

the coordination of services, and control costs.

Beneficiaries with (ESRD) are the only group eligible for benefits under Medicare Parts A and B who are prohibited from enrolling in M+C organizations, although a beneficiary who develops ESRD after enrolling in an M+C plan may remain enrolled.

Medicare coverage of individuals with ESRD was initiated in 1972 with the goal of providing life-saving treatment to patients with chronic renal failure. Over 30 years, the number of individuals with ESRD covered by the Medicare program has grown far beyond its expected size and budget, from 7,000 patients in the first year to more than 350,000 in 2001. The ESRD population is currently growing at 7 percent per year and has doubled in the past decade.

In recent years, the ESRD population has accounted for an increasing proportion of Medicare outlays. Between 1992 and 2001, Medicare spending for outpatient dialysis services furnished by freestanding facilities increased by about 10 percent per year. Intravenous medications have also increased Medicare spending for ESRD. Spending for injectible drugs increased from \$1.3 billion in 1998 to \$2.3 billion in 2001. In 2001, Medicare expenditures for ESRD amounted to \$15 billion. The total Medicare cost for the ESRD program is projected to more than double in the next 10 years.

B. Approaches and Demonstration Project

This demonstration follows an earlier ESRD managed care demonstration. In 1993, the Congress required the Secretary to conduct an ESRD Managed Care Demonstration Project. As a result of this mandate, section 13567(b) of the Omnibus Budget Reconciliation Act (OBRA) 1993, Pub. L. 103-66, we implemented a demonstration that allowed ESRD patients to enroll in managed care settings. Participating managed care organizations were to be responsible for the total medical care of ESRD enrollees as well as provide specific case management functions and additional benefits of utility to the ESRD population.

Responding to our solicitation, three organizations joined the demonstration; Kaiser Permanente in southern California, Health Options Incorporated in Florida, and Xantus Corporation in Tennessee. Kaiser Permanente and Health Options Incorporated remained in the demonstration. Xantus discontinued demonstration operations in March 2000. The organizations that remained were a health maintenance

organization (HMO) and an HMO subsidiary, both with separate M+C contracts.

The CMS-sponsored evaluation for the project shows the demonstration approach to be operationally feasible and the quality of care was maintained or improved. Overall, the patients who were enrolled in the demonstration reported high satisfaction, improved quality of life, and positive clinical outcomes. The executive summary of this report is available at <http://cms.hhs.gov/researchers/reports/2002/execsum.pdf>.

We plan the new demonstration to foster more types of integrated care for Medicare beneficiaries with ESRD. We seek to test innovative approaches to integrating the chronic care management services for patients with ESRD with other acute care services. Responding to published research on the effectiveness of disease management methods in treating ESRD patients, the demonstration aims to test the effectiveness of disease management models to increase quality of care for ESRD patients while ensuring that this care is provided more effectively and efficiently. Disease management techniques are intended to improve patient care and save money by coordinating interventions and educating patients about managing ESRD and its comorbid conditions.

National organizations have defined approaches to disease management, in order to improve patient outcomes while containing health care costs. Disease management programs tend to target persons whose primary health problem is a specific disease, along with comorbid conditions. Interventions tend to be highly structured and emphasize the use of standard protocols and adherence to clinical guidelines.

Common features to disease management include:

- Identification of patients and matching the intervention with the need.
- Use of evidence-based practice guidelines.
- Services designed to enhance patient self-management and treatment plan adherence, including education and behavior modification programs.

Additional features essential for disease management of ESRD include:

- A central role for the nephrologist.
- Management of the many comorbid conditions of ESRD.
- Care managers with specialized knowledge of diet, medications, total health status, and personal needs of ESRD patients.

- Integrated administrative and financial arrangements among providers of services to ESRD beneficiaries.

The new demonstration includes three delivery models and two payment models, or options. The delivery models are: (1) Managed care, (2) models similar to the approach taken under the Program for All-Inclusive Care for the Elderly (PACE-type) under sections 1894 and 1934 of the Social Security Act, and (3) fee-for-service. The two payment options are (1) capitation and (2) fee-for-service bundled payment. The capitation payment option applies to both managed care and PACE-type delivery models. The fee-for-service bundled payment delivery option would apply only to the fee-for-service model. The delivery and payment models have different implementation methods that are discussed in this solicitation. For each model, the organization will take responsibility for operations such as enrollment (capitation payment model), disease management, care coordination, and financial management.

An additional component to the demonstration payment method, for both managed care and fee-for-service is an incentive payment for quality. Under the demonstration, we will reserve five percent of the payment, either capitation or bundled payment, to be available for quality incentive payments. Capitation payments would be set at 95 percent of the risk-adjusted ESRD payment rate. Ninety-five percent of the additional payment for an expanded bundle will be paid for the fee-for-service option.

For both models, goals for a demonstration organization would be to implement clinical protocols for common clinical events, as well as for objectives as anemia management and diabetes management, and for quality of care in areas such as dialysis treatment modality, consideration for transplantation, post-transplantation follow-up, management of vascular access, prevention of peritoneal catheter exit site infections, and monitoring of dialysis adequacy. A site would coordinate inpatient, outpatient, and home-based services, ensuring continuity of care for multiple chronic care problems and comorbidities, in particular, cardiovascular disease, hypertension, and diabetes.

II. Capitation Payment Model (Managed Care and PACE-Type Delivery Models)

Under the capitation payment model, organizations serving ESRD patients would receive a risk-adjusted ESRD capitation payment in order to test the effectiveness of disease management models in increasing quality of care for