



TO: CDC Membership

FROM: Marc Chow and Mike Paget

DATE: August 26, 2008

RE: Overview of ESRD Reform Provisions in H.R. 6331: The Medicare Improvements for Patients and Providers Act (MIPPA)

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### **EXECUTIVE SUMMARY**

On June 24, 2008 H.R. 6331: The Medicare Improvements for Patients and Providers Act (MIPPA) passed in the House of Representatives by roll call vote of 355 Ayes, 59 Nays, and 20 Present/Not Voting.<sup>1</sup> MIPPA was moved to the Senate on June 26, 2008 but failed a cloture motion, preventing consideration of the bill in the Senate<sup>2</sup>. On July 9, 2008 MIPPA passed the Senate with the vote of 69 Ayes, 30 Nays, and 1 not voting.

President Bush vetoed H.R. 6331 MIPPA on July 15, 2008. Both the House (383-41) and Senate (70-26) overturned President Bush's veto on the same day making MIPPA law.

As expected, the legislation includes a significant package of ESRD reform provisions that among other things provides for:

- Coverage of 6 patient education sessions for Medicare beneficiaries with chronic kidney disease (CKD);<sup>3</sup> (Does not include ESRD facilities)
- Establishes a demonstration project at undetermined funding levels for pilot programs in three states starting in 2009 that would increase awareness of CKD
- Elimination of the \$4 per composite rate payment differential for hospital-based clinics;
- Increases of 1.0 percent to the treatment portion of the composite rate in 2009 and 2010 that are folded into the baseline;

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<sup>1</sup> The vote was held under a suspension of the rules to cut debate short and pass the bill, needing a two-thirds majority.

<sup>2</sup> The cloture motion totals were 58 Ayes, 40 Nays, 2 Present/Not Voting (not passing)

<sup>3</sup> (B) Such term does not include a provider of services (other than a provider of services described in subparagraph (A)(ii)) or a renal dialysis facility.

- A fully bundled payment system, with adjustments, and a voluntary phase-in starting in 2011;
- A market basket update minus 1.0 percentage point in 2012 and beyond equal to a positive inflationary adjustment between 1.9 and 2.0 percent per year; and
- A quality incentive program that allows the Secretary to make payment adjustments for quality starting in 2012.

### CHRONIC KIDNEY DISEASE INITIATIVES

The legislation establishes a demonstration project at undetermined funding levels for pilot programs in three states starting in 2009 that would increase awareness of CKD, focusing on prevention; increase screening for CKD, focusing on at-risk Medicare beneficiaries; and enhance surveillance systems to better assess CKD prevalence and incidence.

### EDUCATION PROVISIONS

The legislation authorizes coverage and payment under the physician fee schedule for six education sessions starting in 2010 designed to provide comprehensive information consistent with standards established by the Secretary regarding management of co-morbidities, including for purposes of delaying the need for dialysis; prevention of uremic complications; and options for renal replacement therapy, including in-home and in-center hemodialysis and peritoneal dialysis, and to ensure that patients have the opportunity to actively participate in the choice of therapy and that care is tailored to meet the needs of the individual.

Such sessions may be provided by qualified persons, defined to include physicians, nurse practitioners, clinical nurse specialists, providers of services located in rural areas, but not a provider of services or renal dialysis facilities.

### RENAL DIALYSIS PROVISIONS

#### Updates

1. **2009** – Update of 1.0 percent on the composite rate that is built into the base.
2. **2010** – Update of 1.0 percent on the composite rate that is built into the base.
3. **2011** – There is no update.
4. **2012 and beyond**
  - a. Specific language directs the Secretary to “annually increase” payment amounts by an ESRD market basket percentage increase factor “that reflects changes over time in the prices of an appropriate mix of goods and services included in renal dialysis services” minus 1.0 percent. (Next year ESRD community will fight the minus 1.0 percent)

- b. A market-basket update minus 1.0 percent for those who elect to go into the bundle and those who remain in the transition period. The update applies to those in the bundle on the bundled amount.
- c. To those in the transition, the update will apply to the bundled component and the composite rate component of the portion of the payment tied to the previous reimbursement system. (Market basket update minus 1.0 percent applies to the portion of the payment that is bundled (25 percent in the first year, 50 percent in the second year, and 75 percent in the third year).
- d. CMS estimates that the total updates will be approximately 1.9 percent or 2.0 percent each year.

### SITE NEUTRAL COMPOSITE RATE

Under such system, the payment rate for dialysis services furnished on or after January 1, 2009, by providers of services shall be the same as the payment rate (computed without regard to this sentence) for such services furnished by renal dialysis facilities, and in applying the geographic index under subparagraph (D) to providers of services, the labor share shall be based on the labor share otherwise applied for renal dialysis facilities.'

### Bundle Design Features

Bundle components include:

- Items and services included in the composite rate as of 12/31/10;
- Erythropoetin Stimulating Agents (ESAs) and any oral form of such agents that are furnished to individuals for the treatment of ESRD;
- Other drugs and biologicals that are furnished to individuals for the treatment of ESRD and for which payment was (before application of the bundle) made separately under this title, as well as any oral equivalent form of such drug or biological; and
- Diagnostic laboratory tests and other items and services not in the composite rate as of 12/31/10 that are furnished to individuals for the treatment of ESRD. Vaccines are expressly excluded.

### Payment

- The aggregate payment starting in 2012 will be set at 98 percent of the aggregate amount that Medicare would have paid if the bundle had not been created;
- The amount includes the treatment portion of the composite rate and the drug add-on adjustment.
- To estimate payments, the Secretary must do so using the lowest of per patient utilization rates from 2007, 2008, or 2009.

- The Secretary has discretion to establish the unit of payment at a week, month or other appropriate unit.

### Adjustments

The Secretary shall make adjustments to the bundle for:

- Case-mix, including weight, body mass index, co-morbidities, length of time on dialysis, age, race, ethnicity and other appropriate factors;
- High cost outliers due to unusual variations in the type or amount of medically necessary care, including variations in the amount of ESAs necessary for anemia management; and
- Payment adjustment that reflects the extent to which costs incurred by low-volume facilities (as defined by the Secretary) in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing such services, and for payment for renal dialysis services furnished on or after January 1, 2011, and before January 1, 2014, such payment adjustment shall not be less than 10 percent.

The Secretary has discretionary authority to make additional adjustments to the bundle<sup>4</sup>:

- For pediatric facilities;
- By a geographic index, as the Secretary determines to be appropriate; and
- For any facilities located in rural areas.

### Prohibition on Unbundling

Expressly prohibits the unbundling of oral equivalents and services once they are set in the bundle. Prevents double billing under Parts B and D.

### Limitation on Judicial Review

Limits administrative and judicial review by prohibiting challenges of determination of payment amounts; establishment of appropriate payment units; identification of renal dialysis services included in the bundled payment and its adjustments; application of the phase-in; and establishment of market basket increase factors.

### Phase-In

- The legislation establishes a one-time election opportunity for facilities to opt out of the four year phase-in transition period from 2011 to 2014.

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<sup>4</sup> Urban and rural facilities may qualify for this adjustment and it is not limited by chain association.

- The election is final and may not be rescinded. New facilities opening after 2011 would have the same option.
- The four year phase-in of bundled payment rates would move facilities into a fully bundled system in 25 percent increments starting in 2011 and concluding in 2014. Starting in 2011, the same aggregate payment of 98 percent that applies to facilities that opt out of the phase-in would also apply to phase-in participants.

### QUALITY INCENTIVE PROGRAM

- Establishes a quality program in 2011 tied to the collection of current Clinical Performance Measure data. Starting in 2012, the Secretary is authorized to make payment adjustments for quality on a payment cycle determined by the Secretary.
- Each year, facilities that do not meet performance standards established by the Secretary would have payments reduced by up to 2.0 percent. The adjustment is temporary and would not carry beyond that year. The legislation does not authorize a bonus pool or other funding mechanism for the adjustments.
- The Secretary would calculate a score for each facility for each measure; measures would be evaluated on attainment and improvement. The scores would be totaled by the Secretary taking into account how to weight the different measures. Facilities that fall below the curve would have their payments adjusted for one year, applied prospectively.
- Measures, endorsed by an independent organization (*i.e.* the National Quality Forum); or adopted at the Secretary's own discretion, shall include anemia management and dialysis adequacy. The language also directs the Secretary to adopt, to the extent feasible, measures for patient satisfaction, iron, vascular access, bone and mineral metabolism and other measures.
- Establishes public reporting of quality scores via the internet. Facilities will have an opportunity to review public information before it is released and will be required to post certificates.
- There is no administrative or judicial review of the quality program's operations, including the determination of any payment reduction; the establishment of performance standards; the specification of measures; and the methodology used to calculate performance scores for individual measures.

### OTHER PROVISIONS

#### *GAO Report on ESRD Bundling System and Quality Initiative*

Requires the Government Accountability Office to submit a report to Congress by March 1, 2013 on implementation of the bundled payment system, to include the following information:

- Changes in utilization rates for ESAs;

- The mode of administering such agents, including information on the proportion of individuals receiving such agents intravenously as compared to subcutaneously;
- An analysis of the payment adjustment authority for low volume providers, including an examination of the extent to which costs incurred by rural, low volume providers and facilities (as defined by the Secretary) in furnishing renal dialysis services exceed the costs incurred by other providers and facilities in furnishing such services, and a recommendation regarding the appropriateness of such adjustment;
- The changes, if any, in utilization rates of drugs and biologicals, and any oral equivalent or oral substitutable forms of such drugs and biologicals that have occurred after implementation of the bundled payment system; and
- Any other information or recommendations for legislative and administrative actions determined appropriate by the Comptroller General.

*Rule of Construction re Bad Debts*

Ensures that bad debt payments attributable to deductible and coinsurance on items and services not included in the basic case-mix adjusted composite rate are not increased because of the bundle, effective on the date of enactment.

Sources: Kidney Care Partners (KCP) - <http://www.kidneycarepartners.com/>  
National Renal Administrators Association (NRAA) - <http://www.nraa.org/>