Physician-Focused Payment Model Technical Advisory Committee

Preliminary Review Team Report to the Physician-Focused Payment Model Technical Advisory Committee (PTAC) on the "Alternative Payment Model for Improved Quality and Cost in Providing Home Hemodialysis to Geriatric Patients Residing in Skilled Nursing Facilities" Payment Model

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In accordance with the Physician-Focused Payment Model Technical Advisory Committee's (PTAC's) Proposal Review Process described in *Physician-Focused Payment Models: PTAC Proposal Submission Instructions* (available on the ASPE PTAC <u>website</u>), physician-focused payment models (PFPMs) that contain the information requested by PTAC's Proposal Submission Instructions will be assigned to a Preliminary Review Team (PRT). The PRT will draft a report containing findings regarding the proposal for discussion by the full PTAC. This PRT report is preparatory work for the full PTAC and is not binding on PTAC. This report is provided by the PRT to the full Committee for the proposal identified below.

A. Proposal Information

- 1. **Proposal Name:** APM for Improved Quality and Cost in Providing Home Hemodialysis to Geriatric Patients Residing in Skilled Nursing Facilities
- 2. Submitting Organization or Individual: Dialyze Direct

3. Submitter's 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."

B. Summary of the PRT Review

The proposal was received on March 8, 2018. The PRT met between May 1, 2018, and July 31, 2018. A summary of the PRT's findings is provided in the table below.

The nating of Freposal by Secretarial Criteri	M	
Criteria Specified by the Secretary	DDT Dating	Unanimous or
(at 42 CFR§414.1465)	PRT Rating	Majority Conclusion
1. Scope (High Priority)	Does Not Meet	Majority
2. Quality and Cost (High Priority)	Does Not Meet	Unanimous
3. Payment Methodology (High Priority)	Does Not Meet	Unanimous
4. Value over Volume	Meets	Unanimous
5. Flexibility	Does Not Meet	Unanimous
6. Ability to be Evaluated	Meets	Unanimous
7. Integration and Care Coordination	Does Not Meet	Unanimous
8. Patient Choice	Meets	Unanimous
9. Patient Safety	Does Not Meet	Unanimous
10. Health Information Technology	Does Not Meet	Unanimous

PRT Rating of Proposal by Secretarial Criteria

C. PRT Process

The PRT reviewed the Dialyze Direct proposal as well as additional information provided by the submitter in written responses to questions from the PRT between May 1, 2018, and July 31, 2018. The submitter also participated in an initial phone call with the PRT. The PRT subsequently sent a document with initial feedback to the submitter, and then the PRT held a second call with the submitter. The proposal, questions and answers, initial feedback document and call transcripts are available on the ASPE PTAC website.

1. Proposal Summary

The proposed payment model is intended to support a model of care that is currently operational in approximately 30 sites, with contracts signed at more than 150 sites. Under the proposed model, eligible patients with end-stage renal disease (ESRD) in skilled nursing facilities (SNFs) would have the opportunity to receive staff-assisted more frequent (five times per week) dialysis (MFD) at the SNF ("home hemodialysis"), rather than being transported to a renal dialysis facility (RDF) for thrice-weekly hemodialysis (HD). The submitters propose using the NxStage Hemodialysis System. Patients would include both (a) Medicare beneficiaries who are temporarily residing in the SNF for post-acute care following a hospital admission, and (b) beneficiaries who are long-term residents of the SNF.

Participating SNFs would create a comfortable treatment area or "dialysis den" so that patients could receive staff-assisted MFD in the SNF, thereby avoiding the need for transportation to a separate RDF (typically three times per week). The proposal indicates that the dialysis den would typically be set up for four patients, and 8-10 patients would be treated at each SNF, including some patients who would receive bedside dialysis because they could not be treated in the SNF dialysis den. The dialysis program would provide an on-site interdisciplinary team including a senior registered nurse serving as a home dialysis coordinator, trained home HD caregivers, dietitians, and social workers. The home dialysis coordinator would be highly engaged in care coordination and information sharing and would serve as a liaison between the dialysis program staff and the SNF staff. The dialysis program and SNF would work out a detailed delineation of responsibilities for their staffs.

Prior to admission to the SNF, ESRD patients would be screened to see if they meet medical necessity criteria for more frequent dialysis. Information on the benefits and risks of the program would be provided, and patients would choose whether or not they wanted to participate. (Patients who do not want to participate could continue to be transported to off-site RDFs.)

Participating patients could continue to be treated by the nephrologist who supervised the patient's care prior to the SNF admission (i.e., while they were receiving dialysis at home or in an off-site RDF). The submitters state that they have developed efficient

physician credentialing procedures, and the model includes incentives for nephrologists to travel to the SNF.

Under the proposed model, the nephrologist would receive a one-time bonus payment of \$500 for providing education to a patient on the proposed dialysis program. Medicare would not pay any other facility or physician home dialysis training fees. The nephrologist would also receive 90% of any savings resulting from avoided transportation costs if the nephrologist sees the patient in the nursing facility rather than in the nephrologist's office. There would be no downside financial risk to the dialysis provider or the nephrologist based on changes in Medicare spending.

The submitters propose a nonrandomized comparison of a prospective cohort of patients in SNFs receiving dialysis through the proposed dialysis program and a matched retrospective cohort receiving conventional, in-center hemodialysis. The submitters hypothesize improved patient outcomes, including reduced hospital readmissions, from MFD. Evaluation of the model would be based on comparison of all Medicare Part A and B costs except for those attributable to transplantation.

2. Additional Information Reviewed by the PRT

a) Literature Review and Environmental Scan

The Office of the Assistant Secretary for Planning and Evaluation (ASPE), through its contractor, conducted an abbreviated environmental scan that included a review of peer-reviewed literature as well as a search for relevant grey literature, such as research reports, white papers, conference proceedings, and government documents. The search and the identified documents were not intended to be comprehensive and were limited to documents that meet predetermined research parameters, including a five-year look back period, a primary focus on U.S.-based literature and documents, and relevance to the letter of intent. These materials are available on the ASPE PTAC website.

b) Data Analyses

To explore the extent to which SNFs around the country would have sufficient patients to justify development of dialysis dens, ASPE requested statistics on: (1) the number of Medicare beneficiaries receiving dialysis in 2016 by site of care; and (2) the number of SNFs and nursing facilities with eight or more Medicare beneficiaries receiving dialysis by hospital referral region. These analyses are available on the ASPE PTAC website.

c) Public Comments

The PRT received two public comments on the proposal. The Renal Physicians Association expressed broad support for innovative payment models but identified three areas of concern: (1) the extent to which the model is a physician-focused payment model; (2) issues regarding the quality of care; and (3) the extent to which palliative care and medical management issues are addressed. Fresenius Medicare Care North America commended Dialyze Direct for their proposal to incentivize home dialysis. The two letters are available on the ASPE PTAC <u>website</u>.

d) Other Information

The PRT spoke with a clinical expert (a nephrologist) to obtain additional information and opinions relevant to some aspects of the proposal. ASPE also spoke with staff in the Centers for Medicare & Medicaid Services to gain a fuller understanding of Medicare payment for transportation services for Medicare beneficiaries in SNFs to dialysis centers and to visits with their nephrologists.

D. Evaluation of Proposal Against Criteria

Criterion 1. Scope (High Priority). 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.

Strengths:

- The proposed payment model is intended to encourage delivery of dialysis services for nursing facility residents in the facility where they reside rather than requiring transportation to an offsite dialysis center.
- 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:

- The proposed payment model is designed to support a specific approach to staffassisted home hemodialysis, which may not be the best option for all patients in nursing facilities.
- It appears that only a small proportion of nursing facilities (less than 1%) would currently have the minimum number of eight 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, ESRD patients living in communities with multiple nursing facilities would shift to those nursing facilities that offered the home dialysis service.
- 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 proposed payment model does not address some of the important disincentives to home dialysis care that exist in the current payment system.
- 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.

Summary of Rating:

The majority of PRT members felt the proposed PFPM does not meet the criterion. This proposal is intended to (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. However, it is narrowly focused on one particular approach to dialysis delivery and it does not address all of the barriers that discourage broader use of home dialysis or staff-supported home dialysis in nursing facilities.

Criterion 2. Quality and Cost (High Priority). 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.

PRT Qualitative Rating:	Does Not Meet Criterion

Strengths:

- Avoiding the need for long-term residents of nursing facilities to be transported by ambulance to a dialysis center three times per week would reduce Medicare spending on ambulance transportation. For patients who receive Medicare-paid 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 even if payments per dialysis session were increased 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:
 - reducing the frequency of hospitalizations/readmissions and ED visits for patients on dialysis;
 - 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 not clear what proportion of patients using this service would have received Medicare-paid ambulance transportation to a dialysis center. The model would not be limited to such patients, and it is possible that most patients receiving services under the model would not have received Medicare-paid ambulance transportation.
- It is possible that some patients who 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. It is not clear whether this would increase, reduce, or have no impact on length of stay in the SNF and on total Medicare spending.
- There are risks to patients from more frequent dialysis, including higher risks of infection and access failure from more frequent vascular access, and this could increase spending.
- Patients who might otherwise receive peritoneal dialysis at the nursing facility could be encouraged to use more frequent hemodialysis instead, which would increase Medicare spending.
- 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.
- There are no specific goals for quality or outcomes, and there is no connection between payments and quality measures. Impacts on quality are to be assessed through a post-hoc evaluation study.

Summary of Rating:

The proposed PFPM does not meet the criterion. Most of the long-term residents of nursing facilities who need dialysis are being transported by ambulance to a dialysis center three days per week, and Medicare is paying for most of these ambulance trips. This proposal could enable a subset of those patients to receive dialysis in the nursing facility without the need for Medicare-funded ambulance transportation. This 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.

However, Medicare is not paying extra for ambulance transportation for short-term nursing facility patients who are receiving dialysis at a separate dialysis center, and, for these patients, more frequent dialysis at the nursing facility would increase Medicare spending. It appears that the majority of patients who would receive the more frequent dialysis service

would be in this category, and it is not clear whether the increase in spending for these cases would be more or less than the savings for the long-term residents.

The submitter stated that the biggest source of savings for Medicare would be reductions in hospital admissions and readmissions because of the benefits of more frequent dialysis, not reductions in ambulance transportation, but no data were provided showing how large the savings from reduced hospitalizations would be and whether they would offset the higher spending on more frequent dialysis.

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.

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

Criterion 3. Payment Methodology (High Priority). 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.

PRT Qualitative Rating:	Does Not Meet Criterion
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Strengths:

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

Weaknesses:

- The stated goal of the model is to offset higher spending on more frequent dialysis sessions with savings on reduced ambulance transportation costs, but the proposed payment model is not limited to patients who would otherwise have received Medicare-paid ambulance transportation to a dialysis center.
- 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 hemodialysis for a patient even if peritoneal dialysis or traditional hemodialysis would be 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 only change in the nephrologist's payment would be a one-time bonus payment for patient education about the specific home hemodialysis option.

- One of the two proposed changes in the nephrologist's payment is based on the assumption that Medicare is currently paying an additional amount for transportation of a dialysis patient to the nephrologist's office. However, transportation to a physician's office for a routine office visit during a SNF stay would be paid by the SNF out of its existing payment from Medicare. During a longterm nursing facility stay that is not covered by Medicare, transportation for such a visit would not be covered by Medicare. 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.
- 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.
- The payments to the nephrologists would not be affected by poor quality care or poor outcomes for patients. Although the submitter has indicated that the greatest source of savings would come from reduced rates of hospital admissions and readmissions, the payment model does not require any accountability for achieving low rates of hospitalization. (The payments to the dialysis provider would presumably be adjusted for quality under the standard Medicare dialysis PPS quality incentive program.)

Summary of Rating:

The proposed PFPM does not meet the criterion. 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 transportation to physician offices, but Medicare does not pay separately for such visits.

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 eight 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 eight patients per facility, with even 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.

Criterion 4. Value over Volume. Provide incentives to practitioners to deliver highquality health care.

PRT Qualitative Rating:

Meets Criterion

Strengths:

 More frequent dialysis at the nursing facility would be beneficial 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.

Summary of Rating:

The proposed PFPM meets the criterion. 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 long-term residents of nursing facilities would benefit from receiving more frequent dialysis at the nursing facility.

Criterion 5. Flexibility. Provide the flexibility needed for practitioners to deliver highquality health care.

PRT Qualitative Rating:	Does Not Meet Criterion
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Strengths:

• It is currently difficult for nephrologists to recommend more frequent dialysis for most nursing home patients 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 nephrologist would still be paid less if the patient received home dialysis in the nursing facility than if the patient received dialysis in a separate dialysis center.
- The proposed model appears to be dependent on approval from Medicare contractors to allow delivery of more frequent dialysis to patients.

Summary of Rating:

The proposed PFPM does not meet the criterion. The payment model is designed to encourage use of a new option for dialysis. However, the PRT felt that flexibility for

nephrologists would be limited because (a) the option would likely only be available in a limited number of sites, (b) for patients in a short SNF stay, the transition to and from more frequent dialysis would create additional risks for the patient and care management challenges for the nephrologist, and (c) the payments to the nephrologist would still be lower if they chose the home dialysis option than if the patient received traditional dialysis.

Criterion 6. Ability to be Evaluated. Have evaluable goals for quality of care, cost, and any other goals of the PFPM.

PRT Qualitative Rating:	Meets Criterion

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.
- 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.

Summary of Rating:

The proposed PFPM meets the criterion. It should be feasible to evaluate the model by collecting comparative information on quality and utilization for: (i) dialysis patients in facilities offering the service and (ii) patients in facilities that are using more traditional approaches to dialysis.

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.

PRT Qualitative Rating:	Does Not Meet Criterion
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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.

Summary of Rating:

The proposed PFPM does not meet the criterion. 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.

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.

PRT Qualitative Rating:	Meets Criterion

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.
- 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.
- Patients who are not long-term nursing facility residents would only have access to this option during the time that they were in a SNF following a hospital stay.

Summary of Rating:

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

Criterion 9. Patient Safety. Aim to maintain or improve standards of patient safety.

PRT Qualitative Rating:

Does Not Meet Criterion

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:

- There are risks to patients from more frequent dialysis, including higher risks of infection and access failure from more frequent vascular access.
- Most patients who are not long-term nursing facility residents would have to transition to (or return to) less frequent dialysis. This would require changes in their medications and potentially have negative impacts on their health.
- 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.

Summary of Rating:

The proposed PFPM does not meet the criterion. There are risks to patients from more frequent dialysis, including higher risks of infection and access failure from more frequent vascular access. In addition, many patients who are not long-term nursing facility residents would have to transition to (or return to) less frequent dialysis after discharge from the SNF, which would require changes in their medications and the transition could potentially have negative impacts on their health. The proposed payment methodology does not include any explicit mechanism for assuring that patients receive high-quality care or achieve better outcomes than they would under the current delivery and payment system.

Criterion 10. Health Information Technology. Encourage use of health information technology to inform care.

PRT Qualitative Rating:

Does Not Meet Criterion

Weaknesses:

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

Summary of Rating:

The proposed PFPM does not meet the criterion. There is no discussion of the specific kinds of data that would be collected and how they would be used.

E. PRT Comments

The PRT feels that the basic goals of the Dialyze Direct proposal are meritorious: (1) enabling more End Stage Renal Disease (ESRD) patients who are patients or residents of nursing facilities to obtain dialysis in the nursing facility rather than having to be transported by ambulance to a separate dialysis center three times every week; and (2) enabling the subset of nursing home patients or residents with ESRD who would benefit from more frequent dialysis (i.e., five days per week rather than three days per week) to obtain it, since that is typically not feasible for patients who have to be transported to a separate dialysis center.

However, there is no assurance that the proposed approach for achieving these goals would achieve savings for Medicare. Delivering dialysis to patients more frequently would increase Medicare spending under the payment system for dialysis; the proposal is premised on offsetting this increase in spending with savings from reducing Medicare spending on ambulance transportation to the dialysis center. However, the services and payments are not restricted or targeted to patients for whom such savings would be likely. Indeed, the submitter indicated that the majority of the patients currently receiving its services are patients in post-acute Skilled Nursing Facility (SNF) stays, and for these patients, any savings on transportation costs would accrue to the SNF, not to Medicare. Consequently, the PRT believes that Medicare spending could increase when the proposed services are implemented.

The PRT also does not believe that the proposed payment model would overcome the barriers in the current payment system to implementing the proposed services. The payment model assumes a continuation of current Medicare payment rates for dialysis services, yet the submitter indicated that these rates would not be sufficient to cover the cost of the staff-supported home hemodialysis services it is proposing to deliver. The proposed changes in payment for nephrologists do not address or resolve the current financial disincentives for nephrologists to support greater use of home hemodialysis.

Moreover, because a minimum number of patients are needed at a nursing facility to make staff-supported home hemodialysis financially viable, the model could likely only be implemented in a small proportion of nursing facilities.

The PRT is concerned that the model is narrowly focused on encouraging one particular approach to dialysis, even if that is not the best approach for an individual patient. Although there are benefits to patients from receiving more frequent dialysis and avoiding the need for transportation to a dialysis center, there are also risks of infection and access failure from more frequent vascular access. There could also be risks from changes in medications for the large proportion of patients who would only receive more frequent dialysis during a short stay in a skilled nursing facility. The payment methodology does not include any explicit mechanism for assuring that patients receive high-quality care or achieve better outcomes than they would under the current delivery and payment system.

The PRT concluded that because of these weaknesses, the proposed model does not meet the majority of the Secretary's criteria and it does not meet any of the high priority criteria.

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