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Physician-Focused Payment Model Technical Advisory Committee
c/o U.S. DHHS Asst. Secretary for Planning and Evaluation Office of Health Policy
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Dear Committee Members,

We are pleased to submit for your consideration Dialyze Direct's proposed "**APM for Improved Quality and Cost in Proving Home Hemodialysis to Geriatric Patients Residing in Skilled Nursing Facilities.**"

We wish to bring to your attention key individuals who will be overseeing and implementing the project, should it be favorably reviewed.

Dr. Allen Kaufman, the principal investigator of the project, is Dialyze Direct's Chief Medical Officer and Senior VP for Clinical and Scientific Affairs. He served as the Chief of Dialysis at the VA Medical in the Bronx, New York, Chief of the Renal Research Institute's Yorkville Dialysis Unit in New York City and Chief of the Division of Nephrology and Hypertension at the Beth Israel Medical Center in New York City. Dr. Kaufman has been the Principal or Co-Investigator on numerous research grants that have included NIH funded studies, has published more than 100 manuscripts, articles, book chapters and abstracts and has lectured widely, both regionally and nationally. Dr. Kaufman has served on dialysis-related advisory and editorial boards and received numerous awards including local, regional and national "best doctor" citations and "patients' choice" awards. Dr. Kaufman's educational and professional training occurred at the University of Rochester Undergraduate and Medical School, the Hospital of the University of Pennsylvania's Philadelphia General Hospital and the Mount Sinai Hospital and School of Medicine in New York. During his career, Dr. Kaufman has held academic appointments at the Mount Sinai School of Medicine in New York City and the Albert Einstein College of Medicine in New York City. Dr. Kaufman is board certified in internal medicine and nephrology and is a Fellow of the American College of Physicians.

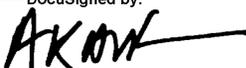
Dr. Nathan Levin, the co-principal investigator of the project, is Dialyze Direct's Chairman of the Medical Advisory Board and Director of Research. He served as Chief of the Renal Section at the V.A. Hospital in Chicago, Head of the Division of Nephrology and Hypertension at Henry Ford Hospital in Detroit and chief of the Division of Nephrology and Hypertension at Beth Israel Medical Center in New York City. Dr. Levin served as the Medical Director of the Survey & Certification Group for CMMS, President of the Michigan ESRD Network, President of the Renal Physicians Association (RPA) and President of the RPA Research and Education Foundation. He was Co-Chairman of the AAMI Hemodialysis Reuse Committee and the National Kidney Foundation-Kidney Disease Outcomes Quality Initiative (NKF-KDQI), member of the Clinical Practice Committee of the American Society of Nephrology, member of the International Society of Nephrology's Membership Committee, member of the Council for the International Society of Renal Nutrition and Metabolism (ISRNM). Among Dr. Levin's most prominent scientific projects are his role as one of the Principal investigators of the HEMO study and the Frequent Hemodialysis Network (FHN) Study. The HEMO study was a randomized, controlled, multi center trial which studied the effects of the dose of dialysis and the flux of the dialyzer on mortality and morbidity among 1846 patients undergoing hemodialysis. The HEMO study was a randomized, controlled, multi center trial which studied the effect more frequent hemodialysis (5+ times per week) versus conventional Hemodialysis (3 times per week) with respect to morbidity, mortality and quality of life. Dr. Levin founded the Renal Research Institute (RRI) in New York City. The institute part of Fresenius Medical Care of North America and represents a collaborative effort among a selected group of dialysis facilities with strong ties to academic research institutions. RRI trains Research Fellows from countries all around the world in kidney-disease related clinical research. Dr. Levin received his medical degree from the University of the Witwatersrand in Johannesburg, South Africa. Subsequently, he received his speciality training at the Presbyterian St. Luke's Hospital in Chicago, Illinois. During his medical career, he held academic appointments at the Northwestern University Medical School in Chicago, the University of Michigan in Ann Arbor, the Mount Sinai School of Medicine in New York City and the Albert Einstein College of Medicine in New York City. Dr. Levin is board certified in internal medicine and nephrology and is a Fellow of the American College of Physicians.

Alice Hellebrand RN, a co-investigator of the project, is Dialyze Direct's Chief Nursing Officer and Senior VP for Education. Ms. Hellebrand serves as the current President of the American Nephrology Nurses' Association (ANNA). She has been a practicing nurse specializing in nephrology and dialysis for over 30 years with a special interest in home hemodialysis and its impact on the frail geriatric population. Ms Hellebrand is certified in nephrology nursing, member of Sigma Theta Tau, American Nurses Association and National Renal Administrators Association. She holds a Master's degree in Nursing and is pursuing a Doctoral Degree in Nursing Research. Ms. Hellebrand is the lead author for the Contemporary Nephrology Textbook Hemodialysis chapter. She serves as a member of the PCORI sponsored Patient Research for Anemia Care project, ANNA palliative care initiative, is a participant in the Kidney Care Emergency Response Task

Force and Kidney Care Partners. Ms. Hellebrand is an internationally recognized lecturer, author, and nephrology advocate.

Dr. Eric Weinhandl, a co-investigator of the project, is an epidemiologist with interests in the benefits and risks of home dialytic modalities; the epidemiology of ESRD; the evaluation of the quality of care rendered by dialysis facilities; the design and evaluation of the Medicare program; and quantitative methods for the control of confounding in comparative effectiveness research with observational data. Dr. Weinhandl has a thorough understanding of Medicare Parts A, B, and D, including reimbursement rules and claims data arising from these programs. Among Dr. Weinhandl's most significant projects are his role as Principal investigator for NxStage Medical Inc. for a series of retrospective cohort studies of the benefits and risks of daily home hemodialysis verses existing dialytic machines, Principal investigator for the Peer Kidney Care Initiative for ongoing studies of dialysis patient outcomes and is amongst key personnel for the United States Data Renal System for annual data reports, with focus on Medicare Part D claims analysis. Dr. Weinhandl received his B.A in Mathematics, graduating *summa cum laude*, at the Saint Olaf College in Northfield, Minnesota, his M.S. in Biostatistics and Ph.D. in Epidemiology at the University of Minnesota, Minneapolis, Minnesota. Dr. Weinhandl is academically affiliated with the University of Minnesota in Minneapolis and has published more than 130 manuscripts and attracts and has lectured widely.

Sincerely yours,

DocuSigned by:

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**APM for Improved Quality and Cost in Providing Home
Hemodialysis to Geriatric Patients Residing in Skilled
Nursing Facilities**

MARCH 2018

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ABSTRACT

Individuals with end stage renal disease (ESRD) represent less than 2% of the Medicare population but utilize more than 7% of the Medicare's financial resources. Elderly dialysis patients that reside in skilled nursing facilities (SNFs) are further outliers with respect to cost of care. Every year, about 70,000 dialysis patients (15% of the dialysis population) reside in a SNF. These patients are characterized by advanced age, frailty and multiple medical co-morbidities and require significant modifications to "standard" dialysis care (which is designed for a younger and healthier population) in order to improve their overall care and outcomes. With the general population aging, the elderly dialysis patient (>65 years old) has now become the fastest growing segment of the dialysis population. Growth of the very elderly (>80 years old) has been especially profound. The proposed model of care brings on-site, staff-assisted, home hemodialysis (HD) services to those individuals with ESRD who reside in SNFs. The proposed model of care repurposes up-to-date technology that has been previously unavailable to the cohorts in the proposed study. A shorter, gentler, more effective and more frequent (5 x per week) mode of dialysis technology (MFD) is utilized. The proposed model uses an uncomplicated alternative physician payment model (APM) to incentivize a nephrologist to become a significant stakeholder in the patient-centric on-site care model. Specifically, the proposed model: 1) Incentivizes physician engagement with the patient and program which results in enhanced coordination of care and information-sharing, 2) Improves patient quality of life and medical outcomes and 3) Reduces the overall cost of care. The proposed model requires no additional infrastructure and therefore its application is feasible in urban, suburban and rural regions. The model is built upon the current Medicare Physician Fee Schedule and can be readily used by independent or employed physicians practicing in groups of all sizes. The financial incentives are straightforward in that it is only upside in providing a one-time bonus payment for patient-education related to the proposed model of care, and another cost-sharing payment related to obviating certain transportation costs by providing on-site medical evaluation(s). The dialysis delivery model is cost-neutral because the cost of transportation to and from an off-site dialysis unit three (3) times per week is used to offset the cost of two (2) extra treatments per week that comprise MFD. When the fewer hospitalizations, ER visits, and hospitalization observation admissions are accounted for, the overall cost saving for Medicare is substantial.

MAIN BODY

I. Background and Model Overview

A three-year study is proposed. The proposed model brings the advantages of home hemodialysis to a patient population that has previously been excluded from this option of care due to logistic reasons. The proposed model brings on-site, staff-assisted, home HD services to those individuals with ESRD that reside in SNFs. An uncomplicated alternative payment model (APM) incentivizes physicians to become significant stakeholders in the process.

One important aspect of the proposed model is its application of developing technology. NxStage Medical, Inc. home hemodialysis methodology has been repurposed for use in the geriatric dialysis population, which is the fastest growing segment of the ESRD population. Elderly dialysis patients have a higher incidence of frailty and medical comorbidities, and relative to the younger dialysis population, are more likely to reside in SNFs. During any given year, at least 15% of the United States ESRD dialysis population resides in a SNF¹. The proposed model of care utilizes a form of more frequent hemodialysis treatments that has only been available to ~2% of the hemodialysis population, and is comprised of younger individuals with relatively few medical comorbidities that maintain an economic status permitting treatment in a private home setting with a network of family caregivers,. The proposed model of care is designed to make this treatment option available to the elderly and frail who, among all dialysis patients, stand to benefit the most from this mode of therapy. The elderly and frail suffer from multiple co-morbid medical conditions they require a disproportionate portion of health care resources relative to younger dialysis patients. MFD home hemodialysis treatments achieve cardiovascular and fluid management benefits that result in fewer hospitalizations and re-hospitalizations due to less volume overload, improved blood pressure control and, in some patients, regression of left ventricular hypertrophy. In addition, because MFD requires the removal of smaller increments of fluid per treatment when compared to conventional dialysis, it reduces the incidence of intra-dialytic adverse events such as sudden decreases in intra-dialytic blood pressure.^{2,3} Further, MFD therapy permits more rapid recovery from a dialysis session and permits greater participation in rehabilitation classes and social activities⁴. This on-site service model eliminates the significant risk and cost of travel to a remote dialysis site. Long, unpleasant and often embarrassing waits in hallways for transportation services are avoided. Meals, rehabilitation sessions and social events are no longer missed. Further, included in the

¹ Medicare Limited Data Sets, 100% Sample. 2014-2016.

² See Supplemental Information. Advancing Dialysis Website.

³ Chertow GN, for the FHN Trial Group: In-Center Hemodialysis Six Times per Week verses Three Times per Week. N Eng J Med 363:2287-2300, 2010.

⁴ Jaber BL, for the FREEDOM study group: Effect of Daily Hemodialysis on Depressive Symptoms and Postdialysis Recovery Time: Interim Report From the FREEDOM Following Rehabilitation, Economics and Everyday- Dialysis Outcome Measurements Study. AM J Kidney Dis 56:531-539, 2010.

proposed model are on-site teams of ESRD caregivers that effect a high degree of care-coordination and comprehensive information-sharing between the SNF staff and the dialysis staff. QAPI activities and ESRD educational activities are local, nursing home relevant, and a significant part of the program. Ultimately, this innovative, value-based model of care improves patient quality-of-life and medical outcomes while achieving a major overall cost savings.

Included in the proposed model are physician-focused payment adjustments that are designed to incentivize nephrologists to participate in this on-site model of care in order to make them fully engaged stakeholders.

How the model would work from the participants' perspective:

Patients:

Provides more choices: Factual information about the potential benefits of staff-assisted home HD is presented and if the patient chooses to participate, enrollment proceeds. If the patient choice is not to participate, the patient will be transported to an off-site dialysis facility three times per week for conventional dialysis therapy. Support of a patient's right to choose their dialysis therapy option is a cornerstone principle of the purposed model and embodies CMS's new interpretive guidelines regarding dialysis in the long-term care (LTC) setting. In October 2016, CMS released reformed guidelines for LTC facilities (effective November 28th, 2017) that included a requirement that when home dialysis is desired by a patient residing in a SNF that does not offer the service, the SNF must work to identify SNFs where the patient may consider transferring for their care⁵. For dialysis patients with fluid removal problems (hypertension, cardiomyopathy and/or episodes of falls in blood pressure during HD), the hemodynamic benefits of MFD are a fundamental reason that underlie the choice of MFD over conventional three-times-per-week therapy. This is the major medical reason why doctors certify medical necessity to prescribe MFD, and why patients embrace MFD. Patients are empowered to choose a form of HD therapy that improves their chances of bettering their medical outcomes and increases their comfort.

In particular, the model proposed provides more choices regardless of economic status. The scope of care of staff-assisted home HD embraces the elderly and frail with hemodynamic instability, and are among the individuals who have never had an opportunity to benefit from a home dialysis program. Included in that group are those who could not meet the home environment requirements necessary for home therapy. The economically disadvantaged have experienced unique barriers to entry to home dialysis programs.

⁵ See Supplemental Information. Federal Register October 2016. Reform of requirements for LTC facilities.

Improves quality of life. The HD schedule of the proposed model is planned around other activities important to the patient. Post-HD fatigue is significantly reduced. Return to function with conventional HD averages 8 hours (but can be much longer).⁶ The proposed model reduces post-HD recovery time dramatically, often to less than one hour. The rapid recovery from HD permits more effective physical rehabilitation and enhances general physical activities. Preliminary data suggests that total rehabilitation scores are higher and reached more quickly with the proposed MFD model⁷. This empowers the patient to be more physically active and participate in social and community activities, hobbies, and family visits, which when all factored together may favorably impact medical outcomes in addition to the obvious improvement in quality of life.

Eliminates debilitating and dangerous transportation to and from remote HD facilities. Transportation can be unpleasant and medically risky for the elderly and frail. In cold or hot climates, transportation exposes the patient to the extremes of weather. Additionally, transfer to and from an ambulance or van represents a significant fall risk. Often patients have long waits in hallways before being brought back to the SNF or, if a patient arrives too early, there are waits before their dialysis station is ready for treatment. For those dialysis patients residing in the SNF, an off-site HD treatment turns into an entire-day event. Meals and social activities are invariably missed.

Facilitates care closer to home. The proposed network of on-site options permits rehabilitation placement as close as possible to a patient's home and family members. Similarly, proximity to the patient's physicians is improved.

Enhances continuity of nephrology care. The patient can keep his/her own nephrologist, which minimizes the disruption of care that often takes place when a SNF placement is far from the home or physician base. Such placement far from home, especially when HD is provided by remote providers, may preclude a patient's nephrologist from participating in care.

Improves ESRD-specific dietary care. On-site dietary coordination between the dialysis team dietitian and the SNF dietitian enhances customization of the patient's ESRD-specific diet. Properly planned meals can ensure adequate protein intake and help reduce phosphate and sodium intake. Phosphate intake reduction can favorably influence soft tissue calcification, which is a major concern for ESRD patients. Sodium intake reduction can favorably influence inter-dialytic fluid gains and decrease the degree of hypertension.

Benefits from higher staff-to-patient ratios. Higher staff-to-patient ratios directly facilitate meeting patients' needs. The proposed model's staff-to-patient ratios of 1:2 far exceed the industry standard of 1:4-1:8. The high staff-to-patient ratio also

⁶ See Supplemental Information. Advancing Dialysis Website.

⁷ See Supplemental Information. Dialyze Direct preliminary data.

facilitates coordination of care with the SNF and enhances care of patients who often have multiple medical co-morbidities.

Pleasant treatment areas. The treatment area is a dialysis “den” and is designed to be comfortable and patient-friendly. Treatment is provided in a community space designed for four (4) patients, with a focus on enhancing patient comfort and sense of security.

Reduces medication pill-burden. Patients on conventional dialysis commonly take multiple antihypertensive and phosphorus-binding pills. Conventional dialysis patients average 10-12 pills per day. The proposed MFD model improves fluid and blood pressure control and results in reduced antihypertensive pill burden. The proposed MFD model enhances phosphorus clearance and helps reduce the phosphorus-binder pill burden.

Reduces hospitalizations and re-hospitalizations. When a dialysis patient is admitted to a hospital for fluid overload complications such as congestive heart failure, there is a 40% likelihood of a re-hospitalization for the same diagnosis within 30 days of hospital discharge⁸. The proposed MFD model improves fluid management and reduces hospitalizations and re-hospitalizations for heart failure and similar conditions, thereby reducing setbacks following previous rehabilitation gains.

Ensures care during natural disasters - more safety, less anxiety. The proposed MFD model has natural disaster benefits by eliminating dangerous travel during natural disasters and ensuring continued on-site care. If required, the proposed model’s technology (NxStage System One) permits HD to be performed without a functional water source. Dialysate bags are stored on-site and can be used to perform treatment until a crisis has passed.

Affiliated Nephrologists:

Continuity of care is maintained. The proposed program has developed efficient physician credentialing procedures that permit effective continuity of care for those who have been the patient’s long-standing nephrologist.

Access to enhanced coordination of care and shared information. As will be described in detail in the body of the proposal, the proposed program provides an on-site interdisciplinary team that includes a senior registered nurse (RN) home dialysis coordinator, trained home HD caregivers, dieticians, and social workers that all work together to enhance the total quality of care. The on-site home dialysis coordinator plays a highly engaged role in care coordination and information-sharing and serves as a liaison between the dialysis team and the nursing home

⁸ See Supplemental Information. USRDS 2017 Annual Data Report.

team, which includes any nursing home nurse clinicians. Such an arrangement is critical in helping the nephrologist treat the patient at the highest level of care. The proposed model of care trains social workers to understand the unique issues that result from the elderly nursing home dialysis population. Enhanced social worker services, particularly with respect to complicated issues such as end-of-life issues, are not only important to the elderly nursing home dialysis population, but also helpful to the nephrologist in treating the patient.

Access to an advanced dialysis-specific EMR. The proposed program utilizes Visonex Clarity, a dialysis-specific EMR system. EMR technology permits individuals involved in the patient's care to access the patient's record in a timely, organized, and efficient manner.

Access to a technologically advanced clinical model of care. The proposed patient-centric MFD model is particularly valuable for the cohort patients in the proposed program [individuals with ESRD that reside in SNFs and receive staff-assisted home HD services]. Similar programs are not readily available in a conventional dialysis setting.

MOC credit opportunity. Access to the Dialyze Direct QAPI program permits the physician to earn education and MOC credits for nephrology specialty re-credentialing.

II. Scope of the Proposed Model

By focusing on the dialysis patient population residing in SNFs, this APM promotes attention and focus on the elderly and frail dialysis population with multiple medical comorbidities. The proposed model of care improves critical medical outcomes and quality of life while reducing the overall cost of care through the blending of increased care-coordination, patient-centric care coordination, and the use of repurposed up-to-date technology.

The proposed model builds upon the current payment structure for dialysis care by utilizing a standard home dialysis physician payment model (~\$268 per month) except for two (2) modifications. First, the nephrologist will be rewarded for his/her patient education efforts with respect to the staff-assisted home dialysis modality option offered in the nursing home. This would be a one-time payment of \$500. Second, the nephrologist will be rewarded for efforts that avoid patient transport to their office. This can be accomplished by the nephrologist performing their monthly comprehensive home dialysis assessment on-site at the nursing home, thereby obviating a transportation cost. Contingent on the nephrologist organizing on-site care so that no off-site nephrology office visits are required, the physician can share in the cost-savings of one-per-month, Medicare-covered, round-trip transportation event, which equate to ~\$400-\$500 per dialysis treatment. The once-per-month proposed share of savings for the obviated

transportation event is split 90% to the physician and 10% to Medicare. Thus the physician is incentivized to become an integral stakeholder in the proposed model of on-site care.

With nephrologists providing ~85% of monthly dialysis services billed to Medicare, this group of physicians and their practices will comprise the majority of participants in this model. In some locations and under certain circumstances, non-nephrologist practitioners (e.g. nurse practitioners) provide dialysis services and would also be eligible to participate in the model.

Due to the aging of the United States population, with the elderly segment of the population serving as the fastest growing segment of the nearly 500,000 dialysis patients, the overall dialysis population is expected to continue increasing in number (and medical complexity)⁹. Data from the Dialysis Facility Reports, which are partially derived from the Minimum Data Set, indicate that, at some point during the year, ~15% of dialysis patients reside in a SNF¹⁰. Consequently, the proposed physician payment model can be applied to potentially ~72,000 patients, 8 x the dialysis patient population that has been currently receiving home hemodialysis. Thus, the potential cost-savings of this APM are significant. If only one (1) annual patient hospitalization or ER visit is avoided, the proposed model could save CMS and other payers more than \$150,000,000 per year.

Patient-centric quality outcome measures

The dialysis patient population residing in SNFs is characterized by a significantly higher prevalence of multiple medical co-morbidities, advanced age, and frailty relative to the general dialysis population. Therefore, the appropriate quality measures by which clinical success is measured differs from the general dialysis population. The proposed study will be a major first step in establishing realistic measures for the cohort to be studied. The proposed study will be a non-randomized comparison of two groups of patients: a prospective cohort of patients residing in a SNF that are receiving on-site, staff-assisted MFD and a matched, retrospective cohort of patients residing in a SNF and receiving conventional, predominantly off-site, in-center HD. The prospective cohort will include 500 patients per year. The retrospective cohort will be matched at a ratio of 5-to-1, and drawn from a claims-based cohort of >60,000 ESRD HD 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. In addition to providing a basis for comparison of the innovative proposed model of care with standard therapy, the data collected will provide a unique database for current practices and outcomes that characterize the cohort of dialysis

⁹ See Supplemental Information. USRD 2017 Annual Report.

¹⁰ Medicare Limited Data Sets, 100% Sample. 2014-2016.

patients residing in SNFs. Thus, meaningful clinical benchmarks defining standards of care for dialysis patients residing in SNFs will be established.

A broad characterization of the model

- A care model specifically designed for the elderly and frail ESRD patient population with multiple medical co-morbidities who reside in SNFs and require HD care.
- Nephrologist ESRD patient care oversight.
- Applicability to the current administrative infrastructure - no need for new infrastructure or administrative burden.
- Applicability to practices of various sizes and locations.
- Applicability to non-CMS payers - no barriers to participation.
- Applicability to nationwide implementation.

Most of the model's payment mechanisms are built upon existing services within the Medicare Physician Fee Schedule except for relatively minor, straightforward modifications that are comprised of one supplemental payment for education a monthly supplemental payment for transportation cost-savings. There is no need for an APM business entity separate from the participating physician's practice. The model works for employed physicians, independent physicians, and physician practices of various sizes within all regions in the United States. The APM entity is built solely upon potential upside financial, and is not designed to incorporate downside financial risk. As this model is not an advanced APM, the current APM is not required to bear risk. With respect to other patient populations, the Minimal Data Set Facility Reports of nursing home annual admissions include populations such as veterans and/or patients with Medicaid-only or commercial insurance. There is no data to suggest that either of these groups of patients would require a different model of care to achieve favorable quality of life and cost-saving results.

Each patient is under the care of a nephrologist, who whenever possible, is the same nephrologist that supervised the patient's care prior to the SNF admission. The proposed model vigorously supports professional continuity of care. The physician-response to the proposed model of care has been heartfelt and positive. To the extent there has been any reticence, it has been related to the intensity of effort necessary to oversee the high prevalence of medical co-morbidities present in the incident patients and the intensity of effort of certain end-of-life issues. The APM model proposed is designed to deal with the reality of certain highly complex medical and social situations that are prevalent in the cohort population.

While staff-assisted home HD has been used on a very limited scale in some parts of the United States, no other entity has duplicated Dialyze Direct's robust model of staff-assisted home HD care, nor the basis for the current proposal. In addition, there are no programs that utilize physician APM's focused on the dialysis population residing in SNFs.

Unlike the ESCO model, which includes the entire dialysis population, the current model is customized for the most complex and expensive segment of the dialysis population.

As noted above, significant numbers of dialysis patients could benefit if the model was expanded to scale. With respect to Dialyze Direct's model of care, and as will be applied to the cohorts of the proposed model, patients must meet certain Local Coverage Determination (LCD) criteria to be eligible for more than three times per week dialysis. Although there are numerous reasons for a medical necessity justification for MFD per the LCD criteria, the medical necessity of MFD often manifests from fluid management issues, including fluid overload manifesting as hypertension or congestive heart failure, or intra-dialytic instability manifesting as falls in blood pressure when fluid is removed on dialysis. Dialyze Direct is mindful of over-utilization and conducts regular internal audits to ensure that LCD criteria are being met program-wide, and such audits will be continued for the participants of the proposed model.

III. Quality and Cost

The proposed model of care improves the quality of care at no additional cost.

The recurring transportation costs that would otherwise occur three (3) times per week when a patient received conventional off-site dialysis are eliminated by on-site dialysis treatments. The savings are retained by Medicare and can be used to [more than] off-set the extra two (2) HD treatments per week and increased staff-to-patient ratios that are integral to the proposed MFD model of care. Further, due to the proposed model's staff-assisted care, all facility patient home training fees are waived.

The physician-incentive costs are achieved at little to no additional cost. By reason of the staff-assisted design of the proposed home hemodialysis model, the nephrologist's home dialysis training fee is also waived. The waived home training fee offsets the physician's patient education incentive payment. Further, the physician-incentive received by performing on-site evaluations (such as the patient's comprehensive monthly home dialysis assessment) eliminates round-trip transportation cost, and results in Medicare sharing a portion of the savings.

This proposal's APM model is designed to 1) reward the physician for meaningful on-site engagement in the proposed model of care and to 2) return funds to Medicare. When reduced hospitalizations, ER visits, overnight hospital observation-stays and reduced complications of transportation (e.g. falls and other accidents) are included in the accounting, the proposed model of care significantly decreases the overall cost of care.

The value of this model is related to incentivizing nephrologists to become a fully-engaged stakeholder in a model of dialysis care specifically designed for the special needs of the dialysis patient population residing in SNFs. The sum of the parts of this patient-centered modality choice will enhance coordination of care, improve quality by improving well-

defined quality outcomes, and significantly reduce the overall cost of care. Multiple studies have demonstrated benefits of MFD compared to conventional dialysis that include: improved blood pressure control with fewer (or elimination of) blood pressure medications, improved extracellular volume, regression of left ventricular hypertrophy, slower ultrafiltration rates, fewer per-treatment episodes of intra-dialytic hypotension, reduced dialysis-induced cardiac, brain and gut injury, improved phosphate removal and phosphate control, improved quality of life (using several different instruments), more rapid post-dialysis recovery time, and reduced cardiovascular hospitalizations. Preliminary Dialyze Direct data indicates that hospital days are reduced by as much as 60% when nursing home patients transition from conventional dialysis to the model of care being proposed.¹¹ While the reduction in hospitalizations are primarily related to fewer cardiovascular events, reduced hospitalizations are also related to fewer central venous catheter dialysis access infections, which are one of the several resulting beneficial consequences of the proposed model's higher staff-to-patient ratios. This vascular access benefit is independent of any of the initiatives to reduce the overall number of central venous catheters used for dialysis access, which are more prevalent in the nursing home dialysis population than in the general dialysis population.

Quality outcomes

Quality Outcomes will be based on Medicare claim data and cost centers that permit tracking hospitalizations, re-hospitalizations, ER visits, observation hospital events, post [initial 100 day] hospital discharge outcomes, and complications of transportation (e.g. falls, fractures). Data MDS 3.0 frequency reports from the CMS minimum data base for active nursing home residents will permit tracking functional, cognitive and emotional status of the patient cohort in the proposed study. Application of Patient Reported Outcome Measures (PROMs) such as the In-Center Hemodialysis Survey Consumer Assessment of Healthcare Providers and Systems (ICH-CAHPS) and Kidney Disease Quality of Life 36 (KDOL-36) data will be tracked and compared with patient experiences with conventional dialysis. Although ICH-CAHPS reporting is not required for home dialysis programs, the proposed model will collect this data for all cohort patients participating in the study.

PROMs have been used to assess Health Related Quality of Life (HRQoL) in well-designed studies (such as the FHN Trial) and have compared MFD with conventional dialysis. These studies have invariably been conducted in a younger patient population. Ultimately, outcome studies must strive for endpoints that are relevant and meaningful for the patients under care. It is important to note that quality of life for the elderly and frail may be perceived differently when in comparison to a younger group of patients. Patient-centered care must take into account a patient's priorities and values. Patients on dialysis often are willing to sacrifice survival for meaningful quality of life improvements. A study cannot be preoccupied with mortality outcomes to the exclusion of other outcomes that

¹¹ See Supplemental Information. Dialyze Direct preliminary data.

are crucially important to patients. A major challenge with respect to PROMs will be to find ways to incorporate this information into the routine care of the patients.

Potential hazards of the model

The hazards of this model are touched upon in Section I of this proposal, which describes the risk that some nephrologists may be reluctant to invest the extra effort required to 1) care for the nursing home dialysis patient 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. The proposed model addresses the former by providing higher than industry standard staff-to-patient ratios and by utilizing advanced technology that, in addition to MFD, includes advanced data aggregation techniques and advanced care protocols to help address the critical volume management issues. The model addresses the latter hazard by expanding the training of the social workers to include psychosocial issues, thereby permitting a significantly expanded role in supporting the patients, families, and caregivers with respect to palliative care issues, and ultimately assisting the nephrologists to oversee this area.

IV. Payment methodology

This model is built upon the current nephrologist fee schedule for home dialysis services and is applicable to large and small practices in rural and urban locations. The alternative payment model in the current study is designed to incentivize nephrologists to fully engage with the proposed innovative clinical care model through two (2) financial incentives. Firstly, the nephrologist shares in savings related to eliminating unnecessary Medicare-covered transportation services to an off-site medical office. Secondly, the nephrologist is eligible for a one-time payment for efforts educating the patient with respect to the potential benefits of on-site, staff-assisted home HD (MFD) in the nursing home. The payment model offers opportunities for nephrologists who are not currently participating in an ESRD-designed APM and their participation in this model does not preclude participation in other APMs such as ESCOs. The current model of care and physician involvement is straightforward and adaptable to other payers. This APM model relies on nephrologists and nephrology practices to become fully engaged to educate patients with respect to the potential benefits of the proposed model of care and to play a central role in the dialysis team's coordination of care and information-sharing efforts that are critical components of the model of care.

Components of the payment model include:

- o **Eligible patients** - Patients with ESRD, residing in a SNF, who meet certain LCD criteria to be eligible for more than three times per week dialysis. In Dialyze Direct's experience, the vast majority of elderly and frail cohorts with ESRD and multiple

medical co-morbidities readily meet LCD criteria and it is anticipated that the same will hold true for the proposed study group.

- o **Episode of Care Duration** - Episode will encompass the time a patient resides in the SNF. Some patients will be permanent residents in the SNF, while others will be transient residents who are admitted for rehabilitation services and will likely return to the community and their original dialysis unit.
- o **Payer type** - The model initially is restricted to patients with traditional Medicare as the primary payer. As previously noted, the model could be readily adapted to other payer types.
- o **Attribution event** – The attribution of the incident dialysis patient will be determined by the date of the patient’s admission to the SNF.
- o **Risk Adjustment and Truncation Methodology** is not applicable to this proposal because the proposed APM does not have a downside risk.
- o **Financial Benchmark** - The financial benchmark for the participating physician will be the dollar value of the average Medicare cost necessary to provide one round-trip to a nephrologist’s office. The benchmark that will be used to quantify the overall value basis for the proposed method of care is the dollar amount of included Medicare Part A and Part B nonrandomized cost derived from comparison of two groups of patients: a prospective cohort of patients residing in a SNF that is receiving on-site, staff-assisted, MFD and a matched retrospective cohort of patients residing in a SNF that is receiving conventional, predominantly off-site, in-center HD.
- o **Included Medicare Costs** - All Medicare Part A and Part B costs with the exception of those attributable to transplantation, which in the patient population being studied is expected to be de minimis.
- o **Minimum Savings Rate** - The minimum requirement for an APM nephrologist participant to be eligible to share in savings is to obviate transportation to and from his/her office by performing on-site clinical evaluations. This is a recurring monthly benefit that can be achieved for as long as the patient remains in the proposed program.
- o **Shared savings split.** The charged savings split will be 90% for the APM participants and 10% for CMS.
- o **Risk** - No downside risk occurs in the APM model proposed.
- o **Patient Education bonus** - For participating patients, the APM participants will be eligible for a one-time, \$500 bonus for educating the patient with respect to the potential benefits of choosing to participate in the on-site, staff assisted, home HD (MFD) program.

V. Value over Volume

Participating nephrologists may have had previous experience with home HD therapy through the utilization of a MFD model of care in the treatment of younger, more stable, independent patients living in a private home setting. However, it is unlikely participating nephrologists have previous experience with the MFD care model as applied to the type of patients who will be enrolled in this study. The proposed model of care described in this proposal is an innovative adaption of technology and modifications of care designed to benefit the elderly and frail dialysis patient, who has multiple medical co-morbidities and resides in a SNF. To that extent, this model does prescribe specific process changes for the physicians. The APM is designed to ensure a nephrologist's wholehearted engagement in the process of patient-centric technology application and care coordination. As physicians and their practices adapt to the model, benefits likely to occur are 1) a coordinated effort to educate patients regarding choice of treatment options while they are in the nursing home, 2) coordination of care with dialysis and SNF staff in order to improve quality of life and avoid hospital admissions, ER visits, or hospital observation admissions, 3) on-site nephrology visits, 4) attention to clinical guidelines designed for the elderly and frail dialysis patient, and 5) regular evaluation of the patient-experience including satisfactoriness, functional, and cognitive status.

VI. Flexibility

Owing to the relative simplicity of the APM proposal, the participating physician is afforded great flexibility and autonomy in all significant care decisions. The model is applicable to any size practice in both rural, suburban and urban settings. Additionally, the model is designed to provide the nephrologist with more effective tools to care for their patient, including technological advances adapted to the elderly and frail patient's dialysis needs, robust coordination of care between the dialysis team and the SNF staff, and care protocols customized for the cohort population. With more effective dialysis care and elder care tools, the highly customized patient-focus of this model of care results in improvements in critical medical outcomes while reducing the overall cost of care.

VII. Ability to be Evaluated

This APM and care model 1) enhances the coordination of care for the patient cohort, 2) removes obstacles for patient choice of modality for the dialysis patients residing in SNFs, 3) promotes quality of life, medical management, and alleviates the end-of-life decision making burden experienced by the patient and family, and 4) improves overall quality while reducing cost. For the first time, critical outcome data will be generated for a cohort of elderly dialysis patients that reside in SNFs.

The physician experience can be tracked by direct survey, as well as measures of engagement including, but not limited to, participation in multidisciplinary meetings, QAPI meetings, etc.

A prior study by DOPPS, with data collected in 2005-2007, reported on dialysis practices and outcomes in elderly hemodialysis patients¹². However, the DOPPS data was generated in an era before a MFD technology was commercially available and did not select for those patients residing in a SNF.

Data regarding critical elements of care will permit CMS and other payers to objectively evaluate the model's impact on quality and cost of care for SNF dialysis patients which are arguably the most difficult and expensive amongst all dialysis patients. As noted in section II (Quality and Cost), quality outcomes will be based on Medicare claim data, MDS 3.0 frequency reports for active nursing home residents, and patient reported outcome data that is part of ICH-CAHPS reporting.

VIII. Integration and Care Coordination

The proposed on-site model dramatically improves coordination of care and information-sharing and is built upon Dialyze Direct's experience. At initiation of the program within any SNF site, preliminary preparations include a detailed delineation of responsibilities with respect to dialysis staff and the SNF staff. Based off this structure, the coordination of care efforts include a detailed hand-off of care procedure for each dialysis treatment that involves a direct description of the physical and psychological status of a patient about to be brought to dialysis, details of any change in condition or medication since the last dialysis, or any other special issues. An identical hand-off is performed after the patient completes dialysis and is returning to his/her nursing home floor.

The proposed model includes an on-site RN home dialysis coordinator at each nursing facility location, who acts as a liaison between the dialysis program and the nursing home's leadership to ensure information sharing. In addition to regional and system-wide QAPI programs, there is a nursing home-specific QAPI program that focuses on parameters directly important for the nursing home care of the patient. This involves parameters relevant to nutrition, blood pressure control, pain and psychological parameters. The home dialysis coordinator typically has many years of dialysis experience and works with the nephrologist to coordinate care with the nursing home's primary care physician and/or nurse practitioner. Dedicated regional dialysis social workers and dietitians coordinate with their nursing home counterparts. The proposed program provides a deep professional support system of on-site education for the nursing home staff with special emphasis on the unique care challenges of elderly dialysis patients, and emphasizes the complex and unique nutritional, psychosocial and medical challenges in this group.

Dialysis patients have multiple symptoms related to ESRD and the associated comorbidities that are often further complicated by depression. The proposed model's

¹² Carnaud B, et.al. Clinical Practices and Outcomes in Elderly Hemodialysis Patients: Results from the Dialysis Outcomes and Practice Patterns Study (DOPPS). Clin J Am Soc Neph 6:1651-1662, 2011.

robust coordination of psychosocial care efforts can be of great help to a dialysis patient's functionality and well-being. Additionally, it is important to note that dietary ESRD requirements are not one-size-fits all. Some technical aspects of MFD relate to sodium, potassium and phosphorus metabolism, and may require modifications of a standard "renal" diet ordered at the nursing home. Protein intake can be estimated from certain [dialysis] kinetic calculations that may bring to light certain requirements for dietary protein supplementation. There are many other examples of special circumstances of the cohort patient population related to age and/or ESRD status that benefit from information sharing. Ultimately, the improvements that result in information sharing from the proposed model's on-site dialysis delivery are majorly significant.

On a higher level, a program-wide regional nurse manager will coordinate care at the nursing director level of the nursing facility. Similarly, a program-wide regional medical director will coordinate care with the medical director of the nursing facility. Additionally, in the event Dialyze Direct is working with nursing home organizations that maintain multiple sites (often across multiple states), Dialyze Direct's senior management (i.e. the CMO, CNO, etc.) will coordinate care with the leadership of the nursing home corporate entity.

IX. Patient Choice

Supporting a patient's right to choose their dialysis therapy option is a cornerstone of the proposed model of care and embodies recent CMS's reformed guideline for LTC facilities, which includes fifteen (15) pages regarding dialysis in the LTC setting. Effective November 28, 2017, CMS directed that where home dialysis is desired by a patient residing in a SNF that does not offer the service, the SNF must work to identify other SNFs where the patient may consider transferring for their care¹³. For dialysis patients with prolonged post-HD recovery periods and fluid removal challenges (hypertension, cardiomyopathy, recurrent congestive heart failure and/or episodes of blood pressure falls during HD), the hemodynamic benefits of MFD are a fundamental reason that underlie the medical necessity reasons why doctors prescribe, and patients embrace, this form of therapy. Patients are empowered to choose a form of HD therapy that improves their chances of bettering their medical outcomes. Barriers to home dialysis therapy have included: 1) patient acuity (impacted by multiple medical co-morbidities), 2) patient cognitive function, 3) adequate numbers of family caregiver(s), and 4) a home with a suitable space for performing the treatments. These barriers to entry have defined the United States' current home hemodialysis population who are generally younger, healthier, and more affluent than the nursing home dialysis population. As a result, only 2% of the United States' dialysis population are being treated by home HD despite the fact that multiple scientific studies have demonstrated the medical, social, and psychological benefits of such therapy. Heretofore, the elderly dialysis patient residing in

¹³ See Supplemental Information. Federal Register October 2016. Reform of requirements for LTC facilities.

a nursing home has never had the opportunity to choose the option of home dialysis. The proposed program grants this type of patient with new choices, regardless of their age or economic status.

X. Patient Safety

Patient safety is improved by higher staff-to-patient ratios, elimination of the risk of transportation to an off-site HD facility, and a gentler dialysis modality (MFD) which enables faster post-HD recovery and less patient down-time. There is a significant increased relative-risk of medical complications associated with inactivity, depression and fatigue. The proposed program facilitates hospital discharge and advances the speed with which a post-acute care period of rehabilitation can be initiated. Other benefits of MFD therapy include reduced cardiovascular hospital admissions and their associated risk. Poly-pharmacy characterizes this cohort patient population. As described in Section VII (Integration and Care Coordination), the proposed on-site model significantly enhances medication reconciliation while reducing the risk of [others] prescribing medications inappropriately dosed or used for a patient undergoing dialysis therapy. MFD reduces or eliminates a number of medications and further reduces complications of poly-pharmacy.

Additionally, the on-site model of care and the machine technology used is far superior to conventional dialysis in withstanding a natural disaster. During a natural disaster, transportation to an off-site facility is highly dangerous, if not impossible. The proposed model has natural disaster benefits by ensuring continued on-site care. If a natural disaster were to affect the community water supply, the proposed model's NxStage System One technology permits HD to be performed without a functional water source. Dialysate bags stored on-site can be used to perform treatment until a crisis has passed.

XI. Health Information Technology

The proposed model of care makes full use of EMR technology. The technology used permits comprehensive data collection and analysis. Data can be used broadly for system-wide and/or region-wide quality-control, or with granularity for an individual patient-centric customization of care. The EMR is used by the entire dialysis caregiver team, including the nursing and ancillary staff, the social workers, dietitians and the physicians. The data generated also serves as an information source for an innovative supply system that ensures an adequate supply chain for the distributed system of care that characterizes the proposal. Further technology data innovation is under development that will customize patient-centric protocols for the critical aspects of hemodialysis care that relate to fluid management.

XII. Supplemental information

- Advancing Dialysis Website. AdvancingDialysis.org.
- Dialyze Direct preliminary data: 60% reduction in hospital days vs. same patients prior to transferring to the Dialyze Direct program (<25% cardiovascular admissions vs. >60% cardiovascular admissions prior to transfer), <0.5 dialysis catheter infections per patient year vs. industry standard ~1.5 catheter infections per patient year, total rehabilitation scores trend higher than [unpaired] patents receiving conventional dialysis.
- Federal Register October 2016. Page 360. Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities. <https://www.federalregister.gov/documents/2016/10/04/2016-23503/medicare-and-medicaid-programs-reform-of-requirements-for-long-term-care-facilities>
- United State Renal Data System 2017. Annual Report. <https://www.usrds.org/adr.aspx>.