

# Highlights of the CMS proposed rules for the prospective payment of dialysis

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The Centers for Medicare and Medicaid Services released on Sept. 15 the proposed rules by which it will administer the bundled dialysis prospective payment system starting on Jan. 1, 2011. The key aspects of the proposed rules are outlined below. Please note that these are not the final rules and are subject to change. There is a 60-day comment period, and community members have until Nov. 16 to send CMS their feedback and recommendations.

There are several fundamental issues that will need clarification and refinement before the rule is finalized, including a need to understand adequacy of funding for the four oral drugs meant to be included in the bundle, understanding the nuances and feasibility of implementing the proposed case mix adjusters, as well as further refining the quality performance metrics that will be used in the bundle.

Here are some questions you might ask about the proposed bundle. For the complete CMS document, go to <http://www.cms.hhs.gov/ESRDPayment>

## What is included in the bundled payment?

- ▶ Everything contained in the current composite rate for delivery of maintenance hemodialysis.

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- ▶ Injectable drugs and their oral equivalents
  - ▶ Erythropoietin Stimulating Agents (ESAs: Epoetin alfa, Darbepoetin alfa)
  - ▶ Iron (Iron Sucrose, NA Ferric Gluconate)
  - ▶ Vitamin D analogues (Calcitriol, Paracalcitol, Doxercalciferol)
  - ▶ Others (Levocarnitine, Alteplase, Vancomycin, Daptomycin, etc.)
- ▶ Laboratory tests ordered by a physician who receives monthly capitation payment for ESRD
- ▶ DME supplies and equipment
- ▶ Supplies and other services billed by dialysis facilities
- ▶ ESRD-specific oral drugs
  - ▶ Calcimimetics (Cinacalcet hydrochloride)
  - ▶ Oral phosphate binders (Lanthanum carbonate, Calcium acetate, Sevelamer hydrochloride, Sevelamer carbonate)

## How do I calculate the new bundled payment?

This will be done on a per-treatment basis (see diagram below).

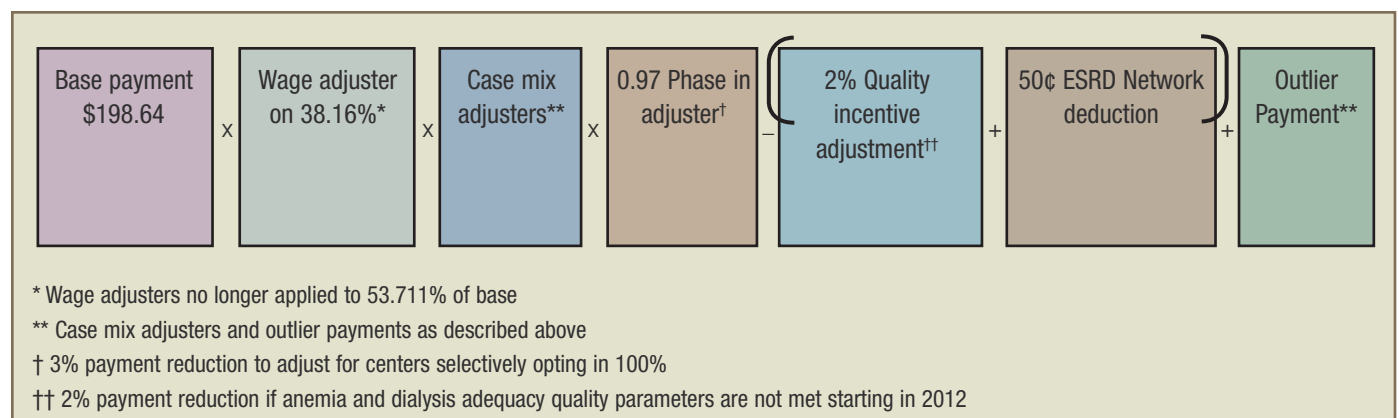
## How did CMS calculate the base payment?

The base payment was calculated based on 2007 data for the individual components of the new bundle. These were then adjusted to predicted 2011 levels: individual adjustments were made for each component, then summed. The predicted 2011 mean bundled payment was \$261.58. This number was then reduced 21.73% to adjust for “anticipated positive effects” of the impact of the case mix adjusters, or ways in which the new payment system might pay more than the current system. It was then reduced by 1% as a cost offset to pay for anticipated outlier payments, and by another 2% to meet the congressional requirement for a 2% reduction in ESRD spend in 2011, to equal \$198.64.

## What are the case mix adjusters?

There are significantly more adjusters than in the current system: 17 patient-

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Patient and facility characteristic	Base Rate Adjuster	Outlier Payment Adjuster
Age		
18-44	1.194	1.018
45-59	1.000	1.00
60-69	1.012	1.006
70-79	1.057	0.960
80+	1.076	0.923
Female	1.132	1.139
Body surface area†	1.034	1.033
BMI < 18.5	1.020	1.060
Onset of renal dialysis: < 4 mo	1.473	1.401
Alcohol/drug dependence*	1.150	1.139
Cardiac arrest*	1.032	1.098
Pericarditis in < 3 mo	1.195	1.595
HIV/AIDS*	1.316	1.220
Hepatitis B**	1.089	1.035
Specified infection in < 3 mo		
Septicemia	1.234	1.715
Bacterial/other pneumonia or OI	1.307	1.412
GI bleed in < 3	1.316	1.965
Hereditary hemolytic or sickle cell anemias**	1.226	1.179
Cancer**	1.128	1.097
Myelodysplastic syndrome**	1.084	1.257
Monoclonal gammopathy**	1.021	1.063
Facility: < 3,000 treatments each year from 04-06	1.021	0.940

\* Based on claims since 2000 or 2728 Medical Evidence Form

\*\* Based on claims since 2000

† per 0.1 m<sup>2</sup>, mean BSA=1.87

level and one facility-level. Adjusters originate from 2728 medical evidence forms or claims, require ICD-9-CM codes, and have numerous exclusions. There are different adjuster coefficients for the base rate and outlier payments.

### How does the outlier payment system work?

The outlier payment only applies to separately billables (not what is currently included in the composite rate). The \$198.64 base payment includes \$64.54 for separately billables.

After that, there is effectively a \$134.96 “donut hole” for adult patients that is not reimbursed, and anything above this amount is reimbursed at 80%. This calculation takes seven steps:

1. Calculate the patient’s case-mix adjuster for the separately billables (see chart at left).
2. Multiply the calculated case mix adjuster (A) by \$64.54 (the separately billable portion of the base payment).
3. Add \$134.96 to the case mix adjusted separately billable allowance (B).
4. Divide the summed cost of the patient’s separately billables for the month by the number of treatments that month.
5. Subtract C from D. This is the amount, after the ‘donut hole’, that you can be reimbursed for.
6. Multiply E by 0.80 (reimbursement is 80 cents on the dollar).
7. This is your total outlier payment.

### How does the phase-in work?

The CMS report calls the “phase in” period for the bundle the “transition.” Dialysis providers will have the option of opting into the new bundled payment system 100% on January 1, 2011, or phasing in over time. The phase in means that payments will be “blended” for the first three years, with 25% based on the new payment system in 2011, 50% in 2012, 75% in 2013, and 100% in 2014. By Nov. 1, 2010, all dialysis units will need to notify CMS of their choice, which will be irrevocable.

The CMS report recognizes that dialysis providers are likely to calculate their payments under the existing system and under the new bundle, and opt in or phase in based on whichever system pays more. This would end up costing CMS more money. Therefore, CMS will reduce the new bundled payment by 3% for all patients at all clinics to pay for this expected practice. In other words, payments will be presumptively reduced in anticipation of selective opt in/phase in, which makes

it in a unit's best interest to make this determination before the bundle is implemented.

### How were the oral drugs included in the bundle?

Under the bundle, ESRD facilities will be responsible for providing ESRD-related oral drugs, formerly covered under Part D, to their patients. The report states two potential issues with the inclusion of oral drugs into the bundle. First, CMS has chosen to interpret the legislation as including all drugs and biologicals formerly separately payable under Medicare Part B and Part D. The report states "We recognize that an alternative reading of the last part of clause (iii) with respect to the phrase "and any oral equivalent form of such drug or biological" could be interpreted to limit the scope of the drugs and biologicals included in the bundle to only oral versions of injectables (or other non-oral routes of administration). However, we believe that 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."

Secondly, the data available for the cost analysis related to these drugs included only the 66.73% of ESRD beneficiaries who are enrolled in Part D. CMS acknowledges this in their report by saying "[the analysis did not have information on] the cost of drugs (part D equivalent drugs) for the remaining third of ESRD beneficiaries who do not have Part D coverage. To the extent these beneficiaries have drug coverage through their employer or other insurance, we do not have access to specific usage or payment information for these medications."

### What else do I need to know?

The CMS proposed rules are 547 pages long, with many more details than can be captured in this brief synopsis. Other key issues are:

1. In-center hemodialysis and home dialysis (hemodialysis, peritoneal, nocturnal) are now paid at the same base rate
2. There will no longer be separate payment for self dialysis training (home training).
3. There are separate case mix adjusters for pediatric patients; incremental payments will be eliminated for pediatric facilities, isolated essential facilities, and atypical service intensity. There will be no incremental payment for Hawaii or Alaska.
4. Home dialysis Method II DME suppliers, laboratories and Part D plans will no longer be able to direct bill Medicare after Jan. 1, 2011, but must seek payment through a patient's ESRD facility.

### How will it work?

Here is an example on how the new bundled rate might work under the CMS proposed rules:

Mary, a 66-year-old female, is 167.64 cm in height and weighs 105 kg. She has a history of chronic Hepatitis B. She was diagnosed with ESRD in 2005 and had a diagnosis GI bleeding in January 2011. Mary receives HD at an ESRD facility which qualifies for the low volume adjustment. The ESRD area wage adjuster at Mary's unit is 1.10.

**Step 1: Adjust Mary's base payment for area wages.** (multiply base payment of \$198.64 x 38.16%, which tells us that \$75.801 of Mary's base payment is subject to wage adjustment (and the remaining \$122.839 is not).

Mary's wage adjusted base rate = (\$75.801 \* 1.10) + \$122.839 = \$206.219

**Step 2: Calculate Mary's case mix adjuster.** Mary's case-mix adjustments are for gender, BSA, Hepatitis B, and upper GI bleeding, as well as a facility low volume adjustment.

**A.** The formula for calculation of a patient's BSA is:

$$BSA = 0.007184 * \text{height}_{\text{cm}}^{.725} * \text{weight}_{\text{kg}}^{.425}$$

Mary's BSA is calculated as:

$$\begin{aligned} BSA &= 0.00718 * 167.64^{.725} * 105^{.425} \\ &= 0.007184 * 40.9896 * 7.2278 \\ &= 2.1284 \end{aligned}$$

Based on the base rate adjuster of 1.034 (see table on page 36), Mary's case-mix adjustment based on her BSA of 2.1284 would be:  $1.034^{(2.1284-1.87) / 0.1} = 1.0902$

**B.** Mary's case mix adjuster can be expressed as:

$$\text{Gender (1.132)} * \text{BSA (1.0902)} * \text{Hep B (1.089)} * \text{GI Bleed (1.316)} * \text{Low Volume Unit (1.202)} = 2.1259$$

**C.** The bundled payment rate per treatment applicable to Mary would be \$206.22 (wage adjusted based rate) \* 2.1259 (case mix adjuster) = \$438.40

**Step 3: Calculate Mary's outlier payment.** Mary's separately billable drugs, labs, etc. came to \$4,000 last month. She had 12 dialysis sessions.

**A.** Mary's case mix is calculated using the outlier payment case mix adjusters (see table on page 36):

$$\text{Gender (1.139)} * \text{BSA (1.0875)} * \text{Hep B (1.035)} * \text{GI Bleed (1.965)} * \text{Low Volume Unit (0.940)} = 2.3680$$

**B.** Multiply 2.3680 by \$64.54 (the allowance for drugs in the base rate) = \$152.831

**C.** Add \$134.96 (the "donut hole") to \$152.831 = \$287.791

**D.** Divide the \$4000 cost of Mary's separately billables by 12 treatments = \$333.333

**E.** Subtract \$287.791 from \$333.333 = \$45.542. This is amount, after the 'donut hole', that you can be reimbursed for.

**F.** Multiply E by \$45.542 by 0.80 = \$36.4336

**Step 4: Calculate Mary's total payment.** Mary's payment is \$438.40 (adjusted payment) + \$36.4336 (outlier payment) for a total of \$474.84. **N**