

# PATIENT MEETING ON BUNDLING OF DIALYSIS SERVICES

March 7-8, 2008 - Washington, DC

Sponsored by Renal Support Network

Hosted by: Kidney Care Partners (KCP)

**Goals:** The purpose of this meeting was to inform patient leaders about the policy discussions regarding a proposed expansion of the current bundled payment system for dialysis services, and provide patient-focused recommendations that should be considered when a bundled system is enacted (see **Appendix A** for background). There were 26 participants in the meeting. (See **Appendix B** for a list of the organizations.)

Pre-meeting background information was provided to help the patient leaders understand what an expanded bundle might mean for them and to prepare them for participation in an interactive dialogue. Input was sought from patients about any concerns they might have about an expanded bundle, with the intent of providing this input to the dialysis community for consideration in the development of policy positions. Participants were asked to provide input on what needs to be considered to ensure that patients on dialysis continue to receive the best care possible.

**Meeting Format:** The majority of the first day of the meeting was made up of presentations from notable renal professionals (see **Appendix B**) who provided their perspectives on the different aspects and issues surrounding a bundled ESRD payment system. Time was provided after each session for questions and answers (see **Appendix C** for the meeting agenda.)

A series of questions established by the patient representatives prior to the meeting served as a foundation for developing dialogue and consensus.

The following points were raised and discussed by the participants during the meeting:

## **Basic Principals of any Dialysis Payment System:**

- Any expanded bundle of the ESRD payment system should do the following:
  - Ensure all patients have access to quality care.
  - Provide incentive payments for achieving quality patient outcomes (not just for completing a process).
  - Provide adequate reimbursement so providers are: (a) not forced to limit services, (b) are encouraged to provide new therapies, such as nocturnal and daily dialysis, and (c) are able to retain qualified staff, etc.
  - Provide incentives for home dialysis modalities.
  - Provide appropriate reimbursement to allow **all** dialysis providers to remain viable.
  - Recognize the disparity between urban and rural providers.
  - Prevent providers from “cherry picking” patients.

## **Key Views of Participants:**

- Any expansion of the current bundling **must** be accompanied by an annual update that is adequate to ensure that providers remain viable and are able to retain quality staff and staff-to-patient ratios to provide patients with high quality care and continued access to new therapies and technologies.

- An expanded bundle might result in an inadvertent increase in patient co-pay amounts if certain services that currently do not have a co-payment requirement are incorporated in the bundle. This could be a hardship for many patients and any new system should provide an adjustment to keep the total co-payment stable.  
*Explanation: Most dialysis patients without a secondary payer pay an average of \$5,000 - \$10,000 in co-pays for treatment and medications annually. If an expanded bundle is enacted, it is unclear how co-payments might be adjusted. Expanding the bundling should avoid increasing the financial burden on patients.*
- Upon implementation of an expanded bundle, key indicators of care should be monitored frequently (e.g., monthly). If predetermined “triggers” of poor care are detected (e.g., decreased percentage of patients in recommended laboratory ranges) the system should be reviewed immediately to determine what revisions may be required.  
*Explanation: Every patient stressed the need for an immediate government response when poor quality care is suspected—intervention that comes too late is useless for patients. It is important to establish “triggers” (e.g., designated reportable metrics) to ensure that the level of quality of care is maintained consistently across all units.*
- Any expanded bundled system should incorporate additional quality of care measures that go beyond blood-based values and provide a better indicator of patient status. Both outcomes-based and process-based measures should be incorporated. Examples of metrics that should be considered include: SF-36 scores, hypotensive episodes, failed cannulation attempts, vascular access choices, hospitalizations, rehabilitation, and work status.  
*Explanation: There has been much discussion about the validity of lab values as a measure of the adequacy of dialysis and the quality of health and life for patients. Dependence on clinical values alone in determining treatment adequacy does not reflect the full picture of patient health. More measures, including most especially quality of life measures, such as hospitalizations and ability to work, that reflect the actual functional wellness of the patient were suggested. The attendees recognized the work of the KCQA patient workgroup that recommended non-clinical measures that NQF endorsed and are ready for adoption by CMS*
- If an expanded bundle includes ESRD-related labs, there should be separate payments for labs not incorporated into bundle.  
*Explanation: In order to guarantee access for patients to necessary lab work for diagnostic work related to suspected infections or other related, but non-routine conditions, these additional tests need to remain separately billable from the bundled structure. Otherwise, these necessary tests are more likely to be used only in extreme cases, rather than as needed.*
- If an expanded bundle includes a quality program, as noted above, there should be a systematic method for timely revisions in the metrics used to evaluate the quality of care and the associated measurement parameters/expectations.  
*Explanation: A planned schedule of updates of the quality metrics needs to be part of any quality program to allow for regular evaluation and fine tuning of metrics, as well as the expanded bundle. It must be responsive to the evolving needs of both the patients and providers.*

- In addition to reforming the reimbursement structure, Congress should provide for and encourage CKD education and support education on different modality options, including home dialysis and transplantation.

*Explanation: Home therapies and transplantation education needs to be clearly addressed. Ideally, Medicare should reimburse for home dialysis training separately from the bundled payment so as not to discourage providers from offering this modality option.*

- Any expansion of the bundle should provide patients with safeguards that prevent shifting of the currently provided ESRD-related care to physician offices or hospitals.

*Explanation: The dialysis center is the optimum location for efficient patient care interventions. The comprehensiveness of the care team available to the patient in the dialysis facility provides for continuity of care and a holistic treatment paradigm. If patients are required to go to another healthcare facility to receive care that is currently being provided by a dialysis facility, it may represent an unnecessary hardship (i.e., due to factors such as limited transportation, inconvenient scheduling, or time constraints) that could result in some patients not receiving adequate care.*

### **Others Issues, Concerns and Observations:**

- Bundling unit of payment (i.e., basing the bundle on a per treatment versus a monthly payment).
  - The CMS Report to Congress on “A Design for a Bundled End Stage Renal Disease Prospective Payment System” (CMS Bundling Report) suggests that an expanded bundled payment could be made on a per treatment or monthly basis. Participating patients felt that a monthly payment system might be problematical when patients are traveling and being treated at other dialysis facilities. Also, there were questions about how a monthly reimbursement system would account for factors such as hospitalizations and missed treatments. While some participants suggested that a monthly payment system might allow the flexibility of providing more than 3 dialysis treatments a week, others were skeptical.
- Route of administration for medications included in the bundled payment:
  - The CMS Bundling Report indicated that, under the “alternate” bundle, to be more efficient providers might be encouraged to give oral medications in substitution for IV drugs. Patient participants strongly stated that the push toward economic efficiency should not jeopardize good clinical care and patient’s quality or length of life.

Several patients echoed the need for economic practicality in reviewing concerns about a bundled system, while others proposed a more idealistic view of patient care that would include a re-design of the system to provide what they view as best for patients. Concepts discussed related to this ideal approach include:

- Allowing expanded treatments or hours on dialysis if that is what a patient needs to maintain quality of life.
- Removing the wall between Part A and B Medicare to encourage more preventative care and education. This could lead to a decrease in hospitalization, which should be recognized as reducing total Medicare spending.

- Providing access to medications (especially transplant medications) so a patient does not have to return to dialysis.

### **Patient Perceptions of the Potential Benefits of an Expanded Bundle:**

- Bundling might provide cost containment for the government, thereby allowing the saved funds to be used in other ways.
- Bundling (especially based on a monthly reimbursement) might make some dialysis facilities more economically profitable, thereby ensuring continuation of patient services.
- Bundling might provide simpler accounting for the government and providers.
- Bundling based on a monthly capitation system might provide the opportunity for extra treatments during the month.
- Bundling might make it possible for dialysis clinics to provide services that are not currently covered by Medicare (*e.g.*, nutritional supplements, vascular access monitoring).

### **Additional Patient Questions on Expanding the Bundle:**

A pre-meeting questionnaire revealed a series of important questions about an expanded bundle for the Medicare dialysis payment system. Many of these questions overlapped and, so for ease of reference, this document highlights these major themes raised by these questions. Those patients who responded to the request for questions asked a variety of questions related to expanding the bundle, as well as several questions that go beyond the idea of expanding the bundle and raise issues about interacting with the Medicare ESRD program generally.

## **Drugs**

The questions related to drugs emphasized a concern that by bundling currently separately billed drugs, including ESAs, Congress would be establishing incentives to change the way drugs are administered and incentives that could result in the substitution of generic drugs for branded drugs and oral medications for IV medications.

During the discussion in Washington, the group acknowledged that the issue of patients choosing a route of administration for ESAs is really beyond the scope of the bundling issue, but still emphasized that patients are worried that any change in reimbursed could result in subcutaneous dosing, which would require them to accept several injections per week.

- ✓ Will patients be able to choose the route of administration for ESAs if bundling is put in place? (i.e., not be required to take painful and uncomfortable subcutaneous injections)
- ✓ How can bundling be designed to preclude substitution of generic injectable drugs?
- ✓ Would bundling create an incentive to use oral meds versus IV meds?

## **Labs**

The issue of labs also arose in the questions submitted prior to the meeting. The underlying concern is that patients must provide blood for a series of laboratory tests and do not want to be stuck multiple times if there can be a consolidation tests.

During the discussion in Washington, meeting participants understood that expanding the bundle will mean that some lab tests are paid within the bundle. However, there may be other lab tests (to which this question seems to refer) that would not be within the bundled payment rate and that would be reimbursed separately. The participants noted that as long as these tests would be reimbursed for separately, there would be no disincentive to provide them. In addition, the expanded bundle would not be any different in this respect than the current system is today.

- ✓ How can the bundling system be designed to prevent delaying or not ordering laboratory tests that would typically be required? (i.e., laboratory tests beyond what is reimbursed by the bundle)

## Quality

The patient questions emphasized the importance of ensuring quality care is protected. As noted above, the meeting participants agreed that it is important to measure quality with meaningful metrics. The participants recognized that the devil is in the details. Most of the concerns raised in the submitted question would be resolved by implementing a robust quality program.

During the discussion in Washington, participants recognized that most of these issues would be resolved through a quality improvement program that included patients in the development of measures.

- ✓ In the past, quality metrics have asked dialysis facilities to achieve laboratory goals for a specified percentage of patients. Could the bundling system threaten those with the worse outcomes who need the most care? How can the system be devised to prevent poorer service being provided to those who need it the most?
- ✓ We know from past experience that there are ways to cut corners on quality despite surveillance and rules governing centers. How can we protect against this?
- ✓ If the goal of CMS is to protect patient quality of care and a bundled system makes a primary goal to contain costs, how can the two be reconciled?
- ✓ The bundling program assumes that some measures of quality (e.g., Kt/V) define quality. But many of the measures do not address all of the aspects of care. How can we create a system that allows us to update existing measures used to assess quality?
- ✓ How can revenue neutrality promote quality improvement versus quality minimalization?
- ✓ How often will the metrics defining quality of care be updated? The policy needs to include ongoing and timely modifications in the metrics of quality of care and quality of life.
- ✓ Could the bundle include transplant education and referral as a potential quality measure?

- ✓ If a demonstration project is not completed, how soon will quality metrics be assessed after the new system is put in place (e.g., 3 months, 6 months, 1 year)? How quickly could a change in the reimbursement structure be made in the system if quality suddenly decreases?
- ✓ How should we define outcomes measures to ensure that we are not “cherry-picking” outcomes that are easier to achieve?

## **Incentives and Education**

Patients are also concerned that the incentives structured to make sure that the patient remains in the same position as they are today in terms of quality of care.

- ✓ How can the bundle system be developed so that it is not a disincentive for home dialysis or peritoneal dialysis? How can the system be developed to ensure that there is not a financial incentive to encourage one modality over another?
- ✓ If dialysis facilities are reimbursed on a monthly basis rather than a per dialysis basis, how can we protect against a decrease in services?
- ✓ Although bundling may decrease unnecessarily excessive spending, how can we protect against the reverse a trend toward providing only minimally acceptable care based on lab numbers?
- ✓ Will the new bundle create a perverse incentive to give the least ESA and IV iron dose to target the lowest “quality” range for Hemoglobin? How can this be prevented?
- ✓ How can the system be designed so that it allows patients access to new revolutionary therapies without having to wait years for a reimbursement adjustment?
- ✓ How will the bundling system protect patient’s ability and options for traveling?
- ✓ How can the bundled system support education on different modality options, including home dialysis and transplantation?

## **Structural Issues**

Those patients who submitted questions also asked about how the expanded bundle would be structured.

- ✓ How can we prevent shift of location care under bundling?
- ✓ How can the case mix system be devised to prevent cherry-picking?
- ✓ When you lump meds and services together, how can you prevent one or the other being shortchanged? (i.e., meds being given at the expense of nursing services, or visa-versa)

- ✓ If they add Access Care into the bundle, will patients be limited to where we get care? Will blood work only be done with the dialysis facility's contracted laboratory for blood work or contracted places for eternal care for access?
- ✓ Currently I am receiving 3 eight hour hemodialysis treatments in-center. How will these types of "non-typical" dialysis schedules be accommodated if the bundling is based on 3 three-to-four hour dialysis sessions?
- ✓ If labor is the biggest cost for dialysis services, how can the bundling system protect against a decrease in higher cost professional medical services (*e.g.*, nurses, dietitians, social workers, pharmacists, etc.)?
- ✓ How can the bundling system protect against dialysis facilities deciding to not open clinics or close clinics in areas having patients with the highest level of co-morbidities and costs (*e.g.*, inner cities)?

## Other Questions

There were also a series of questions that raised important issues.

- ✓ How can the new bundling system protect against further consolidation of the dialysis industry?
- ✓ How can we prevent badgering of patients if they do not meet standards?
- ✓ How can we still encourage care based on individual patient needs, rather than a one size fits all approach?
- ✓ How can patients be protected so that "extra" services that are currently provided do not disappear?
- ✓ How can the system ensure that dialysis facilities hire the best staff (*e.g.*, experienced nurses, CNN) rather than minimally qualified or temporary personnel?
- ✓ Ethnic and racial disparities already exist in CKD. How can the new bundling system be designed to help address (rather than increase) these disparities?
- ✓ Will the bundling system place more of an emphasis on handling acute problems rather than proactive prevention of problems?
- ✓ How can the new system protect against closing of dialysis facilities in rural or underserved areas?

# APPENDIX A

## Background Overview

In the mid-1980s, Congress created the first bundle for the Medicare End-Stage Renal Disease (ESRD) program. Although there has been some tweaking, there has not been a comprehensive review and modification of this bundle since that time. In 2003, Congress asked the Centers for Medicare and Medicaid Services (CMS) to conduct a demonstration project on expanding the bundle of dialysis services. CMS designed the project, but ran into serious obstacles, including issues related to obtaining patient consent for participating in the demonstration project. CMS was also tasked with issuing a bundling report that incorporated recommendations from the “Advisory Board on the Demonstration of a Bundled Case-Mix Adjusted Payment System for End-Stage Renal Disease Services.”

In the meantime, the U.S. Congress has expressed frustration that CMS has not acted on the demonstration project. Given the years of work already done in this area, Members are poised to require CMS to implement an expanded bundle without completing the demonstration project.

Although the details of such a system are not clear, an expanded bundle would likely require CMS to incorporate routine drugs and routine labs in the existing composite rate. There would still likely be some services and items that would not be included in the bundle.

For reason indicated above, there is a strong desire to modernize the Medicare ESRD program by expanding the current bundle. If any reform is enacted, it is important that the system be modified in a way that does not result in harm to patients and does not threaten patients’ quality of care, access to care, or quality of life.

It is vitally important that patients understand what is happening. The views of patients – the people directly impacted – should be heard, understood, and considered.

To help patients learn more about this important issue, Renal Support Network (RSN) with the help of Kidney Care Partners (KCP) convened a two-day educational session for patient representatives. They heard from a variety of speakers about expanding the bundle. Patients were provided an opportunity to ask questions and express any concerns about this proposed policy. Based upon these conversations, the attached is a summary of questions, comments, and concerns that the KCP will consider as it helps to develop a community consensus about an expanded bundle.

RSN will continue to update patient leaders on this process and encourage continued input and participation.

We believe this effort – by and for patients - will help ensure that patient’s voice is heard when the government is considering a revised reimbursement policy for dialysis services.

## **APPENDIX B**

**Attendees:** Patients with kidney disease who are leading advocates from throughout the United States; staff from:

Renal Support Network  
American Kidney Fund  
DaVita Patient Citizens  
National Kidney Foundation

Also in attendance were: medical, legal, administrative, and legislative professionals who are recognized experts in the field of CKD.

### **Expert Faculty**

Thomas A. Gustafson, PhD  
Senior Health Policy Advisor  
Arent Fox

Joyce Jackson  
President & CEO  
Northwest Kidney Centers

Michael Josbena  
President  
Wordsmith Health Communications

Kathleen J. Lester  
Partner  
Patton Boggs ~ Attorneys at Law

Nancy Ray, M.S.  
Analysis  
MedPAC

Kathleen Smith, RN, BS CNN  
Vice President, Government Affairs  
Fresenius Medical Care

# APPENDIX C

## Agenda

### Friday March 7, 2008

- 8:00 a.m.**                    **Breakfast**
- 8:30 a.m.**                    **Opening Remarks and Introductions, Lori Hartwell, Michael Josbena**
- 8:45-9:00 a.m.**            **Overview of the ESRD Reimbursement Structure: How the Facilities Get Paid Today** Kathy Lester
- 8:45-9:30 a.m.**            **Policy Context: Why Is Bundling So Important Now?** Kathy Lester  
(15 min Q&A)
- 9:30-10:15 a.m.**        **How Bundling Could Potentially Benefit Patients on Dialysis** Nancy Ray  
(15 min Q&A)
- 10:15 a.m.**                **Break**
- 10:45-12:00 p.m.**        **Lessons Learned from Historical Experiences of Bundling in the United States and the CMS Point of View** Tom Gustafson  
(15 min Q&A)
- 12:00 – 1:00 p.m.**        **Lunch**
- 1:00 – 2:15 p.m.**        **Provider Perspective on Bundling** Joyce Jackson/Kathleen Smith  
(20 min Q&A)
- 2:15 p.m.**                **Break**
- 2:15-2:30 p.m.**            **Summary and Plan for Discussion**
- 2:00-4:30 p.m.**            **Patient Discussion: Review and Discuss**  
Ø **How Bundling Could Potentially Benefit Patients on Dialysis**  
Ø **Patient Concerns About Bundling**  
Ø **Balancing Potential Benefits and Concerns Related to Bundling: What Do Patients Think?**
- 4:30-5:00 p.m.**            **Day 1 Wrap Up Adjournment**

### Saturday, March 8, 2008

- 8:30 – 9:15 a.m.**            **Breakfast**
- 9:15 – 11:15 a.m.**        **Continuation of previous days discussion**
- 11:15 a.m. – 11:30 p.m.**    **Recap, Next Steps, Adjourn**