

Key Facts Supporting a Revision of Medicare's ESRD Policy

Compiled by Committee on Ways and Means

Background: Dialysis patients with End Stage Renal Diseases (ESRD) suffer from anemia due to their inability to produce enough of the hormone erythropoietin, which helps the body produce red blood cells. They are treated with synthetic versions of erythropoietin, collectively referred to as erythropoietin stimulating agents (ESAs) and sold in the United States as Epogen.

Medicare's reimbursement system for Epogen encourages overdosing: Medicare pays a fixed composite rate for most dialysis services. Epogen, however, is reimbursed separately, per dose and at a higher rate than the cost of the drug to dialysis facilities. Dialysis facilities thus make a profit on every dose of EPO administered. In June 2007, the Office of Inspector General documented that while Medicare paid \$9.48 per 1000 units of Epogen in 2006, large dialysis chains were able to buy the drug at \$8.55 per 1000 units.

Epogen overdosing poses significant health risks for Medicare beneficiaries:

According to a March 2007 "black box warning" from the Food and Drug Administration (FDA), raising red blood cell levels above certain levels puts patients at great risk of blood clots, strokes, heart attacks and deaths. According to the National Institutes of Health, 50 percent of dialysis patients who receive Epogen have their red blood cell levels at or above the upper limit recommended by the FDA.

Overdosing also increases costs to beneficiaries and to taxpayers: Epogen is the single biggest drug expenditure in Medicare. In 2005, Medicare spent \$7.9 billion on dialysis and related drugs, of which \$2.0 billion was spent on Epogen. From 1991 to 2004, Medicare spending on Epogen for ESRD patients grew from \$245 million to \$2 billion - an increase of 716 percent.

A modernized payment system will better protect patients' health while providing for reinvestments in patient quality efforts: The CHAMP bill modernizes the Medicare payment system for dialysis care, following recommendations from both the Government Accountability Office and the Medicare Payment Advisory Commission (MedPAC). A "bundled" payment system will create incentives for efficient provision of care, and the CHAMP bill reinvests the bulk of those savings back into the program in the form of quality incentive payments and other patient education and quality activities. The bill also puts in place strong protections to ensure that every patient will get the Epogen they need to manage their anemia.

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A modernized system ensures appropriate patient care:

The modernized payment system includes safeguards that ensure patients can get as much Epogen as they need to manage their anemia:

- **Case Mix Adjustment** – The Secretary must adjust payments to reflect differences in patient case mix. For instance, if patients need more Epogen because of a higher body mass, then payments for those patients would be adjusted upward to account for that.
- **High-Cost Outliers** – The Secretary must include payments for high cost outliers. This provision ensures that the system is flexible enough to pay appropriately for patients that need more Epogen and can cover those higher costs.
- **Quality Reporting and Payment Incentives** – The bill creates a quality reporting and incentive payment system starting in 2008. In order to be eligible for bonuses, dialysis centers must meet a performance standard for anemia management. Additional measures of quality patient care will be added in future years.

A modernized system is sensitive to certain small, rural and other providers:

The bill provides protections for certain small providers, to ease the transition to a bundled payment system.

- **Payment Adjustments** – The Secretary can make payment adjustments for facilities that are low-volume, not part of a large chain, rural, or serve a majority of pediatric patients. If these providers face higher costs, these payments will help to cover those costs.
- **Extended Phase-In** – The bill allows for an extended phase-in for this same set of facilities (low-volume, not part of a chain, rural, or pediatric). In addition to the two years leading up to the bundled system in 2010, the Secretary can give these providers several additional years to phase-into the system.

The CHAMP Act invests in patient education and quality:

The bill includes several investments in patient education and quality efforts, which is widely endorsed by the larger kidney care community.

- **Provides Patient Education for Pre-Dialysis Patients** – Creates a new benefit to educate pre-dialysis Medicare patients on how to manage their disease and their options for future care.
- **Requires Credentialing of Dialysis Technicians** – Ensures that dialysis technicians are appropriately trained and credentialed.
- **Advances Home Dialysis** – Takes steps to advance home dialysis by commissioning a study on how Medicare can better pay for home dialysis.
- **Creates Demonstration Projects to Increase Screening and Prevention** – Creates demo projects that test ways to increase public awareness about chronic kidney disease and increase screening and prevention.