

# DIALYZE DIRECT

## Environmental Scan and Literature Review: APM for Improved Quality and Cost in Providing Home Hemodialysis to Geriatric Patients Residing in Skilled Nursing Facilities

### METHODS

This environmental scan includes an annotated bibliography and summary information related to the proposal submitted by Dialyze Direct. The research questions and search strategy are described in detail in Appendix A. The environmental scan will provide a brief overview of the proposed model and submitter. The annotated bibliography will group sources by proposal-specific subtopics organized within five topics relevant to PTAC. Each subtopic will be followed with a brief explanation of relevance to the proposed model. Each source will include a citation and an outline of relevant key points, as well as a link if the source is publicly available. This report will conclude with topics which PTAC may consider relevant to the proposal and may be included in future discussions with the submitting organization or other stakeholders involved in model evaluation.

### BRIEF DESCRIPTION OF THE PROPOSED MODEL

The proposed model entitled *APM for Improved Quality and Cost in Providing Home Hemodialysis to Geriatric Patients Residing in Skilled Nursing Facilities*, aims to provide staff-assisted on-site hemodialysis (HD) to SNF patients with end-stage renal disease (ESRD). Currently, ESRD SNF patients travel off-site to receive HD. The proposed model would allow ‘dialysis dens’ to be set up within SNFs, which would eliminate the need for SNF patients to travel off-site three times per week (typically) to receive their treatment. Additionally, the savings accrued from redirecting the cost of transportation can be used to provide HD five times per week as opposed to the current standard of three times per week. More frequent hemodialysis regimens are thought to cause smoother fluid fluctuations that more closely approximate natural kidney function.

### DIALYZE DIRECT

Dialyze Direct is a private organization that provides staff-assisted home HD services to the geriatric population with ESRD. Its programs operate in rehabilitation facilities and residential/long term care (LTC) facilities. They provide services to patients in six different states (Florida, New Jersey, New York, Ohio, Pennsylvania, and Texas). They seek to improve quality of care, experience, and patient outcomes in regards to a high-quality dialysis treatment. Dialyze Direct is experienced with the use of collaborative healthcare professional teams. Additionally, it has a formalized alliance with NxStage, the organization that created the dialysis machine included in the proposed model.

### PROPIETARY TOOLS

- NxStage System One- Dialyze Direct has an alliance with NxStage Medical Inc. They use their NxStage Home HD system in their model.
- Protocols- Dialyze Direct has proprietary dialysis protocols suited to the special needs of geriatric patients with multiple co-morbid conditions
- Visionex Clarity- Dialyze Direct uses this dialysis-specific EMR system.

## Annotated Bibliography

### CURRENT PRACTICE AND STANDARD OF CARE

#### *Kidney Disease*

US Renal Data System 2016 Annual Data Report: Epidemiology of Kidney Disease in the United States

Saran, R., Robinson, B., Abbott, K.C., Agodoa, L.Y.C., Ayanian, J. & Bragg-Gresham, et al. (2017). US Renal Data System 2016 Annual Data Report: Epidemiology of Kidney Disease in the United States. *American Journal of Kidney Diseases*, 69(3), A7-A8. DOI: 10.1053/j.ajkd.2016.12.004 ([Link](#))

#### **Key Points**

- Medicare costs for beneficiaries ages 65 and older with chronic kidney disease (CKD), including ESRD, have exceeded \$50 billion. This cost represents 20% of all Medicare spending for the age group.
- There were 120,688 new cases of ESRD reported in 2014 (a 1.1% increase compared to 2013). A total of 678,383 individuals were treated for ESRD at the end of 2014 (up 3.5% from 2013), a number that continues to rise due to falling mortality rates among those with ESRD. On a positive note, large net reductions in mortality among patients with ESRD were observed.

#### *Home Dialysis*

The proposed model aims to increase access to “home” (or within nursing homes where patients live) HD for patients in SNFs.

Federal Register Notice 2016

Final CY 2017 ESRD PPS Update. 81 Fed. Reg. 77865 (November 4, 2016) (to be codified at 42 C.F.R. Parts 413, 414, 494). ([Link](#))

#### **Key Points**

- Medicare ESRD beneficiaries who meet home dialysis requirements under 42 CFR 494.100, and permanently reside in a nursing home or LTC facility are considered home dialysis patients.
- Several organizations, including small dialysis organizations, cite benefits of patients receiving home HD in the nursing home (either SNF or NF) rather than being transported to an ESRD facility to receive HD. These benefits include lower hospital admission and readmission rates, decreased lengths of stay during hospitalizations, and improved social outcomes.
- Staff-assisted home dialysis using nurses is not currently a Medicare covered service, nor are these services covered in the ESRD PPS.

#### *Care of Patients with ESRD in Nursing Homes*

The proposed model discusses the need for ESRD patients to be provided hemodialysis services within the nursing home.

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### End-Stage Renal Disease in Nursing Homes: A Systematic Review

Hall, R.K., O'Hare, A.M., Anderson, R.A & Colón-Emeric, C.S. (2013). End-Stage Renal Disease in Nursing Homes: A Systematic Review. *Journal of American Medical Directors Association*, 14(4), 242-247. DOI: 10.1016/j.jamda.2013.01.004 ([Link](#))

#### Key Points

- A systematic review based on older studies and data (before 2000) found that 1% or less of nursing home residents had ESRD. This number is likely increasing and higher now, though current information is lacking.
- Nursing home patients with ESRD are a particularly vulnerable population and have poor survival rates of 26-42% at one year—survival was better for those who had been on dialysis longer.
- Conflicting evidence exists regarding dialysis modality (peritoneal dialysis [PD] vs. HD) and relationship to poor outcomes.
- Predictors of poor outcomes include older age, white race, cerebrovascular disease, dementia, hospitalization at time of dialysis initiation.

### Frequency and Modalities

The proposed model aims to increase HD from the Medicare standard of three times per week to five times per week. Several studies have evaluated the effects of increased dialysis treatment frequency on social and health outcomes.

### Intensive Hemodialysis: Time to Give the Therapy Greater Consideration

Collins, A.J. & Chan, C.T. (2016). Intensive Hemodialysis: Time to Give the Therapy Greater Consideration. *American Journal of Kidney Diseases* 68(5), S1-S4. DOI: <https://doi.org/10.1053/j.ajkd.2016.05.027> ([Link](#))

#### Key Points

- Among the 470,000 dialysis patients in the US in 2013, 90% received in-center HD. It is predicted that there will be 700,000 dialysis patients by 2025.
- There are shortages of nephrologists and nurses capable of providing thrice-weekly care to in-center HD patients.
- An increase in the frequency of HD has demonstrated evidence of improvements in fluid volume, blood pressure, and phosphorous level controls. Additionally, patients receiving more frequent HD were found to have significantly reduced post-treatment fatigue and recovery time.
- Vascular access procedures were needed more frequently for patients who received home HD six times per week (compared to less frequent regimens), which may result in increased infectious complications.
- The popularity of three HD sessions per week was based on its effectiveness compared to twice-weekly treatments—not the result of demonstrated clinical superiority over newer regimens.
- More studies are needed to definitively prove the influence of dialysis frequency on mortality, but research suggests patients receiving home HD six times per week have a modest survival advantage compared to those receiving thrice-weekly in-center HD.

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### Effects of Frequent Hemodialysis on Measures of CKD Mineral and Bone Disorder

Daugirdas, J.T., Chertow, G.M., Larive, B., Pierratos, A., Greene, T., & Ayus, J.C. (2012). Effects of Frequent Hemodialysis on Measures of CKD Mineral and Bone Disorder. *Journal of the American Society of Nephrology*, 23, 727-738. DOI: 10.1681/ASN.2011070688 ([Link](#))

#### Key Points

- Among patients who received dialysis six times per week, 23% required phosphorus binders at month 12, compared to 92% for patients who received dialysis three times per week.
- Patients who received dialysis during the day had sessions lasting 1.5-2.75 hours. Patients who received nocturnal dialysis had sessions lasting 6-8 hours. Sessions occurred six times per week for all patients.
- Among patients who received nocturnal dialysis, 60% required phosphorus supplementation to the dialysate to prevent hypophosphatemia.

### Effects of Frequent Hemodialysis on Blood Pressure: Results From the Randomized Frequent Hemodialysis Network Trials

Kotanko, P., Garg, A.X., Depner, T., Pierratos, A., Chan, C.T., & Levin, N.W., et al. (2015). Effects of Frequent Hemodialysis on Blood Pressure: Results From the Randomized Frequent Hemodialysis Network Trials. *Hemodialysis International*, 19(3), 386–401. DOI: 10.1111/hdi.12255 ([Link](#))

#### Key Points

- After two months of dialysis, the group of patients who received frequent or nocturnal HD had a lower pre-dialysis blood pressure than the patients who received dialysis three times per week.
- Frequent HD resulted in significantly reduced need for antihypertensive medications.

### Dialysis Modality and Survival: Done to Death

Trinh, E., Chan, C.T. & Perl, J. (2018). Dialysis Modality and Survival: Done to Death. *Seminars in Dialysis*. doi: 10.1111/sdi.12692 ([Link](#))

#### Key Points

- No clear benefit of one dialysis modality over another (PD vs. HD).
- About 80% of patients still use catheters, associated with infections and increased mortality, as the main vascular access at initiation of hemodialysis.
- Seventeen percent of patients used an arteriovenous fistula exclusively at dialysis initiation, which increased to 65% by end of one year on hemodialysis.
- Early care coordination between nephrologists and primary care is associated with improved outcomes.

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### **Care Coordination**

The proposed model recommends care coordination through an on-site interdisciplinary team that includes a senior registered nurse (RN) home dialysis coordinator, trained home HD caregivers, dietitians, and social workers that all work together to enhance the total quality of care.

#### [Going Upstream: Coordination to Improve CKD Care](#)

Johnson, D.S., Kapoian, T., Taylor, R. & Meyer, K.B. (2016). Going Upstream: Coordination to Improve CKD Care. *Seminars in Dialysis*, 29(2), 125-34. doi: 10.1111/sdi.12461 ([Link](#))

#### **Key Points**

- Care coordination for patients with CKD has been shown to be effective in improving outcomes and reducing costs.
- Few patients with CKD receive care coordination for their kidney disease. As a result, suboptimal outcomes and costs for patients with kidney disease are increased.
- The effectiveness of treatments to delay progression of kidney disease in contemporary clinical practice does not match the efficacy of these treatments in clinical trials.
- Opportunities for early and even pre-emptive transplantation are missed, as are opportunities for home dialysis. The process of dialysis access creation is rarely optimal.

## **CONCERNS WITH CLINICAL CARE**

### **Effects of Payment on Care**

The proposed model identifies a lack of nephrologist incentive as a culprit for the shortcomings of clinical care. Studies show how changes in payment reform affect provider decisions regarding dialysis treatments.

#### [End-Stage Renal Disease Medicare Payment Refinements Could Promote Increased Use of Home Dialysis](#)

U.S. Government Accountability Office. (2015, October). End-Stage Renal Disease: Medicare Payment Refinements Could Promote Increased Use of Home Dialysis (Report No. 16-125). ([Link](#))

#### **Key Points**

- Medicare's monthly physician payments may discourage physicians from prescribing home dialysis. In 2013, the rate of \$237 for managing home patients per month was lower than the average payment (\$266) and maximum payment (\$282) for managing in-center patients.
- Medicare physician payments related to training may provide incentives for prescribing home dialysis. Physicians may get paid in the first month of treatment, rather than the fourth month, for training patients for home dialysis.
- Medicare makes a one-time payment of up to \$500 for each patient who completes home dialysis training under the physician's supervision.

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### Effects of Physician Payment Reform on Provision of Home Dialysis

Erickson, K.F., Winkelmayr, W.C., Chertow, G.M., & Bhattacharya, J. (2016). Effects of Physician Payment Reform on Provision of Home Dialysis. *American Journal of Managed Care*, 22(6), e215-223. ([Link](#))

#### Key Points

- After the physician payment for in-center hemodialysis care shifted from a capitated to a tiered fee-for-service model in 2004, fewer patients received home dialysis.
- The 2011 ESRD Prospective Payment System resulted in higher Medicare payment to dialysis facilities for home therapies, for which peritoneal dialysis is the most common modality. This coincided with a substantial increase in peritoneal dialysis versus hemodialysis.

### Hemodialysis Hospitalizations and Readmissions: The Effects of Payment Reform

Erickson, K.F., Winkelmayr, W.C., Chertow, G.M., & Bhattacharya, J. (2016). Hemodialysis Hospitalizations and Readmissions: The Effects of Payment Reform. *American Journal of Kidney Diseases*, 69(2), 237-246. DOI: 10.1053/j.ajkd.2016.08.033 ([Link](#))

#### Key points

- A Medicare reimbursement policy designed to incentivize more frequent provider visits during outpatient hemodialysis may have been costly but actual costs unknown.
- The policy was associated with fewer hospitalizations and re-hospitalizations for fluid overload, but had little effect on other patient outcomes, including all-cause hospitalizations or re-hospitalizations.

### Variation in Nephrologist Visits to Patients on Hemodialysis across Dialysis Facilities and Geographic Locations

Erickson, K.F., Tan, K.B., Winkelmayr, W.C., Chertow, G.M., & Bhattacharya, J. (2013). Variation in Nephrologist Visits to Patients on Hemodialysis across Dialysis Facilities and Geographic Locations. *Clinical Journal of the American Society of Nephrology*, 8(6), 987-994 DOI: 10.2215/CJN.10171012 ([Link](#))

#### Key points

- Variation in the frequency of physician visits to patients receiving hemodialysis was examined to measure the relative importance of provider practice patterns and patient health in determining visit frequency.
- More recent dialysis initiation and recent hospitalization were associated with decreased visit frequency.
- Provider visit frequency depends more on geography and facility location and characteristics than patients' health status or acuity of illness.
- The magnitude of variation unrelated to patient health suggests that provider visit frequency practices do not reflect optimal management of patients on dialysis.

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### Comparing Mandated Health Care Reforms: the Affordable Care Act, Accountable Care Organizations, and the Medicare ESRD Program

Watnick, S., Weiner, D.E., Shaffer, R., Inrig, J., Moe, S. & Mehrotra, R. (2012). Mandated Health Care Reforms: the Affordable Care Act, Accountable Care Organizations, and the Medicare ESRD Program. *Clinical Journal of the American Society of Nephrology*, 7(9), 1535-1543. doi: 10.2215/CJN.01220212 ([Link](#))

#### Key points

- The ESRD program operates under a fully bundled, case-mix adjusted prospective payment system and has implemented Medicare's first-ever mandatory pay-for-performance program: the ESRD Quality Incentive Program. Other mandated health care reforms are now legislating similar programs.
- As ACOs develop, they may benefit from the nephrology community's experience with the relatively novel ESRD program model for health care payment and delivery reform.
- The new ESRD payment system and the Quality Incentive Program are compared and contrasted with ACOs.
- Better understanding of similarities and differences between the ESRD program and the ACO program will allow the nephrology community to have a more influential voice in shaping the future of health care delivery in the United States.

## CURRENT PAYMENT METHODOLOGY

### *Payment Centered around Dialysis Treatment Episodes*

The proposed model recommends that the Medicare bundled payment be adjusted to accommodate five treatments per week. The current Medicare standard is based on three treatments per week.

#### Outpatient Dialysis Services Payment System

Medicare Payment Advisory Commission (2017, October). Outpatient Dialysis Services Payment System. *Payment Basics*. ([Link](#))

#### Key Points

- The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) expanded the payment bundle to include dialysis drugs, lab tests, and other ESRD-related items and services that were previously separately billable.
- About 90% of all dialysis patients undergo HD in dialysis facilities.
- The base payment was intended to cover the costs incurred by providers for providing dialysis treatment episodes in dialysis facilities or in the patients' homes. The base payment rate for 2018 was proposed at \$233.31 for freestanding and hospital-based facilities.
- The labor-related portion of the ESRD PPS payment rate was calculated at 50.7% for both freestanding and hospital-based facilities.
- In 2018, the dialysis training add-on was set at \$95.60 per treatment.

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### Medicare Benefit Policy Manual Chapter 11 – End Stage Renal Disease (ESRD)

Centers for Medicare and Medicaid Services, CMS Pub. 100-02 (2018, January). Medicare Benefit Policy Manual: Chapter 11 – End Stage Renal Disease (ESRD). ([Link](#))

#### Key Points

- Physician services are excluded from the ESRD PPS.
- Dialysis and certain dialysis-related services, including covered ambulance transportation, are excluded from SNF consolidated billing, and reimbursed separately under Medicare Part B.
- Medicare ESRD beneficiaries who permanently reside in a nursing home or long term care facility, and meet the home dialysis requirements will have all home dialysis items and services paid under ESRD PPS.
- If HD treatments occur more than three times per week, the Medicare Administrative Contractor (MAC) will assess appropriateness and payment for the additional treatments.

### *Payment Centered around Ambulance Transport*

The proposed model intends to reduce cost by eliminating transportation to dialysis facilities and providing dialysis treatment at the SNF where the patient resides. Transportation by ambulance adheres to specific Medicare reimbursement rules.

### Medicare Ambulance Transports

Centers for Medicare and Medicaid Services. (2017). Medicare Ambulance Transports. *Medicare Learning Network*. ([Link](#))

#### Key points

- Transportation via ambulance for dialysis patients who are also SNF residents is not covered under SNF Part A.
- Transportation would be covered if SNF or ambulance supplier bills MAC separately under Part B.

### High Cost of Dialysis Transportation in the United States: Exploring Approaches to a More Cost-effective Delivery System

Stephens, J.M., Brotherton, S., Dunning, S.C., Emerson, L.C., Gilbertson, D.T., & Gitlin, M., et al. (2014). High Cost of Dialysis Transportation in the United States: Exploring Approaches to a More Cost-effective Delivery System. *Journal of Health Economics and Outcomes Research*, 1(2), 134-150. ([Link](#))

#### Key Points

- Dialysis transportation costs about 3 billion dollars per year, about half of which is ambulance costs.
- Medicare covers emergency transport by ambulance for dialysis patients.
- There are concerns about misuse and overuse of ambulances for patients with ESRD.
- New legislation increases payment for emergency transportation by ambulance while reducing payment for non-emergency transportation for patients with ESRD.



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### QUALITY METRICS OR OUTCOMES

#### *Quality Metrics or Outcomes*

The proposed model mentions several methods to report quality outcomes as well as to establish appropriate quality outcomes. There are several established guidelines for quality metrics and outcomes for ESRD patients.

#### [KDOQI Clinical Practice Guideline for Hemodialysis Adequacy: 2015 Update](#)

National Kidney Foundation. (2015). KDOQI Clinical Practice Guideline for Hemodialysis Adequacy: 2015 Update. DOI: <https://doi.org/10.1053/j.ajkd.2015.07.015> ([Link](#))

#### **Key Points**

- The 2015 update of the KDOQI Clinical Practice Guideline for Hemodialysis Adequacy is intended to assist practitioners caring for patients in preparation for and during hemodialysis.
- The literature reviewed for this update includes clinical trials and observational studies published between 2000 and 2014.
- New topics include high-frequency hemodialysis and risks; prescription flexibility in initiation timing, frequency, duration, and ultrafiltration rate; and more emphasis on volume and blood pressure control.
- Appraisal of the quality of the evidence and the strength of recommendations followed the Grading of Recommendation Assessment, Development, and Evaluation (GRADE) approach.

#### [Outpatient Dialysis Services Payment System](#)

Medicare Payment Advisory Commission. (2017, October). Outpatient Dialysis Services Payment System. *Payment Basics*. ([Link](#))

#### **Key Points**

- The bundled payment rate would be reduced by up to 2% for facilities that do not achieve or make adequate progress toward specific quality measures outcomes.
- There are 11 outcome measures tied to payment including efficient dialysis frequency, vascular access, unexpected vs. expected 30-day hospital readmission, quality of care provided by staff, and pain assessment.
- There are five process measures tied to payment including reporting patients' hemoglobin/hematocrit levels and staff's vaccination status.

#### [ESRD Quality Incentive Program](#)

Centers for Medicare and Medicaid Services. (2017). ESRD Quality Incentive Program. Retrieved from the Centers for Medicare and Medicaid Services website. ([Link](#))

#### **Key Points**

- The ESRD QIP establishes incentives for dialysis facilities serving the ESRD population to meet CMS's performance standards.
- The ESRD QIP will tie quality measures to payment. Facilities' performance on quality of care measures will directly link to a portion of payment.

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### SIMILAR OR PRE-CURSOR MODELS

#### Comprehensive End-Stage Renal Disease Care (CEC) Model

Marrufo, G., Negrusa, B., Ullman, D., Melin, C., Hirth, R., & Messina, J. et al. (2017, October).

Comprehensive End-Stage Renal Disease Care (CEC) Model: Performance Year 1 Annual Evaluation Report (Contract #: HHSM-500-201400033I). Lewin Group, Inc. ([Link](#))

#### Key Points

- The CEC Model created incentives for dialysis facilities and nephrologists to coordinate care for Medicare beneficiaries with ESRD across settings by making them responsible – financially and clinically – for care delivered in other health care settings.
- The CEC Model showed lower spending and improvements on utilization and quality measures. Savings were primarily been generated through a reduction in total hospitalizations and readmissions.
- New models of CEC care that tied payment to performance have resulted in improved care and lower costs from reduced inpatient hospitalizations.

### NOTABLE AREAS FOR FURTHER CLARIFICATION

- What are the qualifications and roles required for the members comprising the Dialysis Team?
- What are the responsibilities and role of the nephrologist during treatment of dialysis patients?
- There is conflicting information within the proposal that references, without distinction, skilled nursing homes, nursing homes, and long-term care facilities as well as patients who transfer among these facilities over time. Who comprises the eligible patient population?
- What are the proprietary protocols suited to the special needs of geriatric patients with multiple co-morbid conditions? How will this affect scalability?
- Is the use of NxStage System One necessary for this model to work? How will this affect scalability?
- Is the use of Visionex Clarity necessary for this model to work? How will this affect scalability?

**DIALYZE DIRECT LITERATURE REVIEW**
**Appendix A: Methods**

<b>Research Questions Guiding Search</b>		<b>Sources</b> (Last 5 years unless otherwise stated)	<b>Keywords and Search Terms</b> (Used individually or in combination)
1	Who or what is the submitting organization?	Google, Wikipedia, organization websites and proposal links and citations	<ul style="list-style-type: none"> <li>• Dialyze Direct</li> </ul>
2	What is the clinical care “problem” the proposed model is trying to solve or address?	Proposal, key references cited in the proposal, Google/Scholar, PubMed	<ul style="list-style-type: none"> <li>• Transportation (off-site)</li> <li>• Frequency of dialysis</li> </ul>
3	What is the payment “problem” the proposed model is trying to solve or address?	Proposal, key references cited in the proposal, Google/Scholar, PubMed	<ul style="list-style-type: none"> <li>• Medicare payment rate</li> <li>• Nephrologist payment incentives</li> <li>• ESRD payment</li> </ul>
4	What is current practice/standard of care/evidence-based guidelines? Adherence to guidelines?	National Guideline Clearinghouse, PubMed, Cochrane, AHRQ, USPSTF, relevant professional organizations/associations/ societies, NQF	<ul style="list-style-type: none"> <li>• Medicare/CMS</li> <li>• PPS quality measures</li> <li>• SNF</li> <li>• Dialysis transportation</li> <li>• Medication pill-burden</li> <li>• Patient Reported Outcomes Measures (PROM)</li> <li>• Health Related Quality of Life (HRQoL)</li> </ul>
5	What proportion of SNFs/LTCs, if any, are specifically for HD/PD care? What proportion of SNFs/LTCs provide HD/PD care?		<ul style="list-style-type: none"> <li>• SNF/LTC</li> <li>• SNF dialysis Medicare population</li> <li>• Access to care (home hemodialysis)</li> </ul>
6	What are the current payment methodology and relevant regulations/rules, legislative environment, controversies?	MedPAC, Federal Register, Google/Scholar, PubMed, CMS	<ul style="list-style-type: none"> <li>• Outpatient dialysis services payment system</li> <li>• Medicare Physician Fee Schedule</li> <li>• ESRD Prospective Payment System (PPS)</li> <li>• Medicare Improvements for Patients and Providers Act of 2008 (MIPPA)</li> <li>• Outlier payment</li> <li>• Cost (onsite versus offsite)</li> <li>• Frequency of dialysis</li> <li>• Coverage (onsite versus offsite)</li> </ul>

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7	Is there evidence that current practices and payments are problematic?	Google/Scholar, Pubmed	<ul style="list-style-type: none"> <li>• Higher staff ratio</li> <li>• Patient safety</li> <li>• Patient choice</li> <li>• Quality of life</li> <li>• Transportation (off-site, risk)</li> <li>• Continuity of care</li> <li>• Integration of care</li> <li>• Medication Pill-Burden</li> <li>• ED or inpatient hospitalization</li> </ul>
8	What are the effects of payment reform on patients receiving home dialysis?		<ul style="list-style-type: none"> <li>• Home dialysis trends</li> <li>• Payment influence on home dialysis</li> </ul>
9	What is the basis/evidence that problem is relevant to Medicare: i.e., size of population within Medicare and/or costs	Google/Scholar, Pubmed	<ul style="list-style-type: none"> <li>• Hemodialysis in SNFs</li> <li>• More frequent mode of dialysis technology (MFD)</li> <li>• ESRD SNF patient population</li> <li>• ESRD SNF cost (overall and transportation)</li> </ul>
10	Are there evaluations of the model or similar models of care and/or payment? Pilot studies?	Google, Pubmed, CMS.gov, Medicare Limited Data Sets, Renal Physicians Association (RPA), NxStage Medical, Inc.	<ul style="list-style-type: none"> <li>• Renal Physicians Association (RPA)</li> <li>• NxStage Medical, Inc.</li> <li>• Patient education payment</li> <li>• Transportation avoidance payment</li> <li>• Medicare payments for preventive care</li> <li>• Cost-avoidance-based payment versus cost-of-care-based payments</li> </ul>
11	Have there been alternative models/ solutions to the problem(s) and any evaluations of these?	Google, PubMed, CMS.gov, Lewin Group, Medicare Limited Data Sets	<ul style="list-style-type: none"> <li>• Comprehensive ESRD Care model</li> <li>• Outpatient dialysis services payment system</li> <li>• Hemodialysis trials</li> </ul>
12	Is there support for the validity of quality metrics or outcomes used in the model?	Google/Scholar, NQF, NCQA, Commission on Cancer (COC), CMS.gov, MedPAC, PubMed	<ul style="list-style-type: none"> <li>• Outpatient dialysis services payment system</li> <li>• Local Coverage Determination (LCD)</li> <li>• ESRD variation</li> <li>• Nephrology quality of care</li> <li>• ESRD quality metrics</li> <li>• ESRD outcomes measures</li> <li>• ESRD PROMs</li> </ul>

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13	Are there tools (proprietary or non-proprietary) involved in the model? Evidence for use, costs, effectiveness of such tools?	Google/Scholar	<ul style="list-style-type: none"> <li>NxStage System One</li> <li>Visonex Clarity</li> </ul>
14	How are patient characteristics related to choice of modality of dialysis? Age, etc.	PubMed, CMS.gov	<ul style="list-style-type: none"> <li>Patient choice</li> <li>Clinical practice guidelines</li> <li>Dialysis modality</li> <li>Factors affecting ESRD outcomes</li> <li>Adherence barriers</li> <li>Geriatric ESRD Care</li> <li>Hemodialysis outcomes</li> </ul>
15	Role of dietitian in dialysis care and dietary compliance	Google/Scholar, PubMed	<ul style="list-style-type: none"> <li>Dietitian integration of care for ESRD patients</li> <li>Role of dietitians in ESRD</li> <li>ESRD dietary compliance</li> </ul>
16	Miscellaneous – Any evidence behind statements and claims in proposal?	References cited in proposal, Google/Scholar	<ul style="list-style-type: none"> <li>Vascular Access complication</li> <li>Frequent hemodialysis schedules</li> </ul>

Our search methodology was guided by these research questions. We found answers to these questions by using the listed keywords to search through the identified sources. Due to the quick pace of change regarding the problems this proposal attempts to identify and solve, the vast majority of sources published more than five years ago were omitted. However, in instances where sources outside of the five-year window were identified as relevant or pertinent, they would be included and noted as an exception. Although the environmental scan includes multiple categories of sources, the annotated bibliography was limited to only include peer-reviewed sources. Any exceptions to this are noted.

## **Questions to and responses from Dr. Joel Glickman on Dialyze Direct Proposal (Questions sent 7/31/18; Responses Received 8/6/18)**

One of the criteria we are evaluating the proposal against is “patient safety.” We have come to understand that the majority of patients who would receive MFD in the nursing facility under this proposal may turn out to be short-term SNF patients rather than long-term NF patients. Moreover, it is possible that a large percentage of the patients would be placed on 5-day hemodialysis during the SNF stay and then switch to (or return to) 3-day hemodialysis in a traditional dialysis center following discharge from the SNF.

**Question 1:** Is it correct that the switch from 3-day to 5-day to 3-day would likely involve significant changes in medications, such as blood pressure medication?

**Answer:** Absolutely correct. Managed correctly, 5 day per week therapy will lower blood pressure within a few days and will continue to lower blood pressure for the next 30-60 days in most patients. As noted in the original proposal, 5 day/ week therapy saves medication cost and most of the saving is for blood pressure medication. Converting back to 3 day per week therapy will increase blood pressure and blood pressure medication requirements. The timing is more difficult for me to estimate but my sense is 2-4weeks. Most other medications are not dramatically adjusted and would not result in a safety issue. Electrolyte levels might change but usually not significantly.

**Question 2:** How problematic would the changes in drugs be for these patients (many of whom would be frail and therefore at risk of poor outcomes)?

**Answer:** It depends on how experienced the responsible physician is and how carefully the patient is monitored by the physician. An experienced dialysis nurse should be able to alert the physician but an LPN or patient care technician may not have the insight to alert the physician. Nevertheless, even with a very experienced and informed nephrologist blood pressure management with changing dialysis schedules can be difficult.

**Question 3:** Does the answer to the question above depend on whether the patient is under the care of:

- The same nephrologist in the SNF and in the pre-/post discharge settings?
- Different nephrologists for each setting?

**Answer:** Anytime there is a “handoff” from nephrologist to nephrologist or dialysis staff (especially nurses) or dialysis facility to facility there is a risk of error and adverse event. Even if the nephrologist is the same in SNF and post discharge setting, as noted above, if the nephrologist is not experienced with 5 day per week therapy there is risk of a poor outcome. In

my opinion switching dialysis modality (3 to 5 and then 5 to 3 days) in a short period of time requires multiple adjustments in blood pressure management and does not provide significant short or long term benefit.

**Question 4:** Another criterion is “flexibility” for the physician. We are struggling with whether having this specific staff-assisted home hemodialysis option available in only some nursing homes would be perceived by nephrologists as increasing their flexibility to deliver high-quality health care to patients or not, and we would appreciate your input on that.

**Answer:** I don’t understand why a nephrologist would consider the option of 5 day per week hemodialysis for a short period of time to be an opportunity to deliver high quality care. The opportunity to provide 5 day per week therapy needs to be long term. It is conceivable, but not proven that 5 vs 3 day per week hemodialysis might improve post dialysis fatigue and therefore improve rehab outcomes. I wonder how many nephrologists would think of that- I doubt many would.

PHYSICIAN-FOCUSED PAYMENT MODEL  
TECHNICAL ADVISORY COMMITTEE (PTAC)

PRELIMINARY REVIEW TEAM (PRT)

CONFERENCE CALL WITH NEPHROLOGY EXPERT FOR THE  
DIALYZE DIRECT PROPOSAL

Friday, July 6, 2018

12:30 p.m.

PRESENT:

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

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

JOEL D. GLICKMAN, MD, FACP, University of Pennsylvania,  
Perelman School of Medicine



## P R O C E E D I N G S

[12:34 p.m.]

1  
2  
3 MR. MILLER: So I'm Harold Miller. I'm  
4 CEO of the Center for Healthcare Quality and  
5 Payment Reform, member of the PTAC, and I am  
6 leading this particular Preliminary Review Team.

7 Jeff?

8 DR. BAILET: Yeah. Jeff Bailet. I'm with Blue  
9 Shield of California. I previously was with Aurora Health  
10 Care, leading their physician group. I'm an ENT surgeon,  
11 and I am the chair of the PTAC.

12 MR. MILLER: Rhonda?

13 DR. MEDOWS: Hi. I'm Rhonda Medows. I'm a  
14 family physician. I'm the executive vice president of  
15 Population Health at Providence St. Joseph Health on the  
16 West Coast. Nice to meet you. Thank you.

17 MR. MILLER: And, Dr. Glickman, do you want to  
18 introduce yourself and tell us a little bit about your  
19 background?

20 DR. GLICKMAN: Yeah, absolutely. So I actually  
21 started out in private practice. I was in private practice  
22 nephrology for about 20 years, and about 15 years ago, I  
23 started -- I was going to pursue some other things.

24 I was always interested in home dialysis

1 therapies, started giving lectures on home therapies and  
2 then through a series of introductions became DaVita's  
3 national medical consultant to peritoneal dialysis. Then I  
4 advised them that they needed to start home hemo, and I  
5 became their consultant for home hemo.

6           Then I started one of seven pilot programs for  
7 home hemodialysis for DaVita in 2004, and it was really  
8 successful.

9           From there, I was actually recruited to come to  
10 the University of Pennsylvania to be director of the Home  
11 Dialysis programs, and I've been here for about 11 years  
12 now and have seen tremendous growth in our programs. We  
13 used to have about 28 patients on home dialysis. That  
14 includes PD. And now we have about 115 or 120, which  
15 accounts for about 25 percent of our dialysis population,  
16 so those are actually pretty good numbers.

17           I really consider myself an advocate for home  
18 hemodialysis. I think it's been one of the most rewarding  
19 parts of my career. I've lectured on it frequently and  
20 always try to make sure people are on home therapies.

21           For a short period of time, I was on the  
22 Scientific Advisory Board for NxStage. I think the NxStage  
23 has done an incredible job at promoting home therapies.  
24 The machine that they developed is -- was developed for

1 simplicity to enable patients to do it at home, and I think  
2 they've really done a great job.

3 MR. MILLER: Great. Okay, thanks.

4 So let me sort of just maybe frame up the  
5 discussion today, and then, you know, we'll ask you some  
6 questions. And each of us on the Committee will have --  
7 probably have different questions to ask.

8 I just want to clarify.

9 MS. SELENICH: Harold, really quickly.

10 MR. MILLER: Yes, Sarah.

11 MS. SELENICH: I'm sorry. I just want to  
12 interrupt just to remind everyone that the call is being  
13 transcribed, and for the purposes of the transcription, it  
14 will be helpful if you all remember to say your names.

15 MR. MILLER: Okay. Hopefully, there's not enough  
16 of us that there will be -- hard to remember whose voice is  
17 what, but we can -- we can certainly do that. So I am  
18 Harold Miller.

19 So, Dr. Glickman, it's our job to evaluate the  
20 proposal. So we're not really looking for you to, you  
21 know, sort of say yes or no as to whether you think it is a  
22 good idea or not. We want to get your sort of education  
23 for us about some of the issues that we're facing with  
24 this, since we are not nephrologists ourselves and not

1 deeply involved in this kind of care.

2           We obviously -- and when we get a proposal from  
3 someone, we tend to hear all of the positive things about  
4 it. So, in a sense, we have to do our own due diligence to  
5 try to find out is all of that true, are there any sort of  
6 negatives associated with this thing that we haven't heard  
7 about, are there any unintended consequences.

8           It may well be in many cases that the payment  
9 model that's being proposed could help good things be done.  
10 We have to also be thinking about, though, how it could  
11 potentially be misused and whether there is someone who  
12 might not have the best intentions and whether or not the  
13 way the payment is structure or the entrance criteria or  
14 whatever could potentially lead to things that really  
15 weren't anticipated.

16           So some of the questions that we'll ask you will  
17 really be intended to get at that. So we're not in any  
18 fashion always necessarily skeptical about the entity that  
19 brings us the proposal, but we want to be sure that since  
20 we're approving a payment -- we're talking about  
21 recommending a payment model for Medicare broadly, it's not  
22 just Dialyze Direct that would be participating, and it  
23 could be almost anyone, depending on how the eligibility  
24 criteria are defined. So that's part of why we have to

1 sort of probe these things and understand how this might  
2 work under different scenario.

3           And it struck me that it might be useful if we  
4 broke the discussion into two pieces. One is to talk about  
5 this from the patient perspective, and the other is to talk  
6 about it from the nephrologist perspective. So I'll try to  
7 keep those two parts separate. They may overlap to some  
8 degree.

9           But on the patient perspective, I think it's been  
10 somewhat hard, at least for me and maybe for Jeff and  
11 Rhonda too, to sort out -- there's multiple pieces to this.  
12 So they're talking about trying to do dialysis in the  
13 nursing home rather than having somebody transported to a  
14 center. They're talking about doing something with more  
15 frequent dialysis rather than three times a week. They're  
16 talking about using home hemodialysis equipment and methods  
17 rather than traditional dialysis equipment.

18           So maybe we could just start. If you could sort  
19 of explain what you think in terms of each of those things,  
20 sort of what your actions are to that, and what's good and  
21 what's potentially bad about each of those changes and how  
22 well they line up.

23           DR. GLICKMAN: All right. That's great.

24           So from the patient perspectives, for the most

1 part, people would choose more frequent hemodialysis  
2 because they need to or want to, to maintain quality of  
3 life, so, for example, for the patient working or has  
4 commitments, family commitments, and not having to go to a  
5 dialysis unit is a critical time saver. And they need  
6 that, again, to maintain quality of life, not talking about  
7 any metric of medical care, if you will, blood pressure, et  
8 cetera.

9           Now, it is absolutely true that patients on more  
10 frequent hemodialysis feel better, no question about it.  
11 The more frequent dialysis patients that do nocturnal home  
12 hemo feel the best. So that's where the quality of life  
13 improved.

14           MR. MILLER: Let me just pause. So why, why  
15 nocturnal is better?

16           DR. GLICKMAN: Yeah. So the nocturnal patients  
17 are doing six- to eight-hour treatments typically four to  
18 five nights a week. That is a tremendous amount of hours.

19           MR. MILLER: Okay.

20           DR. GLICKMAN: And removal of toxins is much,  
21 much better and --

22           MR. MILLER: Because it's longer at night --

23           DR. GLICKMAN: Exactly.

24           MR. MILLER: -- than it would be during the day?

1 Okay.

2 DR. GLICKMAN: Yeah.

3 So for the home patients, though, the negative on  
4 quality of life is the work they need to do. They need to  
5 do their own treatments. They need to set up a machine, et  
6 cetera. They draw their own labs, have to come to clinic  
7 once a month. So that's kind of like the negative part,  
8 but the balance is always in the positive in terms of  
9 quality of life and how they feel.

10 And also, a little bit off the topic, though, the  
11 money-saving for more frequent hemodialysis programs is  
12 that the patient is going their own treatment, so you don't  
13 have salaries to pay for the treatments themselves.

14 If a patient was in a facility, a nursing home,  
15 there is certainly going to be benefit of not having to  
16 travel to a dialysis unit three days a week, and it takes  
17 time, and it's a distraction, right? You'd rather be in  
18 your own home, if that's what it is.

19 The downside is after getting treatments five  
20 days a week instead of three, though the time overall would  
21 be saved if you factor in transportation time, they still  
22 have to get stuck or be connected to a machine five days a  
23 week.

24 But the other -- my concern and perspective is

1 the question, "Well, you know, I'm only in this SNF for a  
2 short term. It's" -- I don't know -- "for rehab or for a  
3 set period of time before I move someplace else. Then what  
4 am I going to do when I'm done? Am I going back" --

5 MR. MILLER: Well, just to clarify, so they  
6 appear to be doing this, they're going to do this both for  
7 short-term SNF stays as well as for long-term nursing home  
8 residents?

9 DR. GLICKMAN: Right. So, in terms of the short  
10 term specifically, then, right?

11 MR. MILLER: Mm-hmm. Okay.

12 DR. GLICKMAN: What happens at the end of the  
13 short term? And if I -- let's say I've been on three times  
14 a week. I know about home hemo. I don't want to do it,  
15 but you could do it from here. Yeah, I guess so, but then  
16 at the end, if I feel better, I still have to go back to  
17 three days a week. So that is something to think about.

18 For the long-term resident, I don't see any other  
19 issues other than having to be tethered to a machine five  
20 times a week, and hopefully, the quality-of-life benefits  
21 override --

22 MR. MILLER: Just to clarify, the total time  
23 tethered to the machine, how does that -- because these are  
24 shorter each day --



1 DR. GLICKMAN: Right.

2 MR. MILLER: -- but every day?

3 DR. GLICKMAN: Right. So it's a five-day -- it's  
4 typically five days, and the treatments are typically two  
5 and a half to three hours. So the total dialysis time is  
6 usually about -- it is usually about twelve and a half-ish  
7 hours, maybe a little bit more. In center, typically  
8 people get four-hour treatments three days a week. So the  
9 dialysis time is roughly the same. It's just more  
10 frequent. That's all.

11 MR. MILLER: Okay.

12 DR. GLICKMAN: Right? And patients have  
13 different emotions about that. Some patients say, "I don't  
14 want to be reminded every day that I have dialysis needs,"  
15 and others say, "Well, this is worth it because it's so  
16 much better for me in terms of quality of life, and I don't  
17 have to travel to a dialysis unit." And the patients I  
18 take care of, the counter always is "This is a trade-off  
19 I'm willing to do."

20 MR. MILLER: So talk about the nature of the  
21 patients in the nursing facilities because the implication  
22 of the proposal statement is that most of those patients  
23 would in fact be appropriate for more frequent dialysis on  
24 medical criteria, and you raised some concern about that in

1 the one message I saw that you sent.

2 DR. GLICKMAN: Right. So I actually think, you  
3 know, there was -- I just saw those follow-up responses  
4 from today --

5 MR. MILLER: Mm-hmm.

6 DR. GLICKMAN: -- and there was a question about  
7 they fit something in -- the therapy may not be appropriate  
8 for every patient, and I think that probably every nursing  
9 home patient would qualify. There would not be any major  
10 contraindication medically to dialyzing patients in a  
11 nursing home.

12 My point really was, if I remember correctly, is  
13 the benefits of more frequent dialysis --

14 MR. MILLER: Mm-hmm.

15 DR. GLICKMAN: -- and that if you look at all the  
16 studies done, reported on more frequent dialysis, the  
17 average age was about 52. The average age of a Medicare  
18 hemodialysis patient is about 62.

19 The comorbidity scores, as administered by  
20 Charlson, are lower for home hemo patients. So the outcome  
21 data is not the same population as the nursing home  
22 population, and I think it would be a little bit of a leap  
23 of faith to think that we would drive the same benefits, be  
24 it how they feel after treatment, be it blood pressure

1 control, savings on medications, et cetera.

2 MR. MILLER: So I got -- and, Jeff and Rhonda,  
3 just jump in if you have questions.

4 DR. BAILET: Yeah.

5 MR. MILLER: But I got the impression, at least  
6 in reading this, that what they were saying was that people  
7 in nursing homes, again, in general, were -- had sufficient  
8 disease burden, multiple diseases, advanced disease, et  
9 cetera, that the normal three-day-a-week frequency of  
10 dialysis was even more problematic for them in terms of the  
11 strain on their bodies than others. And so they may not  
12 have been studied in the context that you're looking  
13 because of the fact they were nursing homes rather than a  
14 home.

15 But to what extent is that true, you know, is  
16 that these patients, in fact, really would be better off  
17 less likely to die, less likely to have other kinds of  
18 complications develop because they're on more frequent  
19 dialysis than getting dialysis three days a week, wherever  
20 it happens to be.

21 DR. GLICKMAN: Right. So I absolutely agree  
22 that, physiologically, one would think that a patient would  
23 do much better on more frequent dialysis, and I actually  
24 don't doubt that. But I can't prove that.

1 MR. MILLER: But for -- and just to be clear, for  
2 these kinds of patients who were in nursing home, is that -  
3 - do you think that that is more true or less true? Again,  
4 I don't -- and you may not evidence -- but is your sense  
5 that they would be -- it would be more likely to be  
6 important for them to get more frequent dialysis because of  
7 their overall level of disease burden?

8 DR. GLICKMAN: Yeah. So talking about an  
9 academic point of view or an opinion point of view taking  
10 care of patients? From --

11 MR. MILLER: Well, if they differ, give us both.

12 DR. GLICKMAN: Right, yeah. Well, because if I  
13 was -- if I was giving a talk and you asked me what's the  
14 evidence that these patients do better, I'd say I have no  
15 evidence that they do better.

16 MR. MILLER: Mm-hmm.

17 DR. GLICKMAN: In your professional opinion,  
18 having taken care of people like this, do you think they  
19 would do better? Absolutely, I think they would do better.  
20 I think three -- and one of the things I clearly agree with  
21 in their proposal is that a three-day-a-week dialysis is  
22 inadequate. It definitely is.

23 I also think that what we do with prescriptions  
24 three days a week is inadequate also.

1 MR. MILLER: Yeah.

2 DR. GLICKMAN: But I don't think there's any  
3 comparison, really, in terms of -- and the physiologic  
4 changes during dialysis that occur three days a week versus  
5 five days a week. I mean, for certain, in my mind, that is  
6 true. I would just caution not to make assumptions about  
7 any cost savings of it --

8 MR. MILLER: Right.

9 DR. GLICKMAN: -- or the other benefits. But if  
10 I could get all my patients to do five-days-a-week  
11 dialysis, I am certain the majority of them would feel  
12 better and do better.

13 MR. MILLER: Yeah.

14 DR. MEDOWS: That's great to hear.

15 MR. MILLER: So, in part, they also made a case  
16 not only for the more frequent dialysis related to the  
17 physiologic impact, but also transporting these patients  
18 back and forth to centers --

19 DR. GLICKMAN: Yeah.

20 MR. MILLER: -- three days a week. And because  
21 they have comorbidities, there are other interventions that  
22 they need, other medications and other treatments for their  
23 other diseases. That moving these patients out and back  
24 disrupts that and makes that much more difficult.

1           So I'm trying to take a holistic approach to  
2 their proposal in fact, bring all that in, and does that  
3 matter, in your opinion, those other -- those other  
4 variables that they call out?

5           DR. GLICKMAN: So trying to provide rehab for  
6 patients on hemodialysis is very difficult. Their  
7 hemodialysis schedules will interfere with their  
8 occupational therapy and physical therapy.

9           Medications might be an issue. Eating is  
10 definitely an issue. Patients will miss meals when they  
11 need to travel for dialysis when they're on that dialysis.  
12 So it is clearly less than ideal to have a patient travel  
13 to dialysis, get a four-hour dialysis treatment, come back  
14 and get their physical therapy.

15           Even for those patients that we have a higher  
16 level skilled care, where the OT/PT is provided on site,  
17 they will miss some OT/PT sessions because they're at a  
18 dialysis treatment.

19           MR. MILLER: And so just to be clear, then, on  
20 the other side, do you think that it is in fact the case  
21 that if they're getting dialysis five days a week for a  
22 somewhat shorter dialysis period, but with no  
23 transportation, that then it would be significantly more  
24 likely that they would be able to get appropriate rehab

1 services, et cetera?

2 DR. GLICKMAN: Yes.

3 MR. MILLER: I understand this is just sort of  
4 your sense as a clinician. I'm not asking about evidence.  
5 Just, you know --

6 DR. GLICKMAN: Yes, but there are other  
7 modalities also, dialysis modalities that would also afford  
8 a nursing home patient to get more physical therapy,  
9 occupational therapy too.

10 MR. MILLER: Meaning?

11 DR. GLICKMAN: Well, you know, like peritoneal  
12 dialysis.

13 MR. MILLER: Mm-hmm.

14 DR. MEDOWS: Yep.

15 DR. GLICKMAN: There is -- there is -- we do  
16 thrice weekly nocturnal eight-hour treatment dialysis,  
17 which is physiologically much better, and we see some  
18 improved outcomes. And that would be three times a week,  
19 not five days a week.

20 So, you know, one of -- I don't want to get off  
21 topic because I know you're going somewhere with this, but,  
22 you know, one of -- when I read these proposals, one of the  
23 things I asked myself is what exactly is the goal of this  
24 proposal. Is it to provide the most cost-effective

1 therapy, improve quality of life and outcomes for patients,  
2 you know? Is it to promote more frequent dialysis in this  
3 population and measure outcomes? You know, so --

4 MR. MILLER: That's probably what we're trying to  
5 sort through too, and I think where you were just going is  
6 actually a useful place to go because one of the things I  
7 was going to ask is they have a particular approach in mind  
8 that they are proposing. They're not saying give us the  
9 flexibility to do a variety of different things. They're -  
10 - basically, they have a proposal written around a  
11 particular approach to dialysis with a particular piece of  
12 equipment, et cetera, and so it is helpful to hear what you  
13 think the other options might be and how they compare.

14 DR. MEDOWS: Yeah.

15 DR. GLICKMAN: Yeah.

16 MR. MILLER: Do you want to elaborate on that?

17 DR. GLICKMAN: Absolutely. So I will say that a  
18 lot of dialysis providers are interested in this, to use  
19 the business term, "space," right? And that a lot of  
20 dialysis providers are trying to set up PD programs in  
21 nursing homes. Other people are doing what Dialyze Direct  
22 is doing for many, many reasons, but I don't think anyone  
23 has taken a holistic look at the dialysis patient in a SNF  
24 or nursing home and say, "How do we provide the ideal



1 therapies for those patients?" knowing full well that there  
2 is not one right therapy for everybody. That we try to  
3 really individualize therapies for patients.

4           So if you were to ask me the more generic  
5 question, "Joel, what should we think about in terms of  
6 dialysis options for the nursing home SNF patient?" I would  
7 say, "Well, why don't we think about peritoneal dialysis."  
8 Why don't we think about, like I said, nocturnal dialysis?  
9 Do dialysis while patients sleep on hemodialysis for eight  
10 hours. Ultrafiltration rates, which they point out in  
11 their study, are lower, which is a good thing. Outcomes  
12 are better, and it's multitasking. Now the patients have  
13 their entire day free very day, right? That would be an  
14 option.

15           MR. MILLER: Well, so take -- just take  
16 peritoneal dialysis in contrast to this model, and in  
17 particular, so their proposal is -- at least their model is  
18 that they will send their staff to the facility to sort of  
19 do this as a turnkey service, and the nursing home has  
20 limited involvement, other than providing the space. And  
21 so contrast peritoneal dialysis to their model in terms of  
22 how it would be staffed also.

23           DR. GLICKMAN: So we could take actually the same  
24 concept of staff-assisted peritoneal dialysis which, by the

1 way, is being done in some other countries. You would have  
2 a staff person who is trained in peritoneal dialysis, just  
3 like we would train patients to do it by themselves at  
4 home, who would go to a nursing home, which had whatever  
5 number of patients. Then they would set up the machines,  
6 and they would attach the patients. And they would come  
7 back in the morning and take the patients off the machines,  
8 and there would have to be some training of the nursing  
9 home staff to deal with alarms that may come about, right?  
10 So if the treatment isn't going smoothly because of flow  
11 problems, et cetera, just to know what to do with it.

12 MR. MILLER: Or they could conceivably have  
13 somebody there all night?

14 DR. GLICKMAN: Or, conceivably, they could have  
15 somebody there all night. That is exactly right. Exactly  
16 correct.

17 So, yes, we could develop a staff-assisted  
18 peritoneal dialysis program in a nursing home, especially  
19 for the long-term patient, right?

20 The short-term, they're a little bit more  
21 difficult because you have to have a PD catheter in place,  
22 and if it's a short term, no one is going to switch from  
23 hemo to PD to do that, right? But that's not going to  
24 work.

1           But for a long-term patient, that would work  
2 well, and we actually have significant experience in  
3 geriatric patients on peritoneal dialysis. You know, my  
4 pride and joy is a woman who we started at age 84 who is  
5 now 88 and has not been hospitalized, and we adjust her  
6 goals not to phosphate levels but to quality of life.  
7 Keeping her out of the hospital, that's our plan, and she  
8 has quality of life, and she enjoys it. And that's okay.

9           So there is experience with geriatric patients on  
10 peritoneal dialysis, and it can be very successful. And  
11 I'm not going to tell you it's going to be successful in  
12 every patient, but it is an option.

13           MR. MILLER: Mm-hmm. But it would have to be --  
14 it wouldn't be something that one could do with the same  
15 staff in the same way because it would be at night rather  
16 than during the day. So you sort of -- the two are  
17 somewhat disparate in that sense. You couldn't do both and  
18 with the same staff.

19           DR. GLICKMAN: You couldn't do it with the exact  
20 same staff. If you wanted to -- if you wanted someone  
21 there all night long, that is correct, but you might be  
22 able to do something where you're staff that does the hemo  
23 treatment late in the day, at the end of the day, they then  
24 switch over to putting people on PD. And then in the

1 morning, the staff that comes in to start the morning hemo  
2 patients take the patients off PD.

3 MR. MILLER: But I meant -- I meant in terms of  
4 the same equivalent burden on the nursing home staff in the  
5 sense that if you said, "You don't really have to worry  
6 about doing dialysis or training your staff. You know,  
7 we'll do all of that" --

8 DR. GLICKMAN: Yeah.

9 MR. MILLER: -- you would really have to have  
10 somebody there at night, and it would sort of be then you  
11 would have to be working on a 24-hour staffing basis rather  
12 than just the daylight.

13 DR. GLICKMAN: If -- if -- yeah, I -- I imagine  
14 so, yeah.

15 DR. BAILET: Harold, this is Jeff. Could I --  
16 could I ask a more --

17 MR. MILLER: Yeah.

18 DR. BAILET: So when you take the nursing home  
19 population that are on dialysis, are most of those patients  
20 entering the nursing home on hemodialysis already and this  
21 is -- or is it -- and you may not know, but are these  
22 patients actually going on dialysis when they're residents?  
23 Do you have a sense of that?

24 DR. GLICKMAN: So I don't know the answer. My

1 sense is most patients are on dialysis already when they  
2 transfer to a --

3 DR. BAILET: Okay.

4 DR. GLICKMAN: -- nursing home.

5 DR. BAILET: And where --

6 MR. MILLER: They just sent us answers, Jeff,  
7 that basically imply that sort of they're going to be on  
8 dialysis if they're coming for a short stay. Some people  
9 may actually progress to dialysis if they're on a long-stay  
10 nursing home, but they're saying -- I think it was about --  
11 there are about 60 percent, I think they said were short-  
12 stay patients that they had.

13 MS. SELENICH: Yeah, that's right.

14 DR. BAILET: Oh, okay. Thank you.

15 MR. MILLER: Let me -- Rhonda, any other  
16 questions on sort of this? I want to switch to the  
17 nephrologist sort of aspect to this, but any other  
18 questions on the patient side?

19 DR. MEDOWS: I do. So it was really good to hear  
20 and really helpful to understand the different alternatives  
21 that are already available to people in the nursing home.  
22 Whether or not they're used at the optimal level is  
23 probably the greater issue, right, in terms of actually  
24 making the decision that will actually help them feel the

1 best --

2 DR. GLICKMAN: Yeah.

3 DR. MEDOWS: -- have a better quality of life?

4 What keeps people from eventually being able to  
5 have access to those options? Is it the cost? Is it the  
6 willingness of providers to provide them? Is it just  
7 tradition? Do you have an idea?

8 DR. GLICKMAN: Yeah. So in the nursing home  
9 specifically -- yeah. So I don't believe it's calling this  
10 --

11 DR. MEDOWS: Okay.

12 DR. GLICKMAN: I'll tell you that many, many  
13 years ago, I tried to do a -- start a patient on PD in a  
14 nursing home. I didn't have support really to do it. I  
15 didn't have a company behind me on it, and we didn't do  
16 well because we didn't have a critical mass of patients to  
17 make it worthwhile to keep the staff trained, et cetera,  
18 but, you know, if you had the resources started correctly,  
19 I think the infrastructure could be done. And, actually,  
20 it has been done.

21 So why aren't more people on it? Why aren't more  
22 people on PD in the United States in general, while only 10  
23 percent of people on peritoneal dialysis, when some  
24 countries it's many, many-fold higher?

1           I think our nephrologists in this country are not  
2 educated on peritoneal dialysis. They don't feel  
3 comfortable with it. It's easier for them to see people  
4 in-center. For a long time, the dialysis companies felt  
5 that they made more money on in-center hemos, so they  
6 didn't promote it.

7           And now the tide is turning a little, and again,  
8 I think that's really for economics.

9           So I think that people haven't taken the  
10 initiative, haven't made it a priority, and haven't -- and  
11 nephrologists have not developed the skills they need to  
12 feel comfortable managing a patient on peritoneal dialysis.

13           I think if the dialysis companies decided that it  
14 was in their interest to do it, I think we might see a lot  
15 more of it.

16           DR. MEDOWS: So I know we don't have that data on  
17 the home dialysis and the skilled nursing facilities  
18 because we haven't had enough volume to actually do a study  
19 like that, but from the home dialysis that you do yourself  
20 in your process, you have a quantifiable quality  
21 improvement with this method, right? Clinical quality  
22 measures, outcome measures, consumer experience, quality-  
23 of-life measures; is that correct?

24           DR. GLICKMAN: So -- yeah. You know, when it

1 comes to quality of life --

2 DR. MEDOWS: Yeah.

3 DR. GLICKMAN: -- I -- and this is subjective on  
4 my part, okay?

5 DR. MEDOWS: Yeah. Yep.

6 DR. GLICKMAN: I think if you look at studies and  
7 quality of life, I think it -- personally, I think it's a  
8 little bit more difficult to interpret those studies  
9 because of the way the questions are asked and also a lot  
10 of -- you know, there's a lot of survey -- as you know, I  
11 mean, there's a lot of methodologic issues on survey  
12 studies --

13 DR. MEDOWS: But that's subjective, right? Yeah.

14 DR. GLICKMAN: -- and as well as the patients you  
15 choose to study. So -- and I -- I believe that the studies  
16 do show improvement in quality of life in PD programs.

17 DR. MEDOWS: Okay.

18 DR. GLICKMAN: Again, no data on the nursing home  
19 patient as far as I know.

20 DR. MEDOWS: Okay. And the non-nursing home  
21 patient, again, home dialysis, what about the clinical  
22 quality of patients --

23 MR. MILLER: Distinguish home dialysis versus the  
24 more frequent dialysis.



1 DR. GLICKMAN: Yeah. So, for me, "home dialysis"  
2 is a generic term referring to patients on any dialysis  
3 therapy at home.

4 DR. MEDOWS: Right.

5 DR. GLICKMAN: That would include home  
6 hemodialysis or peritoneal dialysis, and home hemodialysis  
7 can be more frequent, five days a week for short  
8 treatments. It could be nocturnal, six- to eight-hour  
9 treatments, anywhere from three to, you know, five nights a  
10 week. And some people actually do traditional thrice  
11 weekly four-hour treatments at home. Historically, that  
12 was probably the most popular therapy before Medicare  
13 started paying for dialysis treatments in-center, so --

14 MR. MILLER: But I think you said -- let me just  
15 feed this back. I want to focus on the moment on the more  
16 frequent dialysis versus the traditional frequency. You  
17 said that in terms of patient outcomes -- sort of put the  
18 quality of life per se aside and talk about, you know,  
19 medical complications, et cetera. People do better on more  
20 frequent dialysis. You would expect that nursing home  
21 patients would do better. There may not necessarily be  
22 evidence of that, but that you would expect that that would  
23 be the case?

24 DR. GLICKMAN: Yes.

1 MR. MILLER: Okay. So I think that -- we have to  
2 distinguish here we're not talking about home dialysis in  
3 the traditional sense. We're talking about doing dialysis  
4 in the nursing home --

5 DR. MEDOWS: Yep.

6 MR. MILLER: -- but using home hemodialysis  
7 equipment and staff, right? I mean, that's kind of the  
8 narrow issue. So -- that we're focusing on right now.

9 And I think what you're suggesting is that it  
10 would be -- there are other options besides just the  
11 particular staffing model that they are using that could be  
12 used to -- this is now a question to Joel. There are other  
13 methods that they could use to deliver dialysis in the  
14 nursing home drawing on other approaches to home  
15 hemodialysis beyond this particular approach in this  
16 particular proposal?

17 DR. MEDOWS: Right. And that there's no data at  
18 all on the SNF population, period. So it's -- I'm trying  
19 to ask him about any data from the other populations, even  
20 though it's not the same.

21 MR. MILLER: Mm-hmm. Right.

22 DR. MEDOWS: Right?

23 DR. GLICKMAN: Yes.

24 DR. MEDOWS: I'm just trying to figure out, you

1 know, do the -- we're tasked with identifying those models  
2 that will improve quality, and quality could be broadly  
3 defined, right, whether it's clinical quality of patient  
4 safety, the consumer experience, quality of life.

5 DR. GLICKMAN: Right.

6 DR. MEDOWS: We're tasked to look at whether or  
7 not it will either -- if it's going to improve quality, at  
8 least -- and not reduce cost, that's fine, but if it's  
9 going to maintain quality and then reduce cost, it's the  
10 second option. And I'm not quite sure that I see that, but  
11 I'm probably getting ahead of the discussion here.

12 I wanted to ask about whether or not there was  
13 any data about patient safety being improved or clinical  
14 quality being improved in the other population,  
15 understanding that the SNF population, there is no data.

16 DR. GLICKMAN: Right. And this is for the more  
17 frequent hemodialysis. Is that what you're saying?

18 DR. MEDOWS: Right.

19 DR. GLICKMAN: Right.

20 DR. MEDOWS: For the more frequent for what is  
21 being proposed --

22 DR. GLICKMAN: Yeah.

23 DR. MEDOWS: -- in the -- in the candidate  
24 submission, the more frequent home-based, right, or SNF-

1 based?

2 DR. GLICKMAN: And I'm just asking, could you  
3 repeat for me which outcomes are you interested in knowing  
4 about? You said patient safety?

5 DR. MEDOWS: Patient safety --

6 DR. GLICKMAN: Yeah.

7 DR. MEDOWS: -- would be number one. Any  
8 clinical quality measures that would typically be used to  
9 respond, end-stage renal disease patients, okay?

10 DR. GLICKMAN: Sure. Right.

11 So the quote -- let me do the latter first. So--

12 DR. MEDOWS: Okay.

13 DR. GLICKMAN: So for sure in the more frequent  
14 hemodialysis studies show improvement in blood pressure  
15 control --

16 DR. MEDOWS: Okay.

17 DR. GLICKMAN: -- universally decreased blood  
18 pressure medications. Most studies show that you can stop  
19 blood pressure medications in about two-thirds of patients,  
20 and in the one-third who are still on it are on less. So  
21 there's no question that blood pressure control improves  
22 dramatically.

23 The other parameter that we look at is phosphate  
24 levels, and phosphate levels --

1 DR. MEDOWS: Yep.

2 DR. GLICKMAN: -- improve the more frequent  
3 hemodialysis. Not so much in my clinical experience with  
4 the short treatment that they propose, more so with the  
5 nocturnal treatments. Some of these patients actually feel  
6 so much better. They're eating better, and any improvement  
7 in phosphate removal is counteractive by their increased  
8 intake of phosphate-containing foods.

9 They talk about postdialysis fatigue syndrome  
10 being better.

11 DR. MEDOWS: Mm-hmm, mm-hmm.

12 DR. GLICKMAN: That is absolutely true. The  
13 average recovery time after dialysis is about eight hours  
14 for patients. In short daily hemodialysis, the average is  
15 about 60. For nocturnal, it's about 30 minutes. After  
16 dialysis, most instances, three-times-a-week dialysis  
17 patients, after dialysis, they feel completely washed out.  
18 People describe it as feeling hung over, and it essentially  
19 renders the rest of the day useless.

20 But patients on the more frequent therapies, as I  
21 said, very rarely have any post-dialysis fatigue, and it  
22 doesn't interfere with their ability to do things. So from  
23 that perspective, you know, being in a SNF, that would be  
24 advantageous, obviously.

1           And I would -- you know, the rest of the data is  
2 a little bit soft. I think those are the major things.  
3 There is regression of left ventricular hypertrophy --

4           DR. MEDOWS: Yes.

5           DR. GLICKMAN: -- which is a surrogate marker for  
6 survival, but we always are a little bit suspicious of  
7 surrogates. I think it's true, but again, you know, we're  
8 talking about a different population, right? We're talking  
9 about an --

10          DR. MEDOWS: Right.

11          DR. GLICKMAN: -- elevated population. How much  
12 increase in longevity do you think is significant at that  
13 age? I mean, that's not the measure we're especially  
14 interested in. It's more the quality of life. So those  
15 are the major clinical quality measures.

16                 In terms of patient safety, again, the patient  
17 safety now, it's a little bit different when patients  
18 dialyze on their own than staff-assisted, right?

19          DR. MEDOWS: Yeah.

20          DR. GLICKMAN: But -- and the patient safety, in  
21 my mind, is really a function of the quality of the home  
22 dialysis program, you know, how well do we train when we  
23 train our patients. And there's been some studies  
24 anecdotal looking at it, and the safety qualitatively is

1 very good. It's clearly no worse than in-center dialysis,  
2 and almost every single event in the home was due to  
3 patients who did not adhere to policy procedures and made  
4 some stupid mistake, which, you know, theoretically is  
5 modifiable by better training.

6 But so, for me, my program, patient safety, is  
7 not an issue.

8 DR. MEDOWS: Okay.

9 DR. GLICKMAN: But, again, it's apples and  
10 oranges comparing the patient doing the therapy at home  
11 versus the staff-assisted.

12 DR. MEDOWS: The nursing home, yeah.

13 Thank you. That was very helpful.

14 MR. MILLER: So let me switch to the nephrologist  
15 because one of the somewhat perplexing aspects of this  
16 proposal was that there was no change in payment at least  
17 proposed for the actual dialysis service itself. The  
18 proposal was to change the way the nephrologist was paid,  
19 partly to try to offset some concern, I guess, about  
20 whether patients would come to see the nephrologist in the  
21 office and the nephrologist's lack of desire to go see the  
22 patient in the -- in the nursing home and some concern  
23 about whether or not nephrologists would actually recommend  
24 or encourage this.

1           So when you had said earlier that you thought  
2 that neurologists' incentives and familiarity were a  
3 barrier to more -- you know, to greater use of peritoneal  
4 dialysis, et cetera. So talk a little bit about -- imagine  
5 that this kind of -- this kind of a program, you know, is  
6 being put -- is trying to be put in place. How do you see  
7 nephrologists reacting to it, and what kinds of incentives  
8 or disincentives would they face?

9           DR. GLICKMAN: Yeah. So I think a good way to  
10 start is kind of explain what we do now and how we get  
11 reimbursed because there's -- I think that's kind of  
12 important for the physician who has home hemodialysis  
13 patients, right, and then the challenges of someone who  
14 doesn't.

15           So for the physician doing home hemodialysis,  
16 there -- when a patient starts, there's an initial fee of  
17 \$500 which is a training fee, and that's paid for the  
18 physician participation in training the patient. And after  
19 that --

20           MR. MILLER: Just one quick pause. So what's  
21 your sense of -- is that a reasonable -- too low, too high  
22 -- fee?

23           DR. GLICKMAN: I actually think it's a -- I  
24 actually think it's a reasonable fee. I actually think



1 that it is meant to be an inducement to have patients do  
2 dialysis at home because you get it for PD also. So I --

3 MR. MILLER: But the level of work involved --

4 DR. GLICKMAN: I think it's fine.

5 MR. MILLER: -- in educating it, so it's not like  
6 as if it's really -- and it's not an incentive to do it.

7 It's basically compensating them for the time that they do  
8 have to put in the patient education.

9 DR. GLICKMAN: Yes. For education, once they  
10 made the decision to do home, not the decision up to making  
11 home -- up to that point, right?

12 MR. MILLER: Okay.

13 DR. MEDOWS: Okay. Good.

14 DR. GLICKMAN: So the effort we put into teach  
15 patients about modalities before they start dialysis or  
16 even if they're on dialysis and they're thinking of  
17 switching, but the effort that we do to make patients aware  
18 and understand their options for dialysis and getting them  
19 onto a home therapy is not compensated, and again, off  
20 topic, but if you're going to ask me how do we get more  
21 patients at home, that would be -- that would be the  
22 barriers that we would need to fix, is making sure doctors  
23 get reimbursed enough to convince patients to go home. But  
24 that's completely, completely different, right?

1           MR. MILLER: Well, not necessarily, so that's  
2 relevant. So you're saying that basically there is more  
3 effort to get somebody to accept these nonconventional  
4 approaches to -- or not common approaches to dialysis, and  
5 so that sort of leads people to sort of take the default,  
6 which is to go to a center?

7           DR. GLICKMAN: That is correct. Right. It's  
8 much easier to put someone in the center.

9           MR. MILLER: Okay.

10          DR. GLICKMAN: Much less work.

11                 Once a patient is on home therapy, so conditions  
12 of coverage mandate a nursing visit every month. So our  
13 patients have to come to the clinic; therefore, my motto is  
14 that our physicians see patients in the clinic with the  
15 nurse. And many home dialysis programs have that model.

16                 Alternatively, the patient can see the nurse in  
17 the facility and then have a separate visit with the doctor  
18 in their office, and that is what they're referring to as  
19 that separate visit to the doctor in the office.

20                 The nurse -- the mandated nursing visit in the  
21 clinic, I imagine would be done in the home, in the nursing  
22 home, right? So I think that's how they take care of that  
23 part.

24                 But the physician needs to see that patient once

1 a month also, be it in the clinic or be it in their office.  
2 Now, I think that's important because when I see a patient  
3 in my clinic, I have a full half day or a full day of home  
4 patient scheduled for me. So one drive to my dialysis  
5 unit, I spent all day there. I see all my patients, and  
6 then I'm done for the day and drive home. If I'm seeing  
7 patients in my office, again, it's part of my office  
8 schedule, right? So I have my whole clinic schedule with  
9 patients. I don't have any travel overhead, if you will.

10 So now you have to ask me, well, what's it going  
11 to take you to leave your clinic, get in your car, drive to  
12 a nursing home, see one patient, two patients -- I don't  
13 know -- and then drive back? And I think that incentive --

14 DR. MEDOWS: Right. Yeah.

15 DR. GLICKMAN: -- is one to really be examined.

16 I will tell you that I have had -- I had a  
17 patient who was respirator-dependent on home hemo, and I  
18 drove to the patient's house for a visit. It wasn't worth  
19 my while. I did it -- I don't want to sound like a, you  
20 know, martyr here, but I did it because of my sense of  
21 commitment to this particular patient. But it really, you  
22 know, was not sustainable for me to drive, you know, to the  
23 patient's house to see my patient at home.

24 MR. MILLER: But you -- so you would ordinarily -

1 - the nephrologist would not ordinarily go to the patient's  
2 home to see them.

3 DR. GLICKMAN: No.

4 MR. MILLER: They would come to the clinic.

5 So what they're saying here is they're trying to  
6 eliminate that one visit to the nephrologist per month for  
7 these nursing home patients, and I guess I'm trying to  
8 understand. So how important is that to eliminate that  
9 one? They would -- the nursing home patient who was going  
10 to a center would see the nephrologist in the center.

11 DR. GLICKMAN: Correct.

12 MR. MILLER: But they'd be taking an ambulance,  
13 you know, three times a week to go there.

14 DR. GLICKMAN: Right.

15 MR. MILLER: So if they had to see a nephrologist  
16 once a month and they had to go to a clinic for that, is  
17 that somehow disrupting the whole advantage of this  
18 program? Because it doesn't seem to me that it is.

19 DR. GLICKMAN: It's -- it's one-half day a month  
20 for the patient to go to the dialysis clinic.

21 MR. MILLER: Mm-hmm.

22 DR. BAILET: Right. Versus three times a week.

23 DR. GLICKMAN: Correct. Versus three times a  
24 week.

1           But I think -- I think that's -- I don't think  
2 that's necessarily the issue. I think -- I thought the  
3 issue more is how do we get patient -- how do we get  
4 doctors, nephrologists, to buy into the five-day-a-week  
5 modality in the nursing home and save transportation costs?  
6 It sounds like, well, we can take money away from the  
7 transportation cost and just give that to nephrologists to  
8 incentivize them to buy into this more frequent  
9 hemodialysis therapy, right? Trying to make it --

10           MR. MILLER: Well, there's two pieces to it, and  
11 that's kind of what we're trying to sort out here.

12           So there is the notion that you don't want the  
13 patient to even have to go to see the nephrologist in the  
14 clinic --

15           DR. GLICKMAN: Right.

16           MR. MILLER: -- and that you would pay them what  
17 the transportation fee would be. We are not completely  
18 clear on whether Medicare even pays for those transports to  
19 the nephrologist's office in all cases, but a separate  
20 issue there.

21           So there's that piece, and then there's a  
22 separate piece that basically says that if they were on  
23 home hemodialysis, true home-home hemodialysis, they would  
24 be getting the training fee, and they don't get if they're

1 in the nursing home because they don't need training. So  
2 they want to give them that to be able to encourage them to  
3 send the patient to the nursing home or to recommend this  
4 as part of -- sort of those two pieces.

5 DR. GLICKMAN: Yeah.

6 MR. MILLER: So I was trying to focus first on  
7 this issue of why is this such a burden, if you've taken  
8 away three transports to the center every week, why it  
9 would be a real problem for them to have to go to see the  
10 nephrologist once a month.

11 DR. GLICKMAN: Right.

12 MR. MILLER: And it sounds like the answer is not  
13 clear that it would be.

14 So then the second piece is, do you think that  
15 giving the nephrologist essentially the home training fee  
16 without having to do home training is enough reason for the  
17 nephrologist to suddenly start encouraging more patients to  
18 use this nursing home or that they would resist doing it  
19 otherwise, I guess?

20 DR. GLICKMAN: Yeah. So I think that's a great  
21 question.

22 By the way, just -- you know, they said that  
23 there was -- that it wouldn't cost anything. There's an  
24 offset that they would have gotten the training fee if they

1 did home hemo training in-center, but if the patient wasn't  
2 doing more frequent dialysis or home dialysis at all, if  
3 they were doing three times weekly in-center, you wouldn't  
4 get a training fee. So that money isn't appearing  
5 necessarily, right? It's not moving from one hand to the  
6 other.

7 MR. MILLER: Right.

8 DR. GLICKMAN: Right. So the question then is --

9 MR. MILLER: They were -- they were trying to, I  
10 think, basically equalize this, this nursing home dialysis  
11 with home -- true home hemodialysis --

12 DR. GLICKMAN: Right.

13 MR. MILLER: -- and say you get the 500 bucks, no  
14 matter what.

15 DR. GLICKMAN: Absolutely, yeah.

16 MR. MILLER: That's why I was asking sort of was  
17 the 500 bucks actually really paying for time that the  
18 doctor would spend there or was it just an incentive.  
19 Okay.

20 DR. GLICKMAN: Yeah. So I, again, don't know --  
21 I don't know if you had -- let me take a different tack.

22 To make it worthwhile for me to do that, I would  
23 need to see several patients at the same time in a nursing  
24 home. To make that worthwhile for me, I --

1 MR. MILLER: If you had to go to the nursing  
2 home.

3 DR. GLICKMAN: Exactly.

4 MR. MILLER: Yeah.

5 DR. GLICKMAN: Right? And that occurred to me  
6 that some nephrologists may say, "You know what? For this  
7 one patient, it doesn't -- it doesn't pay for me. You  
8 know, if that's what they want to do, fine. There's  
9 nothing I can do about that. Someone else will have to  
10 take care of them."

11 MR. MILLER: Well, what if you took -- take away  
12 that for a second. Say, okay, the patient is still going  
13 to come see you in your clinic, as if they were a regular  
14 home-home, true personal --

15 DR. GLICKMAN: Correct.

16 MR. MILLER: -- private home --

17 DR. GLICKMAN: Right.

18 MR. MILLER: -- patient. But now you wouldn't be  
19 getting the \$500 training fee because they don't need  
20 training because they're getting staff-assisted dialysis in  
21 the nursing home.

22 DR. GLICKMAN: Right.

23 MR. MILLER: How do you think about that as a  
24 nephrologist?



1 DR. GLICKMAN: Well, if I'm doing home hemo  
2 already and I'm seeing patients in my office already,  
3 that's fine, right?

4 MR. MILLER: Mm-hmm.

5 DR. GLICKMAN: That's fine.

6 MR. MILLER: You wouldn't have -- you wouldn't  
7 have the initial training fee, but that's a one-time fee,  
8 anyway, right? And you'd still be getting an E&M for the  
9 patient coming to the -- or sorry -- the monthly, the  
10 monthly capitation.

11 DR. GLICKMAN: You would get the monthly  
12 capitation. That is correct. That is absolutely correct.

13 MR. MILLER: Okay. So --

14 DR. GLICKMAN: But is -- is part of this plan  
15 maybe to have nephrologists who are the nursing home, more  
16 frequent hemodialysis nephrologist, right? And they say,  
17 well, the nephrologists don't want to participate. We have  
18 nephrologists who are willing, and we would just funnel the  
19 patients over to them, let's say, right, to make it --

20 MR. MILLER: Mm-hmm.

21 DR. GLICKMAN: Right? So --

22 MR. MILLER: Potentially. Or it depends on how  
23 often -- I mean, in some areas, it may be the same  
24 nephrologist taking care of all the patients, anyway, so --

1 DR. GLICKMAN: That's true too. Yeah.

2 MR. MILLER: That wouldn't necessarily be true in  
3 an urban area, but it might be true in a more rural area.

4 DR. GLICKMAN: Yes.

5 MR. MILLER: Okay. So is there any other  
6 barrier? Let's suppose the patient was still coming to the  
7 clinic to see the nephrologist. So, you know, nothing has  
8 changed from there. Is there any other reason why the  
9 nephrologist would have any resistance to this model  
10 compared to any resistance that they might have to normal  
11 home hemodialysis?

12 DR. GLICKMAN: Right. So for the -- so yes. So  
13 for the -- for the home hemodialysis nephrologist, I think  
14 the only other thing that I would -- so right now, my  
15 nurses in the dialysis facility take first call for all  
16 patients, and, you know, obviously I've trained them. And  
17 we have a working relationship, and they kind of filter the  
18 calls that I need to know about or not need to know about.  
19 And they kind of execute the plan. So --

20 MR. MILLER: This is if a patient calls with a  
21 problem, you mean?

22 DR. GLICKMAN: Exactly.

23 MR. MILLER: Mm-hmm.

24 DR. GLICKMAN: Right.

1           So I would assume that -- that that would happen  
2 in a nursing home. The thing that I was a little bit  
3 confused about in the proposal is that the dialysis staff  
4 that were actually the staff-assisted were actually not  
5 RNs. They were LPNs or maybe patient care technicians.  
6 There was this coordinating nurse, the home dialysis  
7 coordinating nurse at the nursing home, but I didn't know  
8 if that nurse knew about home hemodialysis or not. So I  
9 wasn't certain if that nurse had the capacity to  
10 troubleshoot issues and inform me of that. You see what  
11 I'm saying?

12           MR. MILLER: Yes. So if I'm in a private home  
13 and I'm getting home hemodialysis and I have a problem, I  
14 have no clinician there of any kind at all, and I have to  
15 call one of your on-call nurses for --

16           DR. GLICKMAN: Correct.

17           MR. MILLER: So the question here is, if the  
18 patient is getting this nursing home-based home  
19 hemodialysis and they have a problem, what -- what is the  
20 staff there capable of dealing with? What is this sort of  
21 floating nurse capable of doing, and who else is going to  
22 deal with that problem? Right? And we have to figure out  
23 kind of what those problems are and how they expect to deal  
24 with them.

1 DR. GLICKMAN: Right. Because the last thing I  
2 want as a nephrologist is more phone calls.

3 MR. MILLER: Mm-hmm. Well, and that gets to  
4 Rhonda's safety issue, is what kinds of issues can come up.  
5 So, quickly, what would be -- what would be an example of  
6 something that might come up in this particular scenario  
7 they're proposing that you would be worried about whether  
8 or not the staff there could handle?

9 DR. GLICKMAN: Yeah. So, I mean, in the -- in  
10 the treatment itself, you know, there is a lower incidence  
11 of hypotension, but it's not zero. You know, we train our  
12 patients to recognize what they need to change in their  
13 therapy to avoid hypotension, and I assume that the staff  
14 would be trained the same way. So the treatment itself  
15 would be no different than our patients -- they may have  
16 mechanical issues with the machine. That shouldn't be  
17 really an issue at all, but it's the overall monitoring.

18 So, you know, my nurses will look over the  
19 treatment sheets, and they'll call me and say, "I noticed  
20 in the last week, the blood pressure is going down. What  
21 do you want to do about it?" Right? So it's that  
22 surveillance of the -- of the treatment itself and getting  
23 feedback on that.

24 And then, you know, labs are drawn. I depend on

1 my nurses to -- when the labs come in to look at them and  
2 make sure there's nothing that I need to address right  
3 away, so that would be an issue.

4           And I think that covers like the major things.  
5 You know, I'll get calls about social issues in the home,  
6 but that wouldn't apply to the nursing home.

7           MR. MILLER: Okay. So we're almost out of time.  
8 Rhonda, other questions?

9           DR. MEDOWS: No. I was going to say that I would  
10 think similar conditions, similar concerns, but perhaps  
11 maybe a little bit more frequent given the frailty of the  
12 population that we're talking about, and I -- you know, I  
13 was just wondering whether or not the nephrologist would  
14 go, you know, "Do I really want to take on a more higher  
15 risk, even higher risk than end-stage renal disease already  
16 is?" Right?

17           DR. GLICKMAN: Yeah.

18           DR. MEDOWS: And whether or not --

19           MR. MILLER: But they're not going to be in a  
20 center where they've got somebody with eyes on, right  
21 there, multiple people, right? You're saying that they'd  
22 be in a nursing home and sort of --

23           DR. MEDOWS: Yep. So maybe that's part of the  
24 reason why they're talking about this incentive or

1 something. I don't know if that's enough to make up for  
2 it, but I guess if you were so inclined to help the more  
3 frail seniors in nursing homes, that would be one of the  
4 responsibilities you'd be taking on, is that you probably  
5 would get more call. You might get more questions about  
6 them because they have other complicating factors in  
7 addition.

8 MR. MILLER: But this is a one-time offset for  
9 that, right? It's nothing that says you get more per month  
10 to be able to deal with that.

11 DR. MEDOWS: Yeah.

12 DR. GLICKMAN: No, no, no. I thought you do get  
13 more per month. I thought that you share in the  
14 transportation cost savings.

15 DR. BAILET: Right.

16 MR. MILLER: Well, that's if they don't come to  
17 your office.

18 DR. GLICKMAN: Right, if they don't come to your  
19 office. Right. Yeah, that's correct.

20 MR. MILLER: But I was trying to separate those  
21 two.

22 DR. GLICKMAN: Okay.

23 MR. MILLER: So if they still come into your  
24 office, but you're dealing with lots of stuff over the

1 telephone --

2 DR. GLICKMAN: Right.

3 MR. MILLER: -- then there's no real compensation  
4 for that.

5 DR. GLICKMAN: Right.

6 DR. MEDOWS: We're going to find out whether or  
7 not those transportation costs are covered by Medicare or  
8 Medicaid, right?

9 MR. MILLER: Yes. Medicare has been working on  
10 that.

11 DR. MEDOWS: Okay.

12 MR. MILLER: I still think the answer is somewhat  
13 iffy, but --

14 DR. BAILET: Yeah.

15 DR. MEDOWS: And then it's how much that actual  
16 fee is because I'm worried whether or not the shared  
17 savings would actually amount to much, to be honest with  
18 you.

19 MR. MILLER: Well, or enough. I mean, if you're  
20 offsetting the fact that the nephrologist had to go to the  
21 nursing home in order to get that, that doesn't offset the  
22 fact that they're getting more telephone calls every month  
23 too, right?

24 DR. MEDOWS: Yeah.

1 MR. MILLER: So that's the issue there.

2 But that's helpful to think about that because  
3 it's not just going to see the patients. It's once a  
4 month.

5 DR. MEDOWS: That --

6 MR. MILLER: It's also responding to the kind of  
7 problems and the changes in meds and everything else that  
8 may come up during the course of the month.

9 DR. MEDOWS: Yeah.

10 DR. BAILET: Right.

11 DR. MEDOWS: We don't want to discourage them  
12 from offering more options, you know, to patients, but I  
13 just have to wonder whether or not there's really going to  
14 be significant financial incentive.

15 MR. MILLER: Right.

16 DR. GLICKMAN: Yeah.

17 MR. MILLER: Jeff, any other questions, final  
18 questions from you?

19 DR. BAILET: No, Harold. I found this to be  
20 really helpful.

21 MR. MILLER: Yeah.

22 DR. BAILET: I guess the last -- oh, I will make  
23 one comment about reimbursing the nephrologists for their  
24 efforts. I think that I'm still -- I still believe, based



1 on what I'm hearing and reading, that the patients are  
2 better off not only for quality of life, but there are --  
3 there are better outcomes which drive lower costs because  
4 of fewer complications over time. So while the  
5 nephrologist might not benefit directly from this model in  
6 certain -- you know, with all of the elements we talked  
7 about to the level that maybe they need to, to provide  
8 support for their efforts, the cost to Medicare over time  
9 in this model potentially is less.

10 MR. MILLER: Mm-hmm.

11 DR. GLICKMAN: Based on data from younger,  
12 healthier patients, correct.

13 DR. MEDOWS: Right.

14 DR. BAILET: That's correct. Okay. So thank you  
15 for that.

16 DR. GLICKMAN: Yeah.

17 And I do want to point -- I'm sorry. Just one  
18 thing on the payment. So, you know, there is a huge, huge  
19 problem now getting paid for more frequent dialysis. You  
20 know, it varies from fiscal intermediary to fiscal  
21 intermediary. CMS recently came out with, you know, a plan  
22 for just paying for three treatments, but if you -- and I -  
23 - if you look at on average across the country, as far as I  
24 know, for five treatment a week, most providers for

1 Medicare are getting paid about four-ish treatments. So  
2 it's variable from location to location, but on average,  
3 five Medicare treatments -- five treatments are not being  
4 paid for by Medicare. It's more like four.

5 MR. MILLER: So you're saying that you --

6 DR. MEDOWS: So that needs to be addressed too,  
7 right?

8 MR. MILLER: You think that -- but what you're  
9 saying, that they don't either say you can only do three or  
10 you can do five and be paid for them, you're saying they  
11 let you be paid for more than three, but they're only  
12 authorizing four?

13 DR. GLICKMAN: No. What I'm saying is that each  
14 -- across the country, the fiscal intermediaries for  
15 Medicare are paying differently. At some point, some were  
16 paying five, and some were paying three, but if you were to  
17 look at a national average, it was about four. So if you  
18 get five treatments and you submitted billing, you would  
19 get paid for four of them. The most recent recommendation  
20 from CMS was to only pay three times a week.

21 MR. MILLER: Regard -- with no exceptions, you  
22 mean?

23 DR. GLICKMAN: And the only exception would be  
24 just like they do in-center. If a patient is volume-

1 overloaded or hyperkalemic or -- and there's a couple other  
2 indications for doing -- a medical indication for doing an  
3 extra treatment a week.

4 MR. MILLER: Okay.

5 DR. MEDOWS: That needs to be updated to reflect  
6 what we believe to be the more appropriate managed care,  
7 right?

8 DR. GLICKMAN: Yeah.

9 MR. MILLER: Okay. Well, Dr. Glickman, thank you  
10 very much. This was, I think, extremely helpful for us.  
11 We appreciate you sharing your expertise with us.

12 If you have any follow-up thoughts afterwards  
13 that occur to you, don't hesitate to just send them on.  
14 They don't have to be in any kind of fancy form, but if you  
15 think one more thing I thought of, that would be certainly,  
16 certainly welcome.

17 But, other than that, thank you for the time  
18 today.

19 DR. GLICKMAN: Oh, you're welcome.

20 DR. MEDOWS: Thank you.

21 MR. MILLER: Thank you all.

22 DR. BAILET: Thank you.

23 [Whereupon, at 1:34 p.m., the conference call  
24 concluded.]