Navigating The End-Stage Renal Disease (ESRD) Payment System

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Mark A. Meier, MSW, LICSW
Mark A. Meier: Hello, my name is Mark Meier, and I am a clinical social worker with 13 years of experience in providing care to individuals with kidney disease. I have worked in the field as a social worker, dialysis unit administrator, at which time I also trained as a Patient Care Technician, and subsequently worked for ESRD Network 11 in the Patient Services Department. In addition to the clinical work I am involved with today, I teach in the Graduate School of Social Work at the University of Minnesota, and I provide training to dialysis professionals on communication, conflict resolution, and professionalism in the delivery of dialysis care. I am happy to be providing this talk on Navigating the ESRD Payment System for the American Kidney Fund. Have you ever really taken time to think about just how complex and interesting the treatment of individuals with kidney disease really is?

Have you ever considered for a moment all that must go into the delivery of an effective dialysis treatment? Often, we think that treatment is delivered just by the technicians who initiate and monitor the treatment, and by the nurses and the social workers and the dietitians and physicians who are involved.

When in reality, several systems are required for a patient to receive a dialysis treatment. In addition to the staff who obviously provide the critical care to patients, the advances that have been made in technology to provide dialysis for patients has changed dramatically.

Other unique and critical factors make up the ESRD program in the United States. For example, the Centers for Medicare and Medicaid Services or CMS, is the primary payer source for dialysis treatments. The ESRD Networks and the State Health Departments work to ensure safe and quality dialysis treatments are being provided for our patients.

In this training session, we are going to take a historical look at the ESRD program, and specifically examine the roles played by CMS, the ESRD Networks, The State Health Departments, and we will also be looking at the conditions for coverage, the interpretive guidelines, the Medicare program and other insurance options that exist for patients, and we will also discuss the newest change in the ESRD program, bundling. So, where are we today? Kidney disease is a significant illness that in its various stages is thought to impact upward of 31 million Americans.

As care for individuals with chronic kidney disease improves, the hope is that many of these 31 million Americans can delay the need for renal replacement therapy such as dialysis or transplantation. As this chart shows though, the number of Americans in the ESRD program continues to rise at an alarming rate.
As you can see, in 1996, there were a total of 308,000 patients in the program with 234,000 of them receiving dialysis. In just 10 short years, the program has grown significantly with 506,000 patients in the ESRD program and 355,000 of them requiring dialysis. What does this all cost?

The spending for the ESRD program is significant. The $23.9 billion spent by Medicare on the ESRD program represents about 5.8% of the total Medicare budget. However, if you compare the roughly 500,000 individuals in the Medicare ESRD program to the 45 million Americans in the Medicare program, you can see just how expensive this program is.

When you think about total Medicare ESRD expenditure by modality, what you see on this slide is that the largest percentage of the Medicare ESRD program expenditures go toward the payment of hemodialysis services. What we see here, looking at point prevalent patients, is that the vast majority of

individuals with the ESRD program, about 425,000, rely on the Medicare program for payment of their care. End-stage renal disease is the only disease state that provides automatic coverage under the Medicare program, of course, as long as other work and citizen requirements are met. Why is that?

Have you ever stopped to think how it was that Medicare come to cover the ESRD program? Let’s shift gears for just a moment and take a step back in time and look at the origins of the ESRD Medicare Program. Back in 1965, during the heightening of the Vietnam war, President Lyndon B. Johnson signed the Social Security Act, which established both Medicare and Medicaid. When Medicare was initially established in 1965, coverage for the ESRD program was not included. Let’s talk just for a moment about what is Medicare. Medicare is the federally funded program that consists originally of Medicare Part A and Medicare Part B.

The original Medicare Part A consisted of hospital insurance and Part B is the medical insurance piece of the program. It is Part B that covers the costs of outpatient dialysis services. We also talked about the establishment of Medicaid. And what is Medicaid?

Medicaid is an income-based program administered by the individual state. Each state sets its own income guidelines and coverage benefits. For some individuals with ESRD, they might be eligible for both Medicare and Medicaid and this is also known as being “dual eligible”.

In addition to providing coverage for healthcare related issues, some state’s Medicaid programs provide transportation, in-home care, or even dental coverage. So what is the Centers for Medicare and Medicaid Services or CMS? This is an organization that you’ve heard a great deal about if you have been working in dialysis.
The Centers for Medicare and Medicaid Services is a federal agency within the United States Department of Health and Human Services that is responsible for administering the Medicare program and CMS also works jointly with each individual state to administer the Medicaid program.

In addition to the Medicare and Medicaid programs, CMS has multiple other areas of responsibility including maintaining quality standards through its survey and certification process in nursing homes, home health agencies, and of course, outpatient dialysis centers.

It is important to recognize that CMS is far more than an insurance company, and in essence, they are charged with maintaining the quality of care their 45 million beneficiaries receive. So, how did we get to this point of the ESRD program? The ESRD Medicare program wasn’t formally signed into law until 1972, about seven years after the creation of the Medicare program when then President Nixon signed section 2991 of Public Law 92-603. Prior to the establishment of the Medicare program, dialysis was being provided in hospitals throughout the United States. Dialysis was very expensive.

And think about it, who was paying the bills for patients back then? Let’s take a step back in time and look at what dialysis looked like pre-Medicare. Before we talk about payment pre-Medicare, let’s just take a couple of minutes to look at critical moments in the history of dialysis.

And if you ever stopped to think about the advances we’ve made, its really quite an incredible program. Back in 1854, Thomas Graham presented the principle of solute transport across a semipermeable membrane, which is of course the absolute essence of providing dialysis.

In 1924, the first dialysis treatment in a human being occurred. And in 1943, Dr. Willem Kolf constructs the first working dialyzer. Jumping forward, we move to 1960, and Dr. Belding Scribner develops the Scribner shunt. And in 1962, Dr. Scribner opens the first outpatient dialysis clinic known as “The Seattle Artificial Kidney Center.” So, as you think about dialysis pre-Medicare coverage and the advent of Dr. Scribner’s outpatient dialysis center, this is what we know. In 1962, he received $100,000 foundation grant from Seattle’s King County Medical Society, and he opened an artificial kidney clinic at Swedish Hospital, and they established two committees that, together, would decide who received treatment. The first was a panel of kidney specialists that examined potential patients. Think about this, back before Medicare we had to make decisions about who would and who would not receive dialysis.
Look at the conditions that could exclude a patient from dialysis older than 45, children and teenagers, diabetes, hypertension, vascular complications or people who were considered emotionally unprepared. In particular of note, is look at diabetes and hypertension, the two leading causes of kidney disease.

Those individuals were excluded from receiving dialysis. The committee that made the decisions about who did and who did not receive dialysis soon became known as the “God committee.” Let’s take a look at what was written about the God Committee. In an article by John Buntin titled “Live or Die?”

That Was for the Panel to Decide”. Patients who passed this first vetting moved on to another panel, which decided their fate. It soon gained a nickname, “The God Committee”. Born in an effort to be fair, the anonymous committee included a pastor, a lawyer, a union leader, a homemaker, two doctors, and a businessman, and based its selection on applicants’ “social worth.” Of the first 17 patients it saw, 10 were selected for dialysis. The seven remaining died. As the technology spread, medical centers in other cities struggled to serve large numbers of patients with limited numbers of dialysis machines.

The rise of home dialysis reduced the number of people excluded from treatment, but panels across the country still met to decide who would receive access to the life-saving treatment. Supply was one limitation. Money was another, and the ability to pay often meant the difference between life and death.

So, as we started to move toward Medicare coverage, we had some choices we had to make. As technology improved and more and more individuals needed access to dialysis, pressure mounted to expand access to dialysis. A sentinel of moment occurred in November 1971, when then AAKP President, Shep Glazer, was dialyzed LIVE before the House Ways & Means Committee. Before Shep entered the hearing room, he told reporters, “Gentlemen, I am going to tell the Committee that if dialysis can be performed on the floor of Congress, it can be performed anywhere.

Kidney patients do not have to be confined to hospitals. I want to show the Committee what dialysis is really like. I want them to remember us,” - and Congress did. A year later, in September 1972, Congress passed the special Medicare ESRD entitlement.

So, as you think about the relatively short history of the ESRD Medicare program, you can see that at a time previous to the existence of Medicare, life and death decisions had to be made based on the perception of worth. Today, we are in a different place where Medicare covers the vast majority of individuals in the ESRD Program.
With some perspective in place now about the scope of the ESRD Medicare program, let’s shift our focus to the newest and a very significant change in the way dialysis services are reimbursed by Medicare, and that’s bundling. Bundling represents a fundamental shift in the way Medicare is going to reimburse dialysis providers for the care they provide. Consider this statement made by Tony Messana, who is the Executive Director at St. Joseph’s Hospital Renal Program: “During its 38 year lifespan, the Medicare ESRD program had limited changes in the area of reimbursement.

From 1972 until 1982, Medicare paid for dialysis treatment, medications and laboratory testing separately. With the implementation of the Composite Rate Payment scheme in 1983, many medications such as albumin and hypertonic saline and lab tests such as hematocrit, which were previously reimbursed separately, were combined with the reimbursement for treatment.” Instead of dialysis and related services being separately billed as they are today, the services provided to dialysis patients should be “bundled” into a composite rate, which is scheduled to take effect in January of 2011.

Why the change? Why would the federal government want to make this change? Well, let’s consider a statement made by Debra Hain: “Why would the federal government attempt to change the reimbursement system that has been in place for more than 30 years? Answer: Value-based medicine.

One of the greatest concerns at the federal level is the projected number of persons at risk for developing kidney failure. The federal government cannot maintain care for this many people indefinitely and Congress has told CMS that they must get value for every dollar they spend.” So, what’s in this bundle?

In this chart above, you can see the bundle includes drugs such as EPO and Calcitrol that used to be separately billable items for dialysis facilities. And it places them in the bundle along with 52 common ESRD related laboratory tests, dialysis facility supplies, dialysis support services and four oral agents.

CMS opted not to add in the other oral agents frequently associated with ESRD such as phosphate binders until the year 2014. The bundled rate minus some congressionally mandated reductions is going to be $229.62 per treatment. In addition to the bundled payment, there are certain Case Mix Adjusters.
that are used to calculate additions to the bundled rate, because we all know certain dialysis patients present themselves with other medical conditions that make providing dialysis more difficult for them than perhaps other patients. Certain patient characteristics, such as body mass index and

other conditions make the provision of dialysis more costly and difficult. The list above details the case mix adjusters that are part of the new bundling system. To ensure quality care is delivered, CMS is also launching a quality incentive program. Addition to the bundling of payments scheduled to

begin in January 2011 is in 2012 is the quality incentive program. The first quality measures will focus on anemia and dialysis adequacy, although at the time of this recording the thresholds have not yet been established. A payment reduction of up to 2% will occur if a facility does not meet the established criteria.

Future quality improvement measures associated with the QIP are likely to include vascular access, vascular access infection rates, hospitalizations, bone and mineral metabolism, patient satisfaction, and other patient reported quality of life issues.

So, the question you might be asking is, how does the bundle impact my patients? Well, patients will be subject to a 20% co-pay on the ESRD bundle payment. As indicated, many of he oral meds that patients take will not be included until 2014. There are incentives created by Medicare to help train

more patients for home-based programs and therapies. And the reality is that facilities will be receiving less money from Medicare. So, then the next question becomes, how will the bundle impact my clinic? Well, there are many unknowns that exist with the bundled payment system.

With any major policy change, such as this, it should be expected that there will be some unintended consequences as well as benefits. The bundled environment is sure to require additional and precise documentation, and it will also increase patient co-pays. Beyond that, only time will tell.

What we do know is that the bundle has certainly caused lots of questions and certainly left people wondering what the future will hold. But again, as we noted, we will have to wait and see. Let’s shift away from the Medicare/payer aspect and look at two other critical components of the ESRD Medicare program.

The first area we will look at is the ESRD Network system. As you consider the ESRD Program, you will recall that it is a multifaceted system and the ESRD Networks play an important role. What are these ESRD Networks anyway? In 1978, the U.S. Congress authorized the formation of ESRD Network Organizations to further support the ESRD Program.
Currently, there are 18 ESRD Networks that support the federal government in assuring appropriate care for patients who receive treatment through dialysis facilities and kidney transplant centers that are certified by Medicare. The Networks’ responsibilities include quality monitoring and improvement of the care ESRD patients receive, the collecting of data to administer the national Medicare ESRD program, providing technical assistance to patients who have ESRD and providers, and addressing patient grievances. The forum of ESRD Networks is the oversight group that all ESRD Networks belong to.

The forum of ESRD Networks is a national organization, which supports and advocates on behalf of ESRD Networks, in promoting methods to improve the quality of care to patients with renal disease. The forum provides leadership in the renal community through education, data management, dissemination of information, and quality improvement, to promote collaboration within the delivery of care. How are the programs funded? Well, funding for the ESRD Network Program is outside of the agency, meaning CMS, apportionment. Per statute, the ESRD Networks are funded by withholding 50 cents per patient per dialysis treatment from the composite rate payment made to dialysis facilities, an equivalent withholding amount for each managed care ESRD patient. The amount withheld has not increased since 1989, when it became effective. What is the structure of these ESRD Networks?

Well, the majority of the ESRD Networks are non-profit organizations with a governing board, basic administrative staff, and infrastructure to support their operations and meet their statutory requirements and other work activities as set forth in the ESRD Statement of Work.

A Network Organization must establish and maintain a Network Council of representatives from dialysis and transplant facilities or providers located in its geographic area and that must include at least one patient representative. The Networks have a Board of Directors.

Each network must be governed by a Board of Directors or BOD composed of representatives from the Network area including as noted, one patient representative. The board supervises and is responsible for performance of the Networks’ administrative staff in meeting contract deliverables, the financial operation of the Network, review and approval of the Network’s annual report, review and approval of request for contract modifications, and certainly review and approval of Medical Board recommendations to sanction ESRD facilities, which brings us to the next critical aspect of the Networks, which is the Network Medical Review Board.
Each Network must establish a Medical Review Board or that includes physicians, nurses, social workers, dietitians and other professionals engaged in treatment relating to ESRD, and who are also qualified to evaluate the quality and appropriateness of care that is being delivered.

The Medical Review Board serves as an advisory panel to the Network on the care and appropriate placement of ESRD patients on dialysis, and the MRB has responsibility for quality improvement and other oversight initiatives in the Network area. Both Boards meet statutory requirements with respect to composition and adhere to strict conflict of interest guidelines. Most Networks also rely upon Patient Advisory Committees to obtain the patient’s perspective on care. Under contract from the Center for Medicare and Medicaid Services, the ESRD Networks have a pre-defined statement of work they are tasked with achieving.

The Network staff, in conjunction with input from its Board of Directors, its Medical Advisory Board, and its Patient Advisory committee, develops strategies to meet the following five tasks, which are: 1. Network Quality Improvement Programs. 2. Community Information and Resources. 3. Administration. 4. Information Management. 5. Special Projects. Let’s take a look at each of these individual five aspects of the Statement of Work. As part of the End-Stage Renal Disease Networks Statement of Work, beginning in July 2003, the Centers for Medicare & Medicaid Services and the ESRD Networks along with key provider representatives, jointly recommended adoption of a National Vascular Access Improvement Initiative under task 1, Network Quality Improvement Program. The primary goal of this Continuous Quality Improvement project was to increase the appropriate use of AV fistulas for hemodialysis access and to reach or exceed the National Kidney Foundation Kidney Disease Outcomes Quality Initiative practice guidelines of 50% in incident patients and 40% in prevalent patients. The Networks have implemented a collaborative approach to the Fistula First effort and they are working very closely with dialysis providers, surgeons, hospitals, payer groups, patient groups, and other concerned individuals. So, how are they doing? Well, as you can see, in August of 2010, the national AV fistula rate reached 56.5%. So, clearly, this has been a successful program which has benefited patients and providers alike.

Let’s take a look at task 2, Community Information and Resources. As part of the ESRD Network of scope, they are tasked with providing this information. For example, Networks distribute a packet of ESRD related information to all new dialysis patients.
They often hold trainings on topics such as anemia management, adequacy, and cannulation training. Your ESRD Network can be an excellent place to start if you have questions regarding resources and community information. As part of their scope of work, the ESRD Networks are also tasked with addressing Medicare beneficiary complaints and grievances. The requirement states, “An ESRD beneficiary or the beneficiary’s representative can file a complaint or grievance to address quality of care issues and concerns.” Patients have different portals of entry for filing.

A patient may file at the facility level; however, this is often avoided by patients for fear of reprisal. In accordance with the ESRD Conditions for Coverage, each facility is required to have a grievance procedure that meets very specific requirements including provisions for alleviating the fear of reprisal.

Section 1881(c) of the Social Security Act mandates the Networks’ responsibility for implementing a procedure for evaluating and resolving patient grievances. So, patients may file at the Network level and, if desired, may do so anonymously. When there are immediate jeopardy issues, Networks will notify State Survey Agencies and cooperate during the investigation. Task 3 is administration. The ESRD Networks also work closely with the State Health Departments and state surveyors to ensure compliance with the conditions for coverage. For example, ESRD Networks staff have provided trainings to the state surveyors on dialysis related care issues, and they might also consult on challenging patient situations. The fourth task, Information Management is a critical aspect that often gets overlooked in the delivery of dialysis care. ESRD Networks are responsible for receiving and processing the Medicare 2728 Medical Evidence form as well as the Medicare 2746 ESRD death notification. The ESRD Networks have been an integral partner in the development and rollout of the CROWN Web Project. CROWN Web stands for The Consolidated Renal Operations in a Web Enabled Network.

As part of the new conditions for coverage there is a requirement that all dialysis facilities eventually submit patient information, for example, events, forms, lab data, to the Networks electronically instead of the old method of paper. The CROWN Web project is an electronic data submission software package being implemented by CMS to improve data consistency, reduce complexity, and provide secured electronic data to help with the collection of this information and to meet this new requirement. The fifth part of the Statement of Work is the Undertaking of Special Projects.
For example, as part of an effort to partner and help provide providers with information on how to deal with conflict in dialysis settings, the ESRD Networks joined forces with the large dialysis organizations, the medium and smaller dialysis organizations, CMS, and other professional groups such as the ANNA, CNSW and others to develop the Decreasing Dialysis Patient-Provider Conflict Initiative. So, this falls under the guise of a special project. The Networks have other tasks as well that aren’t specifically discussed in the Statement of Work, but they undertake other tasks, such as promoting employment and vocational rehabilitation.

They work very closely with underperforming facilities to improve and provide quality of care and they use other evaluating procedures to make sure that patients are being provided access and understanding to all types of dialysis care. So, now that we have talked about the Networks, let’s take a look at the third and final part of the Medicare ESRD Program -The State Health Departments and the role they play in survey and certification using the ESRD conditions for coverage. Remember, as you look at the ESRD Program, you can see that it is a multifaceted system and the State Health Departments also play an important role in this program.

Let’s take a minute and step back and talk about the ESRD Conditions for Coverage. CMS develops the Conditions of Participation and the Conditions for Coverage that healthcare organizations must meet in order to begin and continue participating in the Medicare and Medicaid programs.

So, in other words, if your facility wishes to receive payment from these systems, they must meet the conditions for coverage. These minimum health and safety standards are the foundation for improving quality care and certainly protecting the health and safety of beneficiaries.

CMS also ensures that the standards of accrediting organizations recognized by CMS meet or exceed the Medicare standards set forth in the Conditions for Coverage. The ESRD Conditions for Coverage are the minimum health and safety rules that all Medicare and Medicaid participating dialysis facilities must meet.

The April 15, 2008 ESRD Conditions Final Rule modernized Medicare’s ESRD health and safety conditions for coverage and also updates CMS standards for delivering safe, high-quality care to dialysis patients. The revised regulations are patient-centered, reflect improvements in clinical standards of
care, they look at the use of more advanced technology, and most notably, provide a framework to incorporate performance measures viewed by the scientific and medical community to be related to the quality of care provided to dialysis patients. The Conditions for Coverage are far too in depth and 

lengthy for this training, but listed on this slide are the main conditions a facility must meet in order to participate in the ESRD Medicare and Medicaid program. Under each of these conditions, you would find several standards that are described in greater detail in the actual conditions for coverage.

Although you might not be in charge of implementing the processes by which your facility uses to meet the conditions, it is important for you as a professional to understand the scope and depth of these conditions. Some of the highlights are important to take a look at.

Several changes and updates were made to the conditions, and this short list highlights just a few of those changes. Again, it is important for you to review the new conditions and to understand the changes that have been made, and to also understand how these changes impact the care you deliver to your patients.

A link to the Conditions for Coverage had been provided to you on the course resource list. But some of these highlights include the certification of patient technicians, enhanced attention to individualizing the patient plan of care, the implementation of quality assessment and performance assessment processes, and the discussion about no longer discharging patients for non-adherence issues. So, now that you understand a bit more about the Conditions for Coverage, let’s bring it all together with the State Surveyor role. In conjunction with the Conditions for Coverage, each individual state surveyor is trained in the use of the Interpretive Guidelines. The Interpretive Guidelines are CMS’s interpretation of the Conditions for Coverage, and the Interpretive Guidelines are used to direct the surveyors when looking at the care being provided in a particular center.

Like the Conditions for Coverage, the Interpretive Guidelines are far too long to review, but you should understand and familiarize yourself with these Interpretive Guidelines. That way, when a state surveyor enters your facility to complete a survey, you will be aware of the issues, you will know what the state surveyor is looking for, and you will be able to work in collaboration to make sure your facility is in compliance. A link to the Interpretive Guidelines has been provided for you on the course resource list. So, what does this all mean?
Over the course of this module, we have looked at several critical components of the delivery of ESRD care in the United States. A brief review of the history of dialysis revealed that not too long ago, the decision whether or not an individual would get dialysis and continue to live occurred frequently.

It was only with the signing of the ESRD Medicare program in 1972 did access to dialysis services no longer require the approval of the “God Committees”. In many ways, the ESRD program was static for a number of years with regard to the payment system and the conditions for coverage, but over the last two years, significant changes have occurred in both the conditions and the payment system. The treatment of ESRD has saved and improved literally thousands and thousands of lives and that will continue. However, there is little question the environment is changing and the professionals, patients, payers, and everyone else involved in this program will have to continue to adapt, monitor, and move forward.