



**American Hospital
Association**

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Charlene Frizzera
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, S.W.
Washington, DC 20201

***RE: CMS-1418-P, Medicare Program: End-Stage Renal Disease Prospective Payment System;
Proposed Rule (Vol. 74, No. 187), September 29, 2009.***

Dear Ms. Frizzera:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our 40,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) end-stage renal disease (ESRD) prospective payment system (PPS) proposed rule.

Medicare currently makes payments for dialysis services to 591 hospital-based ESRD providers, of which, 189 are located in rural areas. While this is only a small percentage of the 4,330 independent ESRD facilities that participate in the Medicare program, hospital-based centers provide important access, providing services for ESRD patients who are sicker, with more comorbidities on average. Hospital-based programs also provide the majority of Medicare ESRD services to pediatric patients. It is critical that any ESRD PPS allow hospital-based programs to continue to serve these vulnerable patient populations.

The AHA supports CMS' proposals related to the unit of payment, the outlier policy and quality measures. These policies are reasonable and will help to ensure continued appropriate care in hospital-based settings.

In our comments below, however, we address several concerns regarding the proposed ESRD PPS. Specifically, we are concerned about the inclusion of certain oral drugs that currently are paid separately under Medicare Part D in the ESRD PPS payment bundle; the lack of a specific list of ESRD-related diagnostic laboratory tests that will be contained in the bundle; and the proposal to bundle the costs of home dialysis training into the ESRD PPS. Further, we believe that the threshold proposed for the low-volume adjustment is too low and should be increased to accommodate additional providers. Finally, we are very concerned that the proposed ESRD PPS



will have a significant negative impact on facilities that treat pediatric ESRD patients and recommend that CMS postpone the application of the ESRD PPS to these services.

UNIT OF PAYMENT

CMS proposes to establish an ESRD PPS that relies on a per-treatment unit of payment. It proposes to continue the present per-treatment basis of payment under which ESRD facilities would be paid for up to three treatments per week.

The AHA supports CMS' decision to use a single dialysis treatment as the unit of payment for the ESRD PPS. Other units of payment, such as weekly or monthly payment, are problematic due to difficulties accounting for patients who are receiving treatments in more than one facility, who are hospitalized, and who travel. Dialysis patients average approximately 13 hospital days per year and a payment based on a weekly or monthly unit of payment would be difficult to manage. Further, dialysis patients travel and, depending upon which dialysis facility the patient visits, this may add complexity regarding which facility would receive payments under a weekly or monthly payment unit.

OUTLIER POLICY

The AHA supports the proposed ESRD PPS outlier policy. As required by law, the policy would apply to items and services that currently are separately billable from the ESRD composite rate, such as drugs, clinical laboratory tests, blood and blood products, self-dialysis training services and durable medical equipment and supplies. A treatment would be eligible for an outlier payment if the imputed cost of the services provided exceeds their predicted cost by a fixed-loss dollar amount of \$134.96 for adult and \$174.31 for pediatric dialysis patients. Once the fixed dollar amount is met, CMS would pay 80 percent of the ESRD facility's outlier service costs.

QUALITY MEASURES

CMS is required by law to create a quality improvement program (QIP) for ESRD facilities that would link payment to performance on certain quality measures for services furnished on or after January 1, 2012. CMS must select measures and develop performance standards for health care categories such as anemia management and dialysis adequacy. In choosing measures, CMS must consider the availability of data to calculate such measures. In addition, as part of this program, CMS must develop procedures for making the QIP information public, after giving providers and facilities an opportunity to review the information that is to be released.

The proposed rule outlines CMS' conceptual model for the ESRD QIP and proposes to include three measures that have been in use since 2001; they include one measure of hemodialysis adequacy and two measures of anemia management.

The AHA does not have concerns with the conceptual model for the ESRD QIP; however, we look forward to seeing additional details regarding the performance standards and other implementation issues in the promised separate proposed rule. Further, given the significant changes being put into place with the implementation of the ESRD PPS, we also support CMS' decision to include only the three performance measures that are familiar to dialysis organizations.

BUNDLING OF PART D DRUGS

Section 1881(b)(14)(B)(iii) of the *Social Security Act* specifies that the ESRD bundle must include "other drugs and biologicals that are furnished to individuals for the treatment of end stage renal disease and for which payment was (before the application of this paragraph) made

separately under this title, and any oral equivalent form of such drug or biological.” CMS proposes to bundle all renal dialysis drugs formerly covered under Medicare Part D into the ESRD PPS. The agency bases its decision to include Part D drugs commonly prescribed for ESRD patients as part of this bundled payment on the following interpretation: “Given the reference to ‘this title,’ we interpret clause (iii) as requiring the inclusion in the ESRD PPS payment bundle all drugs and biologicals that were separately billable prior to the implementation of MIPPA under title XVIII of the Act.”

We disagree with this interpretation and recommend that only those oral drugs that have equivalent injectable or other equivalent non-oral forms be bundled. Other oral drugs should be excluded from the ESRD PPS bundle and should continue to be paid separately. If one refers back to the specific statutory language above, particularly the phrase “and any oral equivalent form of such drug or biological,” an alternate and equally reasonable interpretation is that Congress intended only those oral drugs normally given by injection (or other non-oral routes of administration) during the course of a dialysis treatment, but for which there exists an oral equivalent, to be bundled.

Indeed, in the proposed rule, CMS explicitly recognizes that the statute could be interpreted to limit the scope of the drugs and biologicals included in the bundle to only oral versions of injectable or other non-oral drugs. Nevertheless, CMS rejects the interpretation, stating: “This reading of the statute is unduly constrained. Therefore, our view is that the intent of clause (iii) is to include all drugs and biologicals formerly payable under either Medicare Part B or Part D used to treat ESRD, regardless of the route of administration.”

Eleven drugs and biologicals – epoetin alfa, darbepoetin alfa, calcitriol, doxercalciferol, paracalcitol, iron sucrose, sodium ferric gluconate, levocarnitine, alteplase recombinant, vancomycin, and daptomycin – accounted for 99.7 percent of the payments under Medicare Part B for all injectable drugs and biologicals that were furnished to outpatient ESRD patients in 2007. These are the most commonly used injectable or other non-oral route drugs provided in the course of chronic dialysis treatments. We believe that Congress intended these drugs, or their equivalents, to be included in the ESRD PPS bundled rate. That is, they intended to include reimbursement for drugs and biologicals that normally are administered to the patient during the course of chronic dialysis treatment.

Oral agents – such as cinacalcet hydrochloride, lanthanum carbonate, calcium acetate, sevelamer hydrochloride and sevelamer carbonate – are not normally administered during dialysis treatment but are prescribed to the patient to be taken at home on a routine schedule on both dialysis and non-dialysis days. These drugs and biologicals should not be considered a component part of the dialysis treatment for inclusion in a bundled rate.

The implications of CMS’ decision are significant for hospital-based ESRD services. First, it puts a significant burden on hospitals, requiring them to either:

- become commercial pharmacies and directly dispense these oral drugs to patients – this would require that the hospital meet all state pharmacy requirements and certain federal Part D requirements (e.g., access requirements, pharmacy networks and formularies); or
- enter into an “arrangement” with one or more commercial pharmacies in order to provide the patients with the oral drugs. These pharmacies would then bill the facility for the cost

of the drugs they dispense, and the ESRD provider would then be responsible for billing the patient for any co-payments.

Both of these options would be unduly burdensome, if not impossible, for hospital-based programs. Most hospitals, particularly critical access hospitals (CAHs) and other hospitals located in rural areas, are not currently licensed as commercial pharmacies and would be unable to bear the costs and administrative burden related to obtaining such a license. Further, it is unreasonable to expect hospitals, especially small rural hospitals and CAHs, to enter into contractual arrangements with many pharmacies and handle the additional administrative burden and cost related to supporting these arrangements.

Additionally, CMS proposes only a \$14 allowable compensation to account for *all* the ESRD-related drugs and biologicals that currently are paid separately under Part D but are proposed to be bundled during the transition. At an average of 154 dialysis treatments per patient annually, that amounts to a total reimbursement of \$2,156 per year. While anecdotal, one AHA member estimates the average cost of such drugs per treatment to be \$41, or \$6,314 annually. Other ESRD facilities have estimated the total annual cost of these drugs as ranging between \$5,724 and \$20,148. These levels of losses to hospitals and other ESRD facilities are unsustainable. If the system becomes too financially burdensome then we would expect that hospital-based programs would no longer offer ESRD services.

Advocacy organizations representing dialysis patients are concerned that such losses could lead physicians to avoid prescribing drugs that potentially could put the ESRD facility at a financial disadvantage. The clinical implications of such stinting could compromise the management of calcium/phosphorus bone disease, resulting in more patients needing parathyroidectomy, at a higher cost to the Medicare program. In addition, complications due to poorly controlled Ca/P metabolism could occur, resulting in increased morbidity and mortality, with attendant higher Medicare program costs. If CMS does not allow separate billing for these Part D oral drugs then we would expect that, eventually, the ESRD quality improvement program implement a set of quality measures related to these unintended consequences put into place in order to protect patients.

For these reasons, we recommend that CMS continue to pay separately for those oral drugs that do not have injectable (or other non-oral) equivalents.

BUNDLING OF DIAGNOSTIC LABORATORY TESTS

Section 1881(b)(14)(B)(iv) of the *Social Security Act* requires diagnostic laboratory tests that are furnished to individuals for the treatment of ESRD, and that currently are separately billable, be included in the ESRD PPS payment bundle. CMS proposes to define these to include all laboratory tests that are billed separately by ESRD facilities and laboratory tests that are billed separately by independent laboratories after being ordered by physicians (primarily nephrologists) who receive monthly capitation payments for treating ESRD patients.

The AHA recommends that those laboratory tests that are outside the scope of the statutory requirements for the ESRD PPS bundle of services should continue to be paid separately. We are concerned that CMS does not acknowledge the distinction that the bundled tests must be “for the treatment of ESRD.” Because patients with ESRD often also suffer from many related and unrelated co-morbid conditions, this distinction is important. The AHA recommends that CMS clearly identify a list of specific diagnostic laboratory tests directly related to patients’ ESRD that will be included in the bundle. We understand that CMS has a list of 32 laboratory tests

associated with ESRD treatments, which is included in the surveyor guidance documents for the Conditions for Coverage. CMS should review this list for the purposes of bundling diagnostic laboratory tests and pay other laboratory tests separately.

Doing so will allow the patient's nephrologist to be able to continue to provide holistic care. For example, nephrologists frequently order laboratory tests unrelated to the patient's kidney disease, such as diabetes-related tests, cholesterol lipid panels, hepatitis labs, prothrombin time/International Normalized Ratio tests, partial thromboplastin time, lupus/connective tissue disease serologies, prostate-specific antigen test, thyroid-stimulating hormone test or other endocrine tests. Additionally, endocrinologists frequently are contacted by other physicians to order tests in order to spare the patient an additional blood draw. This collaboration, which is meant to ensure comprehensive and convenient care for ESRD patients, would be discouraged if all diagnostic tests, even those unrelated to a patient's ESRD, were included in the bundled payment.

In addition, including all diagnostic tests in the ESRD PPS payment bundle will further increase out-of-pocket expenditures for ESRD patients. Currently, diagnostic laboratory testing is not subject to the 20 percent copayment that is required for other Medicare services, including ESRD services. If these tests are bundled, beneficiaries will see their out-of-pocket expenditures rise, an increase that this largely economically disadvantaged population may not be able to bear.

For all these reasons, the AHA recommends that CMS identify a list of specific diagnostic laboratory tests that will be included in the bundle. Laboratory tests included in the bundle should be limited to tests that are:

- directly related to the patient's kidney disease; and
- needed to monitor the adequacy of their treatments.

BUNDLING OF HOME DIALYSIS TRAINING SERVICES

Section 1881(b)(14)(B)(iv) of the *Social Security Act* requires that the ESRD PPS payment bundle include "other items and services" furnished to individuals for the treatment of ESRD that are currently separately billable. CMS interprets this to include the costs of self-dialysis training services for home dialysis. Therefore, it proposes to include this cost in the ESRD PPS payment bundle. The agency states that training costs under the ESRD PPS should be treated no differently than any other "overhead" expense, and that an explicit adjustment to the bundled payment amount for hemodialysis (HD) and peritoneal dialysis (PD) training expenditures is not necessary.

We disagree that home training costs are similar to other overhead expenses and recommend that CMS add a specific training adjuster to the ESRD PPS. Home training costs are incurred only for a special circumstance – the training of a home patient. Home patients represent only about 8 percent of the entire dialysis population. Additionally, a training adjustment would address the not infrequent circumstances in which a patient begins their dialysis emergently via in-center HD and then later converts to a home dialysis therapy, or circumstances in which an HD patient converts to PD after several years of in-center dialysis.

The training costs associated with preparing a dialysis patient for home treatment can be significant and must include training on procedures and problem-solving skills, concepts of self-management, emotional support, and guidance for behavioral changes. Training patients or their family members to perform the procedures involved in home dialysis includes developing motor

skills and concepts and, thus, cannot be taught exclusively through didactic methods. Thus, training also involves components such as aseptic technique, hand washing, masking, emergency measures for contamination, exit site care, dealing with complications, troubleshooting and ordering of supplies.

The AHA is concerned that including training costs in the base rate would be a disincentive to home dialysis referral. That is, including training costs in the general ESRD PPS bundle would reduce payments to home dialysis programs, thereby discouraging the use of HD and PD for patients who might benefit from these modalities. Further, if there is not a specific training adjustment for the ESRD PPS, the incentive would be to stint on training, which could pose a risk for some home dialysis patients.

Any implication that the “onset of dialysis” adjustment would address some of these initial home training costs is inaccurate. That is, while the proposed case-level adjustment for the first four months of dialysis treatments is beneficial for other purposes (e.g., the higher costs due to stabilization of the patient’s condition or administrative and labor costs associated with the patient’s being new to dialysis), it would not be beneficial in the home setting, as many home dialysis patients begin their dialysis treatments in-center before moving to home dialysis. Other patients may need re-training related to certain circumstances that could occur any time during their course of treatment. For instance, if a patient loses vascular access ability, he or she would need to move to PD as the primary treatment modality, requiring a new course of training. Also, subsequent training may be required due to a change in treatment machines. Home dialysis training frequently does not take place within the first four months of dialysis.

Training costs may arise under many different circumstances and at any time during the course of the patient’s treatment. The AHA believes that additional reimbursement for training should be allowed whenever it is medically necessary to train or re-train patients. Therefore, we recommend that CMS create a separate adjustment for home training.

LOW-VOLUME ADJUSTMENT

Section 1881(b)(14)(D)(iii) of the *Social Security Act* requires CMS to adopt an adjustment for low-volume facilities. Based on an analysis of ESRD data, CMS proposes to define low-volume facilities as those facilities that: furnished fewer than 3,000 treatments in each of the three years preceding the payment year and have not opened, closed nor received a new provider number due to a change in ownership during the three years preceding the payment year.

We are concerned that the proposed definition of low-volume facilities unduly limits the number of facilities eligible for this adjustment. Our concern revolves around the projected significant decreases in payments under the ESRD PPS for providers that primarily furnish pediatric dialysis. We believe that, to help ameliorate these losses, the low-volume threshold should be raised in order to capture more facilities treating pediatric patients. Therefore, we support increasing the threshold for the definition of a low-volume facility to 4,000 treatments per year. This would allow more providers to qualify while having only a small impact on the base rate.

We also seek clarification on which treatments would count towards the proposed threshold. Hospitals offer both inpatient and outpatient dialysis services but only the outpatient dialysis services currently are paid under the ESRD composite rate methodology. As a result, we seek clarification that the treatment threshold refers only to outpatient dialysis treatments and not to total dialysis treatments (both inpatient and outpatient) offered by providers.

PEDIATRIC ESRD PPS

CMS proposes a payment adjuster of 1.199 for the composite rate portion of the ESRD PPS for pediatric patients, which is substantially less than the current adjustment of 1.62. CMS also proposes a pediatric payment adjustment for the separately billable services component that uses two age categories (less than age 13 and ages 13-17), two co-morbidity categories (none and “one or more” co-morbidities from among the following diagnoses: HIV/AIDS, septicemia, cardiac arrest and diabetes), and dialysis modality (HD and PD) as the basis for classifying pediatric patients into one of eight groups. These are combined into a single payment model for pediatric patients that results in eight proposed payment multipliers that range from 0.963 to 1.215. CMS notes that, using calendar year 2007 claims data, the average pediatric patient-specific payment adjustment multiplier, taking into consideration case-mix and low-volume adjustments, was 1.067 compared to 1.287 for adult patients.

Pediatric ESRD patients represent only a very small portion of the overall ESRD population (about 0.6 percent) and only 0.2 percent of dialysis patients in Medicare. However, this population receives the majority of their care in hospital-based programs. Therefore, the AHA is seriously concerned about CMS’ impact analysis indicating that programs with mostly pediatric patients will see an 11.7 percent reduction in reimbursement. This is the largest reduction in reimbursement predicted by CMS for any category of provider.

Further, the proposed pediatric rates are lowest for the youngest patients (less than 13 years old), which is inconsistent with the clinical complexity, intensive staffing and specialized equipment and supplies involved in providing care for this category of pediatric patients. In these hospital-based programs, specially trained pediatric personnel provide care for a diverse group of children, from neonates to teenagers, with different behavioral, medical and social needs that affect their care. Pediatric programs also involve much more intensive staffing than is needed for adult dialysis. One hospital-based pediatric dialysis program has indicated that patients under the age of five use one nurse per dialysis station; patients ages 5-12 use one nurse for every two stations. In addition, owing to their smaller size, completing a treatment for a child takes longer than for an adult. These programs also use a wide variety of specialized equipment and supplies, such as dialyzers, blood lines and disposable supplies, which are needed to provide high-quality services to pediatric patients of many different sizes, ranging from 3 kg newborns to 90 kg teenagers. These supplies are often costly and can be obtained from only very few sources.

The temporary application of the 1.62 multiplier for pediatric dialysis in 2005 and the granting of pediatric dialysis facility exceptions was CMS’ way of recognizing the increased costs of pediatric dialysis. These exceptions worked because CMS based reimbursement on the actual costs derived from the unit’s Medicare cost reports, which reflected their higher expenses for staffing, supplies, equipment and other pediatric-specific expenses.

By contrast, the proposed reduction in the pediatric composite rate multiplier from 1.62 to 1.199 is based upon an analysis that does not appropriately reflect the true costs of providing dialysis to children. If it is finalized, it will put hospital-based programs that specialize in pediatric care at financial risk, potentially reducing access to specialized care for this vulnerable population. The statistical regression model used by CMS, while appropriate for the much larger adult ESRD population, was inappropriately applied to the small numbers of pediatric patients in the analysis. We also understand that missing or incomplete cost data from pediatric dialysis units contributed to this decrease. Most importantly, the analysis does not use data from the cost reports of pediatric dialysis units and is further distorted by the use of cost data from adult units that treat

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some children – thereby incorporating facility costs from units that do not truly represent pediatric-specific services.

In addition, the pediatric model proposed by CMS includes payment adjustment categories that are more reflective of important adult co-morbidities. In fact, very few children with ESRD would qualify for the proposed set of co-morbidity categories. The AHA believes that other co-morbidities may be more relevant to the pediatric ESRD population and should be considered. These include congenital heart disease, renal osteodystrophy, pulmonary hypoplasia, seizure disorder, developmental delay, failure to thrive and deafness.

Given the small number of pediatric patients and the issues around the quality of the data, the AHA recommends that CMS postpone the application of the ESRD PPS to pediatric patients until more accurate data can be collected and analyzed. Doing so may help ensure access to life-saving dialysis services for this small and vulnerable population. In the meantime, CMS should conduct additional analyses of pediatric dialysis units' Medicare cost reports and assess whether there are other pediatric-specific co-morbidities that should be included.

Thank you again for the opportunity to comment. If you have any questions, please contact me or Roslyne Schulman, senior associate director for policy, at (202) 626-2273 or rschulman@aha.org.

Sincerely,

Rick Pollack
Executive Vice President