

Questions on Dialyze Direct PFPM Proposal

May 4, 2018

CRITERION 1. SCOPE OF PROPOSED PFPM (HIGH PRIORITY CRITERION)

Aim to either directly address an issue in payment policy that broadens and expands the CMS APM portfolio or include APM Entities whose opportunities to participate in APMs have been limited.

1. On page 3, the proposal states that the targeted patient population has been excluded from home hemodialysis “due to logistic reasons.” Please explain what you mean by that, and also explain exactly what is different about the proposed approach that avoids these same barriers.

Heretofore, home HD has been performed by the patient and a caregiver, typically a family member, in a private home setting. A patient who has expressed a desire to proceed with a home HD option must pass certain criteria before a program will accept him or her in the program. Firstly, the patient’s general medical condition must be deemed safe to have home HD performed by family member caregivers; patients with multiple medical co-morbidities and high complexity could be disqualified. Secondly, the patient and/or caregiver must be able to demonstrate competence in all the clinical and technical aspects of carrying out home HD therapy. Patients with physical or cognitive impairments that can occur with age and frailty, may be disqualified. A family caregiver must be available on an ongoing basis to provide care. Under circumstances where a family member, for example a child, has other obligations (such as their own family or work responsibilities) they may not be fully available, thereby disqualifying the patient. Thirdly, the space where home HD is performed must be a medically suitable space. An extra room, such as a den, is desirable. A patient can be disqualified because the home may be deemed to have an unsuitable treatment area. The net effect of these categories of requirements is to skew the home HD patient population to a population that, compared to the general dialysis population, is younger, with fewer medical co-morbidities and more affluence.

The proposed model provides staff-assisted home HD. Experienced nursing staff permits home HD to be performed even when patients have multiple co-morbidities and medical complexities. The professional care givers, obviate the need to train the patient or a family care giver. The proposed model utilizes a medically suitable space (“den”) within the skilled nursing facility that obviates the requirement of private home to have such a suitable treatment space. The net effect of the proposed model of care is to offer the benefits of home HD to the elderly and frail with multiple co-morbidities regardless of socio-economic status.

2. In how many nursing facilities have you implemented the proposed model to date? What is the minimum and average number of residents per facility who are receiving services through the model?

Approximately thirty (30) sites are currently operational. There are more than one hundred and fifty (150) sites with signed contracts in six (6) states: Florida, Texas, Ohio, New Jersey, New York, and Pennsylvania. Additional contracts are being negotiated. Dialyze Direct has treated more than two hundred patients. 4-6 patients are currently treated at a site. It is anticipated that each site will be treating 8-10 patients when bed-side care is included. There have been instances where, 1-2 patients have been treated at a site. However, owing to the community demand for service, instances where 1-2 patients were being treated have been temporary.

3. What problems, if any, have you experienced in obtaining Medicare payments for the services you are currently delivering?

Although Dialyze Direct specializes in more frequent dialysis therapy (MFD) for the geriatric populations, this modality isn't appropriate for every patient. As such, our admission criteria states that, in order for a patient to participate in the program, he or she must: (1) freely choose home dialysis, and (2) meet certain more frequent dialysis medical necessity criteria, as set forth in Dialyze Direct internal policies, Medicare local coverage determinations as provided in the Physician Documentation of Medical Necessity Greater than Three Times Weekly Hemodialysis form, and policies of insurance companies. The screening process occurs as part of a patient's evaluation for admission to a skilled nursing facility.

Because the Dialyze Direct is careful to screen patients to ensure that they meet certain more frequent dialysis medical necessity criteria as set for by Medicare local coverage determinations, Medicare payments for the services delivered have been forthcoming.

Additionally, we have found circumstances where a patient freely chooses home dialysis and has comorbidities that meet the local coverage determination for more frequent dialysis, however the Medicare Administrative Contractor has denied payments for more frequent dialysis on unsubstantiated grounds of medical necessity. We appeal these denials and have had some success in obtaining reimbursement.

4. What problems, if any, have you experienced in obtaining participation by nursing facility residents in the services you are currently delivering?

Every Dialyze Direct patient, or, where appropriate, their medical proxy, has requested home dialysis therapy. Every patient, or their proxy, has been educated regarding the model of home dialysis that Dialyze Direct utilizes. Whether because of the more effective and gentler treatment, the more rapid recovery post-treatment, the high staff to patient ratio, the more effective on-site coordination of care, the on-site HD care that eliminates often uncomfortable and occasionally dangerous transportation trips, the certainty that meals, physical therapy sessions or social activities are not missed, the skilled nursing facility residents have overwhelmingly embraced the opportunity to participate in the proposed home dialysis program.

5. What proportion of the patients receiving hemodialysis at your current sites were previously receiving peritoneal dialysis at the facility rather than off-site hemodialysis?

None.

6. Of the patients receiving hemodialysis at your current sites who were previously receiving off-site hemodialysis, what proportion had been receiving more than three hemodialysis treatments per week at the off-site facility?

None.

7. How many patients need to be receiving on-site dialysis at the same nursing facility in order for the proposed services to be economically viable?

Approximately eight (8) patients.

8. How many nursing facilities would need to be participating in close proximity in order for the proposed services at any of the facilities to be economically viable?

Two (2) nursing homes in close proximity.

9. Would the proposed model be financially viable if patients were only receiving the standard 3 dialysis treatments per week?

Dialyze Direct developed a more frequent (5x week, pursuant to a physician order) dialysis model of care (MFD) designed to address the special needs of ESRD population who have highly complex medical problems that, generally, have not been effectively addressed with conventional hemodialysis (3 x per week) therapy. Certain medical conditions that can be improved with MFD serve as a guide with respect to identifying the patients who would be expected to benefit from MFD. Of particular importance to the elderly and frail population are benefits related to improved fluid management. MFD permits superior volume control when compared to conventional dialysis. Excessive volume manifests as hypertension with pre-HD systolic blood pressure ≥ 140 mmHg and/or a post HD blood pressure of ≥ 130 mmHg and/or multiple blood pressure medications and/or left ventricular hypertrophy. Ultimately, inadequate volume management leads to progressive cardiomyopathy with left ventricular failure and/or cardiac arrhythmia, and ultimately death. MFD, when compared to conventional HD, results in lower blood pressure, fewer blood pressure medications and regression of left ventricular hypertrophy. MFD also improves hemodynamic stability during dialytic fluid removal when compared to conventional dialysis. A disproportionate number of the elderly population appear to have autonomic dysfunction that contributes to intradialytic falls in blood pressure. Intradialytic hypotension (IDH), repetitive falls in systolic blood pressure ≥ 30 mmHg or an absolute fall to < 100 mmHg, results in ischemic damage to the heart (myocardial stunning with a progressive and permanent fall in left ventricular function), brain (white matter damage with progressive cognitive impairment), and gut (endotoxin release with chronic inflammation). MFD removes smaller increments of fluid during each HD and consequently is physiologically gentler than conventional dialysis, with fewer episodes of IDH and much shorter post HD recovery periods. The fluid removal rate is generally far slower (gentler) than the conventional benchmark standard of not exceeding 13 ml/kg/hour. In fact, in the Dialyze Direct patient population, fluid removal rates are typically 5-8 ml/kg/hour.

The elderly and frail, those with multiple medical co-morbidities and complex medical needs stand to benefit even more than any other ESRD patients undergoing MFD therapy. It is for the improvements in the quality of life and the improvements in numerous measurable medical outcomes that Dialyze Direct developed the proposed model of care.

With all due respect, whether or not 3 x per week would be financially viable, is, for Dialyze Direct, moot as it is our firm belief that conventional HD therapy for patients who otherwise stand to benefit from MFD, is a misinformed therapeutic approach that we vigorously oppose.

10. Would the proposed model be financially viable using dialysis equipment other than the NxStage System One?

NxStage System One has become the overwhelming national choice for home HD therapies. The NxStage technology is optimized to deliver more frequent dialysis therapy utilizing tap water to manufacture dialysate and obviates the need to build and maintain complex, on-site, water treatment systems. We are not aware of any comparable, economically viable systems that delivers MFD that can be universally applied to the skilled nursing facility environment.

11. Please describe what barrier(s) the proposal is trying to overcome and how this approach was selected. Specifically, what you would expect a nephrologist to do differently if the proposed financial incentives were in place, and what impact do you believe those changes would have on the way nursing facility residents would receive dialysis?

Incentives for nephrologists are designed to overcome certain potential barriers to the proposed model of care, that generally involve a requirement for the physician to expend extra effort with respect to overseeing the care of a patient population with higher medical complexity than is found in the general ESRD population or the typical home HD patient population. Firstly, there is much more intense coordination-of-care requirements for these complex patients with dialysis increasingly becoming one of many components of care under the broader chronic care umbrella. This is particularly true in the target population this model of care strives to serve. Even though the coordination of care is facilitated by the model's on-site registered nurse ("home dialysis care coordinator") and by the specialized geriatric social worker and dietitian that are a part of the caregiver team, the physician will likely be expending more time and effort in overseeing the care of the target patient population of the proposed model of care. Secondly, the elderly and frail patient population will require end-of-life and/or palliative care issues to be addressed with the patient, the patient's family or proxy and the patient's caregiver staff. It is already becoming apparent that, because of the availability of Dialyze Direct's program, certain patients who never would have been discharged from the acute care hospital owing to their need for on-site HD care, are now being discharged to skilled nursing facilities with Dialyze Direct services on-site. The complexity of care needed for these patients can be daunting. Thirdly, unlike traditional home HD, where the patients report to the home dialysis training center and/or the physician's office for their face-to-face assessments, we are taking steps to encourage on-site visit (s) by the nephrologist. From the nephrologist's personal-logistic point of view, the program has certain inherent inefficiencies since smaller numbers of patients are dispersed among different SNF sites. Fourthly, most nephrologists have not had extensive training or experience with the MFD model of care. A commitment to embarking on a learning curve requiring an outlay of time and effort (with our help) will be needed from the nephrologist. The financial incentives proposed rewards the physician for his or her time and effort that will be necessary to become a fully integrated part of an innovated model of care, proven to enhance patients' quality of life and improve medical outcomes. The improved outcomes that involve reduced hospitalizations and re-hospitalizations, combined with transportation savings, are just two of many benefits that more than offset any financial incentive earned by the physician.

From the resident patient point of view, the proposed model of care is profoundly beneficial. Whether because of the elimination of often uncomfortable and potentially dangerous transportation trips, much faster post-HD recovery times with the ability to better participate in rehabilitation and social activities, the elimination of missed meals, the reduction of the number of pills administered, the reduction of hospital admissions, the net effect for the SNF resident patient is a markedly improved quality of life.

12. If a nephrology practice had a sufficient number of ESRD patients living in nursing facilities, and if the practice wished to deliver services similar to what is proposed, could the nephrology practice successfully do so without involvement of Dialyze Direct?

Dialyze Direct has developed a proprietary model of care that is customized for the resident ESRD patient residing in a SNF environment. In addition to increasing the quality of life of a resident patient, the model improves medical outcomes while reducing the overall cost of care. Every Dialyze Direct caregiver, regardless of their years of dialysis experience, is retrained so as to understand and implement the model of care that has been developed. Dialyze Direct corporate clinical leadership includes physicians and nurses who are widely recognized as national, if not world-wide leaders in the dialysis industry. Dialyze Direct regulatory and biomedical ethical leadership is likewise renown. If a local nephrology practice could duplicate the above, and if they, as provider,

fulfilled all necessary requirements to obtain home dialysis licensure/certification in accordance with applicable state and/or federal law there should be no barrier to attempting to deliver care independently. By the same reasoning, if a local nephrology practice so desired, would be no theoretical barrier for the practice to attempt to deliver HD care to ambulatory patients in a free-standing dialysis facility without the participation of an external dialysis organization. We strongly support free-enterprise and believe each dialysis program should be judged on the merits of its outcomes.

13. Are you aware of any ESCOs that are encouraging this service? Have you approached any of them to ask for their support?

We are not aware of ESCO's implementing the model of care that is being proposed in this application. We are open to collaborating with the ESCO's and have had very preliminary discussions with some, but there is nothing to report as yet.

14. What would you see as the disadvantages of limiting this demonstration to patients who are already part of an ESCO?

Limiting the demonstration to patients already part of an ESCO would alter the basic design of the proposal. For HD patients residing in a SNF, we are proposing a comparison of on-site MFD home therapy with off-site conventional HD therapy as is generally performed in the United States. Firstly, adequate numbers of patients to achieve statistical power would appear to be a problem with the ESCO restriction. Secondly, the patient population to be studied is a subset of the general ESRD population; those that are elderly, frail, with multiple co-morbidities and who reside in a SNF. The ESCOs primarily address care in the prevalent general dialysis population that are younger and with fewer complex medical issues. The proposed model of care is standardized to achieve an improved standard of care. ESCO care is not standardized. Although the goal of all of the ESCOs are the same, to improve the standard of care, different ESCOs have different models of care; which is the essence of the ESCO experiment.

CRITERION 2. QUALITY AND COST (HIGH PRIORITY CRITERION)

Are anticipated to improve health care quality at no additional cost, maintain health care quality while decreasing cost, or both improve health care quality and decrease cost.

1. On page 9, the proposal states that physicians may be reluctant to participate because of the "intensity of effort necessary to oversee the high prevalence of medical co-morbidities...and the intensity of effort of certain end-of-life issues." On page 12, the proposal states that a hazard of the model is that some nephrologists "may be reluctant to invest the extra effort to 1) care for the nursing home dialysis cohort with multiple medical co-morbidities and more intense coordination-of-care requirements and 2) address end-of-life and/or palliative care issues with the patient, their family, and their caregiver staff." Wouldn't these needs presumably have to be addressed whether the patient is receiving on-site or off-site dialysis? Why are they a bigger concern if the patient is receiving on-site dialysis rather than off-site dialysis?

We agree that any patient in any dialysis program may have a need to have end of life issues addressed. However, because of the availability of Dialyze Direct's program, certain patients who never would have been discharged from the acute care hospital owing to the needs for on-site HD care, are now being discharged to skilled nursing facilities with Dialyze Direct services on-site. But for the transfer to a SNF facility, these patients would have

had end of life issues addressed in hospital. Thus, by the very nature of the program, Dialyze Direct is expected to receive a disproportionate number of patients with end of life issues. The nephrologist, functioning with a smaller overall support grid in the skilled nursing facility when compared to the acute care facility, must bear a larger overall responsibility.

2. How would you propose to ensure that patients who received dialysis at the nursing facility received adequate attention from the nephrologist, given that the nephrologist's payment would no longer depend on the frequency of visits with the patient?

We are not aware that the incentive payment programs designed to increase frequency of visits to the HD patient in the outpatient setting have been demonstrated to improve medical outcomes. The proposed model of care has many levels of care coordination, information-sharing as well as technological innovations designed to improve outcomes. The proposed model of care incentivizes the nephrologist to fully integrate with the system of care and enhances his or her role as a driver of improved care. The net effect of the proposed model is to not only to enhance the overall attention to care expended by the nephrologist, but to also ensure improved outcomes.

3. On page 14, the proposal states that it is unlikely that participating nephrologists would have experience with more frequent dialysis in the nursing facility for the types of patients who would be participating. What would be done to ensure that the nephrologists make good decisions about which patients should participate?

From the time of nephrologist credentialing, information regarding indications for MFD is shared with the nephrologists. Similar information is shared with the nursing and support staff and this extended care team is well-trained in recognizing the approved indications for dialysis more frequently than three times per week. The Medical Director of the program is charged with overseeing this education process. There is also robust oversight and information dissemination from the Corporate Medical Office. An example of Corporate education regarding MFD is provide below. These comments were excerpted from recent communications sent to the Medical Directors and the Nurse Managers from the Corporate Medical Office.

"I would like to bring to your attention the website "Advancing Dialysis" (www.advancingdialysis.org). It is organized by Allan Collins the CMO of NxStage and contains a wealth of information about more frequent dialysis (MFD) therapy. In particular, it explains in detail the kinds of medical conditions that can be improved with MFD and serves as a guide with respect to identifying the patients who would be expected to benefit from MFD. In fact, there are numerous medical conditions that provide the basis for recommending dialysis more than three times per week. Of particular importance to our elderly and frail population are benefits related to improved fluid management. MFD permits superior volume control when compared to conventional dialysis. Excessive volume manifests as hypertension with pre-HD systolic blood pressure ≥ 140 mmHg and/or a post HD blood pressure of ≥ 130 mmHg and/or multiple blood pressure medications and/or left ventricular hypertrophy. Ultimately, excessive volume leads to progressive cardiomyopathy with left ventricular failure and/or cardiac arrhythmia. MFD also improves hemodynamic stability during dialytic fluid removal when compared to conventional dialysis. A disproportionate number of the elderly population appear to have autonomic dysfunction that contributes to intradialytic falls in blood pressure. Intradialytic hypotension (IDH), falls in systolic blood pressure ≥ 30 mmHg or an absolute fall to < 100 mmHg, particularly when repetitive, results in ischemic damage to the heart (myocardial stunning with a progressive and permanent fall in left ventricular function), brain (white matter damage with progressive cognitive impairment), and gut (endotoxin release with chronic inflammation). MFD removes smaller increments of fluid each HD and consequently is physiologically gentler than conventional dialysis, with fewer episodes of IDH and much shorter post HD recovery periods. The fluid removal rate is generally far slower than the conventional benchmark standard of not exceeding 13 ml/kg/hour. In fact, in our patient population, fluid removal rates are typically 5-8 ml/kg/hour.

As you know, Dialyze Direct developed an on-site, staff-assisted home hemodialysis program that serves the End Stage Renal Disease Population residing permanently or transiently (for rehab) in skilled nursing facilities. We specialize in more frequent dialysis therapy for the geriatric population. Requirements for a patient to participate in our program includes 1) choice and 2) necessity. A separate, detailed comment regarding the latter was distributed earlier today. Please review it carefully.”

And excerpted from a second communication:

“Although Dialyze Direct specializes in more frequent dialysis therapy for the geriatric populations, this modality isn’t appropriate for every patient. As such, our admission criteria states that, in order for a patient to participate in our program, he or she must: (1) freely choose home dialysis, and (2) meet certain more frequent dialysis medical necessity criteria, as set forth in Dialyze Direct’s internal policies, Medicare local coverage determinations (as provided in the Physician Documentation of Medical Necessity Greater than Three Times Weekly Hemodialysis form), and policies of insurance companies. This process must occur as part of a patient’s evaluation to admission to a skilled nursing facility.”

4. Do you believe there should be any minimum standards required for a dialysis provider or nephrologist to participate in the proposed APM? If so, what should those standards be?

With respect to the provider, there are basic standards that must be met with respect to any and all government regulatory requirements. Equally important, is the corporate leadership and its requirement to carry out their ethical, clinical and scientific duties at the very highest level. We believe Dialyze Direct, as a provider, meets or exceeds any standards necessary to participate in the proposed APM.

With respect to the affiliated nephrologist, the credentialing process is comprehensive and includes, but is not limited to, having a valid medical license, being board certified or board eligible in nephrology, in good standing at an accredited acute care hospital, having credible references and acceptable screening of his or her malpractice and disciplinary history. Moreover, the affiliated nephrologist is expected to embrace the learning process necessary to develop expertise, if not already present, with respect to the technical aspects of MFD and the care protocols established by the Corporate Advisory Board and Medical Office. A robust QAPI program, overseen by the program’s Medical Director and facilitated by the program’s Nurse Manager, tracks population outcomes. However, the QAPI also is quite granular in identifying outliers and formulating specific plans of action designed to address and correct any medical issues that resulted in outlier status for any patient. The affiliated nephrologist is expected to embrace this quality improvement process. By meeting Dialyze Direct’s rigorous standards and oversight, we believe an affiliated nephrologist in good standing would meet any standards required for a physician to participate in the proposed APM.

5. You note that MFD lowers the risk of catheter infections and other related complications. How is this possible given more frequent manipulations of vascular access, and how would the model account for adverse events associated with more frequent hemodialysis, such as infections and access failures?

We believe the reduced catheter infection rate is a direct benefit of the highly favorable caregiver staff-to-patient ratio that far exceeds industry standards. The proposed model utilizes two (2) staff for every four (4) patients, a 2:4 ratio. Freestanding HD units utilize a significantly lower staff-to-patient ratio; often 2:8 or, in some cases, even lower. The primary cause of catheter infections is a break in technique. This is much like PD infection rates that are also user-dependent and highly dependent upon correct implementation of connection/disconnection protocol. With a high staff-to-patient ratio and a de-emphasis of rapid shift turnover, the likelihood of correctly

implementing Dialyze Direct's connection/disconnection catheter protocol is increased. In addition to the favorable staff-to-patient ratio there is a robust training program (and, when necessary, re-training program) for the clinical staff.

6. Would you expect any changes in the proportion of patients receiving dialysis through a fistula instead of a catheter?

We are strong proponents of a fistula-first philosophy, even for patients of advanced age. In conjunction with the patient's nephrologist, the program strives to ensure that patients are properly evaluated for a fistula placement. Fistula-first is an established "best-practice" goal and we intend to meet or exceed industry standards.

7. On page 17, the proposal states, "MFD reduces or eliminates a number of medications and further reduces complications of polypharmacy." Please describe the types of drugs that could be reduced or eliminated. Do you have an estimate of potential savings to Medicare Parts B and/or Part D?

Compared to conventional HD, multiple randomized clinical trials show that MFD significantly lowers blood pressure (by improved volume control). In the Frequent Hemodialysis Network trial, the number of antihypertensive medications per patient was reduced from 2.2 to 1.4 (FHN trial Group, Chertow GM, Levin NW, et. al. In-center HD six times per week vs. three times per week. NEJM 2010; 363(24):2287-2300). Subsequent studies have confirmed this finding (Bakris GL, Bukhart JM, Weinhandle ED, et. al. MFD and antihypertensive use. Am J Kidney Dis. 2016;68(5) (suppl 1):S15-S23). In the Frequent HD Network trial, MFD significantly lowered estimated phosphate binder dose per day (by improved phosphate removal during more frequent treatments using a "slow-dialysate" flow setting).

Thus, the primary classes of medications the MFD would be expected to reduce are the anti-hypertensives and the phosphate binders. Approximately 15% of the ESRD HD population resides in a SNF at some time during each year. We have not, as yet, estimated the potential savings to Medicare Parts B and/or Part D. If we are fortunate enough to have the current proposal advance to the next evaluation step, we will gladly have that information available for discussion.

CRITERION 3. PAYMENT METHODOLOGY (HIGH PRIORITY CRITERION)

Pay APM Entities with a payment methodology designed to achieve the goals of the PFPM criteria. Addresses in detail through this methodology how Medicare and other payers, if applicable, pay APM Entities, how the payment methodology differs from current payment methodologies, and why the Physician-Focused Payment Model cannot be tested under current payment methodologies.

1. Please quantify what you mean when you say "the vast majority" of elderly and frail cohorts with ESRD and multiple medical co-morbidities would meet the current criteria for payment for more frequent dialysis.

The elderly and frail ESRD population with multiple co-morbidities have, for logistical reasons as well as socio-economic reasons have been excluded from the option to choose and benefit from more frequent, home HD therapy. We estimate that in excess of 80% of the geriatric patient ESRD HD population meets current criteria for payment for MFD.

Notwithstanding the above points, in order for a patient to participate in our program, he or she must: (1) freely choose home dialysis, and (2) meet certain more frequent dialysis medical necessity criteria, as set forth in

Dialyze Direct's internal policies, Medicare local coverage determinations as provided in the Physician Documentation of Medical Necessity Greater than Three Times Weekly Hemodialysis form, and policies of insurance companies. For example, with respect to Medicare, each Medicare Contractor (MAC) has published reasonable and necessary medical criteria that justify payment for hemodialysis treatments more than three times per week. In fact, there are numerous medical conditions that justify payment for extra HD treatments. Of particular importance to the elderly and frail population are benefits related to improved excess fluid management, a well-established MAC-approved indication for dialysis more than three times per week.

MFD achieves superior volume control when compared to conventional dialysis and more likely than not, improves excess volume conditions that were not effectively managed with conventional HD. Excessive volume manifests as hypertension and/or multiple blood pressure medications and/or left ventricular hypertrophy and diastolic dysfunction. Over 60% of general HD patients are hypertensive, uncorrected by conventional HD therapy (DOPPS). Over 70% of general HD patients manifest diastolic dysfunction uncorrected by conventional HD therapy (Solmaz A, et. al. Changes in LV diastolic function during HD. *Am J Kidney Dis.* 2013; 62(3):549-556). MFD also improves hemodynamic stability during dialytic fluid removal of excess (retained) fluid. A disproportionate number of the elderly population have autonomic dysfunction that contributes to intradialytic falls in blood pressure (De Leo R, Messina C, Savica V. Autonomic function in elderly uremics. *Kidney Int.* 2005; 67:1521-1525). MFD removes smaller increments of fluid each HD and consequently is physiologically gentler than conventional dialysis, resulting in fewer episodes of IDH per treatment.

MACs consider treatment of fluid overload an acceptable justification for dialysis more than three times per week. Heretofore, every patient that has been treated in our program has met the MAC guidelines for justification for dialysis more than three times per week.

2. Would patients who do not meet the criteria for payment for more frequent dialysis be excluded from receiving the on-site services altogether, or would they be able to receive on-site dialysis three times per week?

Our program specializes in frequent dialysis therapy and does not perform conventional, 3 x per week HD therapy.

The decision as to eligibility for MFD occurs prior to admission to the SNF. Those that do not choose or are not deemed medically appropriate for MFD therapy are generally admitted to a SNF that either 1) has an on-site conventional HD unit or 2) arranges for patients to receive conventional HD off-site at a free-standing HD facility. If at any time a patient in our program chooses to withdraw from our program, that individual may 1) be transferred to another SNF with an on-site conventional HD unit or 2) receive conventional HD off-site at a free-standing HD unit.

3. Would patients be included in the model if they do not qualify for Medicare coverage for transportation to the dialysis facility?

Medicare coverage for transportation is not a criterion that is considered when a patient is evaluated for entry to the proposed program. Entry to the program is determined by 1) patient choice and 2) medical necessity as defined in Criterion 2, Response #1 above.

4. Are you proposing that the dialysis treatments would be delivered at the standard Medicare dialysis PPS payment rate?

Dialyze Direct did not include a higher Medicare dialysis PPS payment rate in the formal proposal because we were working under the assumption that the PTAC proposal be specifically focused on physician reimbursement.

In performing on-site home dialysis treatments in SNFs, Dialyze Direct provides significantly higher patient-to-staff ratios and oversight in comparison to freestanding dialysis facilities. The break-even point per treatment for our SNF home hemodialysis model is roughly \$340 per treatment. At this point in time, Dialyze Direct takes a loss for every treatment it performs when we are reimbursed in accordance with the Medicare dialysis PPS Payment rate, and heavily relies on a strong managed-care payor mix in order to be financially viable. In the event the PTAC were able to incorporate a higher reimbursement rate per treatment, it would provide crucial assistance to the success and growth of the model.

5. On page 10, the proposal says the savings from lower transportation costs “can be used to offset the ... increased staff-to patient ratios that are integral to the proposed MFD model of care” – what does that mean and what levels of specific staffing are required?

The proposed model utilizes 2 staff for every 4 patients. This is an increased staff to patient ratio when compared to a freestanding HD unit. Freestanding HD units utilize a significantly lower staff-to-patient ratio; often 2:8 or, in some cases, even lower. There are multiple benefits to the high staff-to-patient ratio, including, but not limited to, 1) a reduced catheter infection rates, and 2) enhanced attention to both the patients’ HD needs and their chronic care needs and 3) enhanced coordination of care with the SNF staff.

The OIG reported that in New York from 2002-2011, the percentage of nursing home ambulance transport to and from a dialysis facility and costing more than the actual dialysis treatment itself, rose 281% while the percentage of the general dialysis population that needed ambulance transport rose by only 1%. When patients receive off-site HD care, round trip transportation costs amount to six (6) trips per week. As noted by the OIG, these costs can exceed the actual HD treatment cost. This is one of the cost saving measures that can be used to offset both the increased frequency of HD, as well as a potential higher reimbursement rate for the dialysis treatments that accounts for increased staff ratios that are in our proposed MFD model of care.

6. On page 12 of the proposal, you propose to give the nephrologist a share of the savings related to “eliminating unnecessary Medicare-covered transportation services to an off-site medical office.” Which patients do you believe would be eligible for Medicare payment for transportation to a physician’s office?

Transportation costs to and from a physician specialist’s office are generally paid for by Medicare or Medicaid. Medicare pays for ambulance transportation when the latter is justified. If a patient does not meet criteria for ambulance transport and other modalities of transportation are used, it falls to Medicaid to cover those costs. Most patients residing in a SNF eventually become Medicaid eligible due to spend-down of their private assets. If a Medicare patient does not meet criteria for ambulance transportation, has private assets remaining and is carrying secondary insurance, the secondary insurance often does not cover transportation, and the patient is required to pay for the transportation with his or her private funds.

7. Are you proposing that anyone (the nephrologist, the dialysis provider, the nursing facility, or the patient) would share in any Medicare savings other than the savings from avoided payments for transportation to the nephrologist’s office? In particular, would anyone share in the savings from the avoided transportation costs to and from dialysis treatments?

Comments regarding cost savings are designed to illustrate the financial benefits that ensue from the proposed model of care. The financial benefits of the model include 1) savings from transportation costs to and from an off-site HD unit and/or a nephrology office visit (s), 2) savings from the reduction in hospitalizations and re-hospitalizations, 3) savings from a reduction of certain anti-hypertensive and phosphate binding medications, 4) savings from higher rehabilitation scores reached more quickly and more likely to favorably impact the outcomes in the 90-day post-acute care period. The benefits of the proposed program are far greater than those limited to transportation costs. The program addresses many of the chronic care needs (and costs) of the geriatric ESRD HD patients.

The nephrologist is specifically incentivized to avoid patient visit (s) to his or her office and is encouraged to provide the mandated face-to-face monthly visit on-site. When he or she does that, the nephrologist earns a monthly capitation payment increment equal to the cost of the transportation that would otherwise have been spent. Recent changes in regulations will permit telemedicine visits for home HD patients, effective 2019. This new development may provide another tool for the nephrologist and we are currently exploring this option. There is no intention to directly add an incremental benefit to the SNF or Provider's payments or to financially reward a patient for participation in the program in the way proposed for the nephrologist.

8. Please estimate (1) the savings per patient from avoiding transportation to an off-site dialysis center for a patient who is receiving dialysis at the standard 3 day per week frequency, and (2) the increase in spending per patient from the additional payments Medicare would make for more frequent dialysis.

As noted above (Criterion 3, Answer #5), the OIG reported that in New York from 2002-2011, the percentage of nursing home ambulance transport to and from a dialysis facility and costing more than the actual dialysis treatment itself, rose 281% while the percentage of the general dialysis population that needed ambulance transport rose by only 1%. When patients receive off-site HD care, round trip transportation costs amount to six (6) trips per week. In a recent abstract using USRDS data and tracking Medicare payments for transportation from long-term care institutions to off-site HD units in 2012, \$310M was expended by Medicare for these services or 1.1% of all Parts A and B expenditures. Medicare services averaged \$411 per round trip, and 75% higher than the \$235 cost of HD in 2012 (Weinhandl E, Upchurch L, Collins A. Medicare payments for transportation between nursing institutions and dialysis facilities. Presented in March 2017 at the Annual Dialysis Conference in Long Beach, CA).

The increased spending per patient from the additional payments Medicare would make for MFD amount to two (2) extra treatments per week. Using Medicare data from 2012 where the cost of HD averaged \$235, the additional cost of MFD would be \$470 per week. Using data from Weinhandl's abstract, Medicare transportation savings of \$1,233 would offset \$470 of extra expenses for MFD, and savings from transportation costs alone would amount to \$763 per week. There are much more significant savings when the additional fiscal benefits of improved medical outcomes as a result of MFD are included in the calculations.

9. Would the nursing facility incur any additional costs to create a "dialysis den?" How would those costs be covered? What would be the incentive for a nursing facility to participate in this program?

The nursing home is responsible for the cost of renovating the room to create the dialysis den, as well as the electricity, heating & cooling and housekeeping within the dialysis den. As with any home HD program, dialysis program assumes all other costs. The only exception, owing to anti-kickback law, is that the nursing home is required to pay for the LPN (or in some states, the HD technician) caregiver time. Those costs amount to approximately \$25.00-29.50 per hour, depending on the fair market value within the market. This cost would not have to be borne if one of the insurance payers assumed the caregiver cost as a separate line-item expense.

Incentives for the SNF to participate in the program include: 1) Retention of patients. Recent Medicare rules effective 11/28/17 mandate: “If a current resident has been identified as meeting the criteria for HD/PD by the dialysis facility team, and the nephrologist or the physician prescribing dialysis, and chooses to receive either HHD/PD, and the nursing home does not allow for these onsite services, the nursing home must assist the resident with the transfer to a nursing home or in the relocation to a setting of his or her choice that provides HHD/PD services.” 2) Increase in occupancy; improved patient referral flow from acute (and chronic) care institutions. 3) No missed rehabilitation sessions (which can be billed) during subacute rehab admissions. Patients receiving off-site HD are often away from the SNF for 6 or more hours, three times per week, and return fatigued with recovery often not occurring until the next day. MFD results in much more rapid post-dialysis recovery; often complete in less than one hour. As a result, rehabilitation scores are higher and more rapidly achieved. Patients are consequently more stable and some of the burden of care is for the SNF staff is alleviated. 4) The SNF overall patient acuity score is increased with more ESRD patients in the census. Upcoming changes in SNF reimbursement will reward those with higher overall patient acuity mixes.

10. On page 6, the proposal says, “the program provides an on-site interdisciplinary team that includes a senior registered nurse (RN), home dialysis coordinator, trained home HD caregivers, dietitians, and social workers...” and on page 16, the proposal says that “a program-wide regional medical director will coordinate care with the medical director of the nursing facility.” Would all of these staff be paid through the standard Medicare dialysis payments? How much would this increase the cost per treatment beyond the cost typically incurred in a dialysis facility?

Except for the SNF payment for the den’s renovation, electricity, heat, cooling, housekeeping and hours of caregiver time as described in Criterion 3, Answer #9, all other costs are paid for by the proposed program in the same way that the positions are paid for by conventional home dialysis programs. Dialyze Direct requires roughly \$340 per treatment to break-even for the increased overhead and support it provides. Managed-care payers have contracted with Dialyze Direct at payment rates higher than the Medicare dialysis PPS payment rate, and an appropriate insurance mix is necessary for the financial viability of the program. This is similar to a conventional dialysis program that also depend on a mix of commercial insurers for financial viability. Nationwide, taking into account all overhead costs, the cost of a HD treatment is generally higher than the Medicare reimbursement rate.

Overhead costs of the proposed program are not strictly comparable to the overhead costs of a dialysis facility. On the one hand, Dialyze Direct incurs higher costs than a freestanding dialysis facility due to our increased patient-to-staff ratio and oversight. On the other hand, dialysis facilities include “brick and mortar” overhead costs. However, on balance, Medicare and a mix of other payers covers the proposed program’s operational costs in the same way as it is covered in a dialysis facility.

11. Would the \$500 patient education bonus be awarded to the nephrologist only if the patient chose to participate in the on-site, staff-assisted, dialysis program, and only if the patient was determined eligible for more frequent dialysis and agreed to receive more frequent dialysis?

Yes.

12. Can you provide an estimate of the average cost per patient to deliver the proposed on-site services and how that cost compares to the average cost per patient of delivering conventional center dialysis?

Essentially, costs are 1.6X greater than conventional HD owing to the MFD treatment schedule of 5 vs. 3 treatments per week. Based on Medicare data payments of \$235 in 2012, notwithstanding the reality that Medicare underestimates the true cost of HD, MFD would average the same Medicare reimbursement per treatment but cost \$470 more per week. This \$470 of extra expenses per week (refer to Criterion 3, Answer #8) is offset by 1) savings from transportation costs to and from an off-site HD unit (\$1,233 per week), 2) savings from the reduction in hospitalizations and re-hospitalizations (our preliminary data shows a 60% reduction in hospitalizations), 3) savings from a reduction of certain anti-hypertensive and phosphate binding medications (calculations not yet available), 4) savings from higher rehabilitation scores reached more quickly and more likely to favorably impact the outcomes in the 90-day post-acute care period (data pending).

CRITERION 4 -There was no such criterion included in the Questions sent to us.

CRITERION 5. FLEXIBILITY

Provide the flexibility needed for practitioners to deliver high-quality health care.

- Do you feel that the current criteria used by Medicare contractors to determine which patients should receive more frequent dialysis are adequate to enable you to include all of the patients who could benefit from the proposed approach to dialysis?

No. We believe the Medicare contractors' criteria should be updated to include important omissions. In September 2017, several Medicare contractors (MACS) released for public comment a draft local coverage determination *inter alia* regarding frequency of hemodialysis. There was a massive response from the dialysis community. Perhaps as a result of the many issues raised, the local coverage determination has not been finalized. Excerpts from the Dialyze Direct comments are presented below:

“Modern hemodialysis therapy is highly effective when defined in terms of urea clearance. Adequate urea clearance (Kt/V) is met in 95% of patients receiving three-times-per-week treatments (DOPPS 2017). These kinetic targets can be achieved in three (3) dialysis sessions per week using any modern hemodialysis equipment, including the equipment typically used for more frequent hemodialysis. Furthermore, kinetic targets are no longer necessarily defined as a “per treatment” Kt/V; advances in kinetic analysis now define a weekly standardized Kt/V (wstdKt/V) that reflects the weekly dose of urea clearance and represents a more comprehensive urea clearance outcome standard.

For fifteen years it has been understood that achieving urea clearance goals, by itself, is not a guarantee of achieving quality hemodialysis outcomes. As demonstrated in the HEMO study, clinical benefits flatten out once urea clearance goals are met, with no further clinical benefit achieved by increasing the “dose” of dialysis further (Effect of Dialysis Dose in Maintenance Hemodialysis. N Engl J Med 2002;347:2010-2019). The HEMO study did not comment at all upon more frequent dialysis venues. In fact, every HEMO study subject received a three-times-per-week dialysis regimen. The proposed local coverage determination document appears to conflate the “dose” of dialysis (urea clearance) with the frequency of dialysis when it states “efforts to increase the dose of dialysis administration above three times per week have not improved survival.” This apparent reference to the HEMO study is conceptually incorrect and appears to misunderstand that the basis for prescribing more frequent hemodialysis has nothing to do with increasing weekly Kt/V beyond acceptable values.

Modern hemodialysis strategy to improve quality of care and outcomes focuses on the hemodynamic and fluid management challenges of hemodialysis patients. Failure to achieve optimal fluid removal predictably results in sustained hypertension, cardiac damage and morbid events that diminish the quality of life and increase the cost of care. Further, the unintended consequences of intradialytic hypotension, as a consequence of rapid fluid removal in the setting of a multitude of comorbid medical conditions such as cardiomyopathy and/or autonomic dysfunction, also results in organ damage - heart, brain and gut - that diminishes the quality of life and increases the cost of care. With the general population aging, and with comorbid conditions highly prevalent in the elderly, the challenge of optimally managing fluid has only increased. Putting fluid overload in perspective, 65% of USA hemodialysis patients receiving three-times-per-week treatment are chronically fluid

overloaded - as manifested by systolic blood pressures ≥ 140 mmHg. Further, for more than a decade, there has been no improvement in managing fluid overload (DOPPS 2017). It has now been well established that, in certain patients, volume overload and blood pressure control with three-times-per-week therapy is unachievable and inferior to more frequent hemodialysis therapy (Frequent HD Network Trial. *N Engl J Med* 2010;363:2287-2300).

The concept of “dry weight” is dramatically evolving from past perceptions. At this weight, different for each individual, there is no excess of fluid, blood pressure is normal and heart failure is rare. Admissions to hospital are remarkably reduced in patients with normal fluid status as demonstrated by numerous specific studies in the USA and other countries. In some patients, the need to remove large quantities of fluid in three (3) dialysis sessions per week results in many serious complications, all of which require hospital admission. When the dialysis can be spread over more frequent treatments, fluid removal is slower and gentler, thereby reducing complications such as intradialytic hypotension. In addition, when used appropriately, more frequent dialysis achieves total fluid removal that is good enough to achieve normal fluid status. Because there are selective groups of patients that cannot be successfully treated with three-times-per-week dialysis, the default definition of successful dialysis therapy should not necessarily be a three-times-per-week dialysis schedule.

Hospitalization costs accounting for 26% of total Medicare expenditures ($> \$160B$), and ESRD hospitalization rates and 30-day readmission rates ($> 30\%$) are far in excess of the general Medicare population (USRDS 2014 ADR, *Kaiser Health News* 10/2/14). Fluid management problems represent a major cause of hospitalizations and, in aggregate, result in thousands of unnecessary hospital admissions that profoundly impact the patients’ quality of life as well as the cost of care.

With this in mind, the concept and practice of more frequent hemodialysis has evolved. More frequent hemodialysis reduces chronic volume overload, the doses and number of blood pressure medications and can induce regression of left ventricular hypertrophy (The Effect of Increased Frequency of Hemodialysis on Volume-Related Outcomes: A Secondary Analysis of the Frequent Hemodialysis Network Trials. *Blood Purif* 2016;41:277-286). In addition, more frequent hemodialysis reduces the per-treatment frequency of intradialytic hypotension owing to smaller volumes of fluid removal per treatment (Frequent HD Network Trial). These benefits of more frequent hemodialysis are achieved in ways that, for selective patients, conventional, three-times-per-week hemodialysis therapy, as currently practiced in the USA, has not been effective at achieving.

Numerous CMS manual provisions clarify that the use of more frequent dialysis therapy is based on “an individual patient’s needs” and “medical justification.” Medicare never proposed to change the process for MAC approval of additional dialysis treatments. It is inconceivable that the MACS do not believe patients should be afforded individualized quality care and a chance to improve their health.

As a leadership team who has cared for patients with advanced kidney disease for over 60 years, as a Chief Medical Officer and a former Chief of Nephrology, and as a Chief Nursing Officer and a former Hemodialysis Nursing Director, we have some insight into the health care delivery system’s numerous challenges in caring for patients with permanent kidney failure. For dialysis patients with hypertension, cardiomyopathy and/or episodes of intradialytic hypotension, the hemodynamic benefits of more frequent hemodialysis are a fundamental reason behind the choice of more frequent hemodialysis over conventional three-times-per-week therapy. This is a major reason why doctors prescribe, and patients embrace, this form of therapy. These benefits are at the very core of the basis for why more frequent hemodialysis therapy can be reasonable and medically necessary. Medicare and its contractors have a tremendous need and opportunity to empower patients to break down regulatory barriers that limit treatment options that improve medical outcomes. Doing so will not only improve the patients’ quality of life but will also save our health care system hundreds of millions of dollars in unnecessary spending.

Allen Kaufman MD (Dialyze Direct: Chief Medical Officer, Senior VP for Clinical and Scientific Affairs)

Alice Hellebrand RN (Dialyze Direct: Chief Nursing Officer, Senior VP for Education)”

CRITERION 6. ABILITY TO BE EVALUATED

Have evaluable goals for quality of care, cost, and any other goals of the PFPM.

- How would you propose to evaluate performance on rates of infection, access problems, etc.?

The proposed study will be a nonrandomized comparison of two groups of patients: a prospective cohort of patients residing in a SNF and receiving staff-assisted, more frequent home HD and a matched retrospective cohort of patients residing in a SNF and receiving conventional in-center HD. We anticipate that the prospective cohort will include 500 patients. The retrospective cohort will be matched at a ratio of 5-to-1 and drawn from a claims-based cohort of >60,000 ESRD patients who have resided in a SNF. The claims-based cohort will be a function of Medicare and Medicaid claims, as Medicare covers outpatient dialysis and skilled nursing facility care after hospital discharge, whereas Medicaid covers long-term skilled nursing facility care. In-center HD patients will be closely matched for demographics, socioeconomic status, medical comorbidity, and vascular access status. The proposed model's EHR technology permits detailed data collection, including quality measures comparable to the quality performance categories of the Merit-based Incentive Payment System ("MIPS") and other measures related to "QIP" and "5 Star" quality metrics. As part of these metrics, a ICH-CAHPs score (In-Center Hemodialysis Consumer assessment of Healthcare Providers and Systems) tracks a patient's perspectives of dialysis care. This metric is, currently only being reported for In-center hemodialysis, will be adapted by Dialyze Direct for our home dialysis program. Infection and vascular access outcome data will be an important part of the overall data collection plan.

CRITERION 7. INTEGRATION AND CARE COORDINATION

Encourage greater integration and care coordination among practitioners and across settings where multiple practitioners or settings are relevant to delivering care to the population treated under the PFPM.

- How would the patient's dialysis care be coordinated with care for their other medical needs?

An advantage of a patient residing in a SNF with an on-site home dialysis program is that there is close proximity of caregivers; the SNF staff and the dialysis staff, and the physicians, nurse practitioners, consultants and nephrologists. Medical records are freely shared. For every dialysis treatment there is a well-organized, written "hand-off" with transfer of care from the SNF team to the dialysis team for a dialysis treatment and vica-versa after HD is completed.

- What incentive would there be for the nursing facility to coordinate its services with the dialysis provider?

The SNF's participation is incentivized for reasons outlined in Criterion 3, Answer #9. The groundwork is set for coordination of services from the initial negotiation between Dialyze Direct and the SNF's leadership and/or its parent company. The point is made that the Dialyze Direct model of care is a part, important that it is, of the larger picture of chronic care management. The SNF's fully understand that successful outcomes cannot be achieved with an uncoordinated, piecemeal approach to care. The proposed model of care is designed to have the on-site nurse home care coordinator be the driver of coordination of care and information sharing.

- Following discharge from SNF, would patients be able to continue the same type of treatment at home, or would they need to return to in-center dialysis three times per week? How would care transitions be managed for patients who are discharged?

Following discharge from the SNF, a patient would have the option to continue as a private home dialysis patient with his or her same nephrologist. If the patient chose not to remain in the home dialysis program or if the patient could not remain in the home dialysis program for logistical reasons, he or she would return to in-center three times a week under the care of his or her nephrologist. If the patient returns to in-center dialysis the transfer of dialysis care would occur as it would for any transfer from one dialysis program to another, with relevant medical and technical information passing to the receiving dialysis program facilitated by our program's social worker.

CRITERION 8. PATIENT CHOICE

Encourage greater attention to the health of the population served while also supporting the unique needs and preferences of individual patients.

- How would the benefits and risks of the proposed on-site MFD model be presented to patients?

The benefits and risks of the on-site MFD model of care are first presented to the patient before they transfer to the SNF. This information is presented to the patient by the discharge planner of the acute care facility; the discharge planners at the acute care facilities having each been trained by Dialyze Direct educational staff. The second presentation of the benefits and risks of the model of care is presented to the patient by the on-site home dialysis care coordinator. The third presentation of the benefits and risk of the model of care is presented to the patient by his or her nephrologist. The proposed model of care includes incentives for the nephrologist to become fully engaged in this educational role.

- Would patients who are currently receiving peritoneal dialysis in the facility be eligible to participate? What would be the advantages and disadvantages for the patient of switching from peritoneal dialysis to more frequent hemodialysis?

Home PD patients would be eligible to enter the program. However, to date, we have not had patients enter the program who were receiving home PD. The reasons for transfer from a home PD program to a home MFD program are several such as: 1) patient choice and/or 2) medical indications that include, but are not limited to, loss of peritoneal membrane ultrafiltration capacity, recurrent peritoneal infections with adhesion and drainage problems, uncontrolled diabetes related to the dextrose load associated with PD. If a patient chose home PD because of the inability to maintain a viable arterio-venous fistula (or graft), a transfer to home MFD would require placement of a permanent venous catheter. The risks of a permanent venous catheter would have to be balanced against the benefits of home MFD.

- Please describe the likely patient cost-sharing obligations under the proposed model compared to the other dialysis options which might be available to the patient (i.e., peritoneal dialysis in the facility, off-site dialysis for three days per week, and off-site dialysis for five days per week).

There are no cost differences to the patient for the proposed model of care when compared to the other dialysis options such as on-site peritoneal dialysis or off-site HD or MFD. The only exception would be if there was a cost to the patient for transportation (depending on his or her insurance) to and from an off-site HD treatment location.

- How does the model ensure that patients who would rather go to the dialysis center or who don't want more frequent dialysis receive care consistent with their preferences?

The decision as to eligibility for MFD occurs prior to admission to the SNF. Those that do not choose MFD therapy are generally admitted to a SNF that either 1) has an on-site conventional HD unit or 2) arranges for patients to receive conventional HD off-site at a free-standing HD facility. If at any time a patient in our MFD program chooses to withdraw from our program, that individual may; 1) be transferred to another SNF with an on-site conventional HD unit or 2) receive conventional HD off-site at a free-standing HD unit.

CRITERION 9. PATIENT SAFETY

Aim to maintain or improve standards of patient safety.

- What methods would you propose be used to ensure that only appropriate patients receive the proposed services?

There are multiple systems in place to ensure that only appropriate patients receive the proposed services. The methodology includes a clear delineation of the approved indications for MFD, education of the physicians and nurses and oversight by the Nurse Managers, Medical Directors and Corporate Medical Office. Dialyze Direct's Corporate Management Compliance Group, comprised of the CMO, CNO, COO and the General Counsel & Chief Compliance Officer regularly performs a medically reasonable and necessary services audits that ensures that only appropriate patients receive MFD services. Please refer to Criterion 2, Answer #3 and take note of the details of the methodology in use.

- What mechanisms would you propose be used to monitor for adverse events?

The proposed staff assisted home hemodialysis model insures that every treatment is supervised by professional staff. The program has a robust occurrence reporting system that meets or exceeds standards for any dialysis program and insures that any adverse events are monitored and addressed. Adverse events are reviewed monthly at QAPI meetings. Depending on the adverse event it will be addressed by the medical director before the monthly QAPI meeting. All adverse events are, additionally, reviewed by the Corporate chief compliance officer.

CRITERION 10. HEALTH INFORMATION TECHNOLOGY

Encourage use of health information technology to inform care.

- Please describe the specific ways that data collected through the EMR would be used to support quality of care and care coordination.

All clinical data is collected in the EMR. This includes, but is not limited to, a broad collections of physiologic and hemodynamic patient data, staff work flow data and technical data relevant to machine function. The data is aggregated and organized via a cloud-based data storage system that is utilized to structure the QAPI and other oversight systems. Aside from the efforts of a patient's individual nephrologist to ensure quality care and coordination of care, the program plays critical role in ensuring quality and coordination. Systems such as the QAPI program have been designed to screen patient outcomes for outliers and formulae strategies to improve outcomes on a patient-by-patient basis. Data collected at each SNF site is used to provide a customized QAPI

information system for the SNF leadership. This program is distinct from the home dialysis QAPI program and is designed to focus on topics relevant to the SNF. This data is reviewed and analyzed at regular meetings where both the SNF and Dialyze Direct staff are present.

- Please explain the extent to which the types of data needed are dependent on proprietary technologies associated with the NxStage equipment.

Data collected will be generated independently and not dependent on the proprietary technologies associated with NxStage equipment.

Q&A re Dialyze Direct PFPM Proposal

July 5, 2018

CRITERION 1. SCOPE OF PROPOSED PFPM (HIGH PRIORITY CRITERION)

Aim to either directly address an issue in payment policy that broadens and expands the CMS APM portfolio or include APM Entities whose opportunities to participate in APMs have been limited.

- The response to the PRT's first set of questions states, "4-6 patients are treated at a site. It is anticipated that each site will be treating 8-10 patients when bed-side care is included." Please clarify what you mean by "when bed-side care is included." Does this mean there is a subset of patients who can receive MFD in the nursing facility with less intensive staffing than what you are proposing?

Bed-side care is designed for individuals with various medical or logistic conditions that preclude HD being performed in the treatment den. Examples of reasons for bed-side care include, but are not limited to, individuals on ventilator support, certain contact isolation precautions such as c. difficile or MRSA infections and/or immobility such as may occur with long bone fractures or certain spine lesions. Under these conditions, MFD is performed at bed-side with a 1:1 staff to patient ratio that is more intensive than the 2:1 staff to patient ratio used in the setting of the treatment den.

- The response to the PRT's first set of questions states, "Although Dialyze Direct specializes in more frequent dialysis therapy (MFD) for the geriatric populations, this modality isn't appropriate for every patient." Approximately what proportion of nursing facility patients would be appropriate for dialysis in the nursing facility but not appropriate for MFD?

By virtue of our patient screening policy for acceptance to our program, every dialyze Direct patient has been deemed to have a medical condition reasonable and necessary for dialysis more frequent than 3 times per week in accordance with a signed physician order from the patient's nephrologist. The primary criteria used has related to patients previously receiving conventional HD who manifest fluid overload, either overt or relative, as by hypertension (systolic pressure ≥ 140 mmHg before or during HD, and/or ≥ 130 mmHg post HD) and/or intradialytic hypotension (frequent falls in systolic BP ≥ 30 mmHg) and/or frequent falls to an absolute systolic value of < 100 mmHg). These criteria are consistent with fluid overload guidelines for justifying dialysis more than 3 times per week that have been published by Medicare Contractors. Patients receiving conventional HD who are not hypertensive and do not exhibit intradialytic hypotension exist and would not be suitable for MFD. In general, these would be younger patients with less complex medical comorbidities. This patient cohort would not be eligible for inclusion in our program. Because these patients are being dialyzed at SNFs that are not contracted with our program, the specific details of this patient population are presently not available to us. Nonetheless, based upon our experience to date with respect to those being referred to our program, it appears that a large majority of HD patients requiring a short term or extended SNF stay are appropriate for MFD therapy.

- The response to the PRT's first set of questions states, "the Medicare Administrative Contractor has denied payments for more frequent dialysis on unsubstantiated grounds of medical necessity. We appeal these denials and have had some success in obtaining

reimbursement.” The PRT would like to better understand the reasons for denials and on what basis the denials were reversed on appeal.

Specific reasons for denials are generally not given. Sometimes the Medicare Administrative Contractor will use a boiler-plate reason (i.e. lacks sufficient medical record documentation) regardless of the completeness of the medical record. It is our impression that more than 3 times per week dialysis, per se, has randomly triggered denials during a randomly chosen time periods. This prompts an appeal and if necessary a reconsideration request whereby we provide a case-by-case summary of the reasonable and medically necessary basis for dialysis more frequent than 3 times per week. We use the Medicare Administrative Contractor’s own published criteria deemed by the Contractor as acceptable for dialysis more frequently than 3 times per week. This approach has proved to be a successful strategy in reversing a Contractor’s denial.

- The response to the PRT’s first set of questions indicates that the proposed model is operational in approximately 30 sites. Based on your experience with these sites, the PRT would like to understand the following:
 - What proportion of patients were in Medicare Part A SNF stays?

Medicare primary SNF stays are ~ 60%. We expect this number to decrease as managed care options increase. Please note that we anticipate opening an additional 150 sites over the next twelve (12) months, giving us even more insight into the insurance demographics of the SNF HD population.

- Do you have any data on what happens to the patients after the Medicare covered SNF stays end? In particular, if they are discharged from the nursing facility, where and how do they receive dialysis after discharge?

The majority of patients enter the program for a short-term SNF rehabilitation admission and have established ESRD. These patients are typically discharged from an acute care hospital and transferred to the SNF. Prior to the acute care hospitalization, these patients have generally been receiving HD treatment in an outpatient HD facility, with care supervised by a community nephrologist. We strive to maintain the established doctor-patient care relationship and, in general, the patient’s community nephrologist oversees home HD care at the SNF. If a patient is discharged from the SNF, the patient generally returns to their original outpatient HD facility with care by their usual community nephrologist. In theory, if an appropriate patient desired to remain on home HD therapy and had family caregivers available, Dialyze Direct would extend home HD therapy to the private home setting. The community physician would continue to oversee care.

- What proportion of non-Medicare-covered stays were being covered by Medicaid?

Medicaid primary SNF stays are ~5%, managed Medicaid represents an additional 20% of the SNF stays. We expect managed Medicaid patients to increase in number.

- What proportion of the patients at your sites had been in the nursing facility for a period of time before starting on dialysis, versus being admitted to the nursing facility with a need for dialysis?

A patient with advanced CKD residing in a SNF could directly start HD with us and bypass an admission to an acute care hospital. Alternatively, a patient with advanced CKD residing in the SNF could be admitted to an acute care hospital to initiate HD and then return to the SNF also as a new HD start with us. We are particularly interested in the first option of starting HD therapy on-site and bypassing an acute care hospital admission. Our home HD care teams are working with the SNF’s to make this option a reality. To date, all new HD patients entering our program were residing in their private residence prior to being admitted to an acute care hospital. In these cases, HD was initiated in the acute care hospital and the patients were subsequently transferred to the SNF because they were deemed unsafe for discharge back to their private residence. Once sufficient rehabilitation was achieved, the patients

have been safely discharged back to their private residence with ongoing HD care arranged as described in the response to the former question inquiring “where and how do they [the patients] receive dialysis after discharge [from the SNF].”

- How long did patients generally participate in the program? Why did they discontinue?

Patients have remained in the program for the duration of their rehabilitation stay. When discharged from the SNF, the patients have returned to their previous outpatient HD unit. Those that were new start HD patients have been transferred to an outpatient facility upon discharge from the SNF. Those patients who are permanent residents in the SNF, have remained in the program. Aside from the rare occurrence when a patient chooses to withdraw from HD entirely, to date, no patient has discontinued the program for reasons other than discharge from the SNF. Patients have expressed interest in continuing home HD therapy in their private residence but, to date, family caregiver support has not been sufficient to support the patient’s wish.

- The response to the PRT’s first set of questions states, “It is already becoming apparent that, because of the availability of Dialyze Direct’s program, certain patients who never would have been discharged from the acute care hospital owing to their need for on-site HD care, are now being discharged to skilled nursing facilities with Dialyze Direct services on-site.” Please provide more information about the nature of these patients. What would have happened to them before the Dialyze Direct services were available? How long do they receive the Dialyze Direct services, and what happens to them afterward? What proportion of your patients are in this category?

Certain hospitalized HD patients who are not medically suitable for transport to and from an outpatient facility remain in the acute care hospital for a prolonged period of time. Examples precluding off-site HD relate to transportation issues as well as medical oversight issues at the free-standing HD unit. These patients include, but are not limited to, those patients 1) on respirator support, 2) requiring extensive wound care, particularly with serious decubiti, 3) with contact isolation requirements such as with *c. difficile* and MRSA infections, 4) with immobilization such as with multiple fractures and certain spine problems, 5) requiring a degree of medical oversight not available in a free-standing facility and, to an increasing extent 6) with end of life and palliative care status. To some extent, these services could be provided by a SNF with an on-site conventional HD unit. However, the SNF’s with on-site conventional HD units are not common, are often far from a patient’s family and, not uncommonly, require long waits for a spot to become available. Additionally, the logistics of these on-site HD unit programs by virtue of the long distance from the referring acute care hospital and the patient’s original HD unit, commonly assign a new nephrologist to the patient and disrupt a long-standing patient-doctor relationship.

Thirty percent (30%) of Dialyze Direct patients are in this category. We expect the percentage to increase.

- The response to the PRT’s first set of questions states, “We estimate that in excess of 80% of the geriatric patient ESRD HD population meets current criteria for payment for MFD.” Please clarify the denominator. Is it 80% of geriatric patients with ESRD receiving hemodialysis in nursing facilities? In addition, please explain the current criteria.

We believe the denominator refers to the general, elderly HD population with multiple comorbidities. As outlined in our answer to a PRT’s prior question “Approximately what proportion of nursing facility patients would be appropriate for dialysis in the nursing facility but not appropriate for MFD?” by the nature of our acceptance screening, all patients that are accepted into our program are appropriate for MFD. Our current criteria were outline previously but in summary are: those, previously receiving conventional HD who manifest fluid overload, either overt or relative, as evidenced by hypertension (systolic pressure ≥ 140 mmHg before or during HD, and/or ≥ 130 mmHg post HD) and/or intradialytic hypotension (frequent falls in systolic BP ≥ 30 mmHg and/or frequent falls to an absolute value of < 100 mmHg).

CRITERION 2. QUALITY AND COST (HIGH PRIORITY CRITERION)

Are anticipated to improve health care quality at no additional cost, maintain health care quality while decreasing cost, or both improve health care quality and decrease cost.

- The response to the PRT's first set of questions states, "We believe Dialyze Direct, as a provider, meets or exceeds any standards necessary to participate in the proposed APM." PTAC does not recommend payment models that use proprietary approaches or are designed for a single organization, so our question was intended to clarify what standards CMS should require in order for organizations to participate. What standards do you believe should be set for organizations to participate? Would organizations other than Dialyze Direct be able to meet these standards?

Dialyze Direct specializes in home hemodialysis and, more specifically, the MFD modality of care. However, with respect to regulatory standards, Dialyze Direct functions under the mandates of Medicare's Conditions for Coverage. In that sense, Dialyze Direct is no different from any duly licensed home dialysis program. That said, Dialyze Direct redefines and raises the bar for the standard of care for certain individuals with multiple and complex medical comorbidities who reside in a SNF and require dialysis therapy. But with respect to the regulatory requirements for organizations to participate in the delivery of home dialysis in the SNF, there is nothing about the proposed model of care that would require a change in the currently existing regulations that guide all home dialysis programs.

CRITERION 3. PAYMENT METHODOLOGY (HIGH PRIORITY CRITERION)

Pay APM Entities with a payment methodology designed to achieve the goals of the PFPM criteria. Addresses in detail through this methodology how Medicare and other payers, if applicable, pay APM Entities, how the payment methodology differs from current payment methodologies, and why the Physician-Focused Payment Model cannot be tested under current payment methodologies.

- The response to the PRT's first set of questions states, "Dialyze Direct requires roughly \$340 per treatment to break-even for the increased overhead and support it provides. Managed-care payers have contracted with Dialyze Direct at payment rates higher than the Medicare dialysis PPS payment rate, and an appropriate insurance mix is necessary for the financial viability of the program"
 - Do we correctly understand this to mean that an entity could not afford to deliver the service you propose if all patients were on traditional Medicare and standard Medicare dialysis payments were made?

Dialyze Direct provides staff-assisted home HD. The cost of the care givers is borne by Dialyze Direct. Contrast this to a conventional home HD program where, when dialysis is performed in a private residence setting, the program bears none of the cost of the caregiver who is, typically, an [unpaid] member of the patient's family. At ~\$30 per hour the cost of Dialyze Direct's home dialysis care giver is ~\$90 per treatment. Standard Medicare payments do not include any reimbursement for a home dialysis caregiver. Dialyze Direct, though a mix of negotiated agreements with insurers is able to achieve financial sustainability. Successful negotiations with payers have been possible based on the model of care proposed because of the superior outcomes that include, but are not limited to, reduced hospitalizations and medication use and, additionally, elimination of transportation costs and risks.

- Would a \$340 base rate (the CY 2018 base rate is ~\$232) make the model sustainable? If not, please indicate what payment would make the model sustainable. Please also explain the value proposition for such a payment.

As noted in the response to the previous question, the primary significant fiscal challenge for Dialyze Direct's staff-assisted home HD model of care when compared to a traditional home HD model of care relates to the cost of the caregiver. A base rate of \$340 will cover the cost of the caregiver and represents a financial break-even point. A base rate of \$370 is required for sustainability. In addition to the benefits of reduced hospitalizations and medications and elimination of the cost and risk of transportation to an off-site HD unit, there are additional value-based benefits that help define the proposed model. Compared to conventional HD, the proposed model results in dramatically shorter post HD recovery times, permitting higher rehabilitation scores that are reached more quickly. This has major implications with respect to improving recovery during the critical 90-day post-acute hospital care period and may help explain why shorter post HD recovery time directly correlate with fewer hospitalizations. Long-term treatment with this model of care, such as would occur with permanent SNF residents, can induce regression of left ventricular hypertrophy, which critically correlates with cardiovascular morbidity and costs of care. When a home HD program is available at the SNFs in a community, an additional value-based benefit includes a marked reduction of the time required to effect discharge from an acute hospital care setting to a SNF setting, due to the immediate availability of HD services for even the patients that are bedbound. Other value-based benefits derive from the home HD team's on-site presence at the SNF. Teamwork, information-sharing and, customized handoffs from SNF staff to home HD staff and vice versa at each HD treatment address chronic care problems much more effectively than can be achieved by an off-site HD system. For example, potential medication errors are effectively identified and patients who experience challenging medical issues in the post HD period can be observed and stabilized on-site. Such an approach reduces the likelihood of an Emergency Room visit as is so often opted for by a remote HD unit with no time or facilities for post HD observation. A developing value-based aspect of the proposed program is the expansion of hospice strategies that can include continuation of HD. Typically, an ESRD patient's hospice period is measured in days. The option afforded by the proposed program could potentially lengthen the patient's enrollment in a hospice program; providing comfort benefits to the patient and cost benefits to the care system which otherwise might house the HD patient in an acute care hospital setting while the details of a hospice program are being worked out.

CRITERION 8. PATIENT CHOICE

Encourage greater attention to the health of the population served while also supporting the unique needs and preferences of individual patients.

- The response to the PRT's first set of questions indicates that approximately eight patients need to be receiving on-site dialysis at the same nursing facility in order for the proposed services to be economically viable. Have you considered what safeguards could be established to ensure that patients, who would otherwise not go on dialysis, are not encouraged to go on dialysis in order to have eight patients participating?

To date, patients entering Dialyze Direct's program have either been established ESRD patients or incident HD patients who started HD at an acute care hospital. It is possible that some patients with advanced chronic kidney disease residing in a SNF may be deemed to have reached ESRD and HD initiated on-site. However, with respect to the latter, Dialyze Direct is never involved in the decision to initiate HD; these decisions are made by the patient's nephrologist and medical team. Dialyze Direct is a provider of care to patients deemed by others to have ESRD.

August 6, 2018

RE: Dialyze Direct: APM for Improved Quality and Cost in Providing Home Hemodialysis to Geriatric Patients Residing in Skilled Nursing Facilities.

To the PTAC Preliminary Review Team:

Thank you for the informative discussion we had on our July 25th conference call. The discussion was very helpful with its focus on several broad questions regarding our proposal. These will be directly addressed in our written responses. After our initial comments regarding the conference call, the specific questions in the initial written feedback from the Preliminary Review Team are addressed.

Responses to the July 25th Conference Call

Medicare Savings.

Significant discussion centered about clarifying the way in which our proposal would result in Medicare savings. There are two major ways that the proposed model of care favorably impacts Medicare costs: 1) By reducing hospitalization costs and 2) By reducing transportation costs. Surprisingly, there is no comprehensive, published data regarding the hospitalization rates of dialysis patients residing in skilled nursing facilities (SNF) that can serve as definitive reference benchmarks. With this in mind, Dialyze Direct, only months ago, embarked on a joint project with the Dialysis Outcomes and Practice Patterns Study (DOPPS) at Arbor Research Collaborative for Health Ann Arbor, Michigan, to address the need for comprehensive information regarding elderly end stage renal disease (ESRD) patients. The DOPPS project is designed to “Describe the treatment and outcomes of ESRD in the elderly and evaluate whether the hemodialysis (HD) prescription for the elderly should differ from that of younger patients.” The DOPPS cohort patients will include the elderly residing within and without a skilled nursing facility and will include all forms of dialysis therapy. Recent data was presented at the 2018 Annual Dialysis Conference by Eric Weinhandl that reported data from the USRDS standard data files for patients with respect to 63,412 *incident* dialysis patients who initiated dialysis between 2006 and 2013, who reside in a SNF, and whom Medicare Parts A&B was the primary payer. The mean age was 71.6 years old. This group represented 7% of incident ESRD patients per year, treated mostly with conventional HD therapy but also including some with more frequent hemodialysis modalities. The hospitalization rate of these incident patients was 2.8 admissions per patient year for those ≥ 65 years old. Cause-specific rate of admission for cardiovascular causes was 21% of the admissions. In contrast, USRDS cause-specific rate of admission for cardiovascular disease is 35% of admissions. Dialyze Direct national (6 states) cause-specific rate of admission for cardiovascular disease is 13% of admissions. The Dialyze Direct data is drawn from incident and prevalent HD patients residing in a SNF and, as such, is not strictly comparable to Eric Weinhandl’s incident HD data. Nor is the Dialyze Direct data strictly comparable to the USRDS data which includes all HD patients, the majority of whom do not reside in a SNF. Nevertheless, Dialyze Direct’s model of care data demonstrates as much as a >50% reduction in cardiovascular (e.g. congestive heart failure) admissions and is the basis for the first cause of savings for Medicare when patients are enrolled in Dialyze Direct’s more frequent HD program. Dialyze Direct only accepts patients who meet strict local Medicare Contractor (MAC) guidelines for the necessity for dialysis more than three times per week. The predominant morbid condition qualifying a Dialyze Direct patient for more frequent dialysis is fluid overload and its complications. The patients entering Dialyze Direct’s program have failed fluid management with a conventional dialysis program and represent a high risk for repeated cardiovascular admissions.

Reductions in transportation costs represent a second major cost-saving for Medicare. The OIG reported that in New York between 2002 and 2011, the percentage of nursing home ambulance transport to and from a dialysis facility, often costing more than the actual dialysis treatment itself, rose 281% while the percentage of

the general dialysis population that needed ambulance transport rose by only 1%. Dialyze Direct/s on-site model of care eliminates transportation costs to and from a dialysis facility.

Ambulance transportation to and from a doctor's office was also discussed at our July 25th conference call. A point was made by the review team that Medicare does not authorize ambulance transport for "routine" office visits. The point is well taken. However, notwithstanding Medicare guidelines, our review of Medicare part B data among patients with ESRD at any time in 2015 shows >100,000 ambulance trips between a physician office and the nursing home in 2015. While the cost for these office visits is small compared to the costs of ambulance travel to and from a dialysis facility, the costs do exist and represent millions of dollars a year.

Peritoneal Dialysis.

A second topic of discussion at the July 25th conference call centered around peritoneal dialysis. A concern was voiced that a physician incentive would exist to recommend hemodialysis therapy when peritoneal dialysis therapy might be more appropriate for a patient. Dialyze Direct does not provide peritoneal dialysis therapy. The Dialyze Direct model of care is built around hemodialysis therapy, specifically, more frequent dialysis (MFD) for those that have failed fluid management with conventional hemodialysis therapies. Every patient referred to Dialyze Direct is a patient already receiving HD. Prior to any involvement by Dialyze Direct the decision for the modality of dialysis therapy (hemodialysis vs peritoneal dialysis) has been made by others. As previously noted, we are not aware of comprehensive published data regarding the relative frequency of dialysis therapy choices among ESRD patients residing in SNFs. However, a 2014 article in Nephrology News & Issues describing ESRD care by Affiliated Dialysis (Peoria, Ill) reported that for 3,943 SNF patients treated from 2007-2013, 86.4% received conventional HD (3x per week), 13.4% more frequent HD (5x per week) and 0.2% peritoneal dialysis. It appears that vast majority of ESRD patients residing in the SNF receive some form of HD therapy. The Dialyze Direct proposal focuses on improving SNF HD therapy, the apparent overwhelming choice for dialysis therapy for SNF residents.

Physician Payment Model.

A third topic of discussion was the physician payment model. The nephrologist's fee for managing patients on home dialysis is unchanged from the existing capitation fee (CPT 90966). Because our proposed model of care is a staff-assisted home HD model, there is no patient or family member care-giver training fee billed by either the dialysis program (Dialyze Direct) or the physician (CPT 90989). To avoid a physician disincentive to participate in the proposed model of care, we propose that that a physician education fee of \$500 be given to offset the \$500 physician training fee that cannot be billed. The unbilled dialysis program training fee is not offset. Finally, for those patients who are transported to the physician's office by ambulance for a monthly face-to-face evaluation, we propose that that transportation fee be redirected to the physician if he arranges for his face-to-face evaluation to be performed on-site at the SNF. As pointed out by the review team, ambulance transport to office visits will not be common. We agree. This minor potential financial addition to the physician payment model is not a crucial component of the physician incentive to participate in our proposed model of care. However, to the extent the on-site visits occur, the physician may also choose to arrange for his face-to-face evaluation of other patients under his care. Although not directly relevant to Medicare savings, other on-site visits could contribute to Medicaid or self-pay patient savings of costs otherwise expended for transportation.

Perplexing was the apparent expectation by the review team that the physician payment model would somehow directly insure integration and care coordination by the dialysis provider. It is hard to imagine how a physician payment model could, independently, drive corporate efforts to provide value-based care integration. The participation of the physician is certainly critical to a multidisciplinary effort but not sufficient, by and of itself, to ensure a comprehensive corporate care integration effort. High-quality provider care integration endeavors, be they major University Systems or Large Dialysis Organizations, rely on complex systems of care integration that are aided by physician participation, but are not driven solely by physician incentives. Economic incentives in addition to physician incentives, however, do drive innovation and outcome improvements. In the case of Dialyze Direct, our managed care contracts are made possible by our improved patient care outcomes. Care integration is one of the critical components of our value-based

care model and, as such, there is an intense corporate focus on care integration. That said, the physician involvement is a critical component of the care-integration effort and the proposed physician payment model was designed to encourage robust physician participation in our model of care.

We would now like to address the specific written initial feedback of the preliminary review team. Please see our responses, incorporated in bolded format within the feedback document below.

Responses to the PTAC Preliminary Review Team’s written feedback

**Initial Feedback from PTAC Preliminary Review Team on
 “APM for Improved Quality and Cost in Providing Home
 Hemodialysis to Geriatric Patients Residing in Skilled Nursing Facilities”
 Submitted by Dialyze Direct**

July 17, 2018

Disclaimer Regarding Initial Feedback:

- Initial feedback is preliminary feedback from a Preliminary Review Team (PRT) subcommittee of the PTAC and does not represent the consensus or position of the full PTAC;
- Initial feedback is not binding on the full Committee. PTAC may reach different conclusions from that communicated from the PRT as initial feedback;
- Provision of initial feedback will not limit the PRT or PTAC from identifying additional weaknesses in a submitted proposal after the feedback is provided; and
- Revising a proposal to respond to the initial feedback from a PRT does not guarantee a favorable recommendation from the full PTAC to the Secretary of Health and Human Services (HHS).

Summary of PRT Assessment Relative to Criteria:

Criteria Specified by the Secretary (at 42 CFR§414.1465)	PRT Rating	Unanimous or Majority Conclusion
1. Scope (High Priority)	Meets	Unanimous
2. Quality and Cost (High Priority)	Meets	Unanimous
3. Payment Methodology (High Priority)	Does not meet	Unanimous
4. Value over Volume	Meets	Unanimous
5. Flexibility	Meets	Majority
6. Ability to be Evaluated	Meets	Unanimous
7. Integration and Care Coordination	Does not meet	Unanimous

8. Patient Choice	Meets	Unanimous
9. Patient Safety	Meets	Unanimous
10. Health Information Technology	Does not meet	Unanimous

CRITERION 1. SCOPE (HIGH PRIORITY CRITERION)

Aim to either directly address an issue in payment policy that broadens and expands the CMS APM portfolio or include APM Entities whose opportunities to participate in APMs have been limited.

Meets Criterion (Unanimous)

This proposal would (1) encourage the delivery of on-site dialysis and more frequent dialysis for ESRD patients and other patients needing dialysis who are residing in nursing facilities, and (2) enable more nephrologists to participate in an alternative payment model.

Strengths:

- The proposed payment model would encourage an approach to dialysis services for nursing facility residents that would reduce spending by Medicare and improve dialysis care for patients.
- There are no current CMS alternative payment models specifically designed to encourage home dialysis.
- There are no current CMS alternative payment models specifically designed to improve dialysis care for patients who reside in nursing facilities.

Weaknesses:

- ESRD Seamless Care Organizations could presumably pursue similar efforts to increase on-site dialysis for ESRD patients residing in nursing facilities and capture the savings from reduced transportation costs and any reductions in complications. However, it does not appear that many or any ESCOs are doing this, and most nephrologists do not have the opportunity to participate in an ESCO.
- The proposed payment model is designed to support a specific approach to staff-assisted home hemodialysis, which may not be the best option for all patients in nursing facilities.

Dialyze Direct (DD) does not claim every patient in the SNF are candidates for more frequent dialysis. DD screens patients and those that do not meet MAC defined medical necessity criteria for dialysis more than 3 times per week, are not accepted into the program.

- It appears that only a small proportion of nursing facilities (less than 1%) would currently have the minimum number of 8 eligible patients that the applicant indicates is necessary to make the proposed staff-supported home dialysis model economically viable. It is possible that if the service were supported and encouraged by an APM, patients living in communities with multiple facilities would shift to nursing facilities that offered the home dialysis service.

On-site conventional HD units located in a SNF are very rare. Their location is often far from the patient's home. There are currently at least 50,000-75,000 ESRD patients in SNF's. If half met MFD criteria, there would be support for thousands of treatment sites. The proposed model of care brings on-site HD close to a patient's doctors and family members.

In addition, the proposed model of care facilitates compliance with new SNF Medicare regulations implemented on 11/28/17: "If a current resident has been identified as meeting the criteria for HHD/PD by

the dialysis facility team and the nephrologist or the physician prescribing dialysis, and [the patient] chooses to receive either HHD/PD, and the nursing home does not allow for these on-site services, [then] the nursing home must assist the resident with the transfer to a nursing home or in the relocation to a setting (e.g. private home, or residential/assisted living facility) of his/her choice that provides HHD/PD services.”

- The goal of the proposed payment model is to support the applicant’s ability to deliver its specific approach to dialysis, and the applicant did not provide any information as to whether independent nephrologists or other providers were interested in delivering similar services using the payment model.

The DD model uses modern and readily available technology available to any licensed provider. Many providers are providing conventional home HD using the technology and are well-versed in the relevant regulations.

CRITERION 2. QUALITY AND COST (HIGH PRIORITY CRITERION)

Are anticipated to improve health care quality at no additional cost, maintain health care quality while decreasing cost, or both improve health care quality and decrease cost.

Meets Criterion (Unanimous)

Tens of thousands of short-term patients and long-term residents of nursing facilities who need dialysis are being transported by ambulance to a dialysis center three days per week. This proposal could enable a subset of those patients to receive dialysis in the nursing facility without the need for ambulance transportation, which would reduce total spending for Medicare even if the patients receive dialysis five days per week rather than three. If a higher payment per dialysis session is needed to sustain the service, the savings would be lower, but it appears that there could still be a small amount of savings for Medicare.

There could be additional savings for Medicare from shorter SNF stays (because patients would be better able to participate in rehabilitation services), fewer hospitalizations and ED visits, and reduced drug spending, but it is not clear how large these savings would be.

Clinicians believe that avoiding the need for ambulance transportation and providing more frequent dialysis would also have clinical benefits for patients. There is no solid evidence to support or refute this, however, because most nursing homes do not currently offer dialysis services.

Although the proposal suggests tracking patient outcomes for purposes of evaluation, the payment methodology does not include any explicit mechanism for modifying payments based on whether patients receive high-quality care or achieve good outcomes.

Strengths:

- Avoiding the need for short-term patients and long-term residents of nursing facilities to be transported to a dialysis center three times per week would reduce Medicare spending on ambulance transportation. It appears that these savings would offset the higher spending from payments for more frequent dialysis sessions per week. It also appears that there could still be savings with higher payments per dialysis session to offset the higher unit costs of staff-assisted home dialysis.
- Patients who are on dialysis and receiving rehabilitation in a Skilled Nursing Facility could benefit if less time spent in transportation and faster recovery time from dialysis enabled them to make faster progress and reduce the length of the SNF stay.
- Patients would benefit and Medicare could achieve additional savings by:
 - avoiding the risk of transport-related injury to patients by avoiding the need for ambulance transportation to a dialysis center;
 - reducing the frequency of cardiovascular and other complications by using more frequent dialysis; and
 - reducing spending on medications related to dialysis treatment.

Weaknesses:

- It is possible that some patients would not currently be placed in a SNF will be discharged earlier from a hospital and transferred to a SNF because of the availability of this service.

The HD care is but one part of the overall care requirements. When evaluated with the whole patient in mind, a SNF must have appropriate general medical and nursing services available for any patient transferred to the SNF from an acute care facility. This issue is being addressed on an ongoing basis but is no different from the challenge that is present for a nursing home with an on-site conventional HD unit.

- There are risks to patients from more frequent dialysis, including higher risks of infection and access failure from more frequent vascular access.

The following comments derive from data from the Frequent Hemodialysis Network trial study (FHN trial: Chertow GN, for the FHN Trial Group: In-Center Hemodialysis Six Times per Week versus Three Times per Week. N Eng J Med 363:2287-2300, 2010.)

There is actually a lower infection risk when MFD is compared to conventional HD and no increased risk of access loss. It has been observed that there is a higher relative risk of access intervention for MFD when compared to conventional HD. The magnitude of the risk is 0.3 additional interventions per patient year. Unlike the reported studies, DD uses smaller gauge needles (16 vs. 15 gauge) than typically used for conventional HD or prior MFD studies. The smaller gauge needles may result in fewer access interventions compared to conventional HD or MFD using larger gauge needles. Our preliminary data shows no apparent increased relative risk of interventions.

- Patients who would otherwise receive peritoneal dialysis at the nursing facility could be encouraged to use more frequent hemodialysis instead, which would increase Medicare spending.

This topic was addressed in detail in our opening comments. There is no reason to believe that a patient who desires and is appropriate for an alternative treatment such as PD would not have that choice. PD is not necessarily less expensive than MFD. The rate of peritonitis in SNF PD patients is higher than the rate of MFD access infections and this adds to the cost of care. Further, since PD outcomes are similar to conventional HD outcomes, it is possible that MFD will result in fewer hospitalizations when compared to PD, thereby saving, again, on the overall cost of care.

- The measures of quality are not specified in detail and appear to be primarily based on events such as hospitalizations and ED visits that can be derived from claims data. No mention is made of measuring potential problems from more frequent hemodialysis, such as access problems, infections that do not require hospitalizations, etc.

Please see our previous response regarding the risk of access complications in patients receiving more frequent hemodialysis. All hemodialysis access events; infections, malfunctions, interventional radiology procedures, and access-related hospitalizations are recorded using our electronic medical record system. These events are tracked as a critical component of our QAPI program and are followed locally, regionally and in our national office.

CRITERION 3. PAYMENT METHODOLOGY (HIGH PRIORITY CRITERION)

Pay APM Entities with a payment methodology designed to achieve the goals of the PFPM criteria. Addresses in detail through this methodology how Medicare and other payers, if applicable, pay APM Entities, how the payment methodology differs from current payment methodologies, and why the PFPM cannot be tested under current payment methodologies.

Does Not Meet Criterion (Unanimous)

The proposed changes in payment are primarily intended to encourage nephrologists to support the use of one particular approach to staff-assisted home hemodialysis in a nursing facility, even if that is not the best approach to delivering dialysis for the patient or the lowest cost approach for Medicare. It is not clear that the proposed changes would significantly affect nephrologists' willingness to support staff-supported home dialysis in a nursing facility, which is the stated goal of the payment model. One aspect of the proposal is premised on achieving savings by avoiding a type of transportation that Medicare does not cover.

The applicant indicates that current Medicare payment amounts for dialysis would be insufficient to cover the cost of the staff-assisted home dialysis service in the nursing facility even with 8 patients receiving dialysis in the same facility. The applicant indicated that a more than 50% increase in Medicare dialysis payments would be needed to sustain the services with 8 patients per facility, with higher amounts presumably needed if there are fewer patients using the service.

Payments to the nephrologists would not be affected if the quality of care or outcomes of care are poor. There is no downside risk to participants based on either spending or quality.

The physician payment model was addressed in detail in our opening comments. The physician payment model is designed to encourage physician participation in the proposed model of care and to make sure that, relative to conventional private home HD care, the physician is not penalized for overseeing staff-assisted home HD in the SNF. With respect to downside risk, please note that it has been waived for some of the ESCO participants, i.e. when the participant is not a large dialysis organization (LDO) such as is the case with the Rogosin Dialysis Program in New York. We believe the model of care proposed is highly likely to improve quality while reducing overall spending. The incentives were designed with this in mind – to encourage physician engagement in the proposed care model.

Strengths:

- The proposed payment changes would be relatively simple to implement.

Weaknesses:

- The applicant indicates that current Medicare payment amounts would be insufficient to cover the cost of the service and to sustain its operations.
- The proposed payment methodology appears to create a financial incentive for nephrologists to recommend more frequent dialysis for patients even if that is not the best option for the patients.

Respectfully disagree. Before a patient is accepted into the program, the patient is screened and must meet medical necessity criteria for HD more than three times per week as defined by the local MAC. This process serves as a check and balance in the unlikely event that a physician would advocate for any treatment that was not the best option for the patient.

- The shift from dialysis at an off-site center to what would be considered “home dialysis” would result in a reduction in payments to the nephrologist.

The proposed physician payment model adds an education fee to offset a lost training fee that is not appropriate for our staff-assisted home HD model of care. There is also an incentive for on-site face to face assessment for those patients (small in number) who would otherwise be transported to the physician’s office by ambulance for a monthly face-to-face evaluation. In a sense, the physician is being encouraged to make a “house call” for a home dialysis patient and is being rewarded for doing that. These incentives offset any loss of the physician’s income from a patient shifting to the proposed model of care from standard off-site HD care.

- One of the two proposed changes in the nephrologist’s payment is based on the assumption that Medicare is paying for transportation of a dialysis patient to the nephrologist’s office, but Medicare does not cover transportation to a physician’s office for a routine office visit. Moreover, it is not clear that avoiding visits by the patient to the nephrologist’s office is necessary to the success of the proposed approach.

This issue was addressed in detail in our opening comments. Obviously, SNF patients in the home HD program cannot independently travel to the nephrologist’s office as occurs with patients receiving home HD and residing in a private home. However, Medicare transportation to the doctor’s office is not invariably denied. When it has been deemed unsafe to travel by other forms of transportation, and when coordination of care is required for multiple comorbidities, ambulance transportation has and would be arranged for an office visit to the nephrologist. As noted in our opening comments, ambulance transportation for ESRD patients residing in SNFs to and from a physician’s office occur more than 100,000 times per year. But the reviewer’s point is well-taken. The overall transportation cost of an ambulance to an occasional physician’s office visit is a small fraction of the ambulance cost of three times a week transportation to an off-site dialysis unit. The redirection of these [relatively] small costs to encourage on-site physician face-to-face evaluation is only a minor component of our proposed physician reimbursement model.

- The proposed services presumably depend on the willingness and ability of the nursing facility to provide space for a “dialysis den,” but there is no discussion of the feasibility or costs of providing such a space.

Nursing homes have enthusiastically supported the proposed model of care. Although there is a cost to the SNF for providing a dialysis den, there are many offsetting gains. These include, but are not limited to, an increased census, fewer hospitalization days (which also increases occupancy), reduced polypharmacy (fewer antihypertensive medications and phosphate binders), and improved rehabilitation scores reached more quickly resulting in a more stable patient.

- The payments to the nephrologists would not be affected by poor quality care or poor outcomes for patients. (The payments to the dialysis provider would presumably be adjusted for quality under the standard Medicare dialysis PPS quality incentive program.)

With respect to downside risk, please note that it has been waived for some of the ESCO participants, i.e. when the participant is not a LDO. The Rogosin Dialysis Program in New York is one such ESCO participant without a down-side risk. The physician incentives were designed to encourage robust physician participation in a model of care specifically designed to improve quality while reducing overall spending.

CRITERION 4. VALUE OVER VOLUME

Provide incentives to practitioners to deliver high-quality health care.

Meets Criterion (Unanimous)

Although there would be a financial incentive to encourage patients to receive more frequent dialysis even if they did not need it, it appears likely that the majority of patients in nursing facilities would benefit from receiving more frequent dialysis.

Strengths:

- More frequent dialysis is beneficial for most patients and may be particularly beneficial for patients receiving rehabilitation services in a skilled nursing facility and for long-term residents of nursing facilities who have multiple conditions and more advanced illnesses.

Weaknesses:

- Because of the need to have a minimum volume of patients and to receive more dialysis payments per patient in order to ensure financial viability of the service, there would be a financial incentive for the dialysis provider and nephrologist to encourage more frequent dialysis even if it was not the best option for the patients.

CRITERION 5. FLEXIBILITY

Provide the flexibility needed for practitioners to deliver high-quality health care.

Meets Criterion (Majority)

The payment model provides the flexibility for nephrologists to offer a new option for dialysis.

Strengths:

- It is difficult for nephrologists to recommend more frequent dialysis for most nursing home patients today because of the challenges of off-site transportation.

Weaknesses:

- There would be no changes in the way that the dialysis provider is paid, so there would be no greater flexibility to deliver services than what exists today.
- The proposed model appears to be dependent on approval from Medicare contractors to allow delivery of more frequent dialysis to patients.

Prior to acceptance to the program the patients are screened to ensure they meet MAC-defined medical necessity criteria for dialysis more than three times per week. Patients who do not meet the MAC-defined criteria are not dialyzed with the proposed model of care and are cared for by alternative conventional HD programs.

CRITERION 6. ABILITY TO BE EVALUATED

Have evaluable goals for quality of care, cost, and any other goals of the PFPM.

Meets Criterion (Unanimous)

It should be feasible to evaluate the model by collecting comparative information on quality and utilization for dialysis patients in facilities offering the service and for patients in facilities that are using more traditional approaches to dialysis.

Strengths:

- Because the proposed approach would only be tested in a limited number of facilities, it should be easy to find a comparison group.

Weaknesses:

- With a small number of participants, it would be difficult to draw conclusions about the results unless there were very large changes in the outcome measures, and it would also be more difficult to risk-adjust the findings.

We performed a power analysis. The proposed study will be a nonrandomized comparison of two groups of patients: a prospective cohort of patients residing in a SNF and receiving staff-assisted, more frequent home HD and a matched retrospective cohort of patients residing in a SNF and receiving conventional in-center HD. Utilizing a primary outcome of hospital admission and a prospective cohort of 400 patients, the power to detect 20% lower risk of hospital admission with staff-assisted, more frequent home HD is 85%, with a type I error rate of 5%. Dialyze Direct national data confirms that [at least] a 20% lower risk of hospital admission can be expected to be achieved.

- It would be difficult to measure many important outcomes or to risk adjust the results unless both the participants and the comparison group were submitting appropriate quality measures to a patient registry.

The retrospective cohort will be matched at a ratio of 5-to-1 and drawn from a claims-based cohort of >60,000 ESRD patients who have resided in a SNF. The claims-based cohort will be a function of Medicare and Medicaid claims, as Medicare covers outpatient dialysis and skilled nursing facility care after hospital discharge, whereas Medicaid covers long-term skilled nursing facility care. In-center HD patients will be closely matched for demographics, socioeconomic status, medical comorbidity, and vascular access status. The proposed model's EHR technology permits detailed data collection, including quality measures comparable to the quality performance categories of the Merit-based Incentive Payment System ("MIPS") and other measures related to "QIP" and "5 Star" quality metrics. As part of these metrics, a ICH-CAHPs score (In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems) tracks a patient's perspectives of dialysis care. This metric, currently only being reported for conventional in-center hemodialysis, has been adapted by Dialyze Direct for the home HD program. Infection and vascular access outcome data will also be an important part of the overall data collection plan. A randomized model is not appropriate. Owing to the relatively limited locations available for on-site home HD, would adversely impact the patient numbers in the prospective cohort group and would not permit sufficient statistical power. More importantly, the benefits of MFD are so substantial that assigning patients to conventional therapy when they would be better served by MFD therapy poses a major ethical problem.

CRITERION 7. INTEGRATION AND CARE COORDINATION

Encourage greater integration and care coordination among practitioners and across settings where multiple practitioners or settings are relevant to delivering care to the population treated under the PFPM.

Does Not Meet Criterion (Unanimous)

Although the ability to receive dialysis care in the facility where the patient is residing should enable more coordinated care, there is no explicit process proposed for ensuring that coordination occurs nor any process of measuring whether it does occur.

Strengths:

- Patients would be able to receive more of their care in the same facility and spend less time in transportation, which could improve the ability for patients to receive both dialysis and nursing home services and reduce conflicts in services.

Weaknesses:

- There is no discussion in the proposal about how care would be coordinated with the patient's primary care provider and other specialists.
- The proposal assumes that the nursing facility staff and the dialysis provider staff will coordinate their activities, but there is no specific mechanism defined for ensuring such coordination occurs.

This issue was addressed in our opening comments. Further:

The proposed model of care includes a detailed, written hand-off data exchange between the SNF facility staff and the dialysis staff both going-to and returning-from every HD treatment. In addition to vital signs, there are comments about the general condition of the patient with specifics about the course of the dialysis treatment and a detailed list of medications given and ordered. This bi-directional medication reconciliation is a powerful information-sharing tool. Absent the receipt of a proper hand-off, a HD will not be initiated. All of these hand-off events are tracked. In addition, there is a HD point person, the on-site RN home care coordinator, who functions as a care coordinator between an SNF charge nurse, SNF nurse practitioner, nephrologist and, not infrequently, the SNF PCP. Generally, the sub-specialty coordination is achieved via the SNF charge nurse and the SNF PCP with the home HD care coordinator an additional contributor. Concomitant with the outlined process, there is coordination of care between the dialysis dietitian and social worker and their SNF counterparts. Finally, there is a individual nursing home QAPI program that is provided by the dialysis program to the SNF monthly, and reviewed jointly with the SNF monthly, that includes, but is not limited to, hand-off implementation, missed treatments, late delivery to treatments, Hoya lift weighing issues, hemoglobin outliers, serum albumin outliers, serum potassium outliers, serum phosphorus outliers and blood pressure control outliers.

CRITERION 8. PATIENT CHOICE

Encourage greater attention to the health of the population served while also supporting the unique needs and preferences of the individual patients.

Meets Criterion (Unanimous)

The proposed model would enable more patients to receive dialysis in the nursing facility where they reside, and to receive more frequent dialysis.

Strengths:

- The proposed approach could give many nursing facility residents a new and better option for receiving dialysis.

Weaknesses:

- The proposed financial incentives for physicians based on patient participation and the need for the dialysis provider to achieve a minimum level of patient participation could result in patients not receiving objective information on the risks associated with the proposed approach.

Objective information regarding MFD, benefits and risks is presented to the patient or, when appropriate, their health care agent, in a multi-tier process. First, information is present to the patient at the hospital site by the hospital's discharge coordinator and nephrology team. No patient starts staff-assisted home HD without their understanding and explicit consent. Once in the SNF, the education process continues, orchestrated by the dialysis program's RN home care coordinator and social worker. In fact, the education process is augmented by all of the dialysis staff who have, in turn, been educated by the dialysis program's nurse educators. The nephrologist also plays a very important role, which is why the physician model includes a physician's fee for patient education.

- The more frequent dialysis service could be denied by Medicare contractors even if the patient could benefit from the service and wanted to receive it.

CRITERION 9. PATIENT SAFETY

Aim to maintain or improve standards of patient safety.

Meets Criterion (Unanimous)

On balance, it appears that patients are likely to receive safe, high-quality care, but it would be desirable if additional protections were included, particularly during the initial phases of implementation.

Strengths:

- All dialysis providers are subject to Medicare conditions of participation and the dialysis quality incentive program.
- The more frequent dialysis service could be denied by Medicare contractors if the patient is not appropriate for the service.

Weaknesses:

- It would likely be more difficult for nephrologists to see patients as frequently in the nursing facilities as they do in the dialysis centers.
- The patient's nephrologist would likely have less oversight and connections with the dialysis care than if the patient were receiving center dialysis.
- The proposed financial incentives for physicians based on patient participation and the need for the dialysis provider to achieve a minimum level of patient participation could result in patients receiving the proposed services even if other options would be better for them.

The applicant indicates that a growing number of patients are discharged from a hospital earlier than they would have been otherwise because of the availability of dialysis services in nursing facilities.

The on-site RN home dialysis care coordinator, responsible for 8-10 patients, is a significant asset for the physician and, in a major way, helps with respect to his oversight responsibilities. Aside from an ESCO model of care, there is nothing quite comparable that can be found in a traditional dialysis center model.

The latter two points, whether a patient receives the best patient-centric dialysis option and whether a patient is discharged too-soon from an acute-care setting has been previously addressed in this document. Briefly, patients are screened both from the general medical and dialysis point of view. Screening ensures that the hospital discharge is appropriate with respect to safety. Regardless of any dialysis issue, the general medical services must be sufficient to care for any general medical problems a patient is likely to encounter in the immediate post-acute care period. From the dialysis point of view, MAC-defined medical necessity criteria for dialysis more than three times per week must be met. Essentially this dialysis modality evaluation process screens for patients in whom conventional dialysis has failed to optimize treatment. Patients who do not meet the MAC-defined criteria are deemed appropriate for conventional therapy and are cared for by alternative conventional HD programs.

CRITERION 10. HEALTH INFORMATION TECHNOLOGY

Encourage use of health information technology to inform care.

Does Not Meet Criterion (Unanimous)

There is no discussion of the specific kinds of data that would be collected and how they would be used.

Weaknesses:

- There is no discussion of the specific kinds of data that would be collected and how they would be used.

The proposed model's EHR technology permits detailed data collection, including quality measures comparable to the quality performance categories of the Merit-based Incentive Payment System ("MIPS") and other measures related to "QIP" and "5 Star" quality metrics. As part of these metrics, a ICH-CAHPs score (In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems) tracks a patient's perspectives of dialysis care. This metric, currently only being reported for conventional in-center hemodialysis, has been adapted by Dialyze Direct for the home HD program. Infection and vascular access outcome data will also be an important part of the overall data collection plan.

The proposed study will be a nonrandomized comparison of two groups of patients: a prospective cohort of patients residing in a SNF and receiving staff-assisted, more frequent home HD and a matched retrospective cohort of patients residing in a SNF and receiving conventional in-center HD. Utilizing a primary outcome of hospital admission and a prospective cohort of 400 patients, the power to detect 20% lower risk of hospital admission with staff-assisted, more frequent home HD is 85%, with a type I error rate of 5%. The retrospective cohort will be matched at a ratio of 5-to-1 and drawn from a claims-based cohort of >60,000 ESRD patients who have resided in a SNF. The claims-based cohort will be a function of Medicare and Medicaid claims, as Medicare covers outpatient dialysis and skilled nursing facility care after hospital discharge, whereas Medicaid covers long-term skilled nursing facility care. In-center HD patients will be closely matched for demographics, socioeconomic status, medical comorbidity, and vascular access status. A randomized model is not appropriate. Owing to the relatively limited locations available for on-site home HD, would adversely impact the patient numbers in the prospective cohort group and would not permit sufficient statistical power. More importantly, the benefits of MFD are so substantial that assigning patients to conventional therapy when they would be better served by MFD therapy poses a major ethical problem.

PHYSICIAN-FOCUSED PAYMENT MODEL
TECHNICAL ADVISORY COMMITTEE (PTAC)

PRELIMINARY REVIEW TEAM (PRT)
CONFERENCE CALL WITH SUBMITTER (DIALYZE DIRECT)

Wednesday, July 25, 2018

5:00 p.m.

PRESENT:

HAROLD MILLER, PTAC Committee Member
JEFFREY BAILET, MD, PTAC Committee Member
RHONDA MEDOWS, MD, PTAC Committee Member

SARAH SELENICH, Assistant Secretary for Planning
and Evaluation (ASPE)
ANJALI JAIN, MD, Social & Scientific Systems (SSS)

ALLEN KAUFMAN, MD, Chief Medical Officer, Dialyze Direct

P R O C E E D I N G S

[5:02 p.m.]

1
2
3 MS. SELENICH: So I'm Sarah Selenich, and
4 I work at the Department of Health and Human
5 Services. And I am in the Assistant Secretary for
6 Planning and Evaluation office, and I am supporting
7 this Preliminary Review Team.

8 We have on the line folks from our
9 contracting staff, including someone who is a
10 transcriptionist that's going to take it -- so this
11 is a recorded call, just so you're aware, and since
12 there's just one of you on the line, it might be a
13 little bit easier for her to identify voices for
14 the transcript.

15 DR. KAUFMAN: Right.

16 MS. SELENICH: But where possible, try to
17 -- including the PRT members, try to say who you
18 are as you're speaking, and from there, I guess,
19 yeah, Harold, continue on.

20 MR. MILLER: Okay. So we'll introduce
21 ourselves, and then you can introduce yourself, Dr.
22 Kaufman. So I'm Harold Miller. I'm CEO of the
23 Center for Healthcare Quality and Payment Reform,
24 and I am chairing the PRT.

1 Rhonda?

2 DR. MEDOWS: Hi. I'm Rhonda Medows. I'm
3 a member of the PRT, and I am from Providence St.
4 Joseph Health.

5 I am so happy to hear from you today.

6 DR. BAILET: Yep. This is Jeff Bailet. I
7 am with Blue Shield of California, and I'm also a
8 member of the PRT.

9 MR. MILLER: Okay. Dr. Kaufman, do you
10 want to introduce yourself?

11 DR. KAUFMAN: So I'm from -- with Dialyze
12 Direct, and I'm the Chief Medical Officer and also
13 the Senior VP for Clinical and Scientific Affairs.

14 MR. MILLER: Okay. And do you want to
15 just explain to Rhonda and Jeff also that you're
16 missing your colleague?

17 DR. KAUFMAN: Yeah. We're missing
18 Jonathan Paull who is our -- I mean our
19 administration and compliance, you know, point, and
20 -- but he's in between Albany and New York in a
21 broken-down car, so that's the problem.

22 MR. MILLER: We feel for him.

23 So let me just give sort of some quick
24 context on all this, and then we can answer

1 questions that you have and discussion.

2 DR. KAUFMAN: Mm-hmm.

3 MR. MILLER: But, first of all, I want to
4 thank you for submitting a proposal. We, the
5 members of the Physician-Focused Payment Model
6 Technical Advisory Committee are really -- we are
7 doing this because we want to see more good payment
8 models be put into place, and the only way we can
9 do that is to have folks like you actually take the
10 time and the effort to put together a proposal. So
11 we appreciate that, and we appreciate you
12 responding to all the questions.

13 Who you have on the call today is three
14 members of what we refer to as the Preliminary
15 Review Team. There are 11 members of the full
16 PTAC. The PRT basically is kind of a pre-screening
17 information-gathering subcommittee for the PTAC,
18 and because the PTAC has to evaluate the proposals
19 against these 10 criteria, which you've seen, we
20 basically do a lot of the work to make sure that we
21 have all of the information that we think is
22 necessary to be able to make good judgments about
23 that and to ask you for that kind of information.

24 We do not as the PRT make the final

1 decision, and the other thing that's important for
2 you to understand is that the whole membership --
3 the 11 members of the PTAC have not discussed your
4 proposal at all.

5 DR. KAUFMAN: Right.

6 MR. MILLER: The only people who have
7 discussed it are the three of us.

8 DR. KAUFMAN: Mm-hmm.

9 MR. MILLER: So when you see the feedback
10 that we sent you, that is just from the three of us
11 and has no necessary relationship to what the other
12 eight people may decide, so just so you understand
13 that.

14 And the reason why this is important is
15 because what has happened in the past up until this
16 spring when the law was changed was we would go
17 through this process. We would issue a report.
18 You would come to the meeting of the full PTAC,
19 where it would be discussed for the first time.

20 DR. KAUFMAN: Mm-hmm.

21 MR. MILLER: This -- we now under law have
22 the ability to kind of give you what we refer to as
23 initial feedback, but it's only feedback from the
24 PRT. So, you know, you have to recognize sort of

1 with a grain of salt that it's what Jeff and Rhonda
2 and I think, not necessarily what the full PTAC
3 members think.

4 And we're giving you this draft really for
5 two purposes. One is so that you understand where
6 at least we are thinking the strengths and
7 weaknesses are at the moment, and you can tell us,
8 first of all, whether we're wrong, whether there
9 are things that we've missed, whether there are
10 areas that we should -- whether we should change,
11 and also for feedback to you so that you can decide
12 whether or not you want to proceed with the normal
13 process and have this that would ordinarily come up
14 at the September meeting of the PTAC.

15 DR. KAUFMAN: Mm-hmm.

16 MR. MILLER: But, as we've started to do
17 this, some of the applicants have decided that
18 based on the feedback, they would rather take the
19 proposal, redo it, and resubmit it. So we'll come
20 back to that at the end of the call, but that's
21 part of the purpose of the feedback is to help you
22 decide whether or not you want to make any
23 revisions to the proposal and resubmit it or
24 whether you want to proceed as is.

1 DR. KAUFMAN: Right.

2 MR. MILLER: What we can -- what we want
3 to do on the call today is, first of all, since
4 you've seen the draft, either get any feedback from
5 you on it or any questions that you have for us
6 about the process, and then we will probably have
7 some questions for you after we hear your thoughts
8 on that.

9 DR. KAUFMAN: Okay.

10 MR. MILLER: And then we can go from
11 there.

12 DR. KAUFMAN: No, I -- okay. Of course,
13 I've been -- I've been, you know, pondering this
14 stuff and reading it.

15 First of all, I, a hundred percent, agree
16 with all your positive comments.

17 MR. MILLER: Okay.

18 DR. KAUFMAN: So you're not wrong on that,
19 by any means.

20 DR. MEDOWS: I like this guy. He --

21 [Laughter.]

22 DR. BAILET: Oh, that's amazing. I was on
23 pins and needles on that issue.

24 DR. KAUFMAN: Right.

1 MR. MILLER: That's the first time we've
2 ever gotten a positive step right now. I'm --

3 DR. KAUFMAN: Okay.

4 But, I mean, I really like the questions,
5 and I want to -- I want to -- and there's a couple
6 of things that I -- and I want to address them, and
7 I -- you know, it sharpens up the thinking. It
8 sharpens up -- you know, it sharpens up the
9 strategy and stuff like that when questions are
10 asked.

11 And I thought I would -- you know, when I
12 go through this, I mean, that we can start with the
13 areas that you thought were -- were not -- didn't
14 meet the criteria that you --

15 MR. MILLER: I think -- I think that would
16 be a good way to prioritize.

17 DR. KAUFMAN: Because all the things --
18 you're trying to -- you're trying to make sure all
19 the 10 areas are met, you know, all the 10 criteria
20 are met.

21 So the first one was the payment
22 methodology, which is -- which was No. 3, and I'm
23 just going to turn to my notes.

24 MR. MILLER: That's one of our high-

1 priority criteria, so that's important too.

2 DR. KAUFMAN: Right.

3 So let me turn to the notes, and let's --
4 I want to just read -- I just want to go over a
5 couple of the key things that struck -- you know,
6 that struck my eye here.

7 One of the things that we're concerned
8 about, one of the comments was that by making the
9 financial incentive for a nephrologist to do
10 something, they might recommend more frequent
11 dialysis, even though, as somebody wrote here, "may
12 not be the best option for the patient."

13 So the patients who are -- so the first --
14 the point I want to first make about that is the
15 patients who are chosen and approved for more
16 frequent dialysis for this model, you know, which
17 is a staff-assisted home dialysis in the skilled
18 nursing facility -- and the feature of this is it's
19 a more frequent type of dialysis -- that's actually
20 the -- you know, one of the really strong points of
21 the approach that we're taking.

22 But the criteria that brings a patient
23 onto this kind of therapy is, number one, that the
24 patient wants that, you know, understands it and

1 wants to have this kind of a therapy, and that,
2 first, it's a patient choice.

3 But, secondly -- and people alluded to
4 this also -- because of the rules and regulations
5 of the MACs, the MACs have set very clear written
6 criteria for what they would -- you know, the
7 Medicare contractors -- what they would approve for
8 dialysis more frequently than three times per week.
9 It's, more or less, the same throughout the
10 country. There's a lot of -- there's a lot of
11 MACs, but they're all very similar.

12 And, as you may or may not know, there's a
13 lot of controversy. You know, this is being
14 discussed right now in the background, and I think
15 everything has been delayed as the discussions are
16 still going on this.

17 But the core criteria for more frequent
18 dialysis, for the permission, you know, or the
19 payment for dialysis more than three times per week
20 is things that relate to fluid management --
21 volume management, fluid management. That's within
22 -- these are almost the exact words of the MACs.

23 And so within that -- so within that world
24 of fluid management, there are two kinds of

1 patients. You know, there are two things that
2 we're screening for as part of the criteria to
3 enter the program.

4 So one is that all the patients are
5 generally coming from conventional dialysis. Many
6 of them in the skilled nursing facility have --
7 most of them have passed through a hospital with
8 some kind of acute illness, but basically, there's
9 a history of the -- you know, maybe 85 percent of
10 the patients are already established end-stage
11 renal disease patients. Occasionally, some
12 patients will be -- 15 percent or so will be a new-
13 start dialysis that starts in the hospital but is
14 deemed unsafe to go home and is going to spend time
15 in a skilled nursing facility.

16 But if we're looking at patients that have
17 a few things related to fluid management and volume
18 overload, one is hypertension. So hypertension, on
19 multiple blood pressure medicines that have not
20 been controlled with conventional dialysis, so
21 that's one criteria to permit a patient, you know,
22 to enter the program.

23 The other criteria is that the removal of
24 fluids on three-times-a-week dialysis. You know,

1 the increment, the amount of fluid that has to be
2 removed for three-times-a-week dialysis is much
3 larger than when you spread out the dialysis over
4 five periods, and so the -- with the more frequent
5 dialysis, fluid removal is much -- is a much
6 smaller amount, and it addresses the issue of rapid
7 fluid removal and falls in blood pressure during
8 dialysis. That for us --

9 MR. MILLER: You're focusing -- you're
10 focusing on the more frequent versus less frequent
11 hemodialysis, but talk to us a little bit about
12 peritoneal dialysis versus hemodialysis, not just
13 the frequency.

14 DR. KAUFMAN: Okay. So there are -- the
15 majority of patients who do on-site dialysis
16 probably in the skilled nursing facilities across
17 the country is peritoneal dialysis.

18 We don't -- we don't -- our -- we don't do
19 peritoneal dialysis because we're specializing in a
20 very specific form of hemodialysis, but peritoneal
21 dialysis is -- the strength of peritoneal dialysis,
22 it's a very strong therapy. When a person has
23 hemodynamic problems, because it's very -- it's
24 gentle, much like the more frequent dialysis is

1 very gentle for the patients, and if a patient --
2 if a patient is -- you know, if a patient is -- has
3 a desire or is -- or is already having peritoneal
4 dialysis, we're not going to -- we are not going to
5 -- we're not looking at that group of patients.
6 They can continue to have peritoneal dialysis on-
7 site.

8 I don't really see that we impact that one
9 way or another particularly.

10 MR. MILLER: The question -- the question
11 was about the payment methodology where there is --
12 you're proposing that there would be a payment
13 change for the nephrologist if the patient -- and
14 let's maybe even talk about a patient who newly has
15 to go on dialysis -- if they go on your more
16 frequent hemodialysis service, but not a payment
17 change if the patient could go on peritoneal
18 dialysis.

19 So that's kind of the question we're
20 asking is --

21 DR. KAUFMAN: Well, I never -- yeah. I
22 understood. I didn't -- I didn't know that I -- I
23 really didn't comment on peritoneal dialysis, but I
24 would say that -- let me just tell you the -- what

1 we're trying to address.

2 When a -- under standard conditions, when
3 a patient, you know, goes on home dialysis therapy,
4 usually in their own house, okay, the physician has
5 a few -- there's a few things beyond the monthly
6 capitation fee that a physician gets.

7 For a conventional peritoneal dialysis
8 patient, a physician will get a fee for overseeing
9 the training of the patient because under
10 conventional home dialysis, patients or their
11 families are the caregivers, and that's number one.

12 Number two, the patients go to the
13 physician's office. They go in their car or they
14 go on a bus, and they go to the physician's office.
15 And the physician receives the patient and has the
16 face-to-face oversight with a home dialysis patient
17 in the course of his office practice. That's the
18 typical way that it's done throughout the country.

19 MR. MILLER: Mm-hmm.

20 DR. KAUFMAN: This particular -- and
21 that's true for peritoneal dialysis or home
22 hemodialysis, you know, in private home setting.

23 MR. MILLER: Right.

24 DR. KAUFMAN: Now, the -- there are two

1 problems with -- there is a -- there is an issue.
2 There is a change in physician reimbursement for
3 patients who are on skilled nursing facility home
4 dialysis. We can talk home hemo, or we can talk
5 home peritoneal dialysis. It's really the same
6 problem.

7 Firstly, the physician loses -- would
8 technically lose the training oversight fee. I
9 think it's about 5- or 600 -- 500-and-some-odd
10 dollars. I think it's \$500 exactly that a
11 physician gets. You can't -- there is no training
12 fee because no patient in a skilled nursing
13 facility is going to be doing their own -- they're
14 not their own caregiver.

15 So, in our case, we have staff-assisted,
16 and in the peritoneal dialysis case, usually they
17 train the nursing home nurses to do that peritoneal
18 dialysis. So, either way, there is no training.
19 So the physician loses the training fee, number
20 one.

21 Number two, none of these patients will
22 get in their car and visit the doctor's office. So
23 there's only two ways -- not counting telemedicine.
24 You know, skip that for now, but there's only two

1 ways that you can have the face-to-face
2 requirement, you know, the technical requirement
3 that you need to have for the oversight of the
4 care, and there's only two ways. Either the --
5 either the patient is brought to the physician's
6 office by some transportation mechanism, you know -
7 - it depends what the insurance is. Sometimes it
8 is Medicare. I know somebody criticized that, but
9 we -- I have a comment about that because we --

10 MR. MILLER: Yeah. We'll get to that in a
11 second, but --

12 DR. KAUFMAN: You know, I screened the
13 whole country for that.

14 But -- so one is that a patient -- well,
15 one way or another, by some kind of transportation,
16 you know, the patient is brought -- that doesn't
17 impact the physician, but it impacts the system, or
18 the physician makes essentially a house call. You
19 know, he gets -- you know, he goes and visits the
20 patient and does his face-to-face by visiting the
21 patient.

22 Think of -- it's equivalent to a physician
23 going to a patient's home. You know, if I had like
24 20 to 30 patients that I have on home dialysis, I

1 would go make 30 house calls.

2 MR. MILLER: Well, pause -- well, pause
3 right there. We understand that.

4 So the issue is you're proposing to change
5 that if the patient goes on your more frequent
6 hemodialysis service --

7 DR. KAUFMAN: Right.

8 MR. MILLER: -- but not to change that if
9 the patient goes on peritoneal dialysis?

10 DR. KAUFMAN: Well, I didn't address it.
11 I mean, we can --

12 MR. MILLER: Well, but doesn't that create
13 an incentive then for the physician to favor your
14 more frequent hemodialysis, even though peritoneal
15 dialysis might be better for that patient?

16 DR. KAUFMAN: Oh. So you're -- you mean
17 of the home dialysis therapies?

18 MR. MILLER: Yes.

19 DR. KAUFMAN: Not of all dialysis
20 therapies, but of home dialysis therapies.

21 MR. MILLER: Yes. The issue what -- if
22 they -- if they couldn't get dialysis in the
23 nursing facility, are you not creating an incentive
24 for the physician to pick your version of it by

1 only giving -- making this change for your version?

2 DR. KAUFMAN: Yeah, I -- I understand what
3 you're saying.

4 So in the home -- in then skilled nurse --
5 in the home dialysis setting, home dialysis not
6 defined, just defined broadly as dialysis --

7 MR. MILLER: Yes.

8 DR. KAUFMAN: In the home dialysis
9 setting, you're saying it puts a -- it puts a thumb
10 on the scale in favor of the hemodialysis?

11 MR. MILLER: Yes. Is that not true?

12 DR. KAUFMAN: Well, I would say that
13 that's -- by the way, it's a weakness for
14 peritoneal dialysis. I mean, it's not because we
15 are -- in other words, the incentives that we want
16 to do is we want to change the training fee to an
17 education fee, and if a physician makes a visit on-
18 site, we want to give him a bonus because we don't
19 want to use resources.

20 It really -- it really should be the same
21 -- you know, an institution like home dialysis is
22 actually, technically different in many ways from
23 private home dialysis, and I think -- I think
24 you're right. I think the overall system really

1 doesn't address that, and it should address that.
2 It frankly is -- it's frankly harder for a
3 physician to take care of an institutionalized home
4 dialysis patient than it is some private patient.

5 MR. MILLER: So part of the concern was
6 that you're not proposing a payment change to
7 encourage dialysis in the nursing home. You're
8 proposing a payment change focused specifically on
9 the kind of dialysis that you provide.

10 DR. KAUFMAN: Yeah. Well, that's because
11 we specialize in ours, but if you look at it in the
12 --

13 MR. MILLER: We're not -- but we do not
14 approve models to do specific services that
15 specific providers deliver. We try to -- the
16 payment model to help --

17 DR. KAUFMAN: Yeah, I understand. I
18 understand. I understand.

19 I guess it's a good -- I mean, look,
20 that's a pretty good point. I will -- you know,
21 usually, the choice between peritoneal dialysis and
22 hemodialysis is as much a patient's choice as
23 anything else, but I understand what you're saying.
24 They could -- you know, they could -- they could

1 tilt the scale and push it in one direction. A
2 physician theoretically could.

3 The -- you know, I would say -- except I
4 would say --

5 MR. MILLER: Well, let's go on to other --
6 go on to other points. Let's go on to other points
7 so we can cover everything.

8 So tell us a little bit more about this --
9 your experience with patients getting
10 transportation to the nephrologist's office.

11 DR. KAUFMAN: Let me just -- I want to
12 wrap this up because I want to say just one thing.

13 MR. MILLER: All right.

14 DR. KAUFMAN: There is one point that I
15 would make. We are not -- we do not have a
16 unassigned patient to a modality. Every patient
17 that comes our way is a hemodialysis patient. I
18 know there -- we don't see the peritoneal patients
19 because they're going in some other direction, but
20 it's not like we get a patient that's stage 5
21 advanced kidney disease and we're going to start --
22 and is not our required -- we're not the starter of
23 dialysis therapy where you have to make a decision
24 whether it goes to peritoneal dialysis or

1 hemodialysis.

2 So every patient that we have is on
3 hemodialysis. I would say that I do not believe
4 that people who are on hemodialysis already and
5 have to go to a nursing home gets a peritoneal
6 dialysis catheter put in and they get switched from
7 hemodialysis to peritoneal dialysis nationwide.
8 People who are on PD have been on PD and are on PD.
9 I'm just saying.

10 So the only point I would make is we are
11 dealing with the hemodialysis world. 100 percent
12 of the patients are hemodialysis patients. Now we
13 were just talking about which type of hemodialysis.
14 That's why we didn't focus on that other part. We
15 never see those patients.

16 MR. MILLER: So let me see if Rhonda or
17 Jeff have any questions about that particular topic
18 before we move on.

19 DR. MEDOWS: I do not. I'm good.

20 DR. BAILET: I don't.

21 MR. MILLER: Okay.

22 DR. BAILET: I'm good.

23 DR. KAUFMAN: Okay.

24 MR. MILLER: So I would just -- let me

1 close it by saying, though, I do think that we try
2 to think about not just what you're seeing and what
3 you're doing today, but if you change the payment
4 model, what else might change.

5 So there are presumably patients who are
6 in nursing homes who have advanced kidney disease
7 and then progress to the need for dialysis as
8 nursing home residents, right?

9 DR. KAUFMAN: Right, right. There are a
10 few. There are.

11 MR. MILLER: They could face this choice
12 of do they get peritoneal dialysis or home --

13 DR. KAUFMAN: Correct.

14 MR. MILLER: Okay.

15 DR. KAUFMAN: Yeah. We probably wouldn't
16 make that choice because, again, we are inheriting
17 the patients who somebody may --

18 MR. MILLER: We're not talking about you.
19 We're talking about the nephrologist --

20 DR. KAUFMAN: In the world, in the
21 nephrology world.

22 MR. MILLER: -- who may get payment or
23 right, you know, into this.

24 Okay. So tell us a little bit about the

1 transportation part.

2 DR. KAUFMAN: All right. So the point was
3 well taken, and it -- and it is well taken that
4 whoever made the point -- you guys made the point
5 that -- you made the point that, by and large,
6 people are not using Medicare ambulance stretcher
7 transportation to go to a physician's office for a
8 -- you know, even for a whatever, for some kind of
9 -- even in advanced evaluation. They made the
10 point for a routine, but even for advanced
11 evaluation.

12 So what I did, just because I thought it
13 was interesting -- I work with somebody who used to
14 -- you know, who is a statistician and knows how to
15 get the data. So I looked in the year 2015 using
16 Medicare Part B data for how many people went from
17 a nursing home to a physician's office by ambulance
18 in America, and the answer is about 120,000 trips
19 were made in that year. So it's far from zero.
20 120,000. 120,000 trips, physician's office visits,
21 that is, from the nursing home to the --

22 MR. MILLER: But are you experiencing that
23 in your service? Are you seeing today -- because
24 you have patients. Are you seeing any patients, of

1 your patients being transported by ambulance to a
2 nephrologist office?

3 DR. KAUFMAN: I'm not aware -- I haven't
4 seen us. In other words, in our -- in our subset,
5 we really are encouraging the physicians to go to
6 the -- to go the patient and not have the patient -
7 - I mean, the whole point of --

8 MR. MILLER: Yeah.

9 DR. KAUFMAN: -- doing care on-site is to
10 keep the patient on-site as --

11 MR. MILLER: You're proposing to pay the
12 physician based on the savings from not having
13 ambulance transportation --

14 DR. KAUFMAN: Right.

15 MR. MILLER: -- but you're not actually
16 seeing any ambulance transportation.

17 DR. KAUFMAN: Well, we would eventually
18 because the world uses it. In other words, people
19 are very inventive in the -- in the country. Let's
20 just use that word, and people -- people kind of --
21 you know, they work the system, and they --
22 somebody will write why a person has to always
23 travel in a -- you know, supplying physician -- I
24 mean, people do what they got to do. It may not be

1 --

2 MR. MILLER: And here's -- you're not
3 saying that there is current spending that could be
4 reduced. You're anticipating that somebody is
5 going to come up with some spending and you're --

6 DR. KAUFMAN: No. Here's what I would
7 say. Here's what I would say. I actually -- I
8 rethought that because the point was well taken. I
9 would just make it -- I would -- actually, that I
10 would change. I would just say that if a physician
11 makes a so-called on-site visit for his monthly
12 face-to-face, instead of bringing a patient to the
13 office, I now would say -- you know, having thought
14 about it, just get the \$250 bonus, period. Get the
15 \$250 bonus. That would encourage -- that would
16 discourage -- I mean, it would encourage physicians
17 to like take care of their requirements on-site as
18 opposed to making the patient go back and forth,
19 and I think -- so that's what I -- I would --

20 MR. MILLER: So how would -- how would you
21 then if you're -- if you were -- if you were to
22 propose that -- and that would be a different
23 proposal than what you sent us, but under that
24 model, where would you see any offsetting savings

1 come from? Because what you were saying in the
2 proposal was that the payment to the physician
3 would be offset by the reduction in the ambulance
4 transportation cost.

5 DR. KAUFMAN: Well, it's always a
6 reduction in some kind of a cost. It may not be
7 ambulance, which is - which is the extreme, but
8 there are tremendous patients throughout the
9 country going on doctors' offices through whatever
10 they have, Medicaid or managed -- some kind of
11 managed care transportation. So it really does
12 happen throughout the country, all those costs,
13 number one.

14 MR. MILLER: But not in -- not in
15 Medicare.

16 DR. KAUFMAN: But for Medicare, to the
17 extent that Medicare was doing it, it would be an
18 offset. But the -- but really, you know, when you
19 look at all the physicians, you look at all the
20 physicians' incentives, and the real incentives is
21 to be a -- is to be a fully engaged participant in
22 the model of care. That really is what the
23 incentive is, and the reason is, as you know -- I
24 mean, the savings of -- the savings for the system

1 for Medicare are tremendous when this mode of
2 dialysis therapy is -- you know, is implemented for
3 patients. It is really tremendous --

4 DR. BAILET: Harold?

5 DR. KAUFMAN: -- aside from
6 transportation, goes back and forth to the dialysis
7 unit, is a major reduction in hospitalizations.

8 MR. MILLER: Jeff has got a question.

9 DR. BAILET: I did. I'm sorry. I'm a
10 little -- I've been a little confused by the last
11 piece of the conversation.

12 In the current state -- forget about more
13 frequent dialysis. In the current state, if you're
14 in a SNF and you're saying 85 percent of the
15 patients who are in SNFs were already on
16 hemodialysis --

17 DR. KAUFMAN: Right. And then what
18 happens is another 15 percent are new starts. In
19 other words are on --

20 DR. BAILET: You're good. Understood.

21 DR. KAUFMAN: Yeah.

22 DR. BAILET: So now you've got that cohort
23 of patients. Forget about more frequent, but right
24 now, what you're telling me is those Medicare

1 patients, they get their hemodialysis at an off-
2 site dialysis center, and they can get --

3 DR. KAUFMAN: Correct. But by and large -
4 - by and large.

5 DR. BAILET: By and large. By and large.
6 This is not your program; this is the state of the
7 union today.

8 DR. KAUFMAN: No, right. Correct.

9 DR. BAILET: Right?

10 DR. KAUFMAN: Yeah. Because --

11 DR. BAILET: And they -- and those
12 patients are transported either by ambulance, which
13 is less frequent than the other modality, which is
14 some kind of transport system to move those
15 patients at a cost --

16 DR. KAUFMAN: Right.

17 DR. BAILET: -- to the dialysis center.

18 Is that correct?

19 DR. KAUFMAN: No. At a cost to society.
20 At a cost to somebody.

21 You know, if it's a -- if it's Medicare --
22 Medicaid, for example, it's at a cost for whoever
23 is running Medicaid.

24 It's -- the dialysis unit never picks up

1 transportation cost.

2 DR. BAILET: I understand, but, I mean,
3 what you're suggesting is that Medicare -- will
4 Medicare pay for a travel van to move that patient
5 from the -- from the SNF to the dialysis center
6 today?

7 DR. KAUFMAN: So the -- it will under the
8 circumstances that the patient has to have a
9 medical justification for transportation in a
10 stretcher as opposed to a wheelchair. So if a
11 patient, whatever, let's say, you know, broke his
12 hip and was -- and a broken hip and had a very
13 unstable something or another and had to go back
14 and forth to -- had to go back and forth to a
15 dialysis unit. A case could be made that that
16 patient, until he's recovered --

17 DR. BAILET: Sure.

18 DR. KAUFMAN: -- back and forth --

19 DR. BAILET: But from my -- my experience
20 -- Harold, and I apologize, and, Rhonda, jump in
21 here. But my experience with dialysis patients is
22 there are a lot of folks that can be transported by
23 a wheelchair.

24 DR. KAUFMAN: Correct.

1 DR. MEDOWS: That is correct.

2 DR. KAUFMAN: That is correct.

3 DR. BAILET: So the savings -- and what
4 we're -- what I'm -- where I'm going, just so you
5 know, is part of this model, whether it's more
6 frequent or just current state of the union three
7 times a week, the savings is coming based on -- the
8 backbone of the savings is transportation, and what
9 I'm hearing is that, well, that may not be as big a
10 driver, an outlay of cash from Medicare's point of
11 view as perhaps we interpreted when we looked at
12 this originally.

13 And, Harold, I'm -- and Rhonda, I guess I
14 need maybe you guys -- I've got it wrong, but
15 that's my -- what I'm hearing is it's not -- it
16 might not be as big an expense outlay for Medicare
17 as we originally thought.

18 DR. MEDOWS: Yeah.

19 DR. KAUFMAN: But it's -- but it's big.
20 There are -- there are -- you know, I don't have
21 the data right in front of me, but it is -- it is
22 millions upon millions of dollars of Medicaid --

23 MR. MILLER: But do you -- do you have
24 data for your patients as to anything in terms of

1 how often they were being transported by ambulance
2 before they started your service? Do you know
3 that?

4 DR. KAUFMAN: Well, no, I -- I generally
5 won't know it for the following reason. That it's
6 very unusual that we -- that we pick up patients
7 who were on -- living in the -- you know, in the
8 nursing home for one reason or another and going
9 back and forth to an outpatient dialysis unit.
10 They don't make the -- that's not our patient
11 population.

12 Our patient population is somebody that's
13 coming from the hospital, you know, and going to a
14 skilled nursing facility. So we don't have data
15 prior to -- to the -- we only have the data, the
16 current data when they're --

17 MR. MILLER: You said -- you said in
18 something you went us that about 60 percent of your
19 patients were SNF patients and the other 40 percent
20 were long-term care nursing patients. Is that not
21 true?

22 DR. KAUFMAN: Yeah. What I meant is --
23 yes. But that means that of the patients, about 60
24 percent are acute rehab patients --

1 MR. MILLER: Yeah.

2 DR. KAUFMAN: -- and about 40 percent are
3 living forever in the -- in the skilled nursing
4 facility.

5 MR. MILLER: But are you saying they only
6 -- they only came to you initially to -- a long-
7 term care facility from a hospital? They didn't go
8 on dialysis in the nursing home?

9 DR. KAUFMAN: That's not our current
10 population. Every single patient that we have had
11 so far has either been an end-stage renal disease
12 patient that got an illness and went to the
13 hospital and was deemed, you know, for a nursing
14 home, you know, admission, or they developed
15 uremia, went into the hospital, started dialysis,
16 and then were deemed unsafe to go home and went to
17 the nursing home. So every patient is already on
18 dialysis.

19 MR. MILLER: Okay. Maybe you can clarify
20 this while we're on the topic. I got the
21 impression from several things you've said that --
22 in your responses to us that you were seeing more
23 patients being discharged from the hospital sooner
24 than they would have otherwise because of your

1 service being available. Is that right?

2 DR. KAUFMAN: I think that's -- that's --
3 that's accurate.

4 MR. MILLER: Can you -- can you talk a
5 little bit more about what the nature of those
6 patients is and what would have happened to them
7 otherwise and why they're not coming --

8 DR. KAUFMAN: Okay.

9 MR. MILLER: -- to the nursing home?

10 DR. KAUFMAN: So there's still -- there's
11 a couple of things on that point.

12 So let's do the simplest point. Let's say
13 that -- I will just tell you from like what happens
14 in New York what I know. Let's say that there is a
15 patient who is a Medicare -- a dialysis patient who
16 is a Medicare patient, and he has -- he's not a
17 Medicare-Medicaid patient. He's a Medicare-AARP
18 patient or something like that, and they -- you
19 know, a person who is not -- who has a certain
20 amount of income, so they're not Medicare-eligible.
21 You know, they have pensions or whatever they have.

22 Those people, let's say they have an
23 illness. They need to go to a skilled nursing
24 facility for a rehab stay. So now --

1 MR. MILLER: So they're -- they're in --
2 they're in the hospital for what reason?

3 DR. KAUFMAN: It could -- it could be for
4 sepsis, for a pneumonia, for a heart attack,
5 whatever it is.

6 MR. MILLER: They were on -- they were on
7 dialysis before they went to the hospital?

8 DR. KAUFMAN: Right. They're on --
9 they're end-stage renal disease patients. They're
10 elderly.

11 MR. MILLER: Got it.

12 DR. KAUFMAN: They go into the hospital
13 with some, you know, condition. They deteriorate
14 in the hospital. They're unable to go home. They
15 need to go, you know, for -- as a minimum, they
16 need to go for a rehab stay in a skilled nursing
17 facility.

18 All right. So now they have to go to a
19 skilled -- now they're sitting in the hospital.
20 The hospital is ready to discharge the patient, and
21 the hospital is looking for options. If the
22 patient is not a Medicare-eligible transport back
23 and forth, that is, he can sit in the wheelchair
24 like we talked about, it is unlikely that their --

1 that their -- that their -- that their AARP or
2 their UnitedHealthcare, secondary insurance --
3 they're not going to pay for transportation.

4 It then falls that the patient would have
5 to pay himself for transportation. What happens if
6 a patient says, "I can't"? What happens if that
7 patient then stays in the hospital, and they begin
8 to look for a dialysis center with on-site
9 dialysis? In the traditional way, it's a
10 conventional dialysis unit that's on some nursing
11 home.

12 In New York City, there's -- I mean, in
13 Manhattan, there's like one. In the Bronx, there's
14 one or two. Those -- there's -- it's very
15 difficult to get placement of dialysis patients in
16 those -- in those -- in those nursing homes that
17 have conventional dialysis on-site, you know,
18 units, dialysis units.

19 MR. MILLER: Mm-hmm.

20 DR. KAUFMAN: And what happens is patients
21 sit. They may sit for five days. They may sit for
22 six days. They might sit for three days or four
23 days, if they're lucky, but they sit in the
24 hospital waiting for being able to make that

1 connection.

2 So one advantage is that by -- by having -
3 - by having general accessibility for dialysis
4 services, when a patient is deemed appropriate to
5 be discharged from the hospital, they are
6 discharged from the hospital. So that's number
7 one.

8 Number two category is -- and it has been
9 certain patients that have difficult conditions
10 that really you might -- you really might not want
11 -- for their medical condition, you might not want
12 them transported back and forth to a freestanding
13 health unit. I mean, the obvious one is if they're
14 on a ventilator, you know, if they're on vents --
15 they're not going to be -- they have to have
16 dialysis on-site when there's ventilator, you know,
17 if a ventilator patient.

18 But there are patients who have quite a
19 bit of acuity, and it's just not appropriate to
20 have them go to some dialysis -- go to some nursing
21 home facility, and even if their transportation --
22 even if their transportation could somehow be
23 arranged, you know, technical aspects were worked
24 out, it may not be appropriate because, you know, a

1 lot of times people sit in the hallway for hours,
2 you know, all the reasons why transportation is not
3 good. That patient will then tend to sit in the
4 hospital for a much longer time because they --
5 their receiving dialysis unit, the freestanding
6 unit is saying, you know, "This patient is too
7 acute. We can't take care of a patient that has to
8 be in a bed," or whatever it has to be.

9 So by having this stuff on site, these
10 patients who are somewhere between -- somewhere
11 between -- they're -- they don't have to be in an
12 acute hospital and --

13 MR. MILLER: Mm-hmm.

14 DR. KAUFMAN: But they are stable enough
15 to leave the acute hospital but not really in such
16 perfect shape --

17 MR. MILLER: Yeah.

18 DR. KAUFMAN: -- you know, will need quite
19 a bit of care.

20 The opportunity to have accessible
21 dialysis on-site also helps those patients.

22 MR. MILLER: Right. So let me ask -- let
23 me ask you just two follow-up questions about that,
24 and I'll just take -- just for simplicity will take

1 the first example that you gave.

2 A patient who was on dialysis, came in the
3 hospital. So, in that sense, they would be
4 discharged from the hospital sooner. They would go
5 to a SNF for longer. From Medicare's perspective,
6 that would increase Medicare spending because they
7 would have to pay for more SNF days, where --

8 DR. KAUFMAN: Well, not really. It's the
9 same amount of SNF. In other words, they're going
10 for rehab. Let's say that they would need whatever
11 you want to say. They need, you know, four weeks
12 of -- or six weeks of rehab, whatever they have,
13 four weeks of rehab, you know, you know, 100 days
14 of rehab, whatever they have. So that same rehab
15 period is -- it doesn't really change. They just -
16 -

17 MR. MILLER: So you're saying that would
18 be the same. They just would get out of the
19 hospital sooner?

20 DR. KAUFMAN: I mean, it would be the
21 same. It might even -- you might even technically
22 be able to shorten the rehab, and we can get into
23 that later because of the people --

24 MR. MILLER: Okay. Then the second

1 question, though, then is these patients were on
2 hemodialysis before, wherever they were getting it.

3 DR. KAUFMAN: Right.

4 MR. MILLER: They're going to go on to
5 more frequent home dialysis in your nursing
6 facility, and then they're going to go back out.
7 And they're probably going to have to go back to a
8 center dialysis.

9 DR. KAUFMAN: That is -- right. If they
10 decided to -- if somehow or another they decided
11 they could put the structure together and do more -
12 - continue home dialysis in their private home,
13 that would be okay, but that is a -- that is a very
14 small minority of the cases. Advanced --

15 MR. MILLER: So is it a good thing -- is
16 it a good thing to be sort of switching the patient
17 for a short period of time to the more frequent
18 dialysis and then having them have to go back to a
19 normal schedule at a dialysis center?

20 DR. KAUFMAN: Well, first of all, the
21 patients that are chosen are the patients who
22 frankly had -- you know, where goals were not met
23 with conventional dialysis. It is -- it is highly
24 suited for these patients to have more frequent

1 dialysis, but the reality is -- the reality is it
2 is impossible to deliver more frequent dialysis,
3 except in a private home setting or a staff-
4 assisted nursing home setting. It can't -- it's
5 impossible to have a patient -- even if it were
6 better for them, they can't go five days a week to
7 an outpatient unit.

8 MR. MILLER: I understand that. What I
9 was asking --

10 DR. BAILET: Harold?

11 MR. MILLER: -- is it a good thing from
12 the patient's perspective to have them get the home
13 -- more frequent home dialysis for a short period
14 of time, given that they're not going to be able to
15 get it on a long-term basis?

16 DR. KAUFMAN: Well, it's a good thing for
17 the following reasons. The volume control is
18 improved tremendously. Blood pressure is improved
19 tremendously. Blood pressure medicines go down.
20 The patients -- patients, you know, the recovery
21 from a conventional dialysis in these patients
22 could be eight, nine hours. Recovery from this
23 kind of dialysis is one hour. So it is a good
24 thing.

1 MR. MILLER: Jeff, did you --

2 DR. KAUFMAN: They get better --

3 DR. BAILET: Harold, could I just jump in
4 again?

5 MR. MILLER: Yes.

6 DR. BAILET: I'm sorry. But there's a
7 couple of key points here. The question is -- what
8 Harold, I think, is asking is on my mind as well --
9 is to whipsaw the patient. Their blood pressure
10 medicine is adjusted because they're getting more
11 frequent dialysis, and then they go back out into -
12 - it's sort of a catch-and-release. They go back
13 out into the universe. Their blood pressure
14 medicine has to then be readjusted because they're
15 not getting the more frequent dialysis.

16 Is -- what Harold is asking -- so I have
17 two questions. What Harold is asking is, Is that
18 in the best interest of the patient to whipsaw them
19 in a 90-, 100-day rehab and then put them back into
20 the environment where they have to adjust to all
21 these medicines again, number one?

22 The second question I'm trying to
23 understand -- because the backbone of this is built
24 on transportation savings, it is not -- if you --

1 could you tell me on a percentage basis, do you
2 think -- where is the money being spent from
3 Medicare's point of view on transportation? From
4 Medicare's point of view because this is a Medicare
5 alternative --

6 DR. KAUFMAN: By the way, the big savings
7 are hospitalizations and rehospitalizations, but
8 okay. I mean, that's the big savings.

9 DR. BAILET: Yeah.

10 DR. KAUFMAN: The transportation issue, I
11 wish I -- you know, I don't have the data, but I
12 will show some tremendous -- I mean, there are tens
13 of millions of dollars being spent on
14 transportation, more than that in Medicare
15 transportation.

16 DR. BAILET: But if --

17 MR. MILLER: We know that. The issue is
18 whether it's being spent on the patients you're
19 talking about here and if it would be avoided.
20 We're not -- by the way, just to be clear, we're
21 not disputing the value of the more frequent
22 dialysis for those patients.

23 DR. BAILET: Right.

24 MR. MILLER: The issue is we have to

1 evaluate this as a payment model, and we have to
2 evaluate whether it's going to achieve savings for
3 Medicare or not.

4 DR. BAILET: Mm-hmm.

5 MR. MILLER: So that's why we're trying to
6 drill in on these things.

7 DR. KAUFMAN: Yeah, I understand.

8 So to bring us back to that, you're just
9 trying to -- you're trying to quantify. You're
10 trying to get a sense.

11 DR. BAILET: Well, if you look at the --
12 let me ask it again. In the universe of savings,
13 my assessment, based on this conversation, is that
14 a better -- a higher percentage of the money saved
15 is getting people -- having the ability to get them
16 out of an acute care hospital setting into a lower
17 cost venue of care quicker.

18 DR. KAUFMAN: That's one -- that's right.
19 That's a plus, right.

20 DR. BAILET: I'm saying that that's the --
21 there is more money there to be saved from
22 Medicare's perspective than there is on
23 transferring people, transporting them to a --

24 MR. MILLER: Well, Medicare doesn't save

1 any money by getting the patient out of the
2 hospital center because Medicare pays a fixed
3 amount for them to be in the hospital.

4 DR. KAUFMAN: Well, where they do lose is
5 when the patient goes back to the hospital.

6 So, for example, if a person is admitted
7 to the hospital with a cardiovascular diagnosis, a
8 dialysis patient, you know, that within 30 days of
9 discharge, 40 percent of those patients are back
10 with the same diagnosis under conventional care, so
11 that is a tremendous cost. Tremendous cost.

12 MR. MILLER: And so are you seeing lower
13 readmission rates in your program?

14 DR. KAUFMAN: Absolutely. So, for
15 example, if you look at the USRDS data, about 40-
16 some-odd percent of patients go admitted with
17 cardiac-related admissions, you know, in the
18 dialysis world.

19 MR. MILLER: Mm-hmm.

20 DR. KAUFMAN: In our patient group, it is
21 almost -- aside from having a heart attack, but
22 admissions for congestive heart failure, fluid
23 overload kind of things, disappear. They do not
24 exist.

1 So, if you look at that pie chart and you
2 look at the reasons for admissions from our
3 patients, that 45 percent pie chart becomes a 10 or
4 15 percent pie chart. You notice that.

5 MR. MILLER: Mm-hmm. Well, you mentioned
6 the readmission issue in your proposal, but you
7 didn't really say what impact you thought your
8 program would have on it.

9 DR. KAUFMAN: Oh, I think it's just --
10 that is the big impact. That is the big impact,
11 you know, aside from quality of life and stuff like
12 that, but that is the big, big financial impact.

13 MR. MILLER: Okay. Well, so, in other
14 words, you're basically saying that you think that,
15 in a sense, the premise of the model is saving
16 readmissions. It's not saving on transportation.

17 DR. KAUFMAN: Everything else --
18 everything helps, but the savings of the
19 readmissions is the -- is really the -- is really
20 the --

21 DR. BAILET: So that's where I'm trying --
22 I'm sorry. That's where I'm trying. I'm trying to
23 frame it up in my head where the money is being
24 spent and where it would be saved. So there's a

1 significant portion of the savings coming from the
2 readmission decline. There is additional savings
3 coming from the transportation. There is
4 additional savings coming from management of
5 comorbid sequelae from getting more -- less
6 frequent dialysis, I guess, or just the
7 conventional dialysis versus more frequent, more --
8 there's more potential comorbidity that comes out
9 of that that is offset by not having the blood
10 pressure swings and some of the other potential
11 problems that these patients face. Is that -- and
12 they're missing their rehab, for example, and other
13 things, right?

14 DR. KAUFMAN: Yeah. I think, you know --
15 and I'd be happy -- we have lots of data. The
16 rehab scores are higher and reach that point faster
17 because they are -- they are -- under conventional
18 dialysis being transported, you're not present for
19 three days out of seven. So --

20 MR. MILLER: Before we lose it, can you go
21 back and answer Jeff's first question, which is --

22 DR. KAUFMAN: Yeah.

23 MR. MILLER: -- the whipsawing issue?

24 DR. KAUFMAN: Yeah, let me go back to that

1 because there was an assumption made that is really
2 not true. Somebody -- we were talking about, oh,
3 they would have to readjust to more medications.

4 Let's just be really clear on one point.
5 They're coming from a conventional dialysis. Many
6 of these patients, conventional dialysis,
7 unfortunately, is not optimal for some -- for
8 patients that we see.

9 So a patient will -- it's not a matter of
10 -- a patient will then go back to conventional
11 dialysis and will be hypertensive again, regardless
12 of medications. Sixty-plus percent of all patients
13 in America are having, you know, what's considered
14 160 systolic or high -- 140 systolic or higher on
15 dialysis. A huge portion of America are having
16 these problems.

17 And so what would happen -- it's a sad
18 situation. They will have -- they will have,
19 whatever, two or three months -- or two months of
20 rehab. Their entire hemodynamic system will
21 improve. Their blood pressure will improve. Their
22 rehab will be better, and yes, they are going to go
23 back to their former state.

24 Whipsaw, it doesn't matter. They will go

1 back to their former state. They will not have
2 volume control. They will have high blood
3 pressure, and a whole bunch of other things will go
4 on. It is -- at the moment, it is the only option
5 because we just don't have a practical way to --
6 everybody does the best they can with conventional
7 dialysis, but for some patients, it's really not
8 good enough. But it is the best people can do. So
9 you're right. They will go back.

10 And the whipsaw isn't an issue. It's not
11 you're harming a patient. They will just have a
12 very good period of time when all sorts of, you
13 know, hemodynamic stressors are removed from their
14 body, and they will have a nice rehab period.

15 But then they will go back, and they will
16 reassume the former status, which is suboptimal.
17 It is not what we wished it would be, but that is
18 what's going to happen. And there's no immediate
19 solution to this. Everybody is grabbling with it.
20 You know, it's the big topic right now in the whole
21 country, you know, on how to deal with this stuff.

22 MR. MILLER: So let me see if Rhonda has
23 any questions on these topics we've just been
24 discussing.

1 DR. MEDOWS: I actually -- I don't. The
2 more I hear, the more confusing it gets.

3 DR. KAUFMAN: Why? Tell me why because
4 either I'm not explaining it right or something,
5 because it seems like it should be -- it should be
6 -- I want to try to get the strong points across as
7 best I can, you know.

8 DR. MEDOWS: No, I think it's more that
9 there's a lot of ifs, right, in terms of who --
10 where the savings actually would occur. I
11 understand the part about the more frequent
12 dialysis. I understand the part about
13 overwhelming; it may be better for the patient. I
14 understand the part about kind of moving back and
15 forth in terms of their previous dialysis and then
16 moving them from peritoneal to home and all that
17 kind of stuff. That, I got.

18 I don't understand who the savings accrues
19 to, and I'm looking at this email that Sarah just
20 sent about transportation. But now it seems like
21 transportation isn't the only thing, or maybe I --

22 DR. KAUFMAN: Oh, no. It's not even a
23 major thing. Let me see if I can --

24 DR. MEDOWS: So actually having some

1 numbers behind what you're talking about in terms
2 of reduced admissions, readmissions, that would be
3 fantastic, right?

4 DR. KAUFMAN: Sure.

5 MR. MILLER: So I think the issue, Dr.
6 Kaufman, is we're not -- we're not really debating
7 kind of the value to the patient of what you're
8 talking about offering.

9 DR. KAUFMAN: You just want to see where -
10 - where -- how it's going to affect --

11 MR. MILLER: No, no, no. We -- the issue
12 is we -- we review payment models. You proposed a
13 payment model to pay nephrologists differently.
14 That was, in fact, all you proposed to change --

15 DR. KAUFMAN: Right. A few -- a few --

16 MR. MILLER: -- based on a certain --

17 DR. KAUFMAN: -- changes. Correct.

18 MR. MILLER: -- assumption, and the whole
19 thing was premised on the idea that this is going
20 to be savings for Medicare from transportation.

21 DR. KAUFMAN: Well, no, no. Actually --
22 wait. I just --

23 MR. MILLER: It was. That's what the
24 proposal said. It said basically that the premise

1 was that doing this is going to save money for
2 Medicare on transportation.

3 So there clearly is some of that on the --
4 the transportation for the patient on dialysis,
5 doesn't seem to be that opportunity for the
6 nephrologist, which was the thing that you were
7 actually proposing --

8 DR. KAUFMAN: Yeah.

9 MR. MILLER: -- to change the payment for.
10 And you're describing a somewhat different patient
11 population for which it's not exactly clear where
12 they would have been going anyway. They might have
13 been in the hospital getting whatever they were
14 getting, dialysis there, rather than actually going
15 sooner and going to a dialysis center.

16 DR. KAUFMAN: Mm-hmm.

17 MR. MILLER: So that's the challenges
18 we're -- you know, you proposed a specific payment
19 model with -- premised on certain kinds of savings,
20 and the questions we're all asking is about that,
21 not about, you know, is it good to give patients
22 more frequent dialysis.

23 DR. KAUFMAN: No, I understand. You're
24 not -- you're not debating the medical benefit.

1 MR. MILLER: Well, that's right.

2 So the care model might be fine. The
3 question is, Is this payment model either necessary
4 or sufficient to be able to support that?

5 DR. KAUFMAN: I think we probably didn't
6 make clear enough where the savings come from
7 across the board and the magnitude of the savings.
8 I would guess that the transportation savings are
9 minor, minor compared to the savings of
10 rehospitalizations.

11 MR. MILLER: Okay.

12 DR. KAUFMAN: I mean really minor, and --

13 MR. MILLER: So we're running down on our
14 time, so I just want to make sure.

15 DR. KAUFMAN: Yeah.

16 MR. MILLER: If there are other points
17 that you want to make in terms of the document that
18 we sent you, where you think we were kind of
19 missing the boat, that we --

20 DR. KAUFMAN: No, it's not that. It's
21 just it's open -- everything -- certain things were
22 up for discussion, you know --

23 MR. MILLER: Well, no, that's okay.

24 Whatever, whatever. But I'm just saying if there

1 are things that you think where we were really
2 inaccurate or misunderstood something, I want to
3 make sure we cover those.

4 DR. KAUFMAN: Okay. Well, let's see what
5 else we have.

6 Okay. The -- let's go to the integration
7 of care --

8 MR. MILLER: Okay.

9 DR. KAUFMAN: -- because that was another
10 thing that you were -- that you were concerned
11 about.

12 MR. MILLER: Okay.

13 DR. KAUFMAN: That was No. 7, integration
14 of care.

15 MR. MILLER: Yep.

16 DR. KAUFMAN: And that -- you know, you're
17 all familiar with the ESCO models, you know, and
18 things like that, and, you know, the ESCO models,
19 more or less -- I mean, I'm going to simplify a
20 lot.

21 Some ESCO models, by the way, are not --
22 are not risk models. In other words, for the large
23 dialysis organizations, it's a risk model. For the
24 small ones like New York -- like Rogosin in New

1 York, they have no downside. They only have
2 upside.

3 But when they talk about integration of
4 care, I think for about every hundred patients that
5 they -- you know, that are in the ESCO models, they
6 add a care coordination or something like that,
7 something like that, and they -- so if you have
8 whatever, if you have a thousand patients, you'll
9 have 10 care coordinators. If you have 3,000
10 patients, you have 30 care coordinators. That's
11 the -- one of the driving things that the ESCO
12 tries to coordinate care and improve outcomes, you
13 know, and stuff like that.

14 Our model is very interesting. We have --
15 there are features of that within our model. On
16 every site, there is a -- it's an RN, a senior RN,
17 which is an RN, and we call her a care coordinator,
18 an on-site RN care coordinator. That care
19 coordinator is the point person for trying to make
20 -- for dealing with the coordination of care and
21 sharing of information.

22 So, for example, multiple systems have
23 been put in place, so that there is a -- there is a
24 handoff that go from the nursing home staff to the

1 dialysis staff. Every dialysis within that handoff
2 is -- you know, the vitals of the patient, the
3 standards of the patient, the medicines listed for
4 the patients, and vice versa. After a dialysis
5 treatment, there's a -- there's a -- you know, a
6 handoff back.

7 The general coordination of care, many
8 times a nursing home will have a nurse
9 practitioner, and our care coordinator works very
10 hand-in-glove with that nurse practitioner to try
11 to -- to try to -- to try to, you know, make the --
12 to share the kind of information that you need to
13 share to take care of an end-stage renal disease
14 patient in the nursing home.

15 There is -- there is coordination of care
16 with wound care people on-site. There is
17 coordination of care with the rehab people on-site.
18 This is what the nurse in the center is doing. The
19 nurse is the liaison between the nephrologist and
20 the primary care physician, who is the primary care
21 physician assigned on -- you know, for the patient
22 on-site of a skilled nursing facility.

23 We do rely on the skilled nursing -- if
24 cardiology needs to be brought in, it's usually

1 done through the primary care physician on-site,
2 you know, with the -- you know, of the nursing
3 home. But it's a very deep system.

4 For example, there's Quality -- there
5 QAPI. That's -- we have our whole big QAPI
6 program, but there's also a little local QAPI for
7 every single skilled nursing home in terms which
8 they can look at, you know, things that they -- how
9 the patient's blood pressure is, how many medicines
10 there are, relevant QAPI topics for the patients
11 within the local site.

12 So the -- I think it's a very deep
13 coordination of care program, far superior to
14 anything that exists when a patient goes back and
15 forth to an -- you know, to a dialysis unit, and
16 has certain features, certain features of the ESCO
17 model. I mean certain features of it, but at the
18 same time --

19 MR. MILLER: Part of what we struggled
20 with -- and we do in other proposals, so it's not
21 just yours -- is you're describing what you do.
22 Part of what we have to understand, though, is if
23 the patient model were -- was put in place, how
24 would we know that in fact that would occur?

1 We understand that you sort of want it for
2 you, but Medicare is not going to create a payment
3 model just for you.

4 DR. KAUFMAN: I -- how did the --

5 MR. MILLER: They're going to create it
6 for --

7 DR. KAUFMAN: You mean how does the
8 payment mode --

9 MR. MILLER: Assure that what you're
10 saying you're doing actually has -- how you
11 translate that into some standards or quality
12 measures or whatever --

13 DR. KAUFMAN: Mm-hmm.

14 MR. MILLER: -- that, you know, you would
15 be obligated to follow.

16 DR. KAUFMAN: Well, we follow every
17 quality measure that any -- you know, I mean, you
18 know, are robust quality measures, you know, that
19 we follow, like any dialysis program would.

20 But the question -- I think if your
21 question is how does the model -- how does the --
22 how does the payment model modifications encourage
23 more coordination of care or shared information, I
24 mean, if that's the question --

1 MR. MILLER: Yes. At the nursing home,
2 right. Mm-hmm.

3 DR. KAUFMAN: Yeah. How does that ensure
4 it? And we have to find a link or a way that that
5 ensures it. Yeah, I understand. You're saying
6 that's what we do because that's our model, but you
7 want to see that the payment model kind of is --
8 also reinforces it or something like that or
9 assures it or makes it more likely to happen.

10 DR. MEDOWS: Right. Because we can't
11 assume that everybody has the resources or access
12 to the proprietary thing that you have created.

13 DR. KAUFMAN: Mm-hmm.

14 DR. MEDOWS: So how do we make sure that
15 it can be applied?

16 DR. KAUFMAN: Yeah, I understand. So
17 you're looking -- I understand. So you're looking
18 very broadly, beyond which -- not -- you're looking
19 at the model, not necessarily our exact model.

20 MR. MILLER: Yes.

21 DR. MEDOWS: Exactly right.

22 DR. KAUFMAN: Yeah.

23 DR. MEDOWS: You may have figured out a
24 best practice. That's very successful, and that's

1 great. Then how do we translate that into
2 something --

3 DR. KAUFMAN: Yeah, I understand. I
4 understand, because your goal is -- your goal is
5 that you want to make a change in some kind of
6 reimbursement model that helps to push this -- best
7 practice things forward. You know what I mean?

8 MR. MILLER: Right.

9 DR. KAUFMAN: So broadly, I think. I
10 guess that's what you're --

11 MR. MILLER: You got it.

12 DR. BAILET: And so my -- this is Jeff.
13 My challenge, Dr. Kaufman, is, again, I compliment
14 you on many levels -- putting together a proposal,
15 redesigning the care delivery for your patients. I
16 think it's great.

17 Our charge is to evaluate a payment model,
18 and what we're challenged with is the model, as
19 it's proposed, on the backbone of transportation,
20 based on this call, that is not really going to be
21 the economic engine of this model.

22 DR. KAUFMAN: Mm-hmm.

23 DR. BAILET: It's going to be other --
24 particularly whether it's getting out of the

1 hospital, all the other things we talked about, and
2 so that is not currently the way the model is
3 constructed. And that impugns our -- or inhibits
4 or limits our ability to evaluate it. That's my
5 point.

6 DR. KAUFMAN: I understand. I understand.
7 I understand exactly, and -- I understand.

8 MR. MILLER: So we're at the end of our
9 time.

10 DR. KAUFMAN: Okay.

11 MR. MILLER: So let me just sort of
12 summarize. It's been very helpful feedback to us,
13 and I hope understanding --

14 DR. KAUFMAN: No, it's very good. It's
15 very good, very helpful for me.

16 MR. MILLER: Right. So here's what we're
17 facing, is so you have a proposal which is before
18 the PTAC. In the ordinary course of things, we
19 would complete our report, which would look
20 something like what you saw, but with some
21 modifications based on the input that we got today.

22 DR. KAUFMAN: Mm-hmm.

23 MR. MILLER: And it would go to the PTAC,
24 and no way to predict exactly how everybody would

1 react, but you're getting some indication of at
2 least what three people, you know, think about.

3 So your choices really are you could say,
4 "I want to proceed with that. Please finish your
5 report. You know, we'll talk about it in
6 September," or you could say you want to rethink
7 the proposal and --

8 DR. KAUFMAN: We're going to modify -- I
9 think we will --look, every time I talk to
10 somebody, I learn something. So I -- no, I feel
11 that this model of care is a very worthy model of
12 care. It's worthwhile to try to design something
13 that meets your -- that meets the criteria that
14 you're looking for because -- and it's because it
15 really is a goal to try to reach. You know, I
16 mean, it really is a goal to try to reach. It
17 really is an improvement, and if we can make -- you
18 know, tweak it here and there or change things or
19 change the focus or clarify things in order to go
20 closer to the goal, that's what I want to do.

21 MR. MILLER: Okay.

22 DR. KAUFMAN: You know what I mean?
23 That's what I want to do. I want to try to --

24 MR. MILLER: Yeah. So I think the process

1 if you want to do that is what you -- because what
2 we don't really favor is people trying to make
3 significant changes to proposals while they're in
4 process. It just doesn't work well for us. It's
5 to basically say you want to -- if that's what you
6 want to do, would be to withdraw the proposal and
7 resubmit a new proposal, and that will -- I mean,
8 what that means is it won't come up in September,
9 but it may end up -- depending on when you resubmit
10 it, we would -- we would, you know, look at it as
11 quickly as we could, and it may -- will be
12 evaluated in December, for example. I mean,
13 there's no guarantee to that, but that would
14 probably be the -- and other people have done that.
15 But that's up to you as to whether you want to do
16 that. But we -- we ordinarily -- there's a general
17 sense that we do not want to consider major
18 revisions to proposals, you know, without a new
19 proposal. So I think it's up to you to decide.

20 DR. KAUFMAN: No, I understand, if a major
21 -- so the question is, in my mind, is there -- you
22 know, is there -- what is the option where you
23 answer the concerns with a response back? How does
24 that go, or how does that work, you know, when you

1 answer all the concerns?

2 MR. MILLER: Well, if we were to proceed
3 with a normal sort of -- just consider this,
4 continue to be a proposal, we would finish this
5 report. You would see something again, like what
6 you've already seen. You would then be able, if
7 you wish, to submit in writing responses to that,
8 that everybody could see before the meeting, and
9 then at the meeting, you would be able to answer
10 questions from the PTAC there.

11 But what I'm saying is that our -- what
12 has happened in the past is if an applicant comes
13 and says, well, my response to the concern you have
14 is that I really want to do it differently than
15 what I said in the proposal, the general reaction
16 of the PTAC is we can't evaluate something when
17 you're changing, you know, fundamental elements of
18 the proposal.

19 So if you think simply that we are wrong
20 about something or we've misunderstood something,
21 you may want to simply response, but if you think -
22 -

23 DR. KAUFMAN: I will see -- I can get
24 information. Let me just -- I will sleep on that.

1 You know, I'll think that one through because I
2 want to see if -- you know, I think I get a sense
3 of the two or three really major concerns that
4 you're trying to deal with.

5 MR. MILLER: Mm-hmm.

6 DR. KAUFMAN: And I -- and I have to just
7 think of -- I mean, we certainly -- the bulk of the
8 -- of the proposal would stay the same, but there
9 might be certain details that would change, you
10 know, from what we --

11 MR. MILLER: Mm-hmm.

12 DR. KAUFMAN: -- what I've learned today.

13 So the question is, in my mind, whether it
14 really just gets that rewrite. You know, 90
15 percent of the thing would not change at all, you
16 know, or 95 percent would not change. But it could
17 be written and made some changes, or do I clarify
18 things by providing more information with responses
19 that may help, you know --

20 MR. MILLER: So you don't -- you don't
21 have to decide that today.

22 DR. KAUFMAN: Yeah, I understand.

23 MR. MILLER: But what I would ask is that
24 if you could let us know by the beginning of next -

1 - by next Monday, say. I mean, this week, if you
2 can, but no later than next Monday, which way you
3 want to go, because we have to decide whether we
4 want to go to the effort of trying to finish this
5 report and put it on the agenda in September or
6 not. So it --

7 DR. KAUFMAN: I might just ask Wednesday
8 because I would tell you my father-in-law is having
9 his ninety-third birthday in Cleveland, and I've
10 got to leave there tomorrow until Monday. But then
11 I -- I will work on it over the weekend, but I
12 probably won't -- can't get it to you until Tuesday
13 or Wednesday.

14 MR. MILLER: Well, I'm only asking you to
15 tell us which way you want to go.

16 DR. KAUFMAN: Yeah, I understand.

17 MR. MILLER: Not to actually send us stuff
18 in writing, but just to think about which way you
19 want to go.

20 DR. KAUFMAN: Oaky.

21 MR. MILLER: And I think --

22 DR. KAUFMAN: I got it. No, I understand.
23 I understand.

24 MR. MILLER: So I guess just because of

1 our time --

2 DR. BAILET: Harold? Harold, if I may?

3 MR. MILLER: Yes, you may.

4 DR. BAILET: I don't mean to interrupt,
5 but I just think, Dr. Kaufman, the lens that I
6 would like you to consider looking at this is we
7 have to essentially evaluate a proposal as it's
8 written, with your feedback for clarification.

9 DR. KAUFMAN: Mm-hmm.

10 DR. BAILET: But our recommendation goes
11 to the Secretary.

12 DR. KAUFMAN: Mm-hmm

13 DR. BAILET: And one of the fundamental
14 elements that the Secretary is going to want to
15 know is how does Medicare -- you know, quality is
16 one piece, but how does the affordability issue get
17 addressed?

18 And as it's currently written, I'm not
19 clear --

20 DR. KAUFMAN: I understand. Yes.

21 DR. BAILET: -- that the backbone on
22 transportation, that that is the sweet spot, based
23 on your own input today, which was very helpful. I
24 think the sweet spot is --

1 DR. KAUFMAN: I'm just telling you -- I'm
2 telling you as it is. You know, I don't -- I'm not
3 big on -- you know, I'm not big on -- I don't spin
4 things too much. I kind of pretty much tell them
5 how they are, and then we try to just go from there
6 and figure out what to do.

7 MR. MILLER: Right. So we appreciate
8 that. So I think just think about whether you
9 think this is the proposal needs to change or you
10 simply need to explain it better, and if you could
11 let us -- it would be great --

12 DR. KAUFMAN: I'll let you know fast.
13 I'll let you know quickly.

14 MR. MILLER: It would be great help if you
15 could just simply let us know which way you want to
16 go on Monday. Again, you don't have to send us
17 anything on Monday other than a decision as to
18 whether you want to proceed with the proposal as it
19 is --

20 DR. KAUFMAN: Okay. That's fine.

21 MR. MILLER: -- or whether you want to
22 withdraw it and revise it.

23 DR. KAUFMAN: That's fine. That will be
24 done. Okay, that's fine. Okay.

1 So I really appreciated this. It was
2 good. It's good. I really have also, I think,
3 much -- I think I have -- really appreciate the
4 insight, you know, into how you're looking at --

5 MR. MILLER: Your time you spend in
6 telling all this, so it was very helpful.

7 DR. KAUFMAN: Yeah. Okay, everybody.

8 MR. MILLER: Thank you very much.

9 DR. KAUFMAN: Thank you very much. Okay.
10 Bye-bye. Thank you.

11 DR. MEDOWS: Bye.

12 DR. BAILET: Bye, now. Bye-bye.

13 [Whereupon, at 6:06 p.m., the conference
14 call concluded.]

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