The ESRD Patient Population:
- Although the ESRD population is less than 1% of the entire U.S. population, it continues to increase at a rate of 3% per year and includes people of all races, age groups, and socioeconomic standings. At the end of 2004 there were 321,539 patients being dialyzed of which 104,056 were new (incident) ESRD patients.

- ESRD patients have a variety of choices for outpatient renal replacement therapy. They have the option of dialyzing at home, in a hospital-based facility, or at an independent facility offering treatment. Some transplant centers, in addition to providing kidney transplants, offer dialysis services. In-Center hemodialysis is the predominate modality. The leading cause of renal failure in the United States is diabetes.

- Each year, the Networks compile profile data, including age, race, and gender on the ESRD population. The pediatric population is consistently the smallest, with approximately 1.1% of the ESRD incident population under 20 years old. Almost half (46.6%) of the incident patients in 2004 were between the ages of 60 and 79. These distributions have remained constant over the past five years. While the majority of dialysis patients are White, ESRD rates among Blacks and Native Americans are disproportionately high. While Blacks comprise over 12% of the national population, they make up 36.4% of the total dialysis prevalent population. In 2004, males represented over half of the ESRD incident (52.6%) and prevalent (51.9%) populations.

ESRD Network Program Statutory Authority:
- The 1972 Social Security Amendments (P.L. 92-603) extended Medicare coverage to individuals with end stage renal disease (ESRD) who require dialysis or transplantation to sustain life.

- The ESRD Network Organizations Program was established in 1978 (P.L. 95292) when Section 1881 was added to the Social Security Act authorizing the creation of ESRD Network Organizations.

- The Omnibus Budget Reconciliation Act of 1986 established at least 17 ESRD Network areas designating a Network administrative organization for each area, a Network Council of renal dialysis and transplant facilities located in the area, and a medical review board.

ESRD Network Program Funding:
- Funding for the ESRD Network Program is outside of the Agency apportionment. Per statute, the ESRD Network Program is self-funded by withholding 50 cents per patient, per dialysis treatment from the composite rate payment made to the dialysis facilities and an equivalent withholding amount for each managed care ESRD patient. This 50 cent withhold has not been increased, since 1989 when it became effective, despite associated cost increases and a significant increase in the consumer price index. The 2006 apportionment for the ESRD Network program is $24,650,000. In 2005, the average one year ESRD Network base contract was $1,045,362.

ESRD Networks at Contractors:
- CMS awards Networks firm-fixed price contracts that establish a price that is not subject to any adjustment. Contracts have been for one base year with two additional option years. In order to exercise the option, the Network must receive a satisfactory evaluation from the Project Officer and demonstrate ability to meet contract requirements and deliverables.
**ESRD Network Structure:**

- Networks are contractor organizations with governing boards that are responsible for their business and contractual obligations. They maintain Medical Review Boards with responsibility for quality improvement and oversight initiatives in their geographic region. There are some statutory requirements and strict conflict of interest guidelines applicable to both boards. Individuals with ESRD are represented on these Boards, and Networks rely upon Patient Advisory Committees to increase patient involvement. Networks may appoint other standing or ad hoc committees as needed to perform their work. *(Please reference relevant sections of the RFP and of the Social Security Act, Code of Federal Regulations, and the CMS ESRD Network Organizations Manual, as referenced in the RFP.)*

- Providers are required by regulation to participate in Network activities, but rarely has lack of active cooperation been an issue in the Network community.

- Board of Directors and Medical Review Board members of ESRD Networks are typically volunteers who contribute an enormous number of hours to the Network program. It is estimated that for the year 2004 Board of Directors/Trustees and Medical Review Boards across the 18 Network contracts donated the equivalent of just under $1 million in volunteer hours. This figure would significantly increase if other committee volunteers were included.

- Network key staff consists of specified senior-staff positions that are supported by other positions, the deployment of which varies by Network. On average each Network has 10 staff members. The average number of staff per Network has grown only slightly since 1988, despite a 154% provider increase and a 202% patient increase in the same time period.

**ESRD Statutory Responsibilities:**

- The Networks’ responsibilities include: quality oversight of the care ESRD patients receive, the collection of data to administer the national Medicare ESRD program, and the provision of technical assistance to ESRD providers and patients. Specifically, per statute, ESRD Networks are required to:
  - Encouraging the use of those treatment settings most compatible with the successful rehabilitation of the patient.
  - Encouraging the participation of patients, providers of services, and ESRD facilities in vocational rehabilitation programs.
  - Developing criteria and standards relating to the quality and appropriateness of patient care.
  - Evaluating procedures used by facilities and providers to assess the appropriateness of patient treatment type.
  - Implementing procedures for evaluating and resolving patient grievances
  - Conducting on-site reviews of facilities and providers, as necessary, utilizing standards of care established by the Network.
  - Collecting, validating and analyzing data for the preparation of reports and assuring the maintenance of a national ESRD registry.
  - Identifying facilities not meeting Network goals, assisting facilities in developing appropriate plans for correction, and reporting to the Secretary (CMS) on facilities and providers that are not providing appropriate medical care.
  - Submitting an Annual Report to the Secretary.
  - Establishing a Network Council to include dialysis and transplant facilities in your Network area and a MRB to include physicians, nurses, social workers and at least one patient.
ESRD Network Program Highlights:

- Balanced Budget Act of 1997 required CMS to develop a method for measuring and reporting the quality of renal dialysis services provided to persons covered by Medicare. Sixteen (16) clinical performance measures, based on Kidney Disease Outcomes Quality Initiative (K-DOQI) Practice Guidelines, were developed. This project involves the collection and reporting of data and provides the foundation for many of the national and local Network quality improvement activities. It provides important feedback on outcome measures to providers of ESRD services and the renal community at both the national and Network levels.

- Highlights from the 2003 CPM project illustrate the significant impact the ESRD Network program has on the quality of care for individuals with ESRD. Specifically:
  - 87% of patients received adequate hemodialysis (defined as URR > 65%) – up from 43% in 1994
  - 90% of blacks and 91% of whites received adequate hemodialysis – up from 35% and 46%, respectively in 1994
  - 80% of patients had a mean hemoglobin > 11 – up from 46% in 1994
  - 6% of blacks and 6% of whites were severely anemic (hemoglobin <10%) – down from 10% & 6% in 1994

- As further example of the impact of the ESRD Network Program, the ESRD Network vascular access project (FistulaFirst) increased the use of Arteriovenous Fistulas (AVFs) for hemodialysis access. At the onset of the project, only a third of patients were dialyzed with a fistula, compared with 60 to 90 percent in other countries. This difference in practice patterns is one of the primary reasons why the unadjusted mortality rate for ESRD patients is much higher in the U.S. (about 21 percent) than in Europe (about 16 percent) and is associated with over 5,000 unnecessary deaths each year. At the ESRD Network project initiation the national average for AVFs were 29% for incident patients and 31% for prevalent patients. With ESRD Network intervention, the current rate of AVF national average for prevalent patients is 40.2%. In 2003, the ESRD Network Fistula First project became a CMS Breakthrough Initiative with the aim of increase the AVF rate in eligible patients to 66%.

- Over the years, the CPM project has been expanded to include new indicators (such as peritoneal dialysis indicators) and changed to reflect more appropriate measures (such as measuring adequacy by Kt/V rather than URR and measuring anemia by hemoglobin rather than hematocrit). It is proposed in the draft ESRD Conditions for Coverage, that dialysis facilities will be required to supply 100% electronic data to the ESRD Networks to support the CPM project.

- In addition to National projects, each Network conducts local quality improvement initiatives that specifically address the regional and local needs to ensure that all individuals in need of dialysis receive quality care regardless of their geographic residence.

- In 2004, with an average of 3 information management specialists per Network, including individuals of all levels (e.g., Data Manager, data entry, analysts, clerks), Networks processed 101,792 Medical Evidence forms, 69,426 Death notifications, 4,829 Annual Facility Surveys, 221,881 Patient events (changes in treatment type and location), 181,395 CPM forms, and 28,650 personnel and provider changes for a total of 609,973 forms.

- ESRD Networks maintain a real-time registry of over 400,000 ESRD patients in over 4,500 dialysis centers and sustain an accuracy rate of 90% or better for all forms.