Bundled-Rate Legislation for Medicare Reimbursement for Dialysis Services: Implications for Anemia Management with ESAs

Chaim Charytan

Renal Division, New York Hospital Medical Center of Queens, Flushing, New York

With the incidence of ESRD on the rise, there is a continuing need to control anemia-related treatment costs in dialysis patients receiving reimbursement through Medicare. Currently, erythropoiesis-stimulating agents (ESAs) are billed separately from dialysis services, potentially creating little financial incentive for more efficient use. The Medicare Improvement for Patients and Providers Act, passed by the U.S. Congress in July 2008, includes provisions intended to address this concern. Under this act, dialysis services will be reimbursed using a fully bundled, comprehensive payment system that includes all services currently covered in the basic composite rate, as well as certain separately billable items, including ESAs. A base rate of $229.63 per treatment has been assigned, to be individualized using case-mix adjusters. The implications of this new system for anemia management with ESAs continue to be elucidated. With fixed compensation for ESAs, management strategies that maximize efficiencies and, thereby, optimize cost savings will be favored. Select strategies may include switching from intravenous (IV) to subcutaneous routes, lowering Hb targets and ESA doses in hyporesponsive patients, increasing administration of IV iron, increasing use of home dialysis, and optimizing ESA dosing intervals. Once-monthly ESA therapy has potential advantages under this new system as an alternative to more frequently administered ESAs and may help achieve quality metrics in a cost-efficient manner.


Anemia is a hallmark complication in patients with ESRD receiving hemodialysis (HD), and erythropoiesis-stimulating agents (ESAs) have become a major element of the standard of care in its management. As the incidence of ESRD continues to rise, treatment of anemia in HD patients becomes an increasing cost burden to the Medicare payment system (1,2).

The current Medicare payment system for provision of outpatient maintenance dialysis services, in place since August 1, 1983 (3), is considered by many to be outdated (2). It consists of a basic composite rate applied on a per-treatment basis for “routine” dialysis services and a fee-for-service payment for dialysis-related services considered outside of the routine (i.e., injectable drugs such as ESAs and vitamin D analogs, laboratory tests) (2,3). Unfortunately, this system inadequately accounts for certain market changes that, over time, have substantially affected (and are likely to continue affecting) the cost of providing care to dialysis patients. For example, new technologies and clinical practice patterns have emerged (2). The current payment rate was originally based on Medicare data reflecting dialysis-related costs from 1977 to 1979 (2,3). Slight inflation-related adjustments to the composite rate have been made over the years on the basis of statutory regulations (2,3), including 1.6% increases in composite rate payment and add-on payments that are based on updated pricing methods for separately billable items (2,3); however, current payment rates overall insufficiently reflect economic developments or realities (as enumerated above). Additionally, there has been concern that the fee-for-service structure of separately billed services, especially ESAs, has contributed to their inefficient/excessive use in some cases, with resultant increased expenditures (2,4). Under the current system, providers have had little financial incentive to efficiently manage ESA use (4,5). Finally, the current payment method does not fully account for patients who require more care and utilize more resources than the average dialysis patient (2). Taken together, there is a clear need for an updated reimbursement structure.

New Legislation

In July 2008, the U.S. Congress passed the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA; HR 6331), which mandates reform of Medicare reimbursement policies for various health care services and pharmaceutical expenses, including dialysis-related services (e.g., dialysis, drugs, laboratory tests) (3,6,7). The Centers for Medicare and Medicaid Services (CMS) released the final ruling for implementation of the ESRD Prospective Payment System (PPS) in July 2010 (3).

How this new legislation will affect daily nephrology practice is an ongoing topic of debate as we move from legislation, to regulation, to implementation. This article reviews select...
aspects of the bundled reimbursement provision for dialysis and related services and discusses implications for anemia management with ESAs under this new system.

Main Features of the New Legislation (HR 6331): Reimbursement for Dialysis Services

Under HR 6331, dialysis and related services are to be reimbursed using a fully bundled payment system that provides a single, comprehensive payment to a provider or dialysis facility for all services currently covered in the basic composite rate, as well as separately billable items. A standardized base rate of $229.63 per dialysis treatment has been set (estimated costs were based on 2007 claims data), to be individualized using case-mix adjusters (discussed below). The reimbursement payment rates are to be increased annually to account for changes to the prices of the individual components (3,6).

Patient-level case-mix adjustments will be made for age, body mass index, body surface area, comorbidities, and length of time on dialysis (3). Adjustments will also be permitted for patients who are particularly costly to treat (high-cost outliers requiring higher than typical resource use) (3). In addition, payment adjustments will be permitted on the basis of certain dialysis center characteristics, including a wage index based on geographic location and low-volume facilities (3). Importantly, under the current ruling, patient-level adjustments for gender and race/ethnicity will not be made (3). The decision to exclude race/ethnicity has been a source of concern among nephrology practitioners (discussed in more detail later) and was an area of substantial comment by the renal community during the comment period.

Per the final regulation, “renal dialysis services” comprise all maintenance dialysis-related services, including all laboratory tests and related services for ESRD treatment (e.g., supplies such as tubing and syringes, equipment) and all injectable and oral (when available, discussed below) dialysis-related medications that were previously billed separately (3). These include agents such as ESAs and other medications or biologicals used for treatment of ESRD, such as vitamin D analogs.

The inclusion of oral medications in the bundle was a cause for concern and generated considerable public commentary (3). The proposed allowance was $14.00, “based on the 2011 per treatment ESRD-related Part D drug payments included in the proposed ESRD PPS base rate” (8). That overall total allowance for oral drugs was perceived as grossly inadequate (3,8). Given this situation, nephrologists will have to balance cost versus potential efficacy by turning to less expensive oral medications when possible, creating concerns about adequacy of patient care. Oral cinacalcet (Sensipar) and sevelamer (Renagel or Renvela) are examples of expensive brand-name oral products that may not be used in favor of less appropriate medications because of the inadequacy of reimbursement. Inclusion of oral medications may also increase administrative complexity because providers will need to comply with variable state regulations and become affiliated with pharmacies or establish their own pharmacies to provide oral medications; both scenarios involve complicated processes.

As a result of the many issues identified during the comment period, the implementation date for the inclusion of oral-only ESRD drugs (i.e., oral medications with no injectable equivalent) has been deferred to January 1, 2014 (until that time, these medications will continue to be covered under Medicare Part D). This will allow CMS time to gather more data and adequately address pricing issues. However, oral ESA medications with an injectable equivalent (e.g., oral vitamin D analogues such as calcitriol) will be included in the bundled payments as of January 1, 2011. Drug categories not specific to ESRD are excluded from the base rate (e.g., vaccines and immunosuppressants) (3).

The legislation provided the Secretary of Health and Human Services the discretion to determine whether the bundled unit of payment is to be based on service provided on a monthly, weekly, or individual per-treatment (dialysis session) basis (3). Per the final ruling, the Secretary has decided on a per-treatment unit of reimbursement, with a maximum allowable three treatments per week (unless justification for more frequent treatments is provided). This decision was made for numerous reasons, including the fact that the current composite rate system for dialysis is based on a per-treatment payment and thus would allow for the smoothest transition to the expanded bundle, as well as the fact that a per-treatment payment provides the appropriate incentive to ensure that providers encourage patients to be compliant with dialysis treatment (3).

Implementation of the bundled payment system is to begin on January 1, 2011 with complete implementation by the end of 2014 (3). Over this 4-year time period, the new bundled payment system will be transitioned “in equal increments” annually as follows: In 2011, 25% of payments; in 2012, 50%; in 2013, 75%; and in 2014, 100% (3). ESRD facilities may elect to forego the transition period and accept full implementation of the new bundled payment system starting January 1, 2011. This election must be made by November 1, 2010 (3).

A Quality Incentive Program (QIP) will be implemented in which quality-related performance of providers and renal dialysis facilities will be evaluated based on prespecified performance standards in various measures (3,9). The proposed parameters to be assessed will include two anemia management measures and a dialysis adequacy measure. The anemia management measures will assess (1) the percentage of patients at a facility who received an ESA and whose anemia falls below the low end of the U.S. Food and Drug Administration (FDA) label recommendation (<10 g/dl), and (2) the percentage of patients at a facility who received an ESA and whose Hb was above the FDA label recommendation (>12 g/dl) (with the exclusion of patients under 18 years of age because of a lack of scientific evidence about the appropriate Hb levels for pediatric patients) (3). The high Hb quality measure will not include patients who are not receiving ESAs because the purpose of this measure is to identify possible overutilization of ESAs, not to identify high Hb attributable to other causes (3). The dialysis adequacy measure will assess the percentage of patients (facility-based HD patients older than 18 years of age) whose urea reduction ratio is ≥65% (3). Facilities’ performance will be measured against the lower of the facilities own past performance or national standards. Beginning January 1, 2012, dialysis facilities not
meeting a total performance score reflective of all three performance measures will have payments reduced by up to 2% (based on a sliding-scale system); 2010 has been suggested as the "initial performance period" (9). Currently these metrics do not address other quality measures tracked by dialysis providers, such as nutritional status, serum phosphorus levels, or management of secondary hyperparathyroidism. In the future, CMS will likely issue an expanded QIP rule with additional quality parameters (3). A Proposed Rule for the ESRD QIP was published on August 12, 2010 in the Federal Register; the comment period closed on September 24, 2010 (9).

The payment reform challenges the Secretary and the Medicare system to generate an equitable program that takes into account the wide variation in patients' clinical presentation and personal circumstances.

Implications of the Regulations on Anemia Management: Maximizing Efficiencies

With fixed compensation for ESA use and quality metrics in place that will continually affect reimbursement, an increasing emphasis will be placed on maximizing efficiencies and meeting target Hb goals. Select strategies for improving efficiencies may include lowering patients' Hb goal within FDA-label parameters and the specified quality target range, switching from the intravenous (IV) to the subcutaneous (SC) route of administration, optimizing effectiveness of ESA therapy with IV iron, and appropriately lowering ESA doses in hyporesponsive patients. The latter strategy is a particular area of focus given the results from the Cardiovascular Risk Reduction by Early Anemia Treatment with Epoetin Beta (CREATE [10]), Correction of Hemoglobin and Outcomes in Renal Insufficiency (CHOIR [11]), and Trial to Reduce Cardiovascular Events with Aranesp Therapy (TREAT [12]) studies. Although these studies were conducted in non-HD patients, clinical implications in relation to potential safety issues with higher Hb targets may be applicable to the broad chronic kidney disease population. Additional strategies may include increasing use of home dialysis modalities and optimizing ESA dosing intervals.

Route of Administration: IV versus SC

Because of efficiencies gained (lower epoetin alfa dose requirements to achieve equivalent efficacy) (13), switching from the IV to the SC route for epoetin alfa is one plausible strategy to reduce treatment costs (4). However, these advantages need to be weighed against the potential downside of SC administration, including pain at injection site and the increased risk of pure red cell aplasia (PRCA) (14). Although rare (14), this potentially life-threatening condition should be considered. With these issues in mind, use of ESAs that require a similar dose whether given via the IV or the SC route (such as longer-acting ESAs) (15–17) may provide an advantage in this new bundled-rate system.

Use of IV Iron

Presence of iron-restricted erythropoiesis (rate of erythropoiesis exceeds rate at which circulating iron is replenished) increasingly is being recognized as an important underlying factor in ESA hyporesponsiveness (18,19). For HD patients receiving ESA therapy, addition of IV iron to the treatment regimen can improve ESA responsiveness, thereby allowing for reductions in ESA dose requirements (20,21). Results of the recently published DRIVE II trial (20) (an extension of the Dialysis Patients Response to IV Iron with Elevated Ferritin [DRIVE] study [22]) demonstrated the efficacy of IV iron in reducing epoetin alfa dose requirements in HD patients with high ferritin levels (500 to 1200 ng/ml) and transferrin saturation ≤25% (19,20). In an earlier study by Besarab and colleagues, 40% reductions in epoetin alfa dose requirements were shown in HD patients treated to a transferrin saturation of 30% to 50% compared with the control group treated to a transferrin saturation of 20% to 30% (21).

Benefits notwithstanding, potential iron-related safety issues should be considered. Although iron-overload-related complications in dialysis patients have not been demonstrated with current practice protocols, a continuing vigilance is required to avoid end-organ damage resulting from iron-related induction or aggravation of an oxidative state, particularly when iron is used on a long-term basis (23,24). Notably, to date, no randomized controlled trials have evaluated the safety or outcome measures of various long-term strategies of IV iron administration. Published safety profiles of existing IV iron products are based only on short-term safety data (25,26). Although there is currently no direct evidence of harm from continuous iron use in the chronic kidney disease setting (as opposed to iron-overload-related harm in patients with blood-transfusion-related anemias) (24), it should be kept in mind that potential adverse events may only surface in longer-term randomized trials (25). Additionally, the absence of data should not be taken as proof of safety; continued vigilance and caution are required. Establishing an effective balance between iron levels, ESA doses, and Hb levels is an ongoing challenge in the quest to optimize anemia management in a cost-efficient manner.

Hyporesponders

Hyporesponsiveness, often a transient phenomenon (27), affects approximately 5% to 10% of patients receiving ESA therapy at any given time (28). Hyporesponsive patients tend to require larger amounts of ESAs and thus represent a cost disadvantage under a bundled-rate payment system. Under these circumstances, providers might choose to accept lower Hb levels when clinically appropriate. Alternatively, they may resort to transfusion therapy for this patient subgroup, increasing risk of transfusion-related complications such as infection and hemolytic reactions, as well as HLA sensitization and the associated negative effect on renal transplant success (29,30). One potential concern with the fact that QIP measures include the percentage of patients at a facility who received an ESA and whose anemia falls below the target of <10 g/dl is the fact that hyporesponsive patients who are unable to reach 10 g/dl will represent a negative financial burden for dialysis providers, which in turn may adversely affect their care (i.e., transfusion observation and/or increased ESA dosing).

Hyporesponders will be partially accounted for in the bundled payment system through the high-cost outlier provision in...
which payment adjustments will be made for patients who require unusual amounts of medical care/medications (3). Outlier items or services will include those that “were or would have been, before January 1, 2011” separately billable under Medicare Part B or Part D, such as ESRD- or dialysis-related medications or laboratory tests (3). However, outlier payments do not cover the full excess cost to the provider. Payments will be made on a cost-sharing basis. When the difference between the Medicare-allowable payment for a drug or service and the provider’s cost for the drug or service exceeds a fixed dollar loss amount (outlier loss threshold) of $135.44 for adult and $195.02 for pediatric patients, a payment equal to 80% of the additional loss will be made to the facility (3).

African-American Race

African-American race, which represents roughly one third of the Medicare dialysis population (8), is among the multitude of factors associated with higher utilization of ESAs (31). Per CMS research examining the effect of race on costs in Medicare dialysis patients, compared with “Asian/Pacific Islander” populations (the reference group considered least costly), “blacks are 20.7% costlier” (8). One study assessed the relationship between the proportion of African-American dialysis patients and ESA costs at the dialysis-center level. Results showed a $30.76 increase in epoetin alfa per member per month for every 1% increase in the proportion of African-American patients (32). The exclusion of race/ethnicity from the case-mix adjusters in the regulations is a major concern among the renal community because many dialysis units will be at potential risk for underpayment (primarily related to costs of ESAs) (33,34).

In light of ongoing reimbursement concerns, protocols that can offer efficiencies, and/or ESAs that could be shown to have equivalent efficacy across races, may be valuable in treating hypo-responders and other subpopulations with higher-than-average ESA utilization.

Home Dialysis

Home dialysis services via all modalities will be part of the bundled payment system, and reimbursement for home dialysis services will be equivalent to in-center dialysis (3). Overall costs for patients receiving home/self-care HD and peritoneal dialysis (PD) have been shown to be an average of $20,000 lower than for patients receiving in-center HD; costs for erythropoietin were lower for PD patients (35). This may serve as an incentive for use of home/self-care dialysis modalities under the new bundled payment system. ESAs that can offer simpler, more efficient approaches to compliant home care (e.g., once-monthly dosing [discussed below]) may assist those patients and providers who choose a home dialysis option.

Efficient ESA Administration Schedules

The FDA-approved administration schedules of currently available ESAs (3 times weekly [TIW] for epoetin alfa; once weekly [QW] to every 2 weeks [Q2W] for darbepoetin alfa) (36,37) are burdensome (38), particularly in light of the nursing shortage (39). There is a growing need to simplify anemia management strategies; use of ESAs at extended dosing inter-

vals is an issue of continuing interest in nephrology practice, including in the dialysis setting.

Data on extended dosing intervals of currently available agents are emerging; however, studies in the dialysis population are scarce. In two studies evaluating extended dosing of darbepoetin alfa in dialysis patients (40,41), only a small fraction of patients ultimately received every-4-week (Q4W) dosing: 36 of 54 patients in the study by Jadoul et al. (41) and 55 of 161 patients in the study by Trachsler et al. (40) Of these preselected patients, target Hb was maintained with once-monthly dosing in 30 of 36 patients in the Jadoul study and 55 of 55 patients in the Trachsler study. However, these patients were previously stabilized on more frequent dosing intervals. Furthermore, it remains unclear whether darbepoetin alfa dosed at extended intervals requires more frequent monitoring and dose adjustments.

Dosing frequencies of Q2W to Q4W have also been shown to be efficacious with methoxy PEG-epoetin β (continuous EPO receptor activator [CERA] or Mircera) (42,43), which has been available in Europe since 2007. Phase 3 studies demonstrating its efficacy in maintaining target Hb levels with Q4W dosing included HD patients whose Hb levels were previously stabilized on epoetin alfa TIW or QW (15,43,44) or on darbepoetin alfa QW or Q2W (45). In a recently published study comparing efficacy of CERA Q4W with darbepoetin Q4W in HD patients previously stabilized on darbepoetin QW (PATRONUS), a higher proportion of patients receiving CERA met the primary endpoint (Hb ≥ 10.5 g/dl and decrease from baseline ≤1 g/dl during weeks 50 to 53) (46). Although CERA is approved in the United States, it cannot be sold there until mid-2014 (per patent infringement-related legal settlement terms) (47).

Hematide™/peginesatide is a synthetic, peptide-based ESA linked to polyethylene glycol. Q4W dosing of peginesatide is being investigated for the correction and maintenance of Hb in anemia of chronic renal failure. The peginesatide phase 3 studies have recently been completed; preliminary top-line results were announced in a press release on June 21, 2010 (48). In phase 2 studies, use of peginesatide Q4W increased and/or maintained Hb levels in ESA-naïve HD patients (during correction and maintenance treatment) (49) and in HD patients previously stabilized on epoetin alfa (maintenance treatment) (50,51). Because its primary amino acid sequence is unrelated to erythropoietin, peginesatide is unlikely to induce a crossreactive immune response (e.g., PRCA) (52). Antibodies to erythropoietin do not crossreact with peginesatide, and antibodies to peginesatide do not crossreact with erythropoietin (52). Recently published data from an ongoing study evaluating the utility of peginesatide in treating patients with epoetin-alfa-induced PRCA look promising (53).

Aspects in Which Extended Dosing Can Benefit Patients and Providers in a Bundled Environment

Time and Cost (Administrative) Savings

Potential benefits of fewer ESA injections have been shown in two similarly designed time-and-motion studies (54,55). Schiller et al. reported results of an observational study that captured activ-
ity-based costs of anemia management using epoetin alfa TIW in five U.S. dialysis centers and then modeled hypothetical time and cost savings gained by switching to a once-monthly ESA (54). For epoetin alfa sessions, an average of 608 minutes per patient per year (PPPY) were spent for observed and unobserved tasks, with an average cost of anemia management in these U.S. centers of $548 PPPY. Results of the modeling analysis predicted that, if 100% of patients were switched to a once-monthly ESA, the estimated total time spent PPPY (including observed and unobserved tasks) would be reduced by 79% (481-minute reduction) and costs would be reduced by 81% (savings of $444 PPPY) (54).

Saueressig et al. reported on a prospective, observational study (based on 12 dialysis centers in Germany and the United Kingdom) that analyzed time and cost of ESA therapy (QW-TIW) and compared it with modeled costs of using a once-monthly ESA (55). Time (per patient per administration) spent on observed and unobserved tasks related to short-acting ESA use averaged 381 and 454 minutes PPPY in Germany and the United Kingdom, respectively. Corresponding PPPY costs averaged €170 and £187 in Germany and the United Kingdom, respectively. Per results of the modeling analysis, in a 100-patient dialysis center, assuming 100% of patients were switched to once-monthly ESA, total annual time spent on ESA use (observed and nonobserved tasks) would decrease by 55% in Germany and 39% in the United Kingdom, translating to a cost decrease of 58% (€98) and 35% (£66), PPPY, respectively (55).

Time savings gained with use of a once-monthly ESA can provide cost efficiencies in a reimbursement-limited bundling environment. Additionally, they may allow nurses more opportunity to provide quality care focused on overall patient needs (e.g., clinical evaluation, disease management, and patient education).

Continuity of Care

HD regimens are complicated, restrictive, and unpleasant; noncompliance with dialysis sessions occurs often (56–58), particularly in U.S. centers (56). Because ESAs are typically administered during in-center dialysis sessions, missing these sessions may result in missed ESA doses. Missed ESA doses due to patient noncompliance may lead to decreased Hb levels and subsequent increased risk for adverse consequences, including hospitalization and death (58,59).

Poor compliance with ESAs in patients receiving dialysis at home is also an important concern. For instance, PD patients self-administer ESA therapy SC at home. The requirement for frequent, painful SC administration of an ESA may serve as a deterrent to compliance. In a study of 54 patients undergoing PD, a 35% rate of noncompliance with ESA therapy was reported (defined as receipt of <90% of prescribed dose, according to questionnaire responses or pharmacy records) (60). For patients who admitted to being noncompliant (n = 14), forgetting to administer the medication was the most common reason cited (64.3%). Extended ESA dosing regimens may help simplify treatment and thereby increase likelihood of improved compliance in PD and home HD patients self-administering ESAs at home.

Hospitalization is another factor associated with missed ESA doses. Recently published data demonstrate that only a small percentage of hospitalized dialysis patients receive ESAs during the hospitalization. For instance, for a 4- to 7-day length of stay (the most common duration), ESAs were received by fewer than 20% of patients (61). A longer length of hospital stay has been shown to be associated with increased risk of declining Hb levels (62). The reasons for interruption of ESA therapy during hospitalization remain unclear. One factor may be that when full patient histories are not available, continuity of care from the outpatient to inpatient setting suffers. Additionally, when patients are hospitalized for nonrenal/nonanemia-related causes, ESA therapy may not be a top priority. Furthermore, some hospital settings may have dialysis services available for inpatients but lack a dedicated dialysis unit that provides the full complement of renal support therapy for patients with ESRD. Gaps in ESA therapy during hospitalization may lead to poor Hb control, the need for higher ESA doses posthospitalization, and a prolonged time to reestablish control postdischarge (62–64).

In light of these issues, extended ESA dosing intervals can be advantageous. ESAs that are administered once monthly (before hospitalization) can potentially minimize the interruption of ESA management during the hospital visit while maintaining stable Hb levels peri- and posthospitalization. Avoiding prolonged time intervals below Hb target range posthospitalization may help reduce the likelihood of rehospitalization. The same applies for patients that are noncompliant with their dialysis sessions. This, in turn, can help dialysis centers meet standards for quality care and Hb targets under the new CMS ESRD PPS rules and avoid a prolonged period of increased ESA dosing when the patient returns to dialysis. Some providers expressed concern that under a per-treatment reimbursement system, payment for a long-acting ESA would not include missed dialysis sessions although the patient remained compliant with ESA therapy. However, providers must also weigh considerations of dose efficiency, dose frequency, Hb stability, and total cost across their patient population in evaluating ESA options. Understanding the full benefit of long-acting therapies under the new reimbursement structure is especially critical given the relative frequency of hospitalization among dialysis patients, during which they are most often not treated for anemia and after which they face an extended period of low Hb levels when returning to the dialysis facility (61,64).

Goals and Challenges of a New Bundled-Rate Payment System

The new legislation aims to account for shortcomings of the previous system, factor in numerous patient- and facility-related issues (e.g., via case-mix adjustments), and optimize the quality of care provided. As we move to the implementation phase, the implications of the new plan on nephrology practice will become clearer. Undoubtedly, the new legislation creates opportunities and challenges for physicians and dialysis services providers, drug suppliers, and regulatory agencies (e.g.,
CMS)—each of which will likely face conflicting perspectives and ethical dilemmas. Physicians and dialysis care facilities will strive to provide therapies that meet patients’ clinical needs in a cost-effective manner so that clinical outcomes can be achieved without jeopardizing financial viability. Eventual inclusion (by 2014) of oral-only medications in the bundled payment raises many concerns of inadequate reimbursement and thereby the potential for undertreatment. Furthermore, the need to develop methodologies for purchasing, storing, dispensing, and tracking oral drugs; hiring or training personnel to perform these functions; and complying with varying state pharmacy regulations will pose additional logistic and cost challenges for dialysis providers. A continuing challenge will be to ensure providers are paid appropriately for services/drugs provided.

For suppliers and drug manufacturers, the ability to provide agents that are clinically effective and have reasonable drug acquisition costs will make them more desirable in this competitive environment. Likewise, regulators and payers face the challenge of recognizing the complexity of the situation and trying to create a fair and equitable regulatory and payment system, taking into account the various obstacles physicians and providers will face in balancing financial, clinical, and ethical issues. It is hoped that the new payment environment will recognize these obstacles so that the financial viability of dialysis units (and thereby their ability to provide quality clinical care) is not threatened and physicians’ ability to make individual patient-oriented treatment decisions will not be infringed upon. Agents and strategies that effectively permit fulfilling the clinical and financial aspects of anemia management will be very beneficial for all involved parties.

Conclusions

The effect of the new legislation on anemia management trends (after implementation in 2011) remains to be seen. It is important to acknowledge that although financially related issues were among the key driving forces behind the new legislation, additional drivers for change likely operate in parallel to influence therapeutic practice patterns, including treatment guideline recommendations, scientific data, and public perception of efficacy (65,66). Recent literature suggests that perceived benefit of treatment approaches, regardless of reimbursement policy, influence trends of ESA use around the world (65). Using the Dialysis Outcomes and Practice Patterns Study database of HD patients from 300 dialysis units across 12 countries, a trend across countries was found toward use of higher ESA doses and achievement of higher Hb levels regardless of reimbursement structure or financial incentives (65).

Nevertheless, on the basis of the final rule, management strategies that optimize cost savings, convenience, and efficiencies, as well as help meet quality metrics will likely be favored in this new reimbursement scheme. For the management of anemia, once-monthly ESA therapy has potential advantages under this new system as a simple, convenient alternative to more frequently administered ESAs.

Acknowledgments

Medical writing and editorial assistance provided by Norma Padilla, PhD, and Sophia Shumyatsky, PharmD, of ApotheCom Associates was supported by Affymax, Inc.

Disclosures

Dr. Charytan has received research support from and/or participated on the speaker bureaus and/or advisory boards of the following companies: Abbott, Affymax, AMAG, Amgen, ARL, Aventis, Fibrogen, Fresenius, and Roche.

References

13. Kaufman JS, Reda DJ, Fye CL, Goldfarb DS, Henderson WG, Kleinman JG, Vaamonde CA, for the Department of Veterans Affairs Cooperative Study Group on Erythropoi-


