

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

July 17, 2018

Disclaimer Regarding Initial Feedback:

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

Summary of PRT Assessment Relative to Criteria:

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

CRITERION 1. SCOPE (HIGH PRIORITY CRITERION)

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

Meets Criterion (Unanimous)

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

Strengths:

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

Weaknesses:

- ESRD Seamless Care Organizations could presumably pursue similar efforts to increase on-site dialysis for ESRD patients residing in nursing facilities and capture the savings from reduced transportation costs and any reductions in complications. However, it does not appear that many or any ESCOs are doing this, and most nephrologists do not have the opportunity to participate in an ESCO.
- The proposed payment model is designed to support a specific approach to staff-assisted home hemodialysis, which may not be the best option for all patients in nursing facilities.
- It appears that only a small proportion of nursing facilities (less than 1%) would currently have the minimum number of 8 eligible patients that the applicant indicates is necessary to make the proposed staff-supported home dialysis model economically viable. It is possible that if the service were supported and encouraged by an APM, patients living in communities with multiple facilities would shift to nursing facilities that offered the home dialysis service.
- 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.

CRITERION 2. QUALITY AND COST (HIGH PRIORITY CRITERION)

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

Meets Criterion (Unanimous)

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

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

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

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

Strengths:

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

Weaknesses:

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

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- There are risks to patients from more frequent dialysis, including higher risks of infection and access failure from more frequent vascular access.
 - Patients who would otherwise receive peritoneal dialysis at the nursing facility could be encouraged to use more frequent hemodialysis instead, which would increase Medicare spending.
 - 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.

CRITERION 3. PAYMENT METHODOLOGY (HIGH PRIORITY CRITERION)

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

Does Not Meet Criterion (Unanimous)

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

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

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

Strengths:

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

Weaknesses:

- The applicant indicates that current Medicare payment amounts would be insufficient to cover the cost of the service and to sustain its operations.
- The proposed payment methodology appears to create a financial incentive for nephrologists to recommend more frequent dialysis for patients even if that is not the best option for the patients.
- 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.
- One of the two proposed changes in the nephrologist's payment is based on the assumption that Medicare is paying for transportation of a dialysis patient to the nephrologist's office, but Medicare does not cover transportation to a physician's office for a routine office visit. Moreover, it is not clear that avoiding visits by the patient to the nephrologist's office is necessary to the success of the proposed approach.
- 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. (The payments to the dialysis provider would presumably be adjusted for quality under the standard Medicare dialysis PPS quality incentive program.)

CRITERION 4. VALUE OVER VOLUME

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

Meets Criterion (Unanimous)

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

Strengths:

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

Weaknesses:

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

CRITERION 5. FLEXIBILITY

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

Meets Criterion (Majority)

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

Strengths:

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

Weaknesses:

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

CRITERION 6. ABILITY TO BE EVALUATED

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

Meets Criterion (Unanimous)

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

Strengths:

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

Weaknesses:

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

CRITERION 7. INTEGRATION AND CARE COORDINATION

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

Does Not Meet Criterion (Unanimous)

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

Strengths:

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

Weaknesses:

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

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.

Meets Criterion (Unanimous)

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

Strengths:

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

Weaknesses:

- The proposed financial incentives for physicians based on patient participation and the need for the dialysis provider to achieve a minimum level of patient participation could result in patients not receiving objective information on the risks associated with the proposed approach.
- The more frequent dialysis service could be denied by Medicare contractors even if the patient could benefit from the service and wanted to receive it.

CRITERION 9. PATIENT SAFETY

Aim to maintain or improve standards of patient safety.

Meets Criterion (Unanimous)

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

Strengths:

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

Weaknesses:

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

CRITERION 10. HEALTH INFORMATION TECHNOLOGY

Encourage use of health information technology to inform care.

Does Not Meet Criterion (Unanimous)

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

Weaknesses:

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