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By John A. Sargent, PhD

The Dialysis Industry Faces Bundling

Coordinating Operations and Information Technology Will Aid Survival

THE CENTERS FOR MEDICARE & MEDICAID SERVICES' (CMS) reimbursement for dialysis is continuing to evolve. Chronic dialysis for end-stage renal disease (ESRD) was included in the Medicare program in 1973[1] as a chronic disability and provides care for any individual who has paid into the Medicare system.

The original reimbursement system was a bundle of treatment elements at that time—staff, supplies, medications, and overhead: the composite rate. There was no inflation adjuster, so the payment for dialysis has remained at the same dollar price since the 1970s. There have been additional items—mainly medications, such as ESAs, which were introduced in 1989—which were paid separately over and above the composite rate. These add-ons have had the effect of increasing the ESRD program's cost and may have added some to a provider's margin, a point that CMS asserted in their final rules of July 2010.

Recent legislation—the Medicare Improvements for Patients and Providers Act of July 15, 2008 (MIPPA)—directed CMS to change the reimbursement for ESRD care and effectively bring it in line with the original approach to include all elements of treatment in one "bundled" payment. However, the new approach is different from the one initially adopted for the ESRD program, which set one global rate for a dialysis treatment.

In setting up the new system CMS has announced several concurrent goals. They view the current system of paying for separate non-composite rate items as an incentive for their use. However, they recognize that one amount for a treatment could encourage "cherry picking" so that treating patients that require more expensive therapy should carry a higher reimbursement rate. They want to motivate providers to control costs and feel that providing a capped amount will encourage providers to economize either by more carefully managing elements of treatment or negotiating more favorable arrangements from their suppliers. An example is the inclusion in the bundle of lab analyses, which currently are paid directly by CMS at 100 percent. Finally, they want to assure that this new payment system does not result in harm to the patients and they indicate that they will be tracking quality of care as this payment system goes into effect.

The rules represent such a dramatic change that the dialysis industry is understandably anxious. In addition, CMS expects an "imaginative" reaction from providers and will be monitoring therapy and business model changes as the rules are implemented. CMS believes they have adjusted payment, using statistical models, to recognize which patients are more expensive to treat and feel that they will be fairly compensating providers who treat such patients.

The Basic Elements of the Rules

While the concept of a bundled payment might suggest a standard payment for treatment (as was the original model in the 1970s) CMS has created a unique level of payment for each patient, which has the likelihood of changing each month and can change for each treatment within the month. It is only possible here to briefly summarize the elements of the new payment paradigm. The following are some of the key parts.

There will be a base rate for each facility, resulting from the standard base rate ($229.63/Treatment) modified by a wage factor (applied to the labor component of the standard base rate.) This reimbursement level will cover treatment, IV medications, some oral medications with IV equivalents, and all ESRD lab tests.

There are patient-specific factors that will modify the standard base rate to result in the patient base rate (hereafter referred to as the "base rate"). These are the patient's age and body size, as represented by body mass index (BMI) and body surface area (BSA)—factors used for the current "case-mix" modifiers to the composite rate.

There are other factors, each of which can cause an adjustment to the base rate and increase the reimbursement rate for a patient.

- Onset adjustment: for a new ESRD patient the base rate will be adjusted by 51 percent during the first 120 calendar days of treatment (as determined by completion of the 2728 form). Note that the Medicare eligibility rules apply. A patient, not covered by Medicare prior to the onset of ESRD, has a 90-day waiting period before Medicare coverage starts.
- There are six co-morbidities that will adjust payments. Three are chronic conditions, and three are acute. Each of these must be documented in the medical record. The chronic co-morbidities are effective throughout the patient's dialysis course. The acute co-morbidities carry an increased level of payment for the month of diagnosis and the three subsequent months.
- There are add-on fees for training a patient for home dialysis, either PD or hemodialysis.
- There is partial additional compensation for a patient for whom average treatment costs during a month are excessive. These are outlier payments.
- On the facility level there is an adjustment of nearly 20 percent for clinics considered low volume (< 4,000 treatments per year).
- There are special reimbursement rules for pediatric patients; the other adjusters described above don't apply.

Note that the per treatment amount that results from the adjustments is the Medicare allowed amount so that CMS will be paying 80 percent of that amount with the patient or a secondary payor liable for the remaining 20 percent. The issue of secondary payors covering this residual 20 percent is seen as problematic by many in the industry and will likely be a work in progress subsequent to the implementation of the bundle.

Additional elements and adjustments: There are items that are not in the bundle. Oral medications that are covered under Medicare Part D will not be in the bundle until 2014. Items provided for non-ESRD reasons can be billed separately with a modifier (note that the provider will have to develop methods to track and apply appropriate diagnoses to such items that are also commonly done for ESRD reasons). Other items such as blood products and physical items (wheel chairs) are separately payable.

CMS intends to monitor the implementation of the bundle both to avoid diminished quality of care as well as to promote the continuation and improvement in "treatment quality." In the second year of the program, 2012, CMS will be evaluating each facility for three quality measures: Two for anemia management (Hgb<10g/L; Hgb>12g/L) and one for treatment adequacy (URR > 65 percent). The result is that facilities that fall outside CMS criteria will have their level of reimbursement reduced by up to 2 percent.

"Budget neutrality": The enabling legislation required "budget neutrality," which effectively is a payment reduction, as the "budget neutrality" factor is a 2 percent reduction in the cost of the program and is based on the lowest annual cost for the past several years. In addition, because of this neutrality concept, money is being taken out of the overall reimbursement amounts for all of the additional payments—outliers, low-volume adjustments, etc. These neutrality factors have been factored into the standard base rate described above. There is also a 3.1 percent reduction in payment during the implementation period because CMS feels that overall reimbursement for facilities that phase in (see below) will be higher than would be the case for those accepting total bundled payment. They estimate that 3.1 percent will retain "budget neutrality." Note that the 3.1 percent reduction applies even if the provider opts for full bundling at the outset.

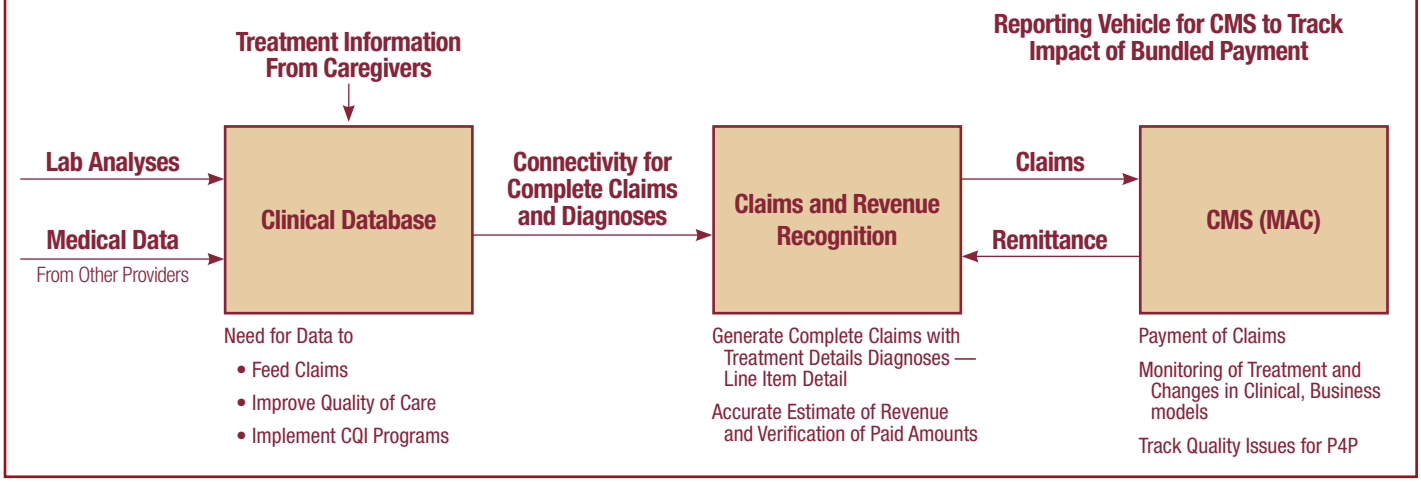
Implementation of bundling—the phase-in as of January 2011: Providers will be allowed to select one of two methods of entering the bundled payment process: elect to start with total bundled payments in 2011, or have bundled payments phased in over three years—a progressive amount of 25 percent per year with total bundling beginning in 2014. The provider can select the first of these options by informing their Medicare Administrative Contractor (MAC) of this election by Nov. 1, 2010. In the absence of making the election by this date the facility will be put into the phase-in category.

The MAC will process claims twice (for either election) by computing the amount payable under the new bundled rules and also by the previous rules, modified for new elements included in the new payment model, e.g., providers will now be obligated to compensate the lab performing analyses for their patients and $8.40 has been added to the bundle to fund lab analyses.

For the provider that selects 100 percent bundling, they will be paid at 80 percent of the amount determined by the bundling calculations. For the provider electing phase in, 25 percent of the

Fig.1

Databases and Required Information Connectivity Needed for the Bundle



computed bundled amount will be added to 75 percent of the modified fee for service amount and 80 percent of the combined amount will be paid to the provider during 2011. The dual computation will also be done for the totally bundled provider because it will be needed for outlier evaluation. It is also suspected that CMS will want to track the effect of the new payment methodology on the use of the elements of treatment, resulting from the change in incentives.

Application of the bundling rules: There are two categories of adjustments: Ones that apply on patient characteristics and those that apply due to co-morbidities and onset of ESRD therapy. The first establishes the base reimbursement rate for the patient at the time of treatment. The adjustments in the second group are mutually exclusive—only the highest adjuster will be applied even though others are present. For example, a patient with sickle cell anemia (1.072), an acute qualifying pneumonia (1.135), who is being trained for home dialysis ($33.44/session), and who is just starting dialysis (1.510) will only receive the 1.510 adjuster (51 percent over the base rate for this patient for the first 120 days of treatment.)

Meeting the Challenges—Effective Use of Information

Information, information flow, and connectivity: A large percentage of the provider community feel that in addressing the new bundling paradigm automated information systems will be essential. It is clear that CMS's new rules are information intensive and complex—considerably more information, originating in the clinical record, needs to be on the claim. In addition to claims processing, CMS intends to monitor the industry's reaction to the new rules and wants detailed information to do so. As a result there needs to be close connectivity between the clinical and reimbursement aspects of a business. The mechanism of CMS monitoring the industry's reaction to these new rules is certain to be the claims process. The industry must approach this new paradigm in two ways:

- Ensure complete reimbursement under the rules.
- Initiate measures to streamline and optimize operations in order to operate within expected reduced revenue.

Interrelation of data systems: Databases and required connectivity needed to respond to the bundle are shown in Fig. 1 (p. 20) and illustrate the acquisition and movement of information to address these new rules. Three separate databases are shown: clinical; claims and revenue recognition; and CMS (represented by the MACs). The box on the left represents the clinical record for a dialysis patient. Inputs come from clinical staff but also from outside labs and external providers, e.g., hospital or other providers' records. These data are needed to care for the patient but as has been described above to pass all relevant treatment and diagnostic information to the revenue function for inclusion on the CMS claim. This clinical database must have tight and efficient connectivity with the revenue function (central box) so that complete claims can be generated with all of the details needed for payment and back up for treatment items; this information is also needed for items that are to be paid outside the bundle. The revenue function will transmit claims electronically to the MAC for payment (the right-hand box). Payment will be received by the provider and amounts paid will be compared with those expected and previously computed for the provider to estimate revenue using the new CMS rules to assure that payment is correct.

Reimbursement—claim generation: The claim generation process is key to survival under the new paradigm. Not only must all of the information relevant to the qualifying adjustments be captured and on a claim, additional information that has heretofore not been the responsibility of the provider must also be submitted. Relevant additional data are represented by complete laboratory analyses (by line item, date of draw, diagnosis, and price for phased in clinics). These data will need to be obtained from all labs that perform analyses for the dialysis clinic. It is necessary that these data be rapidly received. The provider must submit a complete claim and if it takes a lab a week to provide the data to the provider this will hold up claim generation by an equal amount of time which will increase the providers DSO[2]. It will be essential for separately billable items to be identified with appropriate

modifiers to receive payment in excess of the bundle. It is possible that some medications and lab analyses that are commonly done for ESRD may be performed for unrelated reasons and caregivers must document these tests or medications for extra payment. Not only will clinical events need to be documented to support payment adjusters, the date of occurrence is needed because the rate of reimbursement is based on treatment dates not on a per month basis as is now the case. In the past, data in the clinical record was needed only in the event of an inspection or audit. Now accurate data from the clinic (as well as other providers, such as hospitals, and other specialties) will be needed to track qualifying co-morbidities needed for monthly claims.

Estimation of revenue, and ensuring complete payment: For dialysis providers to have a solid grasp of their finances they will need to accurately compute contractual adjustments to estimate their ongoing revenue. For example, if a patient initiates treatment mid-month the 120 days starts at that time so that for the treatment after the 121st day there will be a reduction in the reimbursement rate. Similarly, if the patient has a birthday that throws him into a different age bracket this change could take place in the middle of a month and the rate of reimbursement will change throughout the month. One of the examples used in the final rules[3] is for a patient during the month of July 2011. Three different per treatment payment rates occur during that month—one for the remainder of the 120 day onset of dialysis, one for two PD training sessions in conjunction with treatment, and one for maintenance home PD in the presence of sickle cell anemia. Without the ability to submit accurate and complete claims, effectively compute contractual adjustments, and precisely track receivable amounts a provider will be operating essentially blind. In short the dialysis provider should be able to mimic the MAC's calculations to estimate its revenue and check the accuracy of payment.

Operations—the need for complete information and data connectivity: New operational approaches will be a crucial factor for providers to live within the bundle. It will be necessary to optimally manage the delivery of treatment, particularly regarding the need and use of the most appropriate medications; the proposed and final bundling rules directly state that CMS desires to reduce use of ESAs in this population. There are other areas where cost effective use of medications could have an impact. In fact, this is an area of the treatment model that has until now not been aggressively evaluated. Other aspects of a dialysis provider's business model have been intensively analyzed for cost impact and opportunities for savings for several decades. Since the 1980s there have been shifting staffing models, with fewer licensed personnel, dialyzers have been reused, EPO has been administered subcutaneously, there have been attempts to harvest "over fill" in medication vials, etc. Partially because they were not used at a loss, medications may not have been subject to the same scrutiny. It is clear that CMS intends to change that with the bundling model as well as to perhaps encourage the optimization of lab analyses for this population.

Another aspect of optimization will be continuing to mount quality improvement programs. Effective data coordination will be critical for a provider to assure continued quality care and to implement CQI programs.

January 2011 Is Just the Start

Bundled payment is a starting point: CMS, with the bundling of payments to the ESRD community, is introducing a whole new approach to paying for ESRD care, particularly with regard to the details of payment. They expect fundamental operational changes and are relying heavily on more and better use of information. They expect the industry to significantly modify operational and business models as a reaction to this new paradigm. Consequently, CMS intends to monitor the industry closely and is expected to do so using claims data. Initial quality measures are limited to Hgb and URR. Also with a fundamentally different payment structure unintended consequences would be expected and CMS will be monitoring the implementation of this program closely. CMS, in fact, has directly stated that their intent is to modify behavior—it is unclear what level of behavior modification will be considered "gaming" the rules. The industry needs to adapt to these new rules and be prepared to react to future refinements to this program. We expect that there will be increased demands for reporting where additional coordination of clinical data will be needed.

The claims and revenue recognition box is in the center of Fig. 1 (p. 20). It will also be central in the bundling paradigm. It is the critical revenue piece for the provider. It is also the route from which CMS is expecting to get data to monitor the reaction to the new reimbursement rules. Virtually all of the information that they will be using into the future will be contained in the claim database. They will be able to evaluate what changes in practice are made by what items appear on the claims. Even the quality measures they mention in the proposed Quality Incentive Program (QIP)[4] proposed rules are on the claims.[5]

In summary, the new bundled payment rules represent a major new challenge for the dialysis industry. This is an industry that has met challenges before and has adapted. We feel that the ESRD community will also adapt to this new paradigm by coordinating operations and by the increasingly sophisticated use of information sources and will be able to survive into the future. RBT

Dr. Sargent has been involved in the dialysis field since 1967 and has been president of Quantitative Medical Systems (QMS) since 1976.

Footnotes:
1. PL 92-603 of 1972 which went into effect July 1, 1973
2. DSO: Day service outstanding: Accounts receivable/daily revenue. If claim submission is delayed by 7 days, accounts receivable and DSO will increase by this much.
3. CMS-1418-F, example 4, page 616
4. CMS-3206-P
5. In 2012 CMS will be evaluating quality of care using Hgb and URR. These metrics have been on CMS claim forms for several years and are expected to be the data on which providers will be judged. Subsequent to the initial quality project the QIP document indicates that Kt/V, vascular access, and access infections will be evaluated; CMS required these data to be on claims starting for July 2010 dates of service.

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