialysis because of avoidance of a hospital dialysis start and avoidance of surgeries due to advanced placement and maturation of a fistula instead of the initial and temporary placement of a hemodialysis catheter – which also increases risks of blood stream infections. Additionally, because of the tight management this population will receive under this model we believe they will start dialysis with fewer comorbidities and in a much more stable state than what occurs today preventing hospital admissions and readmissions, which are high during the first several months of dialysis.

Model integration

Ideally payers would encourage participation of PCPs and nephrologists in the same geographic area to participate in the model collaboratively. However, there are significant quality improvements and savings that could be achieved in each part of this model can be realized by performance in either part of the model and for that reason we recommend that payers allow practitioners to participate in the model even if there is not a peer companion participating in the other part of the model. For example, PCPs can refer to nephrologists not participating in the model and nephrologists can participate without a referring PCP practice that is participating in the model. This also allows for greater patient choice in provider.

For practitioners participating in other innovation center models we recommend:

- The monthly/quarterly payments to PCPs for Part 1 of the model and the bonus payments should be excluded from shared savings calculations for PCPs also participating in ACOs for the duration of the model. This will

ensure there is not a disincentive for PCPs in those models, who are already equipped and focused on population health, to participate.

- Nephrologists participating in shared savings models would also continue to be able to participate in shared savings models, but could not receive both a bonus in CKDintercept and shared savings and would choose which financial incentive to receive.
- This model should not have any implication on participation in the Comprehensive ESRD Care initiative as this model is limited to the care of dialysis patients whereas the CKDintercept model intentionally does not address payment for caring for dialysis patients. Instead CKDintercept includes a focus on the easing patients transitions for patients who progress to ESRD to their treatment of choice.

Evidence for Quality Improvement and Cost Reductions

As stated 30 million Americans adults are estimated to have CKD. A number of pragmatic examples of various CKD population health management efforts implemented within individual integrated health systems (i.e. [Kaiser Permanente Hawaii](#)¹⁸, [Kaiser Permanente California](#), [Geisinger Health System](#)¹⁹, [Fresenius Medical Care](#)²⁰, [Dialysis Clinic Inc. \(DCI\)](#)²¹, [Hofstra Northshore-Long Island Medical](#)²², [Cleveland Clinic](#), have demonstrated the impact of proactive and integrated population health management (i.e. population segmentation and risk stratification via an electronic health record, clinical decision supports, etc.), that improves the collaboration between primary care and nephrology and facilitates transitions of care, as well as targeted CKD-specific patient education. However, there are few large-scale studies that have demonstrated the impact of a CKD population health model across local individual practices that actively involve primary care practitioners and payers. We highlight a couple of examples below to illustrate the potential impact the CKDintercept model could have on patient care.

- (1) Chronic Kidney Disease identification and risk stratification in a Patient-centered Medical Home (PCMH): CareFirst in collaboration with the National Kidney Foundation, preliminary results: After identifying that patients with a minimally abnormal serum creatinine value accounted for double the costs of those with normal creatinine values, CareFirst partnered with NKF to pilot a CKD detection and management program in 10 regions in the state of Maryland with 21 PCP panels and 128,000 patients participating in the CareFirst PCMH. After risk stratifying patients CareFirst identified 17% of the patients had CKD. Risk stratification allowed PCPs to identify the appropriate care plan for patients. CareFirst used classes of CKD that aligned with the KDOQI stages of CKD and

¹⁸ Lee B. et. al. Effects of proactive population-based nephrologist oversight on progression of chronic kidney disease: a retrospective control analysis. *BMC Health Services Research* (2012); 12:252.

¹⁹ Norfolk E, Hartle J. Nephrology Care in a Fully Integrated Care Model: Lessons from the Geisinger Health System. *Clinical Journal of the American Society of Nephrology* (2013); 10:2215.

²⁰ Lacson E, Wang W, et. al. Effects of a nationwide pre-dialysis educational program on modality choice, vascular access, and patient outcomes. *American Journal of Kidney Diseases* (2011); 58:235–242.

²¹ Johnson D, et. al. Going Upstream: Coordination to Improve CKD Care. *Seminars in Dialysis* (2016); 29(2):125-34.

²² Halinski C, Fishbane S. Improving outcomes in late-stage kidney disease: The Healthy Transitions program. *Nephrology News* (2014) Available online at <http://www.nephrologynews.com/improving-outcomes-in-late-stage-kidney-disease-the-healthy-transitions-program/>

the KDIGO guidelines to determine care plans (see figure 4). In comparing the CKD pilot population to their overall book of business, CareFirst saw a first-year cost reduction of \$54.61 PMPM due primarily to a reduction in hospitalizations.

While PCPs in the PCMH model did receive incentives in the form of shared savings – there was no penalty or risk for PCPs in the program. CareFirst is considering adoption of alternative payment models for nephrologists who partner with the PCMH program to manage advanced CKD patients.

Figure 4.

Class and Treatment Recommendations for CKD		
Class	Category	Treatment Recommendations
0	Needs Screening	Set up an appointment with the Member Order lab work: Albumin-to-creatinine ratio (ACR) Estimated Glomerular Filtration Rate (eGFR) Determine the Member's classification based on the lab values
1	Green	Provide Member education Schedule annual follow-up visits for regular kidney function testing Manage the underlying risk factors for CKD, such as diabetes and hypertension <i>In addition to:</i> Recommendations listed in Class 0
2	Yellow	Consider instituting automated appointments and testing reminders Consider a comprehensive medication review (CMR) Order the following services as necessary: Nutrition consultation Home based assessment (only if in an active care plan) Smoking cessation Diabetes education Enhanced monitoring (blood glucose, hypertension) Wellness/Disease Management <i>In addition to:</i> Recommendations listed in Class 1 and Class 0
3	Orange	Conduct Semi-annual kidney function screening Initiate a PCMH care plan Consider an Expert Consult Begin PCP-to-nephrologist consultations about the patient's status and collaborate on best practices Referral to nephrologists if the urine albumin to creatinine ratio (ACR) is severely increased <i>In addition to:</i> Recommendations listed in Class 2 , Class 1 and Class 0
4	Red	Kidney function screening three (3) times per year Refer Member to a nephrologist or a nephrology group Expect preferential appointments for these referrals and additional patient support programs (nutrition, emotional support, community resources) Use the LCC to coordinate communication with the nephrologist Collaborate with the nephrologist and Member to discuss kidney replacement preparation <i>In addition to:</i> Recommendations listed in Class 3 , Class 2 , Class 1 and Class 0
5	Brown	Kidney function screening four (4) times per year Work jointly with a nephrologist to manage the patient's care With nephrologist and Member, discuss peritoneal dialysis/home dialysis, hemodialysis access, and transplant options Establish kidney replacement access early to minimize the need for emergent dialysis access placement <i>In addition to:</i> Recommendations listed in Class 4 , Class 3 , Class 2 , Class 1 and Class 0
-	Gray	Needs Classification Review the medical record for lab values Determine the Member's classification based on the lab values

(2) Nephrology Care in a Fully Integrated Care Model: The Geisinger Health System, located in northern Pennsylvania has its own health insurance plan with 290,000 members and a fully integrated electronic health record (EHR) that connects over 60 community practice sites and 5 hospitals. The health system employed several innovations to improve the medical care for its kidney patient population. Geisinger embedded guideline-based clinical decision support in the EHR to facilitate better care coordination and management.

The EHR assisted PCPs in staying current with all guidelines, recalling the specific guidelines that are relevant to each patient, and acting on all relevant guidelines in an appropriate and timely manner. The results showed an increase from 3% to 14.3% among patients receiving CKD guideline concordant care from a PCPs over a three-year period.

Mining EHR data identified patients with CKD stage 4 or greater that had not been seen by the nephrology department to improve referral. A “Care Gap” nurse would submit an unsigned order to the PCP requesting nephrology consultation. When the PCP signed the order, the Care Gap nurse contacted patients to review and schedule the nephology visit. Results showed a decrease from 70% to 35% in the number of late referrals of CKD patients to nephrology. Late referral was defined as not seen by a nephrologist prior to start of dialysis or seen for the first time within 90 days of initiation of dialysis.

Anticipated Reductions in Cost

Since the CKDintercept payment model is an untested intervention we are unable to model actual cost savings. However, the potential for cost savings is illustrated in many publications and by the preliminary results we have seen with our CareFirst collaboration. Recently, a retrospective analysis of EHR data looked at the costs of CKD by stage across commercial and Medicare payers (*see figure 5*).²³ The study looked at the costs of care among patients with an ACEi or ARB prescription and presence of common comorbidities in CKD. This analysis shows the breakdown of costs by CKD stage and includes CKD based on laboratory data – eGFR or diagnosis code and healthcare utilization (medication, hospital inpatient admissions, outpatient care, and emergency department). The article concludes that opportunities to reduce costs include hospital readmissions, and management of comorbidities such as heart failure, diabetes, and hyperkalemia.

²³ Golestaneh, Ladan All-Cause Costs Increase Exponentially with Increased Chronic Kidney Disease Stage, AJMC, Vol. 23; No. 10, Sup. June 2017.

Figure 5.



CKD indicates chronic kidney disease; ED, emergency department; ESRD, end-stage renal disease; IP, inpatient; OP, outpatient; Rx, prescription.
 All Comparisons $P < .0001$. Total Costs and costs by service category have been rounded to the nearest dollar.

Quality and Cost

As outlined above this model is expected to both lower costs and improve quality and patient outcomes. Through reductions in hospitalizations across the CKD 3-5 population and optimal ESRD starts this model is expected to produce savings for all payers as highlighted above. The key drivers for increased costs are the upfront monthly PMPM payments to physicians for CKD management (which are offset by reductions in billing for office visits, evaluation and management, education sessions, medical nutrition therapy, and other fee for service items that would be considered a part of the PMPM and not separately billable), laboratory fees for CKD detection, and reductions in mortality. Savings is generated and quality improved through preventing adverse events

– hospitalizations, slowing CKD progression from one stage to the next, delaying progression to ESRD and need for renal replacement therapy (see Figure 6).

Figure 6.

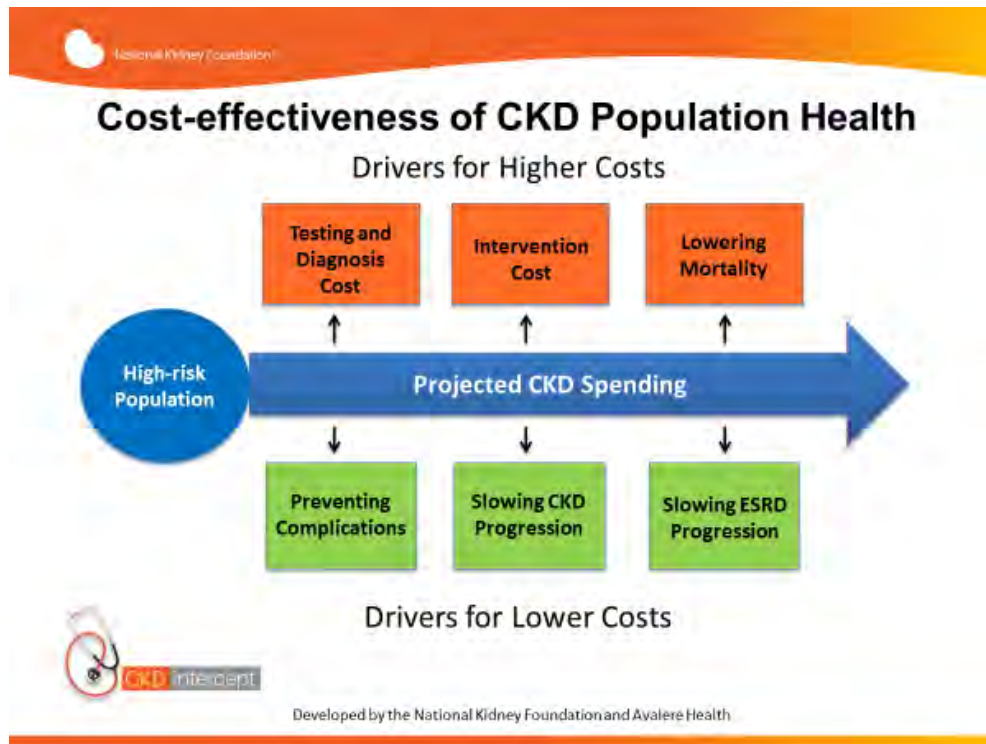


Figure 7 reflects the measures that practitioners participating in the CKDintercept model would be held accountable for. Measures currently not in MIPS are Counseling to Avoid NSAID Use in Patients with Reduced eGFR, Avoidance of Prescription NSAIDs in Patients with Reduced eGFR, Referral to Nephrology, and Diabetic Nephropathy screening. The three prior measures have been developed by the National Kidney Foundation and submitted for inclusion in MIPS in 2019. The Diabetic Nephropathy measure was developed and is used by the Indian Health Services (IHS). IHS does not plan to submit the measure for use in the MIPS program. The National Kidney Foundation recommends that CMS adopt and tailor the IHS Diabetic Nephropathy measure for use in MIPS and for this model. We are also pursuing potential collaboration with NCQA to refine the NCQA Diabetes Nephropathy measure to require eGFR and ACR testing in alignment with the IHS measure.

Benchmarks for these measure and structure for developing a total performance score for model participants still need to be established and the National Kidney Foundation hopes to work with CMS to establish this.

Data on progression of CKD should also be collected to help monitor time to progression across participants. This would help lead to a greater understanding of

which populations are most likely to progress and how various interventions deployed by practitioners in the model impact progression. With refinements in diagnostic coding that would need to occur in this model or with proper laboratory reporting CMS could monitor time to progression of patients participating in the model.

Figure 7.

Measures	Part 1, PCP	Part 2, Nephrology	Modifications suggested
Diabetic Nephropathy (developed and used by Indian Health Services)	Required	No	include requirement for second set of tests <90 days from the first eGFR and ACR if results are positive
Documentation of Current Medications in the Medical Record	Optional	Yes	
Medication Reconciliation Post-Discharge	Optional	Yes	
Counseling to Avoid Non-Steroidal Anti-Inflammatory Drug (NSAID) Use in Patients with Reduced eGFR (awaiting validity and reliability testing - see separate attachment)	Required	Yes	
Avoidance of prescription NSAIDs (awaiting validity and reliability testing - see separate attachment)	Required	No	
Adult Kidney Disease: Blood Pressure Management (< 140/90 mmHg OR ≥ 140/90 mmHg with a documented plan of care	Optional	Yes	
Care Plan (patients with an advanced care plan in place)	Optional	Yes	
Advanced Chronic Kidney Disease with proteinuria: percent of patients on angiotensin-converting enzyme (ACE) inhibitors or angiotensin II receptor blockers (ARBs)	Required	Yes	
Nephrology referral (awaiting validity and reliability testing - see separate attachment)	Required	No	
Adult Major Depressive Disorder (MDD): Coordination of Care of Patients with Specific Comorbid Conditions*	Optional	Yes	
Advanced chronic kidney disease (CKD): percent of patients with qualified nutritional counseling.	Required	No	
Advanced chronic kidney disease (CKD): percent of patients with documentation that education was provided.	No	Yes	Include end of life care education in the measure
Optimal End Stage Renal Disease Starts	No	Yes	

Attribution

The patient population for practitioners participating in Part 1 of the model would be attributed to the model based off the previous 24 months claims. If the patient had two or more claims billed by a participating practitioner and the plurality of primary care services delivered by that provider the patient would be automatically attributed to the

model. Attribution applies to the population at risk and in need of risk stratification as well as the population with CKD 3a and b qualifying for payment under this model.

For the nephrology practitioners participating in Part 2 of the model patients would be attributed to the model upon the second touch of the patient. The first touch is presumed to be a claim for an in-person office visit and the second touch could be a virtual meeting with the patient – for which a code would need to be established. This allows for patients to receive follow up consultations and care from the nephrologist using telehealth. Separate payment for telehealth services would not be provided to either party under this model.

Value over Volume

The CKDintercept model enhances care delivery by establishing a set of criteria that model participants would need to illustrate how they would address when applying to participate in the model. In addition, the model highlights what services would be considered in the model and not separately billable in fee for service. We believe the criteria outlines what is necessary to improve quality, lower costs, and enhance patient engagement while allowing participating practitioners flexibility in how they would address the criteria. Since we are proposing an upfront monthly payment to practitioners as opposed to a shared savings arrangement, we believe the initial investments by practices to meet the criteria will be recovered in a relatively short period of time. This approach is similar to what is used in the CPC+ model and the OCM.

Criteria and services for PCPs to include in the model (not separately payable)

- Medical nutrition therapy by a dietitian (live or virtual)
- All office visits for evaluation – including evaluation of common comorbidities (hypertension, hemoglobin a1c, bone and mineral disorder)
- Consultations with a nephrologist as needed including an option for telehealth consults
- 24/7 access to primary care team
- Access to pharmacists for medication questions
- Patient-centered care planning – addressing patient life goals, culture, and values
 - EHR patient portal with access to the patients care plan
- Care Management
 - longitudinal care annual evaluation
 - Hospital/Emergency Department discharge action
 - Medication reconciliation and medication management
- Referral to a nephrologist if ACR is severely increased or eGFR <30
- Care coordination with nephrologists, pharmacists, symptom assessment/reduction – palliative care
- Evaluation of community/social service needs, wellness and disease management services and linkages to such services
- Depression and anxiety assessment

Criteria and services for Nephrologists to include in the model (not separately payable)

Medical nutrition therapy by a dietitian (live or virtual)

- All office visits for evaluation – including evaluation of common comorbidities
 - Option for telehealth consultations with nephrology care team
 - 24/7 access to practitioner in nephrology care team
 - Access to pharmacists for medication questions
 - Patient-centered care planning – addressing patient life goals, culture, and values
 - EHR patient portal with access to the patients care plan
 - Care Management
 - Short-term episodic care and longitudinal care
- Hospital/Emergency Department discharge action
 - Medication reconciliation and medication management
 - Care coordination with PCPs, Specialists, Hospitals, Emergency Departments, Vascular access/PD access surgeons, transplant centers, dialysis clinics, hospice/palliative care, pharmacists
 - Live or virtual kidney disease education sessions that include modality education
 - Evaluation of community/social service needs and linkages to such services
 - Depression and anxiety assessment
 - Insurance navigation and coordination

CKDintercept a multi-payer model

Our intent to is to ensure the CKDintercept model is multi-payer allowing private payers to align with the model in order to maximize is impact on costs and quality. Since many of the current non-ESRD CKD population are not Medicare beneficiaries, maximizing reductions in costs to the government (via avoidance of ESRD and better preparation of ESRD) requires partnership with private payers and state Medicaid organizations.

Unintended consequences

There is some controversy around diagnosis of CKD in the age over 60 population. One school of thought is that kidney function declines as a part of normal aging and may not constitute a “disease” or indicate risk of progression to ESRD, while another perspective is that the increased risk of cardiovascular disease among anyone with reduced GFR warrants diagnosis and attention. There is also hesitancy among PCPs to tell patients with CKD that they have it because of the uncertainty around risk of progression and a desire to not burden their patients with a disease diagnosis that may not have any signs or symptoms for years to come.

Risk stratification using ACR results can help identify the patient population at highest risk of progression and cardiovascular events – those in need of most intensive management. The National Kidney Foundation, as did the members of the CKDintercept model workgroup, agreed that telling patients their CKD status was important information to their safety and lifestyle management. It allows patients to be empowered to avoid medications that are known to cause adverse events and to make

diet and lifestyle modifications that can reduce their risk of progression and cardiovascular events. Reporting ACR in alignment with the KDIGO/KDOQI guidelines in this model also allows practitioners the flexibility to tailor interventions according to risk, mitigating the concern of causing harm to patients in the form of additional stress and burden.

As with all models that hold providers accountable for cost and or utilization there is the unintended risk of underutilization/under treatment and avoidance of more complex patients. The attribution designs of the CKDintercept model along with tracking and oversight of patients leaving the model will help reduce this unintended consequence.

Patient Choice

Under this model participating providers would be required to notify and provide education to patients about the model and their chronic kidney disease status. We believe that educating rather than simply information patients about the model will help empower them as active participants in their care. Additionally, payments made to practitioners under this model should be made in full without beneficiaries being subjected to coinsurance as that would discourage participation. Patients would retain the flexibility to see any health care provider of their choice.

Education and Support

The National Kidney Foundation recognizes that payment changes alone will not be enough to drive practice improvements. Therefore, we are recommending that the Innovation Center also issue a request for proposals to external organizations who can assist and support practices in this model. Organizations could assist practices with integrating CKD into population health management, care coordination strategies, risk stratification, patient education and performance improvement strategies.

Process

This model was developed in consultation with a workgroup made up of multidisciplinary healthcare professionals and patients across the country who volunteered their time to provide direction and real-world expertise to arrive at this product. The workgroup members are acknowledged below.

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