Physician-Focused Payment Model Technical Advisory Committee
LOI: Environmental Scan and Relevant Literature

Renal Physicians Association
Letter Dated: 3/27/2017
Letter Received: 3/27/2017

The Renal Physicians Association (RPA) has more than 3,500 members that consist of nephrologists, physician assistants, nurse practitioners and practice managers. The first months for adult patients transitioning from Chronic Kidney Disease (CKD) to End-Stage Renal Disease (ESRD) therapies are associated with increased mortality and complication rates, frequent hospitalizations, and notably higher payer costs. RPA proposes a condition-specific, episode-of-care payment model, called the Clinical Episode Payment (CEP), that would span the first six months of dialysis therapy for established Medicare beneficiaries. This model focuses on incentivizing care to more consistently deliver optimal transitions from CKD to ESRD.

CEP is built upon existing infrastructures and utilizes the current Medicare Physician Fee Schedule. RPA anticipates that nephrologists and nephrology groups of all sizes, both in rural and urban areas, would be eligible participants in this CEP. The financial incentives or penalties would be determined in a reconciliation period following the episode of care and would constitute shared savings or shared losses when benchmarked against a risk-adjusted target cost. The CEP upside/downside risk option would allow participants to qualify under MACRA Advanced APM provisions. The only upside option of this APM model would be expected to "allow credit" to a participating physician under the MIPS Quality Payment Program.

RPA anticipates that the enhanced focus on care processes during this early period of dialysis therapies will result in measurable improvements in clinical quality outcomes, as well as a reduction in payer spending. Evidence-based outcomes will be utilized to ensure quality. An emphasis on hospital admission and re-admission avoidance, care coordination, home therapies, and expanded use of palliative care where appropriate will reduce payer spending. Avoiding the need for dialysis altogether by incentivizing pre-emptive and early renal transplantation would result in the "ultimate improved outcome." Per the letter of intent from RPA, currently there exists no financial incentive to encourage transplantation.

Key Search Terms

Bundled payment; chronic kidney disease; CMS; CKD; clinical evidence; ESRD; ESRD bundled payment; GAO; Medicare; MedPAC; payment models; payment policy; payment reform; outpatient dialysis; Renal Physicians Association, renal transplant; statistics; USRDS

Research Task	Section	Contents
Environmental Scan	Section 1	Key documents, timely reports, grey literature, and other materials gathered from internet searches (6).
Relevant Literature	Section 2	Relevant literature materials (4).
Related Literature	Section 3	Related literature materials (2).
References	Section 4	References to both relevant and related literature.

Section 1. Environmental Scan

Environmental Scan		
Key words: ESRD; CMS; payment models		
Organization	**Title**	**Date**
Center for Medicare & Medicaid Innovation (CMMI or the Innovation Center)	The Comprehensive ESRD Care (CEC) Model	Updated: 4/10/2017 Accessed: 4/14/2017
Purpose/Abstract		
Background: In 2013, the CMS Innovation Center (CMMI) announced it would test a new Comprehensive End-Stage Renal Disease (ESRD) Care (CEC) model. The goals of the model are to improve beneficiary health outcomes and reduce per capita Medicare expenditures. Through this new initiative, CMS partnered with groups of health care providers and suppliers – "ESRD Seamless Care Organizations" (ESCOs) – to test and evaluate a new model of payment and care delivery specific to Medicare beneficiaries with ESRD. The CEC Model began September 1, 2015, and will run until December 31, 2020. In 2016, CMS released a solicitation to add more ESCOs for Performance Year (PY) 2 of the model to start January 1, 2017. ***Summary:*** In the CEC Model, dialysis clinics, nephrologists and other providers join together to create an ESCO to coordinate care for matched beneficiaries. The matching process will use historical data on beneficiaries who are receiving care from participating providers. ESCOs are accountable for clinical quality outcomes and financial outcomes measured by Medicare Part A and B spending, including all spending on dialysis services for their aligned ESRD beneficiaries. The CEC Model includes separate financial arrangements for larger and smaller dialysis organizations. Large Dialysis Organizations (LDOs), which have 200 or more dialysis facilities, are eligible to receive shared savings payments. These LDOs are also liable for shared losses, and have higher overall levels of risk compared with their smaller counterparts. Non-large dialysis organizations (Non-LDOs), which includes chains with fewer than 200 dialysis facilities, independent dialysis facilities, and hospital-based dialysis facilities, have the option of participating in a one-sided track. These organizations are able to receive shared savings payments, but are not liable for payment of shared losses. The CEC Model LDO payment track and Non-LDO two-sided payment track are considered Advanced APMs for the purpose of the Quality Payment Program.		
Additional Notes/Comments		
The website linked above has additional links to other CEC model documents, such as the FAQs, fact sheets, attribution methodology, request for applications, and other archived materials.		

Environmental Scan

Key words: ESRD; CMS; payment models

Organization	Title	Date
Centers for Medicare & Medicaid Services (CMS)	ESRD Quality Incentive Program	Last modified: 1/11/2017 Accessed: 4/14/2017

Purpose/Abstract

Background: The Centers for Medicare & Medicaid Services (CMS) administers the End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP) to promote high-quality services in outpatient dialysis facilities treating patients with ESRD. Under this "pay-for-performance" or "value-based purchasing" (VBP) program, CMS pays for the treatment of ESRD patients by linking a portion of payment directly to facilities' performance on quality care measures.

Summary: The ESRD QIP will reduce payments to ESRD facilities that do not meet or exceed certain performance standards. The maximum payment reduction CMS can apply to any facility is two percent. This reduction will apply to all payments for services performed by the facility receiving the reduction during the applicable payment year. CMS publicly reports facility ESRD QIP scores; these scores are available online on the Dialysis Facility Compare website. In addition, each facility is required to display a "Performance Score Certificate" that lists its "Total Performance Score," as well as its performance on each of the quality measures identified for that year.

Additional Notes/Comments

The website linked above has links to additional ESRD QIP Resources, such as FAQs, status of the program, how the program affects patients and dialysis centers, technical specifications for ESRD QIP measures, monitoring and evaluation, and educational resources, among other program details.

Environmental Scan

Key words: Care coordination; CKD; Medicare

Journal	Title	Date
Seminars in Dialysis	Going Upstream: Coordination to Improve CKD Care	3/2016

Purpose/Abstract

Background: Care coordination for patients with chronic kidney disease has been shown to be effective in improving outcomes and reducing costs. However, few patients with CKD benefit from this systematic management of their kidney disease and other medical conditions. As a result, outcomes for patients with kidney disease are not optimal, and their cost of care is increased. For those patients who transition to kidney failure treatment in the United States, the transition does not go as well as it could. The effectiveness of treatments to delay progression of kidney disease in contemporary clinical practice does not match the efficacy of these treatments in clinical trials. Conservative care for kidney disease, which should be an option for patients who are very old and very sick, is not considered often enough or seriously enough. Opportunities for early and even pre-emptive transplantation are missed, as are opportunities for home dialysis. The process of dialysis access creation is rarely optimal. The consequence is care which is not as good as it could be, and much more expensive than it should be.

Summary: Authors describe their initial efforts to implement care coordination for chronic kidney disease in routine clinical care and attempt to project some of the benefits to patients and the cost savings. They discuss potential clinical and financial benefits from slowing progression of CKD, cost savings from decreasing cost of care with each CKD stage, comprehensive conservation care and the cost savings, and increasing access to transplantation and the cost savings. Additionally, the clinical and financial benefits of the delay of dialysis, increasing access to home dialysis, increasing access to dialysis with a permanent access, preferably a fistula, and avoiding hospitalization for first dialysis treatments.

Additional Notes/Comments

Environmental Scan

Key words: Renal Physicians Association

Organization	Title	Date
Renal Physicians Association (RPA)	RPA Public Comment RE: CMS-5517-FC: Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models; Final Rule With Comment Period	12/19/2016

Purpose/Abstract

Background: RPA acts as the national representative for physicians engaged in the study and management of patients with kidney disease. RPA provided comments on selected portions of the Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Final Rule.

Summary: RPA's comments focused on the following issues: (1) impact of 'pick your pace' on MIPS implementation; attribution and nephrology; (2) proposed elimination of the specialty-specific risk adjustor; (3) reduction of administrative burden for advancing care information; and (4) the development of quality measures as part of Qualified Clinical Data Registries (QCDRs). RPA states that the varying and unique characteristics of the kidney disease patient population and kidney care delivery (e.g., numerous comorbidities and polypharmacy issues, partially capitated payment structure for care predominantly provided in a bundled care environment) call for the design of an advanced care delivery model that will achieve optimal quality outcomes and Medicare program cost-savings.

Additional Notes/Comments

Environmental Scan

Key words: GAO; ESRD; payment reform

Organization	Title	Date
Government Accountability Organization (GAO)	END-STAGE RENAL DISEASE: Medicare Payment Refinements Could Promote Increased Use of Home Dialysis	10/2015

Purpose/Abstract

Background: In 2013, Medicare spent about $11.7 billion on dialysis care for about 376,000 Medicare patients with end-stage renal disease, a condition of permanent kidney failure. Some of these patients performed dialysis at home, and such patients may have increased autonomy and health-related quality of life. GAO was asked to study Medicare patients' use of home dialysis and key factors affecting its use.

Summary: This report examines: (1) trends in home dialysis use and estimates the potential for wider use, (2) incentives for home dialysis associated with Medicare payments to dialysis facilities, and (3) incentives for home dialysis associated with Medicare payments to physicians. GAO reviewed CMS' policies and relevant laws and regulations, and GAO analyzed data from CMS (2010-2015), the United States Renal Data System (1988-2012), and Medicare cost reports (2012), the most recent years with complete data available. GAO also interviewed CMS officials, selected dialysis facility chains, physician and patient associations, and experts on home dialysis**.** GAO recommends that CMS: (1) take steps to improve the reliability of the cost report data; (2) examine and, if necessary, revise policies for paying physicians to manage the care of dialysis patients; and (3) examine and, if appropriate, seek legislation to revise the Kidney Disease Education (KDE) benefit. HHS concurred with the first two recommendations but did not concur with the third.

Additional Notes/Comments

GAO Highlights page https://www.gao.gov/products/GAO-16-125

Environmental Scan

Key words: Nephrology care model; CKD; Geisinger Health

Journal	Title	Date
Seminars in Dialysis	Nephrology Care in a Fully Integrated Care Model: Lessons from the Geisinger Health System	4/2013

Purpose/Abstract

Background: At this time, there is a clear understanding of the need for healthcare reform in our country. The key stakeholders—patients, physicians, health insurers, and the federal government—recognize that changes are needed to improve the quality of care and to contain the cost of care. Re-designing the current healthcare delivery system to one with a greater emphasis on coordination of care may have a major effect on the quality of care. With >25 million adults in the United States having CKD, and with CKD and ESRD accounting for approximately 10% of the annual Medicare expenditure, improvement in the care of nephrology patients is a high area of focus by many entities. An integrated health care system, in part by enhancing coordination of care, may provide opportunities to improve the medical care in this highly complex patient population.
Summary: This article summarizes some of the innovations in care for the nephrology patient population that have occurred in the Geisinger Health Systems, as well as other integrated health care systems. Anemia constitutes an important and costly component of CKD management. The article discusses a protocol-driven, pharmacist-managed anemia program responsible for the administration of an erythropoietin stimulating agent (ESA) and iron products in all CKD patients in the department. Additionally, the article walks through three steps for managing the CKD population, (1) the Geisinger's ProvenHealth Navigator, (2) specialty-specific care management, and (3) reporting structure and additional management strategies.

Additional Notes/Comments

Section 2. Relevant Literature

Relevant Literature		
Key words: ESRD; Medicare; payment methods; bundled payment		
Journal	**Title**	**Date**
BMC Nephrology	Comparative changes in treatment practices and clinical outcomes following implementation of a prospective payment system: the STEPPS study	5/1/2015
Purpose/Abstract		
Background: The aim of the US dialysis Prospective Payment System bundle, launched in January 2011, was reduction and more accurate prediction of costs of services, whilst maintaining or improving patient care. Dialysis facilities could either adopt the bundle completely (100%) in the first year of launch, or phase-in (25%) over four years. Differences in practice patterns and patient outcomes were hypothesized to occur in facilities that phased-in 25% compared to those that adopted the bundle completely at 100%. ***Objective:*** To describe trends in dialytic treatment before and after implementation of the expanded bundle in a representative sample of small dialysis organizations (SDOs). ***Methods:*** Data are from the Study to Evaluate the Prospective Payment System Impact on Small Dialysis Organizations (STEPPS), a multi-center prospective observational cohort study of patients receiving care in 51 small dialysis organization facilities designed to describe trends in dialytic treatment before and after bundle implementation. Facility- and patient-level data were collected at enrollment and regularly thereafter. Cox proportional hazards and linear multi-level models were used to estimate the effect of opting-in 25% (vs. 100%) on practice patterns and clinical outcomes. ***Results:*** Twelve facilities (patient n = 346) opted to phase into the bundle and 37 facilities (patient n = 1296) opted to completely adopt the bundle. The study found that patients in facilities that had completely adopted the bundle received lower monthly epoetin alfa (EPO) doses, and had lower mean hemoglobin concentrations; hospitalization and mortality rates were numerically lower in facilities that chose to phase into the bundle. However, these results were not statistically significant. ***Conclusions:*** The economic pressure for dialysis providers to work within an expanded composite rate bundle whilst maintaining patient care may be a driver of practice indicator outcomes. Additional investigations are warranted to more precisely estimate clinical outcomes in patients attending facilities enrolling into the bundle 100% relative to the previous fee-for-service framework.		
Additional Notes/Comments		

Relevant Literature

Key words: ESRD; payment policy; Medicare; bundled payments

Journal	Title	Date
Health Policy	What can we learn from the U.S. expanded end-stage renal disease bundle?	5/2013

Purpose/Abstract

Background: Episode-based payment, commonly referred to as bundled payment, has emerged as a key component of U.S. health care payment reform. Bundled payments are appealing as they share the financial risk of treating patients between payers and providers, encouraging the delivery of cost-effective care. A closely watched example is the U.S. End Stage Renal Disease (ESRD) Prospective Payment System, known as the 'expanded ESRD bundle.'
Purpose: In this paper, the authors provide insight into the expanded ESRD bundle 2 years after its implementation.
Summary: First, authors discuss emerging lessons, including how implementation has changed dialysis care with respect to the use of erythropoietin stimulating agents, how implementation has led to an increase in the use of home-based peritoneal dialysis, and how it may have contributed to the market consolidation of dialysis providers. Second, authors use the expanded ESRD bundle to illustrate the importance of accounting for stakeholder input and staging policy implementation. Third, authors highlight the need to consider system-wide consequences of implementing bundled payment policies. Fourth, authors suggest how bundled payments may create research opportunities.
Conclusions: Bundled payment policies offer opportunities and challenges. Their success will be determined not only by impacts on cost containment, but also on whether or not they encourage high quality care.

Additional Notes/Comments

Relevant Literature

Key words: Medicare, ESRD, payment policy

Journal	Title	Date
Health Affairs	Medicare's Payment Strategy for End-Stage Renal Disease Now Embraces Bundled Payment and Pay-For-Performance to Cut Costs	9/2012

Purpose/Abstract

Background: Medicare has provided health insurance coverage to all people who have been diagnosed with end-stage renal disease (ESRD), or kidney failure since 1973. In this paper, the authors review ESRD payment policies and trace the history of payment policies in Medicare's dialysis program from 1973 to 2011, while also providing some insight into the rationale for changes made over time. The authors discuss the program's early years (1973-82), introduction of the composite rate (1983-89) and the Erythropoiesis stimulating agents and payment reforms (1989-2006), and the recent pay-for-performance initiatives.

Findings: The authors remain uncertain whether bundling of dialysis payments can stem the increase in the total cost of dialysis to Medicare. Additionally, authors were also uncertain whether the consequences of bundling dialysis payments could inform implementation of bundled payments in other clinical contexts, since bundling is unique in that there is only a single provider affected by bundling.

Conclusions: Payment reform in other areas of Medicare may have implications for the costs of end-stage renal disease. To the extent that screening identifies patients earlier, it may help reduce the number of patients with diabetes who progress to end-stage renal disease. Improving the screening and management of chronic conditions that predispose patients to end-stage renal disease may be a particularly successful strategy in stemming the growth in costs.

Additional Notes/Comments

Relevant Literature

Key words: Medicare cost savings; dialysis

Journal	Title	Date
American Journal of Nephrology	Timing of Arteriovenous Fistula Placement and Medicare Costs during Dialysis Initiation	5/11/2012

Purpose/Abstract

Background/Aims: Arteriovenous fistulas (AVFs) appear to be clinically superior to catheters as vascular access for maintenance hemodialysis, but higher insertion costs and high disease burden and mortality obscure the issue of whether AVF placement before hemodialysis initiation represents a net cost savings. We aimed to investigate Medicare costs for patients beginning maintenance hemodialysis, as related to the timing of AVF placement.

Methods: Data were from Medicare claims for incident hemodialysis patients aged ≥67 years in 2006. The study period extended from 2 years before to 1 year after dialysis initiation. Patients identified as having AVFs were categorized by timing of placement (mature AVF at dialysis initiation, maturing AVF at initiation, post initiation AVF placement). Because timing may be influenced by factors that also influence overall costs, the model accounted for this nonrandom treatment assignment. An ordered probit extension of the classic Heckman correction was employed after identifying an appropriate instrumental variable. A cohort with Medicare coverage before and after dialysis initiation was identified, and Medicare claims were used to identify comorbid conditions and treatment costs.

Results: Principal findings are that earlier AVF placement leads to lower costs, with the potential for about USD 500 million in savings. Additionally, the effect of nonrandom treatment assignment is real and significant. In our data, the impact of AVF placement timing was understated when treatment selection was ignored.

Conclusion: For appropriate AVF candidates, having a mature AVF in place at the time of dialysis initiation appears to confer cost savings.

Additional Notes/Comments

Section 3. Related Literature

Related Literature		
Key words: ESRD; bundled payment; Medicare		
Journal	**Title**	**Date**
Health Services Research	Effect of Medicare Dialysis Payment Reform on Use of Erythropoiesis Stimulating Agents	10/30/2014
Purpose/Abstract		
Objective: In 2011, the Centers for Medicare & Medicaid Services (CMS) replaced fee-for-service reimbursement for erythropoiesis stimulating agents (ESAs) with a fixed-sum bundled payment for all dialysis-related care and pay-for-performance incentives to discourage maintaining patients' hematocrits above 36 percent. Authors examined the impact of the new payment policy on the use of ESAs. ***Data Sources and Extraction:*** CMS's Renal Information Management System. Secondary data from 424,163 patients receiving hemodialysis treatment between January 2009 and June 2011. ***Study Design:*** Regression discontinuity design assessing the use of ESAs by hematocrit level before and after the implementation of the payment policy change. ***Principal Findings:*** The introduction of bundled payments with pay-for-performance initiatives was associated with an immediate and substantial decline in the use of ESAs among patients with hematocrit >36 percent and little change in the use of ESAs among patients with hematocrit ≤36 percent. In the first two quarters of 2011, the use of ESAs during dialysis fell by about 7–9 percentage points among patients with hematocrit levels >36 percent. No statistically significant differences in ESA use were observed at the thresholds of 30 or 33 percent. ***Conclusion:*** CMS' payment reform for dialysis care reduced the use of ESAs in patients who may not benefit from these agents.		
Additional Notes/Comments		

Related Literature

Key words: Dialysis treatment; ESRD; comorbidity; alternative care

Journal	Title	Date
Clinical Journal of the American Society of Nephrology (CJASN)	Is Maximum Conservative Management an Equivalent Treatment Option to Dialysis for Elderly Patients with Significant Comorbid Disease?	10/2009

Purpose/Abstract

Background: There is ongoing growth of elderly populations with ESRD in Western Europe and North America. In [UCL Center for Nephrology, Royal Free and University College Medical School], they offer an alternative care pathway of 'maximum conservative management' (MCM) to patients who elect not to start dialysis, often because of a heavy burden of comorbid illness and advanced age. The objective of our study was to compare clinical outcomes for patients who had ESRD and chose either MCM or renal replacement therapy (RRT).

Design, Setting, Participants, & Measurements: This is an observational study of a single-center cohort in the United Kingdom that evaluated 202 elderly (> or =70 yr) patients who had ESRD and had chosen either MCM (n = 29) or RRT (n = 173). We report survival, hospitalization rates, and location of death for this cohort. Survival was measured from a standardized 'threshold' estimated GFR of 10.8 ml/min per 1.73 m(2).

Results: Median survival, including the first 90 d, was 37.8 mo (range 0 to 106 mo) for RRT patients and 13.9 mo (range 2 to 44) for MCM patients (P < 0.01). RRT patients had higher rates of hospitalization (0.069 [95% confidence interval (CI) 0.068 to 0.070]) versus 0.043 [95% CI 0.040 to 0.047] hospital days/patient-days survived) compared with MCM patients. MCM patients were significantly more likely to die at home or in a hospice (odds ratio 4.15; 95% CI 1.67 to 10.25). A survey of the literature describing elderly ESRD outcomes is also presented.

Conclusion: Dialysis prolongs survival for elderly patients who have ESRD with significant comorbidity by approximately 2 yr; however, patients who choose MCM can survive a substantial length of time, achieving similar numbers of hospital-free days to patients who choose hemodialysis.

Additional Notes/Comments

Section 4. References

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PHYSICIAN-FOCUSED PAYMENT MODEL TECHNICAL ADVISORY COMMITTEE (PTAC)

PRELIMINARY REVIEW TEAM (PRT)

CONFERENCE CALL

INCIDENT END-STAGE RENAL DISEASE (ESRD) CLINICAL EPISODE PAYMENT MODEL

SUBMITTED BY RENAL PHYSICIANS ASSOCIATION (RPA)

Wednesday, September 20, 2017
10:30 a.m.

PRESENT:

JEFFREY W. BAILET, MD, PTAC Committee Member
PAUL N. CASALE, MD, MPH, PTAC Committee Member
HAROLD D. MILLER, PTAC Committee Member

SIDDHARTH P. SHAH, MD, Associate Professor of Clinical Medicine, Perelman School of Medicine, University of Pennsylvania

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ADELE SHARTZER, PhD, Urban Institute
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P R O C E E D I N G S

[10:31 a.m.]

DR. CASALE: Hi. Thanks for joining. This is Paul Casale. I'm one of the members of PTAC, and I'm leading this particular review team. And, also on the call is -- well, Harold, do you want to just say hi, since you're there, and then Jeff?

MR. MILLER: Hi. This is Harold. I'm Harold Miller. I'm from the Center for Healthcare Quality and Payment Reform, and I am also a member of this, under Paul's excellent leadership.

DR. SHAH: Thanks.

DR. BAILET: Hi, Dr. Shah. This is Jeff Bailet. I am currently the executive vice president of Health Care Quality and Affordability with Blue Shield of California. I'm an ENT (ear, nose, and throat) surgeon and very happy that you have agreed to participate on the call today to help us.

DR. SHAH: Thank you.

DR. CASALE: Great. And then we have staff from ASPE.

Adele, do you want to just introduce

yourself and just say who else is there?

DR. SHARTZER: Sure. My name's Adele Shartzer, and I'm an Urban Institute employee and a former ASPE staffer who has been pulled in to kind of help staff this PRT. So I'm listening in and kind of taking notes, and I'll try to only pipe in when needed and let the PRT members really do -- drive the discussion.

And Sarah Selenich is here.

MS. SELENICH: Yes. Hi. I'm Sarah Selenich. I work at ASPE, and I think Mary Ellen Stahlman, the PTAC staff director, will be joining shortly as well.

DR. CASALE: Great. And did someone just join?

DR. PAGAN-SUTTON: Yes, Paul. This is Janet Sutton.

MS. SELENICH: Hi, Janet.

DR. PAGAN-SUTTON: Hi. How are you?

DR. CASALE: So, Dr. Shah, they probably told you, but the conversation's transcribed, and just -- so -- just so you know, and sometimes the transcriptionist may ask who made a comment in case there's any confusion.

DR. SHAH: Okay, no problem.

DR. CASALE: Good. So before we get started, if I could just ask you a question, because it was asked of me, because this -- this proposal has come from RPA, and apparently, you're a member of RPA. I didn't think that was necessarily going to be an issue, but I just thought I'd -- before we get started -- did you see any conflict with you being a member of RPA and this being --

DR. SHAH: I personally do not see a conflict. I mean, I'm -- I'm really just a -- I'm a member in payment mostly that I -- you know, it's part of my -- one of the professional societies that I -- that I'm part of, but I have not contributed to this proposal and do not have any financial stake in it whatsoever.

DR. CASALE: Yeah. Okay, great. Well, thanks for clarifying. None of us thought there was, but just to clarify.

So I know Adele, I think, has sent you a list of some of the questions after -- so -- sorry. I should go back. So the initial process was, just so you know, we have a -- the PTAC, which is 11

members, there is a Preliminary Review Team (PRT) for each proposal, and Harold, Jeff, and I are the PRT team, and so we met by phone to kind of go through the proposal, and it generated discussion amongst us and some questions about it. And we thought it would be very helpful to meet with -- with you and then sort of work through these questions, and we may have some additional ones to get your -- your views on it.

So I don't know if you just want to start with the first question and give us your thoughts?

DR. SHAH: Sure.

DR. BAILET: Paul? Paul, this is Jeff.

I think for the purposes of the transcriptionist, we probably should read each question --

DR. CASALE: Yep.

DR. BAILET: -- so that we're clear --

DR. CASALE: Yep.

DR. BAILET: -- on the record. That would be helpful.

DR. CASALE: Thanks, Jeff.

Yeah. So the first one was, At what point in the disease progression, generally, does a

nephrologist see a patient with CKD (chronic kidney disease)?

And, again, in the -- in the model, as you know, the -- the triggering event is related to dialysis, so -- but the question was, How long is the -- you know, when -- when generally will a nephrologist get involved in seeing a patient with CKD?

DR. SHAH: Yeah, sure. So this is an area of substantial heterogeneity. Really, it depends on when a referral is made to the nephrologist by the primary care physician or another specialist or -- or if CKD is, you know -- is identified during a hospital admission and then makes it out to a nephrologist then. So it -- it's highly variable.

And I think that our initial point of contact with patients with CKD has ranged from very early in the course of disease, like Stage 1 CKD, where somebody has what -- you know, what's called "microalbuminuria." So let's say that they're a diabetic patient who's being watched very closely by their primary care [unintelligible] -- primary care provider and they develop some small amount of protein in the urine. They might make it to see us

early versus we have some patients who we meet for the first time when they already have Stage 5 disease. And so, you know, ideally, we would meet people, you know, as early as possible when there's time to intervene and, frankly, when there's kidney tissue to save, but it's a broad range of when we meet them.

DR. CASALE: Okay. So -- and I think the second question sort of follows up in terms of the -- What's the patient flow, I know it can be variable from CKD to ESRD (end-stage renal disease), and how much involvement do nephrologists have in the process prior to dialysis?

And this relates to, you know, is there ample time to educate patients and family members about treatment options, you know, to schedule fistula or graft placement or other care management activities.

DR. SHAH: Sure.

DR. CASALE: Yeah.

DR. SHAH: Yeah. So, I mean, to some extent, the flow will depend on when they are referred to us, right, so how -- how much time do we have to work with them prior to dialysis

initiation.

But, in general, if we have -- you know, if we have the opportunity to meet them at, let's say, Stage 3 disease, what we would do is -- our normal flow is that we would use every visit as an opportunity to educate the patients about their -- about their kidneys and their disease, and in that way, we would build their base of knowledge about modalities, access, transplant, diet, et cetera.

And in our practice, we generally refer patients to a formal CKD education class when they hit Stage 3 disease. So in this class, as part of the flow, they learn about CKD. They learn more about modalities and transplants and access, and they do this in a group setting, so they can hear each other's questions as well and -- and then sort of downstream from there, if they choose hemodialysis as their modality, we will generally refer them for an access evaluation when their estimated GFR (glomerular filtration rate) is approximately 20.

There is some variation to this rule based on the trajectory. So, for example, if someone has very slowly progressive disease and is unlikely to

be on dialysis for years, even when their GFR hits 20, then you might delay access planning a bit.

But, if not, if they follow along a more routine trajectory, then about 20 is when we refer for access.

As far as transplant, it's a similar time frame. So we -- we refer for transplant evaluation when their eGFR (estimated glomerular filtration rate) is about 20.

And so in order to really educate patients sufficiently and earn their trust and give them time to digest what they're hearing and, you know, sometimes even go through the stages of grief about their diagnosis, you really need -- you need time, and so, you know, we need to meet them early enough to do all of this upstream work.

And if -- if the patient doesn't make it to us until they have Stage 4 or 5 disease, then we don't always have enough time to do all the things we would like to do, like this.

MR. MILLER: So this is Harold.

Let me dig into sort of this and the previous question a little bit. So just to sort of -- I mean, this is not intended to be a

scientifically, statistically accurate question, but roughly, what proportion would you say of patients end up starting dialysis without having -- really had any kind of nephrology care before that?

DR. SHAH: That's a good question.

MR. MILLER: I mean, just give me order of magnitude, right? I mean, so is -- is it 1 percent, 10 percent, 40 percent? You know, what would -- what would your sort of gut reaction be?

DR. SHAH: Yeah. My gut reaction is probably -- probably closer to 40 percent.

MR. MILLER: Forty percent.

DR. SHAH: Too many.

DR. BAILET: Harold? Harold?

MR. MILLER: Yeah.

DR. BAILET: This is Jeff.

I think it's important for this -- I want to just have a follow-on question about the 40 percent. Does that usually emanate from patients who are -- are hospitalized, potentially related to their kidney disease or unknown sequelae, but found out that they're sick enough to require going on dialysis at that time, and so they didn't have the luxury of getting a nephrology -- sort of get in

the nephrology pipeline?

DR. SHAH: So that would be a subset of the 40 percent, you know, people who -- let's call it, "crash and burn" and then need to start dialysis imminently, and therefore, there is no opportunity to educate them.

And then another, you know, subset of that 40 percent is people who just present late in the game, so not yet on dialysis and not imminent in, say -- let's say days or weeks, but who might at their initial contact with a nephrologist have stage -- late Stage 4 or early Stage 5 disease, where again, that their -- you can try to get education to happen, but again, you have to keep in mind that -- that the patient, when they first hear of this diagnosis, especially if it's late stage, they're not always ready for education.

They have -- there's -- many patients go through a grief period of -- to some extent even being in denial about the diagnosis before they can even accept education. So even at a major academic center where I am, where we have really robust programs, you know, I have a portion of patients who refuse to go to the class because they're, “not

ready."

MR. MILLER: Well, I was going to ask as a follow-up -- so of the people who were kind of, you know, showing up, showing up with no prior nephrology interaction -- and again, these are just sort of gut reactions -- I'm just trying to get a picture of what some of the potential flows would be here from your experience, but -- so how -- how many of those patients do you think really might have been known to someone as having kidney disease but were, in fact, ignoring it, either because they didn't want to confront the fact that they had it, they didn't want to pay an extra copay to go to a nephrologist, et cetera, and how many of them -- you know, so they were -- they were kind of in the system, and -- and some kind of better outreach might have been able to have gotten them involved earlier? But, we've got a structure of a payment system today that doesn't really encourage that kind of proactive outreach, versus patients who may, you know, have no primary care physician, who may have -- you know, are just completely ignoring their health, and all of a sudden only -- as Jeff was describing, sort of, you know, only have to

confront this when they end up in the hospital.

DR. SHAH: That's a good question. I think that the portion of -- the second group you described, who -- who just ignored their health or didn't see a doctor, there is that subset, but it's relatively small. And I would say the majority of patients that we see have had some contact with a health care system or provider earlier in their life, whether it was in a hospital, in an ED (emergency department), through a primary care, or through another specialist, some contact somewhere in their pipeline earlier, but again, people's trigger levels for consulting a nephrologist are quite heterogeneous.

And so a creatinine of 1.5 might not raise any eyebrows for Dr. A, but it might raise eyebrows for Dr. B. And so, you know, to some extent, there is a lot of heterogeneity in the system for potential points of referral.

MR. MILLER: And then, I guess, just as a follow-up to that, to what extent do you think that primary care physicians are trying to be the manager of Stage 3 and particularly Stage 4 CKD because of whatever? I mean, at one extreme, you

know, "Hey, PCPs (primary care physicians) can do everything. What do we need a nephrologist for?" a concern that the patient simply won't go to see specialty support, and so the PCP is trying to manage it, because I'm -- I'm now trying to distinguish the -- we've been asking when do they see a nephrologist? I'm sort of wondering. So what proportion of patients were actually being managed by a primary care physician up to this point? And -- well, anyway, so what's your thoughts about that?

DR. SHAH: You know, I think it's -- it depends on where in the country you're looking at it. It depends on academic medical center versus, you know, rural setting and so on, but you're right. There's a -- there's a proportion of internists who feel like they can and should manage CKD up until a certain point and then refer to a nephrologist, whereas -- like I can give you my institutional bias here. So I'm on the East Coast. I'm at a major academic center.

MR. MILLER: Mm-hmm.

DR. SHAH: And here, the tone is very different. So we get -- we get earlier referrals

here. So if our primary -- if our internal medicine, you know, primary care group identify a disease, they generally refer it to us early because they -- they know that we, A, want that and, B, that there is value to that, and so it really depends on what institution you're at, what part of the country you're in, and other things in terms of how much the internists hold on versus let go, so to speak.

MR. MILLER: So if I'm in a rural area, you know, and I'm going to the rural health clinic, there's no nephrologist anywhere nearby, one might well see those -- those primary care physicians trying to do what they can because they figure it's a travel burden. It's a cost burden. It's likely to be something that the patient will resist.

And we might actually see, if you looked across the country, more patients being managed, but by -- managed by a primary care physician further along the CKD progression than we would see in areas where you're right down the street from, you know, a dozen nephrologists.

DR. SHAH: That's right.

MR. MILLER: Okay. So -- I mean, one --

because one thing to think about in all these models, I think, is this is a specialty model, which is fine, and you're sort of getting it at the -- the specialist is the one who really has to do what they're talking about doing, but they have this concept that there's an upstream activity. And one of the things that's a little perplexing about the model is that it starts at dialysis, but it's supposed to be involving things that happen before dialysis starts, you know. So it's kind of an interesting question -- is, well -- Who is it that's supposed to be doing that, and when are they supposed to be doing it?

And this is presuming that the nephrologist is doing that, but there may well be some significant number of cases where it's actually a primary care physician who would be either the only or the more logical person to be doing at least some of that ahead of time. And does that make sense to you?

DR. SHAH: Yes. That's exactly right. That was one of my -- my own observations about this proposal when I read it is, you know, for what the goals are in terms of, you know, a lot of the

upstream work, as you said, it may be either a primary care physician, or frankly, it may also be another nephrologist who needs to be incentivized and not the nephrologist who's involved --

MR. MILLER: Mm-hmm.

DR. SHAH: -- from month zero to six about -- you know, that -- I'll just take a second of your time and say that what really stood out to me in this proposal was, you know, if you're talking about a reimbursement model for the nephrologist who cares for the person on dialysis from month zero to six, but a different nephrologist was caring for them before that, who is being incentivized to do what?

MR. MILLER: Well, elaborate on that a bit in terms of how often and when does that happen?

DR. SHAH: So, it's very different in the community versus in the cities and in the academics, but I'll say that in a private practice in the community, I think that it's often the same nephrologist that sees the patient pre- and post-dialysis.

MR. MILLER: Okay.

DR. SHAH: But, in a major -- major urban

environments and in academic centers, it's -- it's quite often that the nephrologist that was caring for the patient pre-dialysis is not the nephrologist caring for them post-dialysis.

MR. MILLER: And is that a subspecialty kind of an issue?

DR. SHAH: No. It's actually more of a geographic issue. So --

MR. MILLER: Okay.

DR. SHAH: -- for example, I have patients who come to see me from, you know, probably at least a two-and-a-half-hour radius, and they'll see me for their chronic kidney disease. And they'll drive that distance to do it because that's, you know, what they want. And then when the time comes for them to start dialysis, they'll usually do that more locally to where they live.

MR. MILLER: Oh, okay.

DR. SHAH: Yeah. I think --

MR. MILLER: This is more -- this is more related to the -- the frequency of the interaction. "I'm willing to go three hours to see somebody who I think is really good and trying to help keep me well, but once I'm at the point where I have to get

dialysis, it's local, so I got to have somebody local."

DR. SHAH: Right. And that's an extreme example, but I can -- you know, even on a smaller scale, I have people who come from one part of the city, to my part of the city, and that may be, at most, a half an hour of travel time, which they're willing to do during CKD. But when it comes to dialysis, then they go to a center that's a block from their house.

MR. MILLER: Well, I didn't mean to limit it to the three hours.

DR. SHAH: Yes.

MR. MILLER: But I'm just saying that people might make -- might make a more extreme -- extreme investment of time to be able to come, and do you -- do you think that's -- that is related to the idea that I'm trying -- I know I have it, and I'm trying to prevent it, and I'm seeing the best specialist to do that versus too late now, it's -- I'm on dialysis now, I just need to get the treatment?

DR. SHAH: Yes. I think that's a, you know, a reasonable way of putting it. I think

people want the best care that they can get always.

MR. MILLER: Mm-hmm.

DR. SHAH: But then when the reality of dialysis sets in and it’s three times a week, four hours and there's just major logistical burdens to the therapy that they're going to -- geography trumps everything.

MR. MILLER: Okay. So that's very helpful.

So, I mean, one can imagine at least three different kinds of -- or four different kinds of paths here. You've got patients seeing nephrologist, same nephrologist before and after; patients seeing nephrologist, different nephrologists before and after; patients seeing non-nephrologist before and nephrologist after; patient seeing nobody before, seeing nephrologist after.

DR. SHAH: Correct.

MR. MILLER: Okay.

DR. CASALE: And sorry to interrupt, but so in that scenario, the education, -- so, I would imagine if you're -- if they're coming to see you, you would be referring them to your CKD classes and

management and potentially do the referral for either transplant or graft placement at your institution, so all the prep would be done there? And then if, indeed, they then go into dialysis, then they might end up with a different nephrologist because of geography.

DR. SHAH: That's right.

DR. CASALE: Yeah.

DR. SHAH: Well, and on rare occasions, the patient will choose to get their access placed at a more -- at a local hospital either because of preference for that hospital or, again, geography, or because somebody told them that the surgeon there was good. But we try for the most part to work with surgeons we know.

DR. CASALE: Right, right. Yeah.

DR. BAILET: So this is Jeff.

I'm struck by where we're going, I think, with this conversation relative to the stream. How far upstream will provide or yield the highest savings and higher quality for the patients, given there's so much at risk in these first six months of dialysis? And if you don't have that upstream ability to influence and avoid -- for example, 80

percent of the folks have a central venous catheter when they start dialysis, and of course, that sets them up for all kinds of high -- higher challenges with complications and increased mortality.

I'm reading this one sentence here from the proposal that says “despite longstanding evidence that the best outcomes in transitioning patients from CKD to ESRD involve early transplantation, avoidance of hemodialysis catheters, and encouraging more home dialysis, care coordination with patient education used with palliative care, et cetera, the barriers continue to exist, given its current state.”

And so I'm not sure -- and I'd like your opinion, Dr. Shah -- that the model as it's constructed, meaning the guy, the nephrologist with the catcher's mitt, who starts dialysis for these patients, which is the trigger point, all of these interventions get people with AV (arteriovenous) access, et cetera, happens before that -- or should happen before that. But we're talking about a population of 40 percent or greater where that doesn't happen. Is that -- is that right?

DR. SHAH: Yeah. I mean, that the 40

percent is a -- again, a rough number. I don't have that data [unintelligible] the exact numbers, you know, at my fingertips, but -- but what you said is right. That it is -- you're talking about a model for the catcher, but it -- but the work that needs to be done is upstream of that catcher.

MR. MILLER: So, Paul, can I insert a -- a different question that's kind of related to this?

DR. CASALE: Of course. Yeah, yeah. There's no -- yeah.

MR. MILLER: So one of the issues that we asked about along these lines in the questions that we directed to the applicant was, “Why are you triggering it based on dialysis versus based on -- based on GFR?” And I was -- I was, frankly, somewhat surprised at the "You can't rely on the GFR" answer that we got.

I mean, you know, obviously, you know, any kind of measure, you know, has its -- has its variabilities and uncertainties associated with it.

But along the lines of this conversation, you know, yes, dialysis is a -- is a, you know, pretty well-defined objective, you know, measure, but if what you're really trying to do is to get

upstream of that and you actually would like to prevent it, as opposed to simply facilitate transition to it, then you would really want to have some way of trying to trigger earlier.

And so I'm interested in your thoughts about this issue of the reliability of the estimated GFR and how -- how fixable that is, if one were to try to define a model around the GFR to say, "Well, yeah, you know, it could be affected by medications, et cetera, et cetera, et cetera, but, you know, we've been -- we nephrologists have been working on this for a long time, and we have a pretty good sense of how to identify when those things occur so that we could pinpoint reasonably accurately for most people when their -- you know, some period of time upstream of really needing dialysis."

DR. SHAH: Yeah. So, I mean, I think that it is true that estimated GFR is a -- it's a value that is subject to a lot of sort of gray, because the equations that are used to calculate GFR from creatinine are imperfect, and they are vulnerable to variables that can influence the patient's serum creatinine, so, for example, muscle mass, age,

hydration, et cetera.

And so, you know, relying heavily on GFR as if it is gospel is a problem because, again, it's imperfect, but at a population level, it is the most commonly measured tool.

You know, I'll give you a clinical example. Let's say that you have a patient with a low GFR, meaning that they're -- they have advanced disease, and then they stop eating because they have symptoms of their kidney disease. They've lost their appetite, and now they're going to start to lose weight.

MR. MILLER: Mm-hmm.

DR. SHAH: As part of that weight loss, they lose muscle mass. When you lose muscle mass, your creatinine goes down, which means your GFR goes up, and so now it's going to look like your kidney disease is not so bad.

So GFR is -- you know, you could actually be really sick and have your numbers "get better" because you stopped eating and you're losing muscle mass, and so that's why you don't want to rely exclusively on GFR. And this is where, you know, it kind of takes sort of a --

MR. MILLER: So I would think the profession had developed a somewhat more sophisticated predictive model than that, then.

DR. SHAH: It's -- but that's -- that predictive model is largely subjective, right, because you're using a subjective determination of what's called clinical uremia to make a decision about whether to start dialysis.

So sometimes the timing of dialysis -- we're kind of jumping ahead to number 6 here, but basically, the timing of dialysis is driven by a lot of things. It's driven by your style of practice, the patient and the physician's level of comfort with risk, and most important is, subjective determination that it is -- that the person has symptoms driven by their renal disease aka (also known as) clinical uremia.

So uremia is a constellation of symptoms basically resulting from the cumulated waste products and toxins, and it's not a yes-or-no, all-or-nothing, black-or-white diagnosis. It can be as subtle as weight loss. It can be fatigue. It can be nausea. It can be a pericardial infusion.

And so once it occurs, the only real

mechanism for managing it is to start dialysis, and so the determination that uremia is present or not and potentially requires dialysis is really depending on a subjective evaluation and the clinical judgment of the physician.

MR. MILLER: Okay.

DR. CASALE: Yeah. No, I'm just thinking. I had the same question, Harold. Thanks. Thanks for bringing that up [unintelligible] our discussion.

But -- but at least in your description of the -- you know, when you refer to education -- and I know it is, obviously, the clinical judgment, but GFR is certainly part of that. I imagine a significant part of the trigger.

DR. SHAH: It is part of it.

DR. CASALE: Yeah.

DR. SHAH: It is part of it, but you can develop uremia with a GFR of 20. You can --

DR. CASALE: Right.

DR. SHAH: -- have no uremia with a GFR of 7. So you have to temper the GFR with clinical judgment.

DR. CASALE: Yeah, sure. Okay. Yeah.

MR. MILLER: So you could -- but let me -- so what I'm -- what I was sort of pondering here is, again, it's kind of like, you know, the fact that there is some unreliability in the measure because I don't have quite a sort of a quantification of the unreliability measure, but if there is value using the measure, in other words, I'd be happier if I could identify the patients somewhat upstream -- then you would want to potentially say, "Well, even though it's somewhat unreliable, it's better than saying I'm going to wait until dialysis to be able to do anything." So then -- then the further question is that's one thing whenever payment doesn't depend on it. If payment depends on it, then the question is, Do you have gaming or shading of the clinical judgment in a different direction because of that particular thing?

So I was trying to think about whether there would be a way to control for that, you know. I mean, you kind of -- I mean, this gets to the whole issue of diagnostic accuracy in medicine as to whether or not you could say, "Okay. We're going to trigger -- trigger this based on the

clinician's judgment that the patient is at the following point," to be defined, but somewhere upstream of dialysis, and that there would be some measure of -- of the accuracy of that judgment down -- down the road.

They've got something in here, in this model, that's kind of -- because when we asked the question about, well, how do we know that you're not going to just start, you know, sending more patients to dialysis earlier, then all of a sudden, GFR reappears as being the way that they're going to control for that, even though they, you know, said it wasn't reliable before.

So I guess part two of the question is, Is there some way to determine or control for the unreliability and the accuracy of the clinical judgment by the progression subsequent to that but doesn't require dialysis to be -- I guess maybe the way to phrase the question is, Is it -- is it then possible to tell somewhere later on, more definitively through some kind of more definitive tests, that the patient is, in fact, at an advanced stage of kidney disease through imaging or other kind of laboratory test?

DR. SHAH: I think I understand your question, yeah -- So not -- not in clinical practice right now. So, you know, in terms of other tests to try to define the status of kidney disease, there are novel biomarkers and things that are all in the research phase that will likely come into play years down the road --

MR. MILLER: Okay.

DR. SHAH: -- but they're not in practice now.

But, you know, to answer your other question, you know, how do you -- if GFR is so soft, you know, how do you divorce what you're trying to accomplish from GFR? You know, unfortunately, the thing that jumps to mind is sort of, well, what's the bottom line like, because from what I understand, it's not so much that you care about the GFR and that X happened at X GFR, but what you really care about is whether they started dialysis with a permanent access, whether --

MR. MILLER: Right.

DR. SHAH: -- attempts were made to transmit. You care about the bottom line, correct?

MR. MILLER: Yeah. But if -- the concern

on the other side is if you're going to have a payment --

DR. SHAH: Yeah.

MR. MILLER: -- that somehow, right, is an additional, bigger payment, flexible payment that's triggered by something, then you have -- right now, we have a model where the concern is there would be some unfortunate, you know, perverse incentive to start dialysis on people who didn't really need it because then, all of a sudden, everything else looks good because -- you know, because of that.

The converse to that is if you start farther upstream, there would be a tendency to say -- you know, to declare people to be in Stage 4 CKD simply because you made a point of measuring their GFR at the, you know, most favorable time.

DR. SHAH: I see.

MR. MILLER: I don't think we can resolve that. I just wanted to try to understand more clearly kind of whether there was some other thing that could be -- because if you said, “Well, there's some -- there's a test, it's a definitive test, it's just an expensive test, nobody does it,” then you could say, "Oh, okay." Well, then the

solution might be a random sample of patients to get the definitive test to be able to determine, you know, that the clinician is not gaming the system.

DR. SHAH: Right. Yeah, not -- not yet.

MR. MILLER: Got it. Okay.

DR. CASALE: Just to follow up on that, well, could you imagine that you could combine the GFR with a sort of list of clinical -- just the things you said, the clinical judgment, whether it's, you know, uremic symptoms or [unintelligible] status, et cetera, to create a trigger that would be more upstream?

I would imagine, as you said, even referral to the education class for dialysis, I mean, that's a big psychological, you know, issue. All of a sudden, you're telling the patient they may need dialysis -- I would imagine, you know, even just the education of it -- I would imagine that that --

MR. MILLER: You're saying that the natural resistance of the clinician to tell somebody they --

DR. CASALE: Yeah.

MR. MILLER: -- had it, if they didn't, might be the control --

DR. CASALE: To temper -- temper the unintended consequences of moving upstream and having a fuzzier trigger because, you know, it's not a number or a test.

DR. SHAH: Yeah. I mean, I think your concerns are very appropriate and well -- well said. But that said, most of us feel comfortable broaching this subject and moving the education piece along. So that -- that's one of the few things where I think using a hard GFR cutoff might actually help the system overall, because CKD education has been shown to improve outcomes. It's a good thing, and --

DR. CASALE: Right.

DR. SHAH: -- I understand that it might be a little scary for patients to see that if they're not totally ready for it. But most educational programs are delivered well and delivered in a sensitive way and don't -- you know, can be delivered in a, "Hey, we're not starting dialysis right this second. In fact, it may not be anytime soon, but, you know, here's a lot of --

here's how you should understand your kidneys and all these other things." So, you know, it's -- I personally would feel comfortable with a GFR trigger for a CKD education class, and I think we are, you know, indirectly using that in our own practice now.

MR. MILLER: But you're saying in that particular situation, even if the GFR is unreliable, the fact that it's even in the range, that would be suggesting that this would be enough to argue that the education class would probably be a desirable thing, right?

DR. SHAH: That's exactly right.

MR. MILLER: Right.

DR. BAILET: This is Jeff.

I have a kind of related question relative to vascular access, because that sets patients up for significant complications. What's the -- what is the downside risk if you're establishing vascular access? Because it's a process -- You have to work with the surgical community, et cetera, but if you establish vascular access and it has -- the access has to mature, I get that. But what's the downside risk in getting the access

lined up and in place and then finding that potentially dialysis is delayed -- I'm talking months, but it's -- it's delayed. Is there -- is that worse, or does that set the patient up for worse circumstances than actually coming late to the party and putting in the dialysis access after they've started?

DR. SHAH: You know, that's an excellent question. That's a question we ask ourselves all the time, and -- and the answer is that for the most part, the most part, there's not a lot of risk to putting the access in upstream. I think that the major considerations are, A, cosmetic, B -- the access, it diverts blood flow in a way that it creates what's called a "shunt," and so when a shunt --

DR. BAILET: Right.

DR. SHAH: You know, when a shunt occurs, it has the capacity to create additional work for the heart, and so, you know, in -- in some group of patients, depending on the size of the access and the amount of blood flow that goes through it, it can put additional work/tax on the heart and create what's called a "high output state."

And so we're always balancing that consideration against the fact that starting dialysis with a catheter is associated with separate and worse outcomes, and so for the most part, even though there is this theoretical risk of additional hemodynamic burden on the heart, it's -- it's felt to be largely outweighed by the benefit of not starting dialysis with a catheter.

DR. BAILET: Well, and the follow-on question -- again, I'm reaching back to my surgical -- my general surgery training and serving on the vascular services -- Patients need to understand and learn how to support and manage their shunts, their fistulas, and that a lot of times when they get into trouble, it's because they didn't, you know, protect their shunt in the right way or they're not familiar or they crimped it off, and you know --

And so there's -- there's that advantage, too, by -- by helping these patients and getting -- getting those access -- getting the shunts established earlier, at least I would think. Is that -- is that accurate or not really?

DR. SHAH: I think they generally get a

robust amount of education about their access at the time it's placed and shortly before in terms of how to take care of it to prevent issues from occurring.

I think if the access is placed too early and it's not used, you know, it may require interventions before it's ever used. So, for example --

DR. BAILET: Yeah.

DR. SHAH: -- you know, if it clots off because it's been in the person's arm for two years before they start dialysis, they may have to go to IR (interventional radiology) and get a fistulogram, get it opened up again, and so there is a risk to putting it in too, too early and a risk to putting it in too, too late.

DR. BAILET: Yeah.

DR. SHAH: There's a sweet spot.

DR. BAILET: Thank you.

And, again, I was characterizing it in terms of months, not years.

DR. SHAH: Yeah.

DR. BAILET: You know, I mean, I would say even six months or six months -- I'm just trying to

-- I'm trying to determine in evaluating this model how up -- how upstream should we be as we approach the analysis of this model. How much -- how much upstream should we really be thinking about? And if it's a six-month period or a four-month period, what other kinds of things should this model be considering to incentivize clinicians to jump in and participate earlier, I guess? That's why I was --

DR. SHAH: Absolutely. In our practice, we -- we -- generally, you want to give the access at least three months to mature before you use it, and so at a minimum, it needs to be in place three months before dialysis.

But assuming that, you know, there are other barriers, there may be some issues and it may require some revision and other things, really six months before starting dialysis is probably more ideal.

And so, you know, again, not every patient is the same. Not everyone's trajectory for loss of renal function is the same, but as a rough rule, we make the center of our bell curve for referral for access at a GFR of 20.

DR. CASALE: Yeah. So could I just -- again, I think maybe you're hearing it from the questions. You know, one of the struggles I have with this is that the model starts [unintelligible] triggered by the first outpatient dialysis, yet what it says its goals are, are to get more people into education, you know, more on to [unintelligible] dialysis, more into transplant, more with a vascular access rather than catheters. And I'm still struggling [unintelligible] this trigger being the first outpatient dialysis is what I'm trying to understand, how you're going to achieve those, you know, sort of [unintelligible] they're all good goals as it relates to end-stage renal disease, but how -- you know, how are you going to achieve that if the trigger is the first outpatient dialysis?

And then the -- and before you answer, I'll just -- and I should -- we should have said this at the beginning. So just so you know -- and I don't know if you knew this, but I am a cardiologist. Jeff is an ENT surgeon. Harold is not a physician, but he's like an honorary physician --

[Laughter.]

DR. CASALE: -- because he talks to physicians all day long.

DR. SHAH: Sure.

MR. MILLER: I know enough to be dangerous.

DR. CASALE: Yeah.

DR. BAILET: Yeah. You play one on TV, Harold.

DR. SHARTZER: Sorry. Someone joined the call a few minutes ago. Could they please introduce themselves?

MR. WALDO: It's Dan Waldo from Actuarial Research Corporation.

DR. SHARTZER: Okay, perfect. Thank you.

DR. CASALE: Yeah. So, anyways, just about this trigger that at least I'm struggling with, you know -- the first outpatient dialysis.

DR. SHAH: You know, I think that your -- your question and your point is valid -- is that unless it's the same nephrologist who cares for the patient pre and post --

DR. CASALE: Right.

DR. SHAH: -- the initiation of dialysis -

- that there is a -- there's an issue with this model in the sense that you -- I think the group that you're trying to incentivize to accomplish this list of things that is being incentivized is the pre-dialysis nephrologist.

MR. MILLER: It's an interesting question, Paul, and I guess prompted maybe by Dan appearing on the phone was if, in fact, this is supposed to be a model for patients, except for this sort of -- you know, this immediate initiation of home dialysis triggering Medicare benefits -- but if this is supposed to be a model for patients who were on Medicare already, we could actually, I think, do a lookback and see how many patients had the same nephrologist or any nephrologist pre- and post-dialysis in the data.

And I don't want to delay our discussion with Dr. Shah with that, but I just flag that because --

DR. CASALE: Right.

MR. MILLER: -- if you -- I have this now sort of four -- four-branch tree in my mind from the earlier discussion, and it's -- it's kind of a relevant question, to Dr. Shah's point a second

ago, is, What proportion of the patients do have the same nephrologist pre and post, and, you know, is that one percent, 10 percent, 40 percent, or whatever? We might be able to get at least some look at that.

So let's -- we can keep going, but I just flag that, flag that for Adele and for Dan.

DR. CASALE: Yeah.

DR. BAILET: And since we're flagging -- getting -- I'm not harping on the shunt, but what -- what I've taken away from the conversation is, you want to have a mature shunt. You want to get that in six months before dialysis, which is six months before the triggering event. Is that -- is that accurate?

DR. SHAH: Yeah. I think that's a reasonable time frame to have a working shunt in place.

DR. BAILET: Okay. So if you look at this model on the whole, they're six months late to the party. At least -- at least when they're looking at the triggering event -- that's not to say that they -- they did all that work prior to dialysis.

DR. SHAH: Yes and no, because they -- it

looks like on the – hold on, I'm going to flip ahead here to -- to page 11, where they have the metrics that they're being judged on. You know, they're not -- in an optimal setting, they want to start Day One of outpatient dialysis with no catheter, and there's points associated with that, but you -- you also have this 90-day and 180-day catheter percentage. So, you know, that part is not them being too late to the game, so to speak, right?

So if you -- let's say that you are not going to follow this [unintelligible] for the patient before dialysis, but you meet them on Day One of this model. You still have 90 days to get an access in them that's functional, and this model incentivizes that.

You don't get the full points because you don't have any control of what happened on Day One, and you have a fraction of the points available to you, unfortunately a small fraction.

So they're part of the way late to the game but not fully late to the game, I guess, is the way to explain it.

DR. CASALE: All right. Okay. I guess

moving on, you know, as I'm looking down this list of questions, some of them, I'm not really that thrilled with, to be honest with you. The --

MR. MILLER: Well, I think we've covered them in a somewhat different way.

DR. CASALE: Yeah, I think that's right.

I guess I would like your take on the [unintelligible] from this model, and I guess before I have you answer, are you -- is -- is Penn in an ESCO (ESRD Seamless Care Organization)? Are you part of the ESCO care model, the comprehensive ESRD?

DR. SHAH: That's a good question. We are not a financial participant in the ESCO, but we do care for patients who are -- who are ESCO patients. So, I don't know if that answers your question. We don't -- we don't have an upside-downside [risk], but we care for those patients. And we are collaborating in a nonfinancial way with LDOs (large dialysis organizations) to try to build the infrastructure to care for these patients better.

DR. CASALE: What was that acronym you used? Sorry? The --

MR. MILLER: Large dialysis organizations.

DR. SHAH: Oh, LDO, large dialysis organizations.

DR. CASALE: Oh, yeah, yeah. Okay. I see. So whether it's with DaVita or the other? Oh, I see. Okay.

MR. MILLER: Because there's a Delaware Valley ESCO, right? Isn't -- I think, if I remember correctly.

DR. SHAH: That's right.

MR. MILLER: Yeah, that's the one. Okay.

DR. CASALE: Okay. So, you know -- so I only bring that up only because the ESCO is, you know, for a year. So this model says six months, and I'm just wondering what your thought was --

MR. MILLER: Well, pause for a second, Paul, before we leave the ESCO thing.

So what's -- what's your sense, I mean, in terms of the ESCOs? Are they doing anything along these same lines? Is their thinking there about any upstream activity? Is there advantages or disadvantages to that, in that model? Or if you haven't thought about it, just say, "I really haven't thought about it, and I'm not close enough to know."

DR. SHAH: Well, I -- unfortunately, I can say that I've thought about it a lot. I wish I could say I don't know, but, you know, I -- this is an area of deep interest for the health care system because, you know, it falls under the larger umbrella of ACO (accountable care organization)/integrated care/you know, improved resource utilization.

MR. MILLER: Mm-hmm.

DR. SHAH: So it's something we think about a lot, and, you know, our -- my perspective on the ESCO is that it -- its goals are slightly different than this proposal, right? So the goal of the ESCO is to reduce hospitalization, reduce mortality, and reduce cost for -- for prevalent dialysis patients through enhanced care coordination in the dialysis unit and enhanced focus on high-impact areas like fluid overload, like access, like medications, missed treatments, primary care, et cetera. And so, we are basically trying to build infrastructure at the dialysis unit to take better care of patients and prevent hospitalizations, and we're trying to build better infrastructure in the emergency department to care

for patients appropriately and avoid unnecessary admission, if possible.

And so, the ESCO has a goal in mind that's different than what this proposal is.

MR. MILLER: Well, but if I'm an ESCO and I'm -- my patients are getting catheter-related infections and they're ending up in the ED or the hospital as a result of all that, then I would be concerned about that.

And sort of the same concept, if I'm only grabbing the patient after they start dialysis and only then thinking about starting a fistula, I lose some opportunity. Whereas, if I could suddenly go upstream and be able to reduce that, then I would be looking golden in terms of my catheter-related infection, hospitalization rates for my patient population relative to the Medicare benchmarks.

DR. SHAH: That's exactly right.

So the ESCO would -- would benefit in that way from better upstream care.

MR. MILLER: So I'm just wondering -- I mean, is there anything being done there to, in fact, reach upstream and to try to deal with these different branches of entry that we talked about

earlier? I mean, because this -- this model is trying to basically get at an issue for nephrologists who aren't in ESCO, who are in small practices, et cetera. I'm just wondering, for heaven's sakes, what -- you know, shouldn't the ESCOs be thinking about the exact same thing and would be able -- theoretically be able to do it with more resources, given their scale?

DR. SHAH: I think that's a -- so that's a great question, and I think in some geographies, the ESCOs are reaching further upstream.

But the problem there is an issue of territory, really. So when you talk about reaching upstream, you're talking about the time during which the only relationship is the patient and the nephrologist.

MR. MILLER: Mm-hmm.

DR. SHAH: And ESCO participants can include industry/large dialysis organizations. So if -- if as an ESCO participant, you now have a for-profit dialysis center coming into the patient's care before they're on dialysis, there's a concern there, as you can imagine, right? I mean, you know, do you only let DaVita come into

your office, or do you let DaVita and Fresenius come into your office and participate in the -- as ESCO members and participate in the upstream care?

And so what we've done at Penn is we've said we need to keep this unbiased to any single industry participant, and therefore, we -- we have enhanced our upstream care of patients because we think it's the right thing to do but not because we have any financial incentive to do it.

DR. CASALE: Just to add on to that -- and, again, this is my experience here while at Cornell -- we [unintelligible] Rogosin Institute, which is a smaller entity, but they are an ESCO, and they're not part of the -- you know, the for-profits. And what you've just -- what you've described, Harold, is exactly what they are trying to do because they -- they recognize that if they wait until they come in, crash and burn in the hospital, they're very expensive. And now they're in their ESCO. So they are doing a lot of work on just what we've talked about -- education, potential referral to transplant, peritoneal dialysis, all the things in this model.

So, you know, there's not as many ESCOs

like them, which are a smaller nonprofit ESCO, but -- but in that setting, that is exactly what they do.

MR. MILLER: But they would be -- they would be in an environment, back to our sort of East Coast urban-concentrated area, which would be more likely to have easier access to that upstream patient population, potentially, than other parts of the country with independent nephrologists. So I'm saying that and then see if Dr. Shah agrees with that.

DR. SHAH: Yeah. I think the other geography and demographics of the area certainly affect the ability to do this.

MR. MILLER: Yeah. Okay.

DR. CASALE: It does, but they are doing -- I mean, they are doing outreach into the community with their education, et cetera, to -- for community nephrologists to refer --

MR. MILLER: Oh, yeah. I was just saying I would think it would be easier, potentially, there, given where they're located, than it might be in other parts of the country where you didn't have that level of concentration of kind of

resources. That's all I --

DR. CASALE: Right.

DR. SHAH: I think one point of consideration I would put on your radar, though, is that -- so Rogosin I think is nonprofit.

DR. CASALE: Yeah.

DR. SHAH: But when you talk about doing outreach and you talk about, you know, enhancing upstream infrastructure and processes, the biggest issue there, is ownership of the process and ownership, to some extent, of the patients, right?

So, you know, we can have a University of Pennsylvania CKD education program. There could be a DaVita CKD education program. There could be a Fresenius CKD education program, and I think that, you know, we've tried very hard to avoid letting branded products like that enter in the upstream phase because there's -- it adds bias into the equation, right? To some extent, it's advertising a certain company to the patient, which we've never felt comfortable with. We've tried to keep things as unbiased as possible for the patient's sake.

But, when you talk about reaching primary care providers to do education and outreach and you

talk about, you know, whatever CKD education has been done in the renal clinic, per se, I think that it's definitely valuable, and it should be incentivized, but who should be incentivized is the big question. You know, who has the ownership?

DR. BAILET: This is Jeff.

I have a -- I have a question about home dialysis.

DR. SHAH: Sure.

DR. BAILET: Because that doesn't happen in Fresenius, and that doesn't happen in DaVita centers. How -- how does home dialysis or how do you see potentially home dialysis fitting into this, this model, or is it -- you know, or does it at all?

DR. SHAH: Good question. So home dialysis -- first, to correct something that was said, so home dialysis does occur with the dialysis organizations. So DaVita has a home program, Fresenius has a home program, and they have small sub-clinics within their clinics that they operate out of.

So like there might be a traditional in-center hemodialysis clinic that has an area where

they host their home program, and that's where patients come to work with their [unintelligible] to get monthly evaluations in labs, and supplies and other things.

And so home is something that -- the majority of home dialysis is actually run in participation with one of these large dialysis organizations.

In terms of -- in terms of how to incentivize home, I think that it can be incentivized on both sides of the dialysis coin, so to speak. So you could -- you could incentivize those taking care of CKD patients based on the number of their patients that start on home therapy or go on to home therapy, and then you can also evaluate post-dialysis, how many patients are transitioned from in center to a home modality.

DR. BAILET: Okay. Thank you.

DR. SHAH: Sure.

DR. CASALE: So, while we're still on sort of this topic of the ESCO and then this model and -- you know, when we asked the submitters, you know, sort of -- you know, at least one of those [unintelligible], well, couldn't you just sort of

tweak the ESCO or -- you know, what's the issue with the ESCO as compared to their model? And the things they identify was minimum of 350 dialysis patients needed. You have to participate in a single dialysis organization and geographic size limitations, but I'm just wondering -- In your -- as you think through what you've read in their model and your knowledge and experience peripherally with the ESCO, is there potential to, as opposed to creating a new model, somehow -- and, again, this is just your opinion -- or sort of revising the ESCO that could incorporate some of this that would allow more nephrologists to participate?

DR. SHAH: Yeah, that's an excellent question. That thought crossed my mind as well because there is substantial overlap between the -- I guess the mission of these two --

DR. CASALE: Right.

DR. SHAH: Right? And so it's -- the major difference as I can tell is really the time frame that's being targeted. That's really the big difference. This model is trying to control cost in the first six months, and the ESCO is trying to

control cost for all prevalent patients. And so the place for intervention to control cost in the first six months is what we've been talking about this whole time, which is pre-dialysis.

And so I guess the difference between these two things, ESCO and this proposal, are the time frame being targeted and the participants being targeted, because if it's a different nephrologist pre-dialysis, then it's a different -- that's a different person who's at risk and involved in the model.

DR. CASALE: Okay. All right. So it sounds like -- I mean, from that -- what you're thinking, it's not that different. I mean, again, you could tweak it in terms of inclusion or exclusion. That would allow more nephrologists, potentially to participate, although recognizing these time differences and --

MR. MILLER: Well, part of the issue is it's the nature of the cost risk that's attached to it, right? CMS (Centers for Medicare and Medicaid Services) has been trying to define all of its models as total cost-of-care models, so you have to have some minimum scale of patients to be able to

do something like that.

So if you wanted to go to smaller populations with small nephrology practices, you'd just have to have some stricter limits in terms of exactly what costs they were accountable for or limits on how much of the costs they were accountable for. I mean, that would be, to me, a way if you wanted to extend the concept and say let's let smaller entities be able to do that.

I mean, that's essentially what they're doing here, is they're saying, "We're a small entity. We want to take accountability for a piece of the cost with certain kind of limits around that," you know, and that's just their way of making that -- making that jump between 350 to smaller and how to have the cost risk be more manageable -- I mean, it seems to me.

But you could potentially say they could do more than six months or they could do whatever. You'd still be -- you'd still have to have some kind of limits on what the nature of the accountability was.

DR. CASALE: Yeah. Okay.

Before I move to another question, any

other -- either Jeff or Harold, any other questions particularly around this topic?

DR. BAILET: I'm good, Paul.

DR. CASALE: Okay.

MR. MILLER: Well, let me just ask again for Dr. Shah, just -- maybe just one sort of wrap-up question on that.

So, I mean, this does get at an issue that comes up constantly about what is the nature of the accountability that physicians of any particular specialty can take with respect to patients and their total costs, and, you know, oncologists in the oncology care model are being expected to be accountable for total costs. ESCO is accountable for total costs. Nephrologists here are clearly focusing on a narrower set of that.

Would you -- would you say -- to what extent do you think nephrologists think of themselves or want to think of themselves as the total patient care managers during dialysis versus the physicians who are managing the dialysis, but other doctors are going to continue to manage the patients' other conditions? And I have heard kind of differing opinions about that from nephrologists

-- so, I'd be interested in your thoughts about that.

DR. SHAH: So just to clarify, we're talking about patients already on dialysis?

MR. MILLER: Yes, correct. Mm-hmm.

DR. SHAH: I think, you know, we've discussed this a bit internally in our group as well. I think that just given the realities of how care is delivered for dialysis patients and what's required to do a good job with just the dialysis aspect of their care, I would say that most nephrologists, at least that I work with and that I know, they -- they are not prepared to be the primary care physician for the patients based on the time allotted for the activity and even the way that -- [unintelligible] you know, care is delivered in the dialysis unit.

So, you know, in terms of taking care of all of their other issues, per se, I don't -- I don't know that that's feasible in this current model.

MR. MILLER: Mm-hmm. And, particularly, if patients were traveling to a dialysis center -- might be even harder to do that? I mean, the sense

is that they're going to have other conditions to manage, and if they could be managed by a primary care physician closer to home, that would be better than having somebody who may be at a more distant, whatever it is, a half an hour or otherwise, dialysis center trying to be responsible for their care.

DR. SHAH: I mean, I think there is potential for that depending on the geography.

I think in most circumstances, it's flipped in that the dialysis center is closer to their home than anybody else because of how frequently they have to go there.

MR. MILLER: Mm-hmm. Okay. Okay.

DR. CASALE: Great. Thanks.

I was going to then turn to the quality measures -- that I know you referenced a little bit earlier. I just wondered what your thoughts were around the ones they've proposed and the relative weights. Any reaction to that list, in general?

DR. SHAH: I did look these over, and, you know, for the most part, I think that they -- the metrics, they seem like clinically relevant and important metrics to choose, but in terms of the

relative weighting and the way points are distributed, that part is -- you know, I'm a little more uncertain about because some of these things could be out of the physician's control and I guess, How does this reward system or risk system correct for that?

So, for example, under advanced care planning -- advanced care planning, I think, is a good thing for all patients, not just renal patients, but many of our patients refuse to do it. They refuse to have these conversations, you know, regardless of how that opportunity is delivered to them, and so, you know, to have a zero- or 15-point option in Year Two, is -- it seems a little aggressive to me if it's out of your control.

DR. CASALE: Right.

DR. SHAH: And, I would say that that same concern exists for any of the other metrics, where it may be out of your control. So I wonder if the reward or risk system can be tempered by whether, you know, attempts were made and can be verified and if the patient refuses, in some way, that's -- you know, the physician is not necessarily penalized for that.

You know, coming to the second one, where it talks about catheter rate, right? Even there, there is a subpopulation of patients that, A, refuse to have a permanent access placed or, B, are told by surgeons that they do not have access options because they don't have suitable anatomy. And so it's not a lot of patients, but it is certainly some patients.

And you know, if you're going to -- if you're going to start listing specific percentages for these different things, I think that, you know, some correction has to be made for those events as well.

DR. CASALE: Mm-hmm.

DR. SHAH: You know -- I didn't really have an issue, I think, with the metrics. I think it was really the percentages, the points, and the weighting that could be tempered, I guess, by, you know, variables that are outside the physician's control.

MR. MILLER: Well, let me -- let me turn the question around a little bit, and it kind of gets at the question 10 we had on the list, but -- so if the nephrologist is responsible in some

fashion or potentially can benefit from reducing spending during this six-month period, what kind of things could they potentially stint on for a patient during that period of time that would make the spending look lower but might be harmful to the patient in the longer run?

DR. SHAH: Let's see. So, here's a tough question to answer, you know, how can the system, you know, be sort of, [unintelligible] you know, taken advantage of, and I guess --

MR. MILLER: Because then I want to go back and say if there are such things, then is there -- should there be a quality measure attached to any of those things, but go ahead.

DR. SHAH: Well, you know, so let's just start at the beginning right with advanced care planning.

You know, they make mention many times throughout this proposal of how it somehow incentivizes palliative care when appropriate, okay? I guess I don't understand how. So how -- financially, where is that? How does that appear in these metrics?

But, you know, outside of this proposal, I

do have the concern that, you know, patients who are -- who may be seen as ill, have many comorbidities, are frail, and could potentially have increased hospitalizations and costs attached to that, you know, you wonder whether they would be more pushed towards palliative care, and whether that's appropriate, or not, is a question to ask.

But there's one point where, you know, some evaluation needs to be made of who's getting recommended for palliative care and why and when.

MR. MILLER: Mm-hmm.

DR. SHAH: Okay. Similarly for vascular access, you know, the second that you have this fistula-first kind of initiative and you say we want more permanent accesses in people -- well, you know, a blunt way to respond to that by physicians in the community would be to try to push everyone to get this type of access.

And for sure, for the majority of patients, it will be appropriate, but for some patients, it will not be appropriate, right? So if the life expectancy is, you know, less than two years and they're elderly and the perioperative risk is high, you know, there is a subset of

patients for whom a catheter may -- may, in fact, be appropriate, and this is a controversial area. So, I don't have a -- I can't plant my flag one way or the other on this subject, but I can tell you that if you're incentivizing this behavior, the behavior will happen more, and the question is whether everyone who gets a permanent access should have a permanent access.

MR. MILLER: Well, let me ask you, maybe, the kind of flip of that, though. So if I've got a patient who is starting dialysis, there's been no upstream activity, so they don't have a fistula, so they're going to start on the catheter -- and I actually refer them for a fistula, there's going to be a vascular surgery charge associated with that. And, doing that for the first six months to have it mature, if I'm correct -- correct me if I'm wrong -- the patient would still be getting dialysis through a catheter, right? Not through the fistula.

DR. SHAH: That's right, although the six-month span, you know, that's not exactly correct.

So, for example, in an ideal world, you'd have a working access ready anywhere up to six

months ahead of needing dialysis, but in terms of how long it takes to be usable once it's placed, it could be anywhere from six weeks to three months, and so --

MR. MILLER: Okay.

DR. SHAH: -- the fistula might be ready to use as early as six weeks, and a graft -- a graft could be ready to use as early as two days.

MR. MILLER: Okay. Well, because what I was trying to play through here was if you -- if you initiate the process of the fistula after the patient starts on dialysis and you might argue that the benefits of that will be realized over a longer period of time, but the costs of it would be incurred in a short period of time, is the six-month episode limit on this, does it create some bias towards some subset of patients that you would say, "I'm going to spend a bunch of money on them to get the fistula, but I'm not going to reap equivalent benefits in terms of their potential infections through the catheter?" And I'm not sure if there's -- if -- you know, I mean, this is kind of "Which things could you predict as a nephrologist?" But could you -- could somebody

say, "I figured these patients really are low risk, low risk of infection through the catheter, at least in the course of six months, and I'd be better off not doing a fistula for them because it will impact my short-run costs."

DR. SHAH: Ah, that's interesting. I never thought about that.

MR. MILLER: Because you're not -- that's because you're not used to gaming payment models.

DR. SHAH: We don't have the time for that.

[Laughter.]

DR. SHAH: We're busy seeing patients.

MR. MILLER: Well, these things don't exist, but, I mean, anytime you put an arbitrary limit on something, like at six months, right, then there becomes potential incentive to shift people, you know, before or after the border of that. So that's what I'm just trying to play through here is -- Is there any kind of, you know, perverse incentive that gets created by the structure of this model to do something less for somebody because it would raise your short-term -- short-term costs?

DR. SHAH: That's possible.

So, for example, you know, there's something called the primary patency rate. So that means how likely is the access to be patent and working -- open and working.

MR. MILLER: Mm-hmm.

DR. SHAH: Right? And so if somebody is a poor vascular access candidate, but you still want to push them through to attempt it because of, you know, you're -- either because you believe that it's good to have a permanent access or because there are some metrics you're trying to achieve --

MR. MILLER: Oh, interesting.

DR. SHAH: -- but, you know, you have concerns about their likelihood of primary patency. That could, you know, influence --

MR. MILLER: So you would be less likely to take -- to pursue it for the patients who would be -- have a higher failure rate because that would be basically a cost with no benefit?

DR. SHAH: Or -- yeah. Or -- or it could incur additional cost because it requires --

MR. MILLER: You have to keep reopening it, et cetera.

DR. SHAH: Yeah.

MR. MILLER: Yeah.

DR. SHAH: Yeah.

MR. MILLER: Okay. So what would be -- can you think about is there any way -- just to take that example, is there any way that one could put a control in for that?

DR. SHAH: Let's see. So --

MR. MILLER: So they've got a measure in here, and they've got catheter percentages, but that's kind of my point, is that you'd -- you'd have a fistula rate.

DR. SHAH: You know, it's hard -- and I don't know if it would be possible to do this, but if there was a way to incentivize the rate of primary patency, you know, that -- that's -- that's really what you're trying to accomplish with the patient, right? You don't just want them to have -- you don't want them to undergo a surgery for the surgery's sake. You want them to get an access that's actually going to be usable, and so a usable access has a meaningful primary and secondary patency rate.

MR. MILLER: Yeah, but I thought from what

we were just talking about earlier that if I thought that the patient was going to have more difficulty getting that, then that would -- the payment model would discourage that, and if I would add a measure for that, then I would be further disinclined to try to develop it on a patient who --

DR. SHAH: I see. I see.

MR. MILLER: Right?

DR. SHAH: Yeah, I'm not sure how you can predict which patients will succeed and won't succeed with the surgery. The surgeon probably has a good sense for that when they look at the vein mapping.

MR. MILLER: Mm-hmm.

DR. SHAH: But I don't know that the dialysis --

MR. MILLER: So who -- what would be the characteristics of the patients that you would not ever want to pursue a fistula for? A patient has already started on dialysis. They've come in the door, right? There's been no upstream. They started on dialysis. What patients -- under what criteria would you say it makes no sense to be -- I

mean, regardless of financial incentives, it makes no sense to even try to start a fistula with this patient?

DR. SHAH: I guess the two criteria that come to mind would be short overall survival, short expected survival -- let's say less than two years -- and the other one would be high operative risk.

DR. BAILET: Yep. This is Jeff.

So, Harold, I think where you're going is you could control for those two.

MR. MILLER: Well, the problem with the short expected life is that's like predicting hospice, you know.

DR. BAILET: Well, I guess I'll turn it around. There are surgical referrals that are made, [unintelligible] Dr. Shah, where the surgeon says -- you know, “evaluated the patient and they're not a candidate.”

MR. MILLER: Mm-hmm.

DR. BAILET: Right?

MR. MILLER: Mm-hmm.

DR. SHAH: That's right.

MR. MILLER: So you could --

DR. BAILET: So I --

MR. MILLER: So you could say there ought to be at least a referral and evaluation of them --

DR. BAILET: Right, exactly.

MR. MILLER: -- as opposed to not having it done at all and not knowing whether it was even evaluated. That's an -- that's an interesting point. Yep. I mean, you could certainly have the surgeon and the nephrologist in cahoots with each other, but it would certainly control -- control -- control that if you said that there needed to be a referral in a surgical evaluation.

DR. SHAH: Yeah. Again, not every surgeon is going to think about longevity in their equation for whether to do the surgery or not, so, you know --

MR. MILLER: Yeah.

DR. SHAH: This is ultimately a hard thing to control for, and I guess I don't want to -- I want to make sure that as a nephrologist that I'm still championing the right mission here, which is that for the majority of people, a permanent access is a good thing, and we should champion it.

You know, in terms of how one might game the system is a different question, but I think

that overall, it is good to champion permanent access.

MR. MILLER: Well, right. What I -- the thing I was really most focusing on was this -- this six-month accountability for spending, and I was just trying to identify what things one might stint on. So that's -- that's kind of what I was getting at, so -- and we talked about -- we talked about the vascular surgery. Are there any other things that you can think about that one might stint on?

DR. SHAH: You know, there's a lot of talk in this about transplant as well, right? And so --

MR. MILLER: Well, they've exempted themselves from any transplant costs, so there -- there's -- and they actually get a reward for doing that. It's kind of a double reward in the sense that they get a bonus for doing a transplant, and they're not accountable, responsible for the transplant costs.

DR. CASALE: Which is going to be one of my questions, if you had any thoughts around that transplant bonus of $3,000?

DR. SHAH: You know, it has the

theoretical risk of, again, stimulating people to push people down the transplant pathway that they might not have.

And, you know, the infrastructure for evaluation for transplant is pretty robust, so I don't -- I don't know that you could force things through just because you were incentivized to do so. I mean, organs are obviously very limited --

MR. MILLER: Mm-hmm.

DR. SHAH: -- and the process is overseen by UNOS (United Network for Organ Sharing) and by the institution pretty closely. So I don't know that the system can be gamed in the transplant.

MR. MILLER: So that's a case where there would still be -- there would be some external party that would be pushing back on that, right?

DR. SHAH: Yes.

MR. MILLER: Yeah.

DR. SHAH: But I will say this. You know, somebody -- somehow -- you know, when this exempts the cost of transplant, I'm not sure -- what I'm not sure of is how that integrates to this model because right now the evaluation for transplants, whether that involves, you know, an echocardiogram

or it involves a pulmonary evaluation or laboratory testing, you know, that -- how that is paid for is uncertain to me, and I think that --

MR. MILLER: Okay. Well, thank you for raising that, right? That's an example. So there would be costs associated with the transplant referral.

DR. CASALE: Yeah, that's a great point. I mean, because as a -- I remember always doing these stress echoes yearly to keep people on the transplant list or whatever. I mean, there are some ongoing costs related to that.

DR. SHAH: So I can tell you at our institution, right, there's a -- there's a professional fund that derives from our institution that covers the cost of this testing and the -- and the clinical visits that are associated with this testing. And ultimately, I think the institution is only reimbursed for any of this activity if the person actually gets transplants, and then they get some lump sum. And that goes into this pot from which subsequent testing occurs for other patients.

And, you know, I had -- you know, I think it's a whole separate conversation to think about

the economics of all of this and how it will be influenced by this, but it -- it needs to be thought about.

MR. MILLER: Well, so an interesting question, Paul, is that they refer to excluding Medicare costs. All kidney transplant-related services would also be excluded. So that question of, sort of what's included in that, and then I guess the other thing I would ask is, So are there things that one might otherwise have to spend money on that one would declare to be a kidney transplant-related service simply because you said I'm referring patients for kidney transplant?

DR. CASALE: Right, right. And they can stay on the list for quite a while. Yeah, yeah.

MR. MILLER: So what -- just to stay on that point for a second. So what kinds -- patient starts dialysis first six months. What kinds of testing, imaging, et cetera, would the patient get during that period of time if they're getting good care?

DR. SHAH: And we're not talking about transplant. You're just talking about --

MR. MILLER: No, I'm just talking about --

forget transplant for a second. Plain old patient on dialysis, you know, just getting dialysis. What kinds of testing, imaging, et cetera, expenses would good care argue that they should get in that first six months?

DR. SHAH: There will be an abundance of lab testing that's connected to dialysis and all the biochemical parameters that dialysis [unintelligible]. So, you know, much of that is bundled into the reimbursement for dialysis already through Medicare, but lab testing is number 1 through 10, and then separate from that would be -- separate from that would really be testing that is clinically indicated for some other reason.

You know, we don't -- we don't do -- usually, I think a chest x-ray and an EKG (electrocardiogram) are considered standard at the beginning of dialysis, and then after that, the only other testing that's done is indicated by some issue.

So, for example, if you're having poor function of your fistula, you might have to get a fistulogram interventional radiology. If you're having poor function of a catheter, you might have

to get your catheter exchanged. If you have shortness of breath that's mysterious in any way, you might require chest imaging, but again, that wouldn't be the standard for everybody.

So I think, at minimum, it's labs, chest x-ray, EKG, and then everything else is driven on a need basis.

MR. MILLER: Mm-hmm. Is there a set of nephrology standards anywhere, kind of written standards, here is what defines good care during the first six months of dialysis?

DR. SHAH: I don't know that there's something about the first six months.

MR. MILLER: Well, it doesn't have to be. I'm trying to say -- I mean, you might say, “You know, down -- once patients get more progressive, it's hard to define exactly what they need.” I'm just sort of wondering if there's sort of a standard of care that potentially, if there were such a thing, one could argue that there is at least a process measure attached to this that says that, in fact, the nephrologist should document that they followed the standards of care or document why they had deviated from it, rather than

leave it completely open the way it is.

DR. SHAH: I mean, yeah, there are a number of different standards that we report on in an aggregated fashion in each unit, and that -- that is all connected to basically what's called QIP (Quality Improvement Program), which is how Medicare --

MR. MILLER: Oh, yeah. Okay, right.

DR. SHAH: Yeah. So that's how Medicare determines how much to reimburse the dialysis unit for its care, and that's driven in part by clinical quality measures that include adequacy of dialysis, you know, post-weight above target weight, and in the past, it had included other lab values like phosphate and PCH (paroxysmal cold hemoglobinuria) and hemoglobin and albumin and other things. But each year, it -- each year, those metrics, those clinical quality metrics get modified a little bit by Medicare.

MR. MILLER: Okay. So there's the potential, given that they're just -- they're just sort of P4P (pay-for-performance) kinds of metrics that one could decide that some of the more expensive parts of that, if one was incented on

expenses, might -- I might go short on them because I'm saving more than I'm being penalized, potentially, through the metrics -- possibly.

DR. SHAH: I think there are clinical quality metrics yet to examine --

MR. MILLER: Yeah. But we ought to -- we ought to look at that and just see whether there's some way to kind of build -- build what is good care in here besides just to focus on catheters and transplants.

DR. SHAH: So --

DR. BAILET: Harold, this is Jeff.

So when I look at their -- the statistics in their report, 56- to $65,000 are spent the first six months, and they're saying around average of $15,000 per month. When you think about some of these testings that are transplant-related and that they're not assuming responsibility for, I think in the grand scheme of things, if you get up on the balcony and look at the proposal, the kinds of things that they're looking at -- readmission rates, hospitalizations, and other -- you know, other catheter-related complications, that's probably driving the majority of this 56- to

$65,000 in the first six months.

But I guess I would ask Dr. Shah. Is that accurate, or do you really think that those transplant-related tests are material compared to that figure?

DR. SHAH: That's a good question.

You know, I think in most cases, not a -- a substantial portion of the transplant workup is not really done in the first six months because a patient is, for lack of a better term, settling down into dialysis first. And they have a lot of optimization that needs to occur before they can be meaningfully evaluated for transplant.

And so, you know, it -- the first six months of dialysis are -- are often characterized by trying to identify the correct dry weight and various issues with fluid, fluid status up and down, and access-related care, and cost is certainly a part of that, you know, part of the first six months as well.

So I would say between -- between fluid management and optimization in that realm and access optimization and hospitalizations that might be connected to either of those two things, that's

the majority of where big cost comes from the first six months.

DR. BAILET: So if you play that through, then, their model -- I mean, they're focused on -- at least from a cost perspective, they're focused on the right things.

DR. SHAH: I think so.

DR. BAILET: Harold, Paul, do you guys have a feeling about that?

MR. MILLER: Well, I guess the -- the question -- and I think maybe this is, again, a data question that we should explore -- is these patients, as we often say with Medicare patients, probably don't just have one thing wrong with them. So what's driving their expenses during that period of time isn't just their kidney disease, and we don't know exactly what that breakdown is right now. So it's something that we ought to explore.

Just so I get, again, a sense of order of magnitude -- so, roughly, what proportion of patients who get a kidney transplant are already on dialysis?

DR. SHAH: I think that the majority of patients get transplanted after they're on

dialysis.

MR. MILLER: So when you say majority, do you mean vast majority? In other words, not 55 percent, but more like 80 or 90 percent?

DR. SHAH: Yes.

MR. MILLER: Okay.

DR. SHAH: I think that it's a small population that gets the preemptive transplant.

MR. MILLER: Okay. All right. That's kind of what I assumed. I just wanted to make sure.

So you're basically saying that it would be -- most of them would be after dialysis starts, and you would say it's probably after six months has already passed.

DR. SHAH: That's right.

MR. MILLER: Okay. So just to follow up, then, on that point, so if -- if these guys are in this model are suddenly eligible for transplant bonuses and things like that, are they -- are they screwing up the dialysis process for the patient by trying to jump the gun on that prematurely?

DR. SHAH: I don't think so. I don't think the transplant -- the mechanism for

transplant in this country is -- would really let that happen. I don't think you can, "push" a transplant through inappropriately or prematurely just because of disincentive. Like there's too many other stakeholders involved.

MR. MILLER: Well, I didn't mean -- right. I didn't actually mean getting the transplant. I meant, though, if they're starting to get testing, et cetera, is the testing ordinarily done by the transplant center who says, "No, we're not ready to do that for this patient yet," or is the nephrologist referring for a whole bunch of tests to try to sort of speed up the process and essentially forcing the patient to be getting a bunch of things earlier than they should whenever they're just starting dialysis?

DR. SHAH: I see. Yeah. No, the testing is driven pretty much exclusively by the transplant center --

MR. MILLER: Okay.

DR. SHAH: -- not the nephrologist.

MR. MILLER: Okay. So it's not a "Please run all the following tests and then send the patient to us." It's a "Send the patient to us,

and then we'll determine what they should get."

DR. SHAH: Yes.

MR. MILLER: Okay. All right.

DR. BAILET: Harold?

DR. CASALE: And just so I understand it, from a renal point of view, having the -- it's actually a good thing, right, if they had the transplant, theoretically, before they started dialysis? I mean, that is -- is that preferable if everything was in place? Is that true?

DR. SHAH: That is true, yes.

MR. MILLER: Yeah.

DR. SHAH: The best outcomes occur --

DR. CASALE: Yeah.

DR. SHAH: -- with preemptive transplant.

DR. CASALE: Okay.

MR. MILLER: I was more -- I was trying to tie that to our earlier discussion, is if nobody is really involved early on, right, you know, then they end up going on dialysis, and then they end up being on dialysis for six months, and then is when something would happen.

It would be desirable to get something to happen earlier, but that comes back to somebody has

to be doing something way upstream.

DR. CASALE: Exactly. Right.

So I know -- I'm looking at the time. I know we only have a couple of minutes. So I did want to just -- back on the quality measures, I just wanted your opinion. When I look at them, there's a little bit around patient experience, but, you know, more around all those fistula and catheters, and the patient experience -- the part is 10 points, is this patient-centeredness thing, but I'm just wondering if you had thoughts in terms of the balance between the sort of patient experience measures versus the -- you know, the access and utilization measures, et cetera.

DR. SHAH: You know, that's also a good question. I mean, I think that it's important to keep the patient in mind and, frankly, at the center, and we definitely -- I think we all want the patient experience to be as excellent as it possibly can be, but I think that the patient's evaluation of their experience [unintelligible] highly subjective, and it is -- can be influenced by things that are, again, not under the control of the nephrologist and not really being objectively

evaluated.

MR. MILLER: And they have -- they have no basis of comparison, right? I mean, dialysis is going to be a miserable experience for them, and they're not going to be happy about it, no matter what.

DR. SHAH: That is often the case.

MR. MILLER: Mm-hmm.

DR. SHAH: Yes. And so -- and that -- and that manifests itself in -- in reporting that we already see because we -- you know, we already collect some data in terms of satisfaction and quality of life and things.

And so, you know, when you attach points to it like this -- about variables that you care about, but you don't have the ability to fully control or impact, it's -- I'm not sure what it's meant to incentivize in the provider.

MR. MILLER: So if you were to pick a -- what would be the right measure, would it be something like a rating of access to the physician, you know, responsiveness to calls or problems as opposed to just experience?

DR. SHAH: I think that when we -- the

current patient satisfaction tools that we use already break that down into those -- those types of things and other things, so yes. You know, responsiveness of physicians, how much does my doctor care about me, and how much does the staff care about me? How comfortable is the physical environment, you know, how -- how much pain do I experience when the needles are put in? -- And so on -- it asks a lot of, I think, reasonable questions. But what is hard about this, is the subjective nature of the response.

DR. CASALE: Mm-hmm. Okay.

DR. BAILET: Dr. Shah? Dr. Shah, this is Jeff. I want to thank you for your incredible insights and input here to help us sharpen our thinking on this proposal. I've got to hop [unintelligible] the top of the hour.

DR. CASALE: Yeah, yeah. Right.

DR. BAILET: So, again, appreciate -- appreciate this conversation. I found it incredibly helpful. Thank you, everybody.

DR. SHAH: It's my pleasure.

DR. CASALE: Yeah. Yes, Dr. Shah. I would just add my thanks as well. Yeah, this has

been a very helpful 90 minutes, so thank you for all of your insights.

MR. MILLER: Yes. And Harold just says ditto. Excellent.

DR. CASALE: Thank you.

DR. SHAH: Yes.

MR. MILLER: Thanks very much.

DR. BAILET: Thank you, guys.

DR. CASALE: All righty. Have a good day. Thank you, everybody.

[Whereupon, at 12:03 p.m., the conference call concluded.]