



# California Dialysis Council

1904 Naomi Place • Prescott, AZ 86303 • Prescott, AZ 86303 • Phone: 928-717-1156 • Fax: 928-441-3857



## NEWS UPDATE

Last week, the Centers for Medicare and Medicaid Services (CMS) released the proposed rule for Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2010 (Proposed Rule).

Attached and below you will find a summary memorandum from Kathy Lester of Kidney Care Partners for your review and information.

Today, the Centers for Medicare and Medicaid Services (CMS) released the proposed rule for Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2010 (Proposed Rule). The Proposed Rule does not contain the proposed implementation policies for the MIPPA Payment Reforms related to bundling or the value-based purchasing program. It does, however, include the FY 2010 payment proposals and the proposed kidney disease education services program.

### I. **Payment Proposals**

CMS proposes to:

- Increase the current ESRD composite rate by 1.0 percent effective January 1, 2010, consistent with MIPPA (\$135.15 per treatment base rate);
- Decrease the drug add-on percentage in light of the higher 2010 composite rate to 15.0 percent (\$20.33 per treatment) from 15.2 percent in CY 2009; and
- Eliminate the hospital-based facility differential payment for services furnished on or after January 1, 2010, and applying the same labor share of the geographic index that is applied to renal dialysis facilities.

The Agency indicates that these modifications are self-implementing under MIPPA and provide “no substantive exercise of discretion on the part of the Secretary.”

In addition and exercising discretion, CMS proposes to:

- Update the drug add-on adjustment using a refined methodology for projecting growth in drug expenditures. Even though the Agency projects a negative update equal to -3.5 percent, it proposes to use a zero percent update to the drug add-on adjustment. CMS indicates that the statutory mandate to “annually increase” means “a positive or zero update to the drug add-on.”
  - CMS proposes to use trend analysis from drug expenditure data to update the per treatment drug add-on adjustment. For 2010, it will use 3 years of drug expenditure data based upon ASP pricing. The analysis leads to a finding of a 2.2 percent decrease in the drug expenditures.
    - For the proposed rule, CMS relied upon the final CY 2006 and CY 2007 ESRD claims data and the latest available CY 2008 ESRD facility claims updated through December 31, 2008. Because the 2008 data does not reflect an entire year, the Agency inflated the CY 2008 drug expenditures to estimate the June 30, 2009, update of the 2008 claims file. The Agency specifically did not perform a separate estimate for EPO, other top 10 drugs, and the remaining separately billed drugs, as it had done in previous years.
    - For the Final Rule, the Agency plans to use additional updated CY 2008 claims with dates of service for the same time frame, including claims received, processed, paid, and passed to the National Claims History File as of June 30, 2009.
  - To estimate per patient growth in drug expenditures, CMS proposes to remove growth in ESRD enrollment from growth in total drug expenditures, which leads to an estimate of 1.3 percent.
- Update the wage index adjustment to reflect the latest available wage data, including a revised

- budget neutrality adjustment; and
- Reduce the ESRD wage index floor from 0.7000 to 0.6500.
  - The Agency notes that it “may reduce the floor gradually until full implementation of the ESRD PPS required by [MIPPA].”
  - CMS proposes to apply the wage-index budget neutrality adjustment factor of 1.057888 to the ESRD wage index values, which apply only to the labor-related portion of the composite rate.

CMS expressly states that it is not proposing any changes to the case-mix adjustment measures for CY 2010.

## II. CKD Education Proposals

CMS provides a great deal of background about CKD and its process for considering public input. In terms of the actual rule, the Agency proposes to:

- Define “kidney disease patient education services” as face-to-face educational services provided to patients with Stage IV CKD.
- Define:
  - Physician – a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he or she performs such function or action (including a physician within the definition of the Social Security Act (SSA))
  - Qualified person – a physician, physician assistant, nurse practitioner, clinical nurse specialist, and a provider of services located in a rural area. CMS would define the later to include hospitals, critical access hospitals, skilled nursing facilities, comprehensive outpatient rehabilitation facilities, home health agencies, and hospice programs in rural area as defined by the SSA and regulation. It is not clear what the status of hospital-based facilities, which are defined at 42 U.S.C. 1395rr as being “providers of service” is under this definition. These entities could be included in the term “hospital,” but generally the Agency distinguishes these entities by using the term hospital-based facility.
    - All qualified persons must be “able to properly receive Medicare payment” under the Conditions for Medicare Payment Rules.
    - The Agency would exclude hospitals, critical access hospitals, skilled nursing facilities, comprehensive outpatient rehabilitation facilities, home health agencies, and hospice programs physically located outside of a rural area unless they are treated as being located in a rural area under current regulations.
    - The Agency would expressly exclude renal dialysis facilities.
    - The Agency does not propose specific education, experience, training, and/or certification requirements in the Proposed Rule, but is seeking comments on these areas and indicates that it may include such criteria in the Final Rule. It seeks comments about:
      - Specific education and experience regarding this topic
      - The ability to explain these areas:
        - General kidney physiology and test results that would be associated with CKD;
        - Psychological impact of the disease on the beneficiary, and impact on family, social life, work, and finances;
        - The management of comorbidities (such as cardiovascular disease, diabetes, hypertension, anemia, bone disease, and impairments in functioning) common in persons diagnosed with CKD;
        - Renal replacement therapeutic options, treatment modalities and settings, and advantages and disadvantages of each treatment option;
        - Diet, fluid restrictions, and medication usage to include side effects and informed decision-making;
        - Encouragement of patient active participation in decision-making and the ability to tailor educational needs to the individual beneficiary; and
        - Other areas of health deemed important to patients with CKD.
  - Renal dialysis facility – a unit which is approved to furnish dialysis services directly to

- ESRD patients.
    - Stage IV CKD – kidney damage with a severe decrease in GFR quantitatively defined by a GFR value of 15-29 ml/min/1.73m<sup>2</sup>, using the Modification of Diet in Renal Disease (MDRD) Study formula.
- Provide coverage to “covered beneficiaries,” which are Medicare beneficiaries with Stage IV CKD that have been referred for such services by the physician managing the beneficiary’s kidney condition.
- Establish standards of content for these services
  - The Agency indicates that patient education needs will vary by severity of disease, age, comorbidities and disabilities, language and culture, and desire to learn more about the disease and treatment options.
  - Services should include:
    - Basic information regarding CKD, how the kidneys work, what happens when the kidneys fail, and the permanence of the disease;
    - Survival rates with and without renal replacement therapy and survival rates if the patient refused treatment for their CKD;
    - The need for kidney transplantation;
    - Unbiased information about renal replacement therapy (RRT) options including advantages and disadvantages for all modalities;
    - Adequate information regarding why some RRT options were not viable for a patient;
    - How different RRT options affected the patient’s co-morbid conditions;
    - Effect of RRT choices on lifestyle, such as treatment flexibility and treatment session length;
    - Whether a patient will need assistance based on RRT modality choice and training requirements for helpers;
    - The right to refuse treatment;
    - Effects of the disease, and the subsequent treatment, on the patient’s physical appearance;
    - Patient recognition of the symptoms that would empower the patient with the knowledge to seek help;
    - Disease and treatment complications related to renal replacement therapy such as hypertension, catheter migration, temporary/permanent loss of dialysis access, and risk of infection at the access site;
    - How to control and manage consequences of complications and symptoms (for example: treatment for itchy skin or insomnia);
    - The ability to travel and organize holidays depending on RRT choice;
    - Maintenance of social relationships, activities, and commitments;
    - How the disease and RRT may affect the patient’s ability to continue working;
    - Available support services; and
    - Medication management, including side effects and risks related to non-compliance to prescribed medication regimen.
- Limit the number of sessions to six with each session defined as 60 minutes
- Permit the qualified person to tailor the design of the services to meet the needs of the beneficiary in terms of individual or group sessions
- Require that beneficiaries be assessed at the conclusion of the sessions and that program assessments be used by educators and CMS to assess the effectiveness of the services, help improve the program, and better facilitate patient understanding of the materials.
  - Qualified persons would develop outcomes assessments
  - Beneficiaries would be assessed during one of the education sessions to measure his/her knowledge about CKD and its treatment as it relates to the beneficiary’s ability to make informed health care decisions (including treatment options)
  - Assessments should be tailored to beneficiary’s reading level and language
  - CMS is seeking comment on the development and administration of outcomes

assessments including input about the following factors:

- Specific topics that should be included as part of the assessment;
  - Whether standardization of the outcomes assessment is feasible and/or should be considered;
  - The applicability of any standardized assessments that may currently be in existence;
  - The feasibility of providing both pre- and posteducation assessments; and
  - Methods for collecting assessments and disseminating best practices for KDE services.
- Establish specific payment rules for these services, including:
    - Paying only one qualified person on the same day for the same beneficiary
    - Not applying the “incident to” requirements for physician services
    - Establishing two new HCPCS codes (GXX26 (individual) and GXX27 (group)) to describe and bill for these services. They consist of one hour face-to-face kidney disease education services for an individual or group. They would be paid at the nonfacility rate. They would be cross-walked to CPT codes 97802 and 97804, respectively.
    - Reimbursing the G-codes based on the medical nutrition therapy benefit.
    - Reimbursing hospitals, critical access hospitals, skilled nursing facilities, comprehensive outpatient rehabilitation facilities, home health agencies, and hospice programs based upon the proposals in the CY 2010 hospital outpatient/ambulatory surgical center final rule.

### **III. Quality Measures**

For purposes of the Physician Quality Reporting Initiative (PQRI), CMS proposes the following measures for either claims-based reporting or registry-based reporting:

- ESRD – Influenza Immunization with Patients in ESRD
- CKD – Laboratory Testing (Calcium, Phosphorous, Intact Parathyroid Hormone (iPTH) and Lipid Profile)
- CKD – Blood Pressure Management
- CKD – Plan of Care – Elevated Hemoglobin for Patients receiving ESAs
- CKD – Influenza Immunization
- CKD – Referral for AV Fistula
- Pediatric ESRD – Influenza Immunization

CMS proposes the following measures for registry-based reporting only:

- ESRD – Plan of Care for Inadequate Hemodialysis in ESRD Patients
- ESRD – Plan of Care for Inadequate Peritoneal Dialysis
- Pediatric ESRD – Plan of Care for Inadequate Hemodialysis

CMS proposes the following measures for the 2010 CKD Measures group:

- CKD – Laboratory Testing (Calcium, Phosphorous, Intact Parathyroid Hormone (iPTH) and Lipid Profile)
- CKD – Blood Pressure Management
- CKD – Plan of Care – Elevated Hemoglobin for Patients receiving ESAs
- CKD – Influenza Immunization
- CKD – Referral for AV Fistula

### **IV. Other**

- CMS would also add ESRD to the list of telehealth eligible services.