

Section I: Defining a Complex Medical Management Model

- How should CMS define a complex medical management model, in terms of the applicable medical conditions or diseases, the services furnished, and the payment mechanism?

1. What specific health conditions and/or specific specialties should the model target? Why?

- The Medicare population with end stage renal disease (ESRD) is a natural fit for an episode-based payment rate for their vascular access needs. It represents a small (1.4%) yet costly (7.2%) subset of Medicare beneficiaries and expenditures. Medicare payments for the dialysis population totaled \$25.6 billion in 2011.
- The disproportionate share of expenditures reflects the highly complex nature of treating a population in an organ failure state, which can be treated over a long period, with multiple medical conditions and the need for proper care coordination among the numerous specialties that provide ESRD-related care.

One important aspect of care for those with ESRD is the placement and maintenance of a vascular access, which is necessary to receive dialysis treatments. This access to the bloodstream allows for the removal and return of blood from the body to the dialyzer and back to the individual. There are several different types of permanent access including peritoneal dialysis catheters, native arteriovenous fistulas (AVF) and arteriovenous grafts (AVG). There are also temporary accesses, including both tunneled and non-tunneled catheters (TC).

A large body of literature confirms that permanent access types are associated with better clinical patient outcomes, while catheters lead to higher rates of infection, vascular complications, hospitalization, and mortality, accompanied by dramatically higher Medicare expenditures. Indeed, proper vascular access placement *prior to the need for dialysis initiation in the pre-ESRD patient* is ideal and has been demonstrated to be critical to reducing the very high patient morbidity, hospitalization, and mortality in the first year of dialysis therapy. Complications of temporary access account for much of the significantly higher costs of incident ESRD patient care. Additionally, whenever a patient has to be dialyzed with a catheter due to complications with his or her permanent access, the effectiveness of dialysis treatments is reduced, complications increase, and costs rise.

Patient outcomes are much worse in a system where care is fragmented and not optimally managed to place and maintain permanent access. Medicare and other payers also incur much higher costs when this is the case. As of 2006, vascular access repair and maintenance services accounted for about 5-10% of total ESRD costs, excluding the cost of access-related infection hospitalizations (USRDS 2008 Annual Report). The inclusion of these infection hospitalizations would make the proportion of total ESRD cost much higher. Fistulas are associated with the lowest average per-beneficiary-per-year expenditures of \$3,284, while catheters and grafts have higher expenditures (\$6,828 and \$7,377, respectively) (USRDS 2008 Annual Report). This difference was the impetus for the Fistula First Breakthrough Initiative (FFBI), which achieved success in increasing prevalent fistula rates in the United States from approximately 25% to 60%

in the past 10 years. Despite this success, there is still a long way to go in ensuring patients have optimal dialysis access and are not affected by the complications of suboptimal care.

Patient care can be optimized in a well-coordinated system of care. Regular maintenance and surveillance from a dedicated care team can improve outcomes and lower Medicare spending. A study published in *Seminars in Dialysis* (August 2013), a peer-reviewed journal, confirmed in more than 55,000 Medicare beneficiaries that receiving care from a freestanding, office-based vascular access center could result in statistically significantly better patient outcomes, including fewer related or unrelated hospitalizations, vascular access-related infections, and septicemia-related hospitalizations, as well as lower mortality rates. These better outcomes were achieved at a significantly lower average per-beneficiary-per-month Medicare payment (Dobson, El-Gamil, et al., 2013). These freestanding centers typically bill as a physician office under the Medicare Physician Fee Schedule or as an Ambulatory Surgery Center.

The results of this and other studies demonstrate that proper management of vascular access services – the type of management that is fostered with good care coordination and dedicated networks of care providers – aligns with CMS’ triple aim to improve the patient experience, improve the health of the population and reduce the cost of healthcare. An episode-based bundled payment for dialysis access services would provide the proper incentives for this high quality care.

Summary of Episode-based Payment System:

In this response to CMMI’s request for Information (RFI), we outline an episode-based payment system that bundles all vascular access related placement, repair, and maintenance services into a single payment rate for all incident and prevalent Medicare ESRD patients. For purposes of this RFI, we are assuming that a Medicare beneficiary enters the episode-based system at the point at which ESRD diagnosis is imminent and vascular access needs to be placed, or the first dialysis treatment after a prevalent dialysis patient transitions to Medicare coverage. The episode then continues through patient withdrawal from dialysis, death or transplant. Therefore, this is a variable length episode structure that could span several years.

While the services involved in vascular access care are currently provided by several different physician specialties, we emphasize the importance of nephrologists’ management within the episode, as they are the primary specialists current managing the patients’ CKD and ESRD care. Other specialists routinely involved in care include vascular/general surgeons, interventional nephrologists and interventional radiologists. Nephrologists within dialysis centers provide primary access surveillance as they can track blood flow, other pressure and lab parameters, physical exam, and access function during dialysis.

Numerous sites of service and specialists are involved in vascular access placement, repair, and maintenance. This proposed episode-based payment system would include all placement and maintenance services provided in any outpatient care setting (physician office, hospital outpatient department, and ambulatory surgical center). Placement services include vessel mapping, creation of fistula or grafts, catheter placement, and peritoneal dialysis abdominal catheter access placement. Maintenance services include, but are not limited to, surveillance, ultrasound evaluation, angiography and angioplasty, thrombectomy, and placement of stents.

The proposed episode-based payment system contains three “phases” of vascular access care, each with a different payment modifier, regardless of the site of service in which the care is

provided. This would allow the episode-based payment system to capture incident and prevalent ESRD patients at different stages of their ESRD care, with appropriate adjustments in the Medicare payment rates for the different phases to reflect the changes in resource intensity to treat patients across different phases of the proposed bundle.

- **Phase 1: Initial Placement** - would include the placement of a vascular access for Medicare beneficiaries with chronic kidney disease who will soon require dialysis care (i.e., incident ESRD patients). All services by all physician specialties required to achieve successful maturity of the access site are covered. These services include all preoperative evaluation including fistula/graft planning (i.e., vessel mapping), the access surgery, postoperative care including the monitoring of the access site until it is mature and ready for dialysis. Given that there is generally a high rate of failure of fistulas to mature (20-50%), this phase would also include additional interventional care such as ultrasound, angiography, angioplasty, surgical revision. (Allon M, *Kidney Int*, 62: 1109–1124, 2002 & Allon M, *Clin J Am Soc Nephrol* 2: 786–800, 2007). In the event that a patient enters ESRD abruptly and does not have the advanced placement of the fistula/graft prior to the need for dialysis, catheter placement services would be included as well. This phase is variable in length and would continue until the access site is used for a successful dialysis treatment. This first episode payment would effectively incentivize a multidisciplinary approach to placing the optimal access for the patient in the setting that allows the most coordinated, efficient and highest quality care. It would incentivize the placement of fistulas before the patient requires dialysis – sparing the increased morbidity and costs of catheters. This would greatly benefit patient care since, despite the FFBI, nearly 80% of ESRD patients in the US begin dialysis with a catheter.
- **Phase 2: Surveillance & Maintenance** - of a functional vascular access (either fistula, graft or catheter). This phase will include all surveillance and procedures such as ultrasound, angiography, angioplasty, thrombectomy, coil embolization, and stent placement. Appropriate placement of fistulas in Phase 1 could reduce the need for maintenance and repair services during Phase 2. This phase is also variable in length and would continue until a new access is required, which would trigger Phase 3. This would typically be the longest phase. Because peritoneal dialysis patients do not require ongoing catheter surveillance or maintenance, this phase would not pertain to those patients on any form of peritoneal dialysis.
- **Phase 3: Access Failure & Replacement** - captures the intense services at the point of access failure or pre-emptive need for additional access placement, anticipating that the current functioning access will imminently fail. This phase will typically be initiated by a reversion from a fistula/graft to a catheter or an additional fistula/graft placement while the patient receives dialysis through the failing fistula, graft, or recently placed catheter. Similar to Phase 1, this phase may contain additional services due to the newly placed/created access's failure to mature. This phase is variable in length and would be initiated by the need for placement services of a new access, and continue until the access site is used for a successful dialysis treatment, upon which the patient would re-enter phase 2.

Over the course of the episode, a patient can move through Phases 2 and 3 repeatedly, but cannot enter Phase 1 again.

Roughly half of ESRD beneficiaries are not eligible for Medicare when their dialysis care is initiated. While these individuals could not be included in Phase 1 (unless the model could be extended to involve private payers), they would be included in the episode-based payment system once they are eligible for Medicare, presumably when they are in Phase 2. Appropriate adjustments would have to be developed to accommodate this portion of the Medicare ESRD population, but the same general model should be adaptable to reflect their special characteristics and costs. In this fashion, the entire Medicare-eligible ESRD population could be included and receive the advantages of this payment system.

By bundling these services in an episode-based payment rate, there is an opportunity to encourage better care coordination and the use of dedicated care teams with a proven track record of superior clinical outcomes. Under the current Medicare fee-for-service system, vascular access services provided in the hospital outpatient department have a higher Medicare payment rate than services provided in the freestanding vascular center (physician's office or ambulatory surgery center). Despite this difference, this proposed payment system would establish a site-neutral payment rate to encourage the provision of services in the most cost-effective way while optimizing patient outcomes.

Alignment with CMS' ESRD Seamless Care Organizations (ESCOs)

CMS is currently developing the Coordinated ESRD Care (CEC), ESRD Seamless Care Organization (ESCO) initiative, which bundles all ESRD related care for Medicare beneficiaries under a standardized payment rate. Similar to the accountable care organization (ACO) model, this initiative assigns beneficiaries to a convener in their market area that is responsible for managing the care and accepting risk for the Medicare payments. The episode-based payment structure outlined in this RFI differs from the ESCO model in several important ways. Therefore, this program is not duplicative of the ESCO initiative; rather, it is complementary to it.

The primary difference between the ESCO and the proposed episode-based payment system is the included services. Unlike the ESCO initiative, this episode-based payment structure focuses on a discrete, yet critical, service provided to ESRD patients. The proposed system is clinically coherent in that it reflects one distinct aspect of ESRD patient care, while the ESCO includes the full continuum of ESRD care, such as vascular access, fluid management, hypertension control, anemia management, renal bone disease and mineral metabolism, dialysis services (including drugs), and cardiovascular complications. By excluding all services other than vascular access in this proposed model, the convener will be better able to manage a specific focused process with a dedicated care team.

Another major difference between the two concepts is the inclusion of only ESRD patients within ESCOs. Under the proposed vascular access episode-based payment system, Medicare patients with advanced chronic kidney disease would be included as they receive vascular access placement services anticipating the need for dialysis. This is an important addition, since advanced planning for vascular access leads to higher rates of fistula placements and lower rates of catheter placements. Because of inclusion of the advanced chronic kidney disease population, providers would be incentivized to coordinate the access placement so that access is mature prior to patients entering ESRD. Proper modality education and management of the condition

prior to the need for dialysis could maximize patient clinical outcomes and reduce Medicare payments in the long term.

Within the ESCO, the convener (identified as either a dialysis facility or nephrologist/nephrology group practice) will need to manage care across several sites of service, specialists, and clinical functions. We recognize that one of the pillars of bundled payment is that the more inclusive the services in the bundle, the better coordination across providers and higher probability for improved outcomes as a whole. However, the focus on a single type of service (dialysis access) mitigates providers' risk and allows for focused treatment protocols and processes. As providers currently operate within a fee-for-service environment, this episode-based payment can be a smaller step towards more global bundled payment models such as the ESCO. Having this as an option will allow providers not currently prepared for global risk contracting in an ESCO to establish provider networks and work through the logistics of managing care across specialties and settings.

Since the ESCO bundle includes all ESRD services, the financial risk may be too great for smaller providers, especially in non-metropolitan areas, limiting their presence in these areas. This separate episode-based payment system allows geographic areas without adequate patient volume or infrastructure for an ESCO to achieve efficiencies through the vascular access bundle. This will extend the value of bundling and other risk-sharing models to smaller geographic areas, benefiting ESRD patients more broadly. It is estimated that, by design, ESCOs are limited to approximately 15,000 of the 429,000 patients being treated for ESRD. By implementing this proposed episode-based payment system in tandem with ESCO, advanced learning and best practices can be developed, even where ESCO enrollment is not available.

Partners in Developing the Proposed Episode-Based Payment System

This response was developed by the Coalition for Vascular Care. This Coalition is an alliance of specialty societies, physicians, freestanding vascular access center owners and managers, and other industry stakeholders involved in providing the highest quality vascular access outcomes for dialysis patients. The Coalition includes the following societies: the American Society of Diagnostic and Interventional Nephrology (ASDIN), the American Society of Nephrology (ASN), and the Renal Physicians Association (RPA), , groups which include nephrologists, vascular surgeons, interventional radiologists, and allied health professionals in the kidney disease care arena. Industry participants represent key aspects of the kidney care continuum including DaVita Health Partners' Lifeline Vascular Access, and Fresenius Medical Care's Fresenius Vascular Care (FVC).

2. Would new services be required under this model in order to improve beneficiary care? If so, what are these new services and how should they be paid for under this model?

- No new billable Medicare services would be required. However, in order to improve care, conveners and providers will focus on increasing care coordination services. Providers will need to consider the impact of others' care on the health of the access site. Without care coordination, which is not explicitly provided under the current fee-for-service system, patient outcomes and Medicare savings cannot easily be achieved. Additionally, providers will need robust electronic medical records to allow both the clinical management of patients and monitoring of quality outcomes

3. How could accountability for drugs prescribed be factored into the payment model?

- Proper surveillance and maintenance of vascular access does not rely on the provision of drugs; however, post-surgical medication and anti-infectives could be included in the payment model. In addition, this proposed episode-based payment system is unrelated to the dialysis payment system.

4. What are the important considerations in assigning the responsibility for care (to either the co-managing specialist practitioner or the primary care practitioner) in such a model?

- In an episode-based payment system, appropriate assignment of the “convener” or risk-bearing entity is critical to the success of the system. The convener is responsible for managing patient care across specialties and, ultimately, distributing payments (or gains and losses) across providers. In assigning the convener, the payment system must consider how care is provided across different physician specialties and settings. The dialysis access episode-based payment model proposed will encourage maximal interdisciplinary collaboration as physicians are incentivized to work together in the patient’s interest.

The nephrologist is the key physician specialist coordinator in this comprehensive episode-based model for dialysis access care. General nephrologists coordinate patient care in the dialysis facility where much of the work of monitoring new and established accesses occurs. Interventional nephrologists who are often already closely aligned with the nephrology practice provide much of the interventional procedural care. Freestanding vascular access centers in many locations provide coordination of all aspects of dialysis access care through a multidisciplinary team under the direction of the nephrologist. For the model to succeed and not disrupt patient care, nephrologists should be part of the convening body at risk for clinical and financial success. While procedures may be done at several sites of service, freestanding centers are likely to become the primary site of care because of their ability to focus efforts on this specific patient population, responding rapidly and economically to their needs. Their demonstrated superiority in service, coordination, patient outcomes, and cost will be optimized even more in a bundled payment environment.

The described episodes will encourage inclusion of all specialist physicians providing care within the convener’s provider network: nephrologists, surgeons, interventional radiologists, and interventional nephrologists. Conveners will benefit from all physicians having incentives to better coordinate care through risk sharing and rewards. This proposal increases such collaboration from what is common today. Any model that did not provide an incentive to multispecialty collaboration would be disruptive to patient care and unlikely to succeed.

5. What examples of this model have been tested in the private sector that further the evidence base?

- Development and implementation of this payment system serves as the logical extension to the research presented in a published, peer-reviewed article in *Seminars in Dialysis* (August 2013), conducted by Dobson DaVanzo & Associates, LLC. This retrospective cohort study analyzing over 55,000 Medicare beneficiaries was based on a 100% sample of incident and prevalent Medicare-covered ESRD patients over four years (using USRDS claims data, which

augments the administrative claims with select clinical information). Patient episodes of care for all vascular access repair and maintenance services, including all dialysis, drugs, and related and unrelated hospitalizations, were linked over time. Patient cohorts were developed to compare the outcomes and Medicare payments for those who received the majority of their vascular access care in a freestanding office-based vascular access center as opposed to those who received care in a hospital outpatient department. Using propensity score matching techniques, patients were matched across cohorts to control for patient severity and selection bias using demographic and clinical characteristics. The study concluded that patients who received vascular access care in a freestanding office-based center had statistically significantly better outcomes at a lower cost to Medicare.

This proposed payment system would extend the research beyond claims analysis and test the power of providers to achieve better outcomes and lower Medicare costs through dedicated access care. In an at-risk environment, providers will reengineer the way they provide care to increase care coordination and improve outcomes. If the literature is correct, care management under a convener would result in more patients receiving care in freestanding office-based centers, as opposed to hospital outpatient departments, at a reduced per-beneficiary-per-month and annual cost to Medicare, and the beneficiaries would benefit by the improved clinical outcomes including reduction in mortality rate.

- Study Abstract: Dialysis vascular access (DVA) care is being increasingly provided in freestanding office-based centers (FOC). Small-scale studies have suggested that DVA care in a FOC results in favorable patient outcomes and lower costs. To further evaluate this issue, data were drawn from incident and prevalent ESRD patients within a 4-year sample (2006-2009) of Medicare claims (USRDS) on cases who receive at least 80% of their DVA care in a FOC or a hospital outpatient department (HOPD). Using propensity score matching techniques, cases with a similar clinical and demographic profile from these two sites of service were matched. Medicare utilization, payments, and patient outcomes were compared across the matched cohorts (n = 27,613). Patients treated in the FOC had significantly better outcomes (p < 0.001), including fewer related or unrelated hospitalizations (3.8 vs. 4.4), vascular access-related infections (0.18 vs. 0.29), and septicemia-related hospitalizations (0.15 vs. 0.18). Mortality rate was lower (47.9% vs. 53.5%) as were PMPM payments (\$4,982 vs. \$5,566). This study shows that DVA management provided in a FOC has multiple advantages over that provided in a HOPD.
- Full citation: Dobson, A., El-Gamil, A. M., Shimer, M. T., DaVanzo, J. E., Urbanes, A. Q., Beathard, G. A. and Litchfield, T. F. (2013), Clinical and Economic Value of Performing Dialysis Vascular Access Procedures in a Freestanding Office-Based Center as Compared with the Hospital Outpatient Department among Medicare ESRD Beneficiaries. *Seminars in Dialysis*, 26: 624–632. doi: 10.1111/sdi.12120

6. What quality measures should be assessed for this model to ensure safe and effective care?

- Possible quality measures include:
 - Fistula and catheter rates: Fistula First and other programs demonstrate the value of permanent vascular access for the beneficiaries and the Medicare program, as these access types have lower complication rates and reduced Medicare spending. Given that

catheters have higher complication rates, this episode-based payment system should incentivize placement and maintenance of permanent access modalities. Using existing CPT codes, CMS could easily monitor the change in the number (or rate) of fistula and graft placements compared to catheter placements. Both incident and prevalent rates should be monitored. Incident rates of starting dialysis with permanent access (AVF, AVG and PD catheter) should increase. Quality targets would need to be set for each access type.

- Access-related hospitalizations: to determine if proper surveillance and maintenance was provided in order to avoid access failure or other causes for readmissions.
- All cause hospitalizations: while many hospitalizations are not access related, this parameter would be useful to follow.
- Access-related infection rates: Infections are partially avoidable through regular maintenance of the access site. This quality measure would capture all access types, including catheters and fistula/grafts.
- Access thrombosis rate: important measure of the effectiveness of a surveillance program because thrombosis leads to greater risk to the patient for catheter exposure, missed dialysis, hospitalization and other complications.
- Procedure number per beneficiary year: procedures necessarily impose a burden on patients so the most effective program should obtain optimal outcomes with least number of procedures.
- Patient satisfaction: While difficult to measure, a patient's overall satisfaction with their care team and outcomes can provide valuable information to providers and the Medicare program as additional or alternative policies are designed.

7. What opportunities and challenges would exist in defining an episode of care?

- Opportunities:

Using an episode-based payment rate to reimburse for all vascular access-related services provided over a period of time encourages the coordination of care across providers and across the three proposed episode phases. This proposed episode-based structure would pay for all vascular access services under one standardized payment rate, which includes payment modifiers to account for the differences in intensity of care within each phase of the episode. This would provide results for the patient (in the form of better clinical conditioning and outcomes from care coordination) and for the Medicare program (in the form of lower total payments for vascular access care). Indeed, the greatest opportunity is to finally incentivize high quality, efficient care exposing patients to the lowest procedure burden required to achieve favorable outcomes. Accomplishing this will save Medicare money compared to a purely fee-for-service system that actually incentivizes inefficiency and increased numbers of procedures. A second opportunity is to be able to align the incentives of all providers in the patient's best interest.

- Challenges:

Designing an episode-based payment system around a clinically complex patient population poses several challenges for the providers and the Medicare program. As noted above, ESRD patients receive their vascular access services from a variety of settings. This can pose a significant challenge in the development of a vascular access episode-based payment system, as the risk-bearing entity is not easily identified for all patients. Providers will need to be able to collaborate to develop an integrated system of care and will need to work with a convener responsible for assigning financial risk to the various clinical groups providing care within the bundle.

A second challenge of this system is that the episode-based system must be well enough defined so that each phase has a clear beginning and end. This is critical to ensure that appropriate payment rates can be established for each phase. As patients shift across phases based on their care needs, the transition from one phase to another must be measurable and traceable using administrative claims data through the claims processing system and not rely on clinical information. Payment rates within each phase of the bundle must match the required intensity of the services so that providers are not undertaking undue risk.

A third challenge will be that in a number of locations across the country, where freestanding access centers provide care, the outcomes have already improved significantly. Many of these centers operate efficiently with lower hospitalization and fewer procedures per beneficiary per year in the population of patients that they manage. If these centers are to be successful in an episode-based model, the payment rate and quality benchmarks set will need to be based on “expected” or national/regional levels so that they are not penalized for the coordination and improvement efforts done prior to application to participate in the episode model.

The final challenge relates to hospitalization. Including the cost of hospitalizations in the episode payment would greatly increase the risk to providers. Indeed, properly managed access sites should rarely result in hospital admissions. The average ESRD patient is hospitalized multiple times a year, most of which even now are not related to access issues. Therefore, on the one hand, it would not make sense to include hospital inpatient costs (Medicare Part A) in the episode payment. On the other hand, however, this could lead to an unintended consequence. If hospitalizations are not included in the episode-based payment rate, providers may be incentivized to admit patients to the hospital to receive vascular access care in order to not be held accountable for that care. This clearly should not be allowed. A solution that addresses this possibility, as well as the costs of access complications that appropriately lead to the need for inpatient care, will need to be delineated.

Section II: Other Factors and Challenges

8. What should be the distinctive characteristics between this complex medical management model and the chronic care management model discussed in the 2014 PFS final rule or other primary care initiatives currently operated by CMS?

- The chronic care management model is essentially aimed at coordination of an array of services for patients with chronic conditions, stressing, continuity of care, systematic assessment of all medical needs, and management of care transitions, among other elements. This model is more general than that contemplated here, where some of the same elements come into play (such as coordination across applicable providers) but where the focus is on a narrower set of specialty services.

9. Which factors would influence a practitioner’s decision about whether or not to apply to participate?

- A practitioner’s decision to participate would likely be based on three aspects of the bundle. First and foremost, the practitioner must be able to effectively direct patient care and align him/herself with a network of providers. Without overlaying care coordination across the multiple specialties that provide vascular access care, neither the episode-based system, nor the provider individually, can be successful in improving patient outcomes and reducing Medicare payments. A provider aligned with a freestanding vascular access center would typically have the infrastructure in place to conduct this care coordination, likely increasing the likelihood of participation and success.

The second aspect is the risk required for participation. This risk can be mitigated through a cohesive care coordination network, but also through adequate payment for the services provided in each phase.

The last aspect that would determine practitioner’s participation would be who controls the payment. We believe that the model described that includes multiple phases of vascular access care, multiple physician specialties, and multiple sites of service all working together in an interdisciplinary fashion coordinated by a convener administrative function, is the best way to address this competitive concern. Any model that merely creates competition for “control” of access care would be disruptive to the overall care of the ESRD patient.

10. How can CMS encourage the adoption of such a model among other payers?

- Medicare is the primary payer for patients with ESRD and, therefore, is likely to be the primary payer involved in this model. However, any health plan that is responsible to cover ESRD for the first 30 months of Medicare ESRD entitlement – such as the Qualified Health Plans within the Exchanges – are likely to be attracted by the potential for significant improvement in outcomes and lower costs that the episode-based payment model provides. If a system like this were adopted by other plans/payers, patients could be receiving the coordinated care through a dedicated access team earlier, possibly resulting in better outcomes and lower rates of access failure once they are Medicare eligible.

11. What challenges might be encountered in implementing such a model?

- Implementing an episode-based payment system in an existing fee-for-service environment will result in challenges. First, there may be general reluctance from providers to shift from a fee-for-service environment to an at-risk environment. While there are potential benefits for the

providers in the form of gain sharing, there is also considerable risk that may deter providers from participating. However, as discussed above, appropriate payment rates relative to the services provided could help mitigate that risk.

Second, there are some geographic areas that do not have access to freestanding vascular access centers. Therefore, these communities will have a harder time achieving the better outcomes and lower costs that can be achieved elsewhere through the use of these centers. The use of payment transitions, blends, and risk corridors can help mitigate the risk for these providers while they develop their own networks to coordinate care and streamline patient access.

How payments are distributed and how risk is shared is another challenge that has yet to be fully addressed, even within the post-acute care bundling initiatives. The logistics of how and when payments are distributed to providers needs to be considered. One option is a per-beneficiary-per-month payment paid by Medicare to the convener and distributed to the other providers. How risk is shared across providers must be determined for each convener and network with enough transparency across providers to understand what care is provided and at what cost.

12. What other factors should CMS consider in the development of a complex medical management model?

- CMS should consider the risk of inaction and potential reward for this specific patient population. In this instance, the patient population involved is clinically complex and costly. Under the current system, many patients are receiving unmanaged vascular access care, which is resulting in potentially avoidable hospitalizations and infections. By implementing this proposed episode-based system, patients could be incentivized to receive care in freestanding vascular access centers, with an estimated decrease of 17% in per-beneficiary-per-month Medicare costs compared to costs for those treated urgently in the hospital outpatient department.

13. In addition to general information, CMS welcomes presentation of any examples of specific complex and chronic diseases for which actual episodes have been developed, with an explanation of how the questions above were answered in those episodes.

- Not applicable