

## **E. IMPROVE THE COLLECTION, RELIABILITY, TIMELINESS, AND USE OF DATA TO MEASURE PROCESSES OF CARE AND OUTCOMES; MAINTAIN PATIENT REGISTRY; AND TO SUPPORT THE ESRD NETWORK PROGRAM**

### ➤ **Information Management**

#### **- System Architecture:**

CMS is charged with the effective administration of Medicare benefits to eligible persons with ESRD. Integral to the effective management of the ESRD program is the operation of a comprehensive data system covering medical and demographic information for the Medicare ESRD population. Medicare data, along with other ESRD program related data, are contained within the Program Renal Management and Information System (PMMIS). This system, as required by public law 95-292, section (c)(1)(A), is designed to serve the needs of the Department of Health and Human Services in support of ESRD program analysis, policy development, and epidemiological research. Renal Management Information System (REMIS) is PMMIS application that determines Medicare coverage periods for ESRD patients and serves as the primary mechanism to tracks the ESRD patient population for both Medicare and non-Medicare patients.

CMS has established uniform IT system architecture for all 18 Network Organizations. The purpose is to facilitate the collection and maintenance of information about the Medicare End Stage Renal Disease (ESRD) program, its beneficiaries, and the services provided to those beneficiaries and to monitor improvement in patient care. In order to interact with the ESRD providers in the six new England states, other ESRD Network Organizations in the country and CMS, Network of New England functions within a secure ESRD Information Technology environment (ESRD IT Environment) as defined by CMS.

CMS is moving into new ESRD disease management system is called “Consolidated Renal Operations in a Web-Enabled Network” (CROWN) the purpose of which is to collect data directly from ESRD facilities.

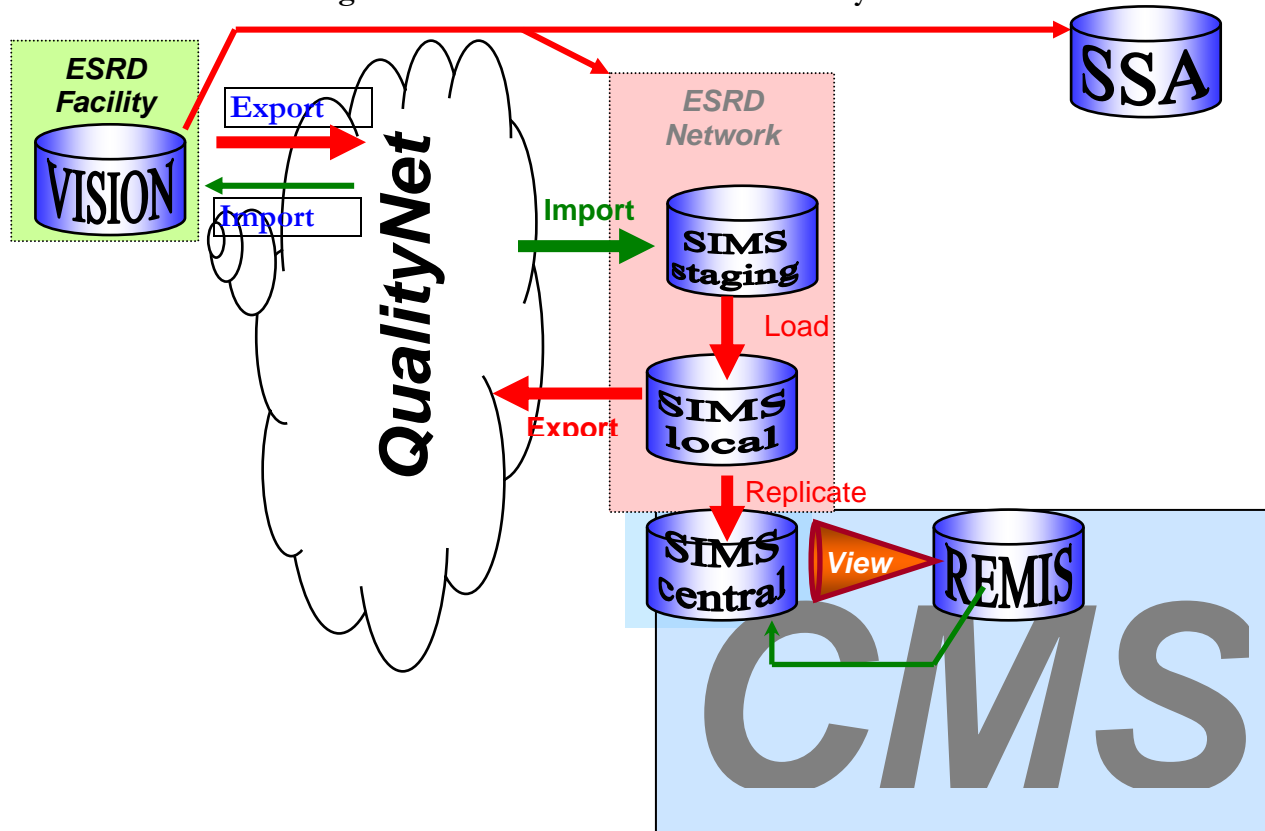
- **VISION:** The Vital Information System to Improve Outcomes in Nephrology is a program that supports electronic data entry and storage of patient information at the facility level. Using this software, facilities can encrypt the data and transmit directly to their respective Networks via a secure, Web-enabled environment called "QualityNet Exchange". This program is going to become obsolete once CROWNWeb is implemented in Feb of 2009
- **SIMS:** The ESRD Standard Information Management System is a program that allows the data entry, storage and retrieval of the patient data at Network level. It also supports the business processes of the ESRD Network Organization such as maintaining provider information and contact information. Servers located at the Network Organization function as both file server and data base server. This program is going to become obsolete once CROWNWeb is

implemented. Also the servers located at the Network Organizations will function as file servers only and not as database servers

- **Central-SIMS:** The Central ESRD Standard Information Management System is a program that holds data from all ESRD Network Organizations. Central SIMS database server is maintained at the C3 complex in Baltimore. Data from individual Network organizations SIMS server is replicated nightly to the SIMS central repository.
- **REMIS:** The Renal Management Information System which determines the Medicare coverage periods for ESRD patients and serves as the primary mechanism to store and access ESRD patient and facility information in the ESRD Program Management and Medical Information System Database. REMIS includes an operational interface to the SIMS Central Repository; and it interacts with Enrollment, Medicare entitlement, National Medicare claims and Social Security Administration databases. REMIS is maintained at the C3 complex in Baltimore.
- **QualityNet Exchange:** Qnet Exchange provides an interactive secure web site that allows ESRD Facilities to transmit electronic patient data to their corresponding ESRD Network. ESRD Networks use the QualityNet Exchange to transmit, i.e., "seed", patient databases to ESRD Facilities, receive electronic patient data files from ESRD Facilities, and provide feedback to ESRD Facilities regarding data transmission. The QualityNet Exchange is responsible for routing files to/from the appropriate ESRD Facilities and Networks, ensuring each ESRD Facility and Network access only their data files. QualityNet Exchange is maintained by IFMC.
- **REMEDY** is inventory management system. Networks are required to purchase and use CMS approved software and hardware for conducting their business under CROWN environment using REMEDY and maintain inventory in it.
- **National Help Desk for ESRD CROWN System:** In order to support the use of VISION, SIMS, REMIS, Remedy, Internet, Email, computer infrastructure and QualityNet Exchange there is a need for a system to provide support. ESRD facilities and networks can call the help desk 8AM to 8PM to request help and for troubleshooting. These calls are processed by Computer Sciences Corporation for issues related to SIMS, VISION and REMIS applications, Buccaneer Computers Systems and Services Incorporated for hardware, email and Internet problems, by Quality Net exchange contractor (IFMC) for issues related to Quality net and REMEDY or by the Network of New England for Network # 1 facilities depending on the type of assistance needed. With the implementation of CROWNWeb the help desk will include support for CROWNWeb application as well as support for deployment and training for CROWNWeb. Deployment of CROWNWeb includes identifying a security administrator (SA) at each facility and providing the SA with access to QualityNet Identity Provisioning System (QIPS). Helpdesk also covers supports for the QIPS program.
- **Individual Network's IT Infrastructure:** These include but not limited to file servers and database servers (in case of Network of New England they both are one and same), workstations, commercial off the shelf (COTS) products, custom written software, webEx conferencing capabilities and secure Email and Internet services. All workstations contain standard image that complies with CMS security standards. All Network #1 employees using CMS approved workstations must complete QualityNet System Security Awareness Training.

Employees are trained on policies regarding code of ethics, confidentiality, rules of behavior, destruction of sensitive information, Internet and email usage. New employees must pass the training before gaining access to a CMS workstation and current employees must take and pass the training annually. Network Organizations are required to develop policies and procedures, in accordance with CMS requirements, to maintain the security and confidentiality of the data and use reasonable safe guards to protect it.

Figure 27: ESRD Data Flow in Crown System



#### – Patient Registry

The Network of New England collects, maintains, validates and analyzes the end stage renal disease (ESRD) patient data for individuals receiving ESRD services in the six New England states as mandated by the Social Security Act. The purpose of maintaining the patient registry is to ensure a patient's renal medical condition has reached end stage and to register all ESRD patients (Medicare and Non-Medicare) with the National Renal Registry as mandated by law. The first step in the process of registering a patient as ESRD is to submit a Medical Evidence form (CMS Form 2728-U4) by the dialysis or transplant facility. Network 1 staff enters the information on the 2728 form in to SIMS database using SIMS software program. Providers also submit a death notification form (CMS Form 2746) when a patient dies.

– **Updating Status of Medicare ESRD Beneficiaries:**

The Network staff tracks change of treatment provider and modality for each patient through reporting of events. Each provider submits event changes through a reporting tool called Monthly Patient Activity Report (MPAR) on a monthly basis. The events for change of treatment provider can be transfer-in, transfer-out or transplant and events of different treatment setting can a change to home dialysis from incenter hemodialysis. Annually, all ESRD providers (166 dialysis and 15 transplant centers for 2008) submit the year-end CMS Facility Survey Form (CMS 2744) reconciling all the patients at the facility as of December 31<sup>st</sup>.

– **Verification of Patient Data:**

The patient data is also verified through the process of accretions and notifications that are received from CMS. Accretions are ESRD patients that do not exist in SIMS database but are known to CMS through other related data systems. Notifications are mismatches in data elements in SIMS database for existing patients with other renal related data systems including Social Security Administration database. These mismatches could be due to reporting or data entry errors in different data systems. Network staff verify accretions and notifications with the facilities and either rejects or accepts the changes to data elements. REMIS alerts are discrepancies in the patient entitlement status. When CMS is unable to resolve a patient's status a request for clarification is sent to the Network staff to verify and correct these discrepancies. Data processing, validation, compliance monitoring and data verification are daily activities conducted by data staff. As of December 31, 2008, the New England region has prevalent patient population of 11,558. During 2008, Network #1 staff processed 4,106 Medical Evidence Forms, 2,826 Death notification Forms and Monthly Activity forms that represent 14,290 events.

– **Provider and Personnel Database**

The Network of New England maintains a provider database in its SIMS database. This information is updated when Departments of Public Health of various states inform the Network Organization of certification of a new facility ownership updates, or changes in services provided for existing facilities. Providers update personnel information on an annual basis.

The current and active provider information maintained in SIMS database is uploaded to maintain demographic information on providers listed on CMS's Dialysis Facility Compare (DFC) website <http://www.medicare.gov/Dialysis>. Information on facility address, phone and fax numbers, type of services provided, number of dialysis stations, etc. can be obtained for every facility in the geographic area of New England using Dialysis Facility Compare. This information is updated on a quarterly basis from SIMS provider database. Dialysis Facility Compare also allows comparison of the quality measures of dialysis facilities in every state. The quality measures such as adequacy of the treatment, anemia management and patient survival on the Dialysis Facility Compare are obtained from United States Renal Data Systems (USRDS) based on the billing records of the Medicare patients.

The Network Organization also maintains facility personnel information in its SIMS database. This information is used to communicate with the facility personnel as well as to distribute educational

materials. The Network staff communicates with facilities via regular mail and also uses email and fax to broadcast important and emergency information.

### ➤ **Quality Assurance of Patient Data**

The primary function of the Network of New England is to identify opportunities to improve health care related to the quality and appropriateness of ESRD patient care. The basis for objective and informed decisions about quality of patient care is reliable patient data. Network #1 not only obtains and maintains the ESRD patient information as described above but also verifies the data for completeness and accuracy. The completeness and accuracy of the data in the SIMS database is maintained due to the cooperation and dialogue between the Network data staff and the staff of each dialysis and transplant program in New England. Network of New England provides reports such as missing data-element or reject reports and missing forms reports to facilities. This process allows the facilities to update missing data and submit missing forms. Biannually, Network of New England provides required forms submission compliance reports to the facilities. Facilities are expected to maintain more than 90% compliance in forms submission. Table N shows the comparative number of facilities that met CMS compliance goal semiannually and annually. Due to internal quality improvement efforts, the number of providers below 90% has dropped from 2006 to 2008.

**Table N: Facility Forms Submission Compliance 2006 - 2008**

	Annual compliance below 90%		
	Jan – Dec		
	2006	2007	2008
# Facilities	107	39	30

In 1994, the United Network for Organ Sharing (UNOS) and the Centers for Medicare & Medicaid Services developed a process of reporting transplantation events to the National Renal Registry. The Network of New England receives kidney transplant updates from UNOS. The data received from UNOS is compared and validated with the data submitted by transplant facilities in the New England states. Transplant data validation and compliance reporting is still the responsibility of the Network, as is monitoring the appropriateness of the transplantation. On a quarterly basis the Network notifies the transplant centers of delinquent registration and follow up forms that need to be submitted to UNOS. In 2008, very seldom were transplant centers delinquent with its transplant related forms.

### – **VISION and Quality Net Exchange**

In 2003, VISION was introduced to allow eligible ESRD providers to electronically enter and transfer data to Network Organizations. Provisions were given for the Large Dialysis Organizations (FMC, DaVita, DCI, RRI and RCG) to submit data electronically to CMS. Only independent or hospital-owned ESRD providers can use this software if it meets specific IT requirements. The data are transmitted from facilities to the Network using Quality Net Exchange, a secure Internet transport method. This method of transfer of information is safe and protected as it involves passwords and encryption of the data. Network of New England is responsible to register users for the facilities, manage those users and train them in the use of Quality Net Exchange along with

VISION. Network is also responsible for technical assistance if facilities encounter any problems in using VISION or transferring data via Qnet Exchange.

#### – **VISION Generated 2728 Forms Validation**

When Network #1 receives VISION data electronically, it is directly imported into the SIMS database. However, Network staff will continue to validate the data received for appropriateness of initiation of ESRD, quality of care and reconcile patient events. The 2728 forms imported via VISION cannot have physician or patient's signature. The facilities are required to generate the form after it is completed in VISION and obtain both patient's and physician's signature in blue ink. The person submitting the form via VISION only verifies the signatures and enters the dates of the signatures in VISION. This necessitates the validation of the forms submitted using VISION for signatures of both physician and patient and the dates of those signatures. In order to perform validation of forms, 3% of the total forms imported were randomly selected. The names of the patients on the selected forms were sent to the appropriate provider that submitted the forms. The facilities were then asked to send the VISION generated forms signed by physician and patient.

The following are the results of the VISION imported forms verification process:

a.	Number of forms imported from VISION for 2008.	437
b.	Total number of forms requested from VISION facilities.	15
c.	Total number of forms received from VISION facilities.	15
d.	Total percent of forms validated from VISION facilities.	100%

#### ➤ **Information Management Support for Quality Management Reports**

To reduce the reporting burden on the facilities, CMS has worked with Large Dialysis Organizations (LDO's) to obtain clinical data electronically. At the request of CMS, LDO's provide data electronically to the CMS contractor, Computer Sciences Corporation (CSC). CSC screens the data by parameters set by the CPM committee, lab data committee or vascular access committee depending on the type of the data. It then loads the data in to SIMS database. The Network Organizations are thus expected to collect the above clinical data from only independent and hospital owned facilities that are not associated with LDO's.

**Clinical Performance Measures:** In order to use SIMS database to store clinical data for quality oversight, provisions were made in SIMS database to enter the Clinical Performance Measures (CPM) forms. Every year 5% of the random sample of patients is selected from the national patient population as of 12/31 and the patient information from SIMS is populated on the CPM form. These forms are sent to providers for completion and when returned to the Network Organizations, the data are entered in to SIMS database. National data collected in such a way is used to generate Clinical Performance Measures reports that are sent to providers once a year. This report compares all Network Organizations by specified CPM (See QI section for details) and provides Network and National level profiles. However this project does not provide facility level data to conduct quality improvement projects at facility level. For the year 2008 CPM data collection was suspended due to proposed implementation of CROWNWeb in Feb of 2009.

**Lab Data Collection:** In order to conduct oversight on the quality measures at the facility level, Network Organizations obtain, on a voluntary basis, lab data annually on 100% of the patients. These data are not part of the SIMS database. The voluntary patient specific data is entered in to a standard data file. Large dialysis organizations submit data directly to CMS contractor. ESRD Network #11 coordinates analysis of lab data that is collected from the facilities by network organizations for independent providers and submitted by the dialysis organizations in order to generate national, Network specific and facility specific quality reports. Feedback reports are sent to facilities annually. Network also provides trend data to independent providers called Clinical Performance Measures reports. These data are used to conduct the quality over sight of the facilities.

**Vascular Access:** As part of the National Vascular Access Improvement Initiative, aggregate data on access are collected from the independent and hospital based facilities on monthly basis by Network Organizations on the placement and use of arterio-venous fistulas and catheters. Facilities associated with large dialysis organizations do not submit data directly to Network Organizations but the data are provided to CSC (CMS contractor). Data collected from independent providers and large dialysis organizations are stored in the SIMS database. The vascular access data are used by CMS to create vascular access dashboard that compares AVF rates by Network Organizations. The dashboard is used to evaluate the performance of Network Organizations in improving AV fistulas in dialysis patients. These data are also used to trend providers on monthly basis. Vascular access reports by provider are sent to providers once every quarter. These feedback reports are aggregated data at the facility level. Based on the data fields related to vascular access on 2728 form, Network of New England generates reports specific to nephrologists' and provider. These report cards are also sent to providers on a half yearly and yearly basis.

### ➤ **Information Management Support for Administrative Reports**

SIMS has the capability to generate reports that allow the Network Organizations to conduct its functions. All data tables in this annual report are generated from SIMS. This function gives standardized information across all Networks Organizations.

In 2003, CMS made the decision to make SIMS the authoritative source for provider forms 2728, 2746, 2744, and patient event/status information. Due to this change, the accuracy and completeness of the patient data and patient status in SIMS is of great importance. The SIMS database is also quickly becoming a single source database for Network Organizations to perform all of its quality of care and over sight activities. The 2744 form contains information on facility staffing and vocational rehabilitation. This information is now part of the SIMS database. In 2004, CMS added the capability of entering the Clinical Performance Measures in to SIMS database. The vascular access data collection is also integrated in to SIMS database in 2004. It is the intention of CMS to incorporate capabilities for entering patient specific clinical data to perform quality improvement and oversight activities by comparing facilities. This new system will help CMS run reports and compare all the facilities in the country. CROWN Web will contain clinical modules.

## ➤ **Information Management Support for Patient Services**

SIMS database also stores the information on contacts received by the Network Organizations. These contacts are classified as grievances, complaints, facility concerns, facility enquiries and data management related contacts. There are different areas of concern under these different classes of contacts that are also captured in SIMS database. Reports can be generated on the contacts received and are used for quality improvement purposes.

## ➤ **Information Management Support for Provider Education**

### – **Statistical Summary Booklet**

Annually, the Network of New England publishes the statistical highlights by state that are distributed to the providers and is posted on the Network of New England's website <http://www.networkofnewengland.org/>. This report has comparative data from 1989. It illustrates trends in incident and prevalent patients and analysis of the patient characteristics. Statistical analysis such as crude mortality rates, trends in transplantations are included in the statistical summary.

### – **Facility Directory**

Once a year, the Network of New England prepares a facility directory that contains information on all the facilities in the New England area. This booklet contains information such as the address, telephone and fax numbers of the facility, key staff positions, and types of services provided. This is distributed to all the providers in New England states. This has been a useful tool for providers and hospitals in the placement of patients and in patient referrals.

### – **Information for New Facility / Data Packet:**

Network #1 provides a new facility packet, which contains information on regulations, QI information and materials as well as information on how to submit required data to the Network organization. In 2007, a data packet was developed that accompanies the new facility packet. This data packet contained several educational tools for providers to complete and submit required data to Network #1 as well as CMS manual "Instruction Manual for Renal Providers" that was updated by Network of New England.

### – **Information for New Patient Packets**

For the past four years, CMS, via Network Coordinating Center, mailed informational materials to all new ESRD patients. The addresses were obtained from Network Organization's SIMS database on a monthly basis. Any mailings that are returned are held in a central place until each Network Organization investigates the reasons as to why the materials did not reach the intended party. Network #1 monitors the monthly return rate as part of its internal quality control activities. Network #1 consistently stayed below a 10% return rate this past year.

- **Technical Assistance:**

Technical assistance provided by the information management consists of data processing related request from providers. These are data related, information, request for technical assistance related to data, request for forms such as 2728 and data requests such as patient count by zip code.

- **Data Requests:**

Throughout the year, the Network #1 staff responds to written data requests for special data analysis from facility personnel, researchers, corporations, managed care organizations, State Health Departments and health care consultants. Data that are released comply with CMS contractual requirements and HIPAA regulations to protect patient and facility confidentiality.

- **Disaster Preparedness and Business Continuity and Contingency Plan (BCCP)**

In order to prepare for disasters such as hurricane Katrina, CMS required each Network Organization to outline its disaster preparedness plans in the form of a document called Business Continuity and Contingency Plan as required by CMS. This document requires the Network Organization to outline the roles and responsibilities of its staff, CMS and the CMS contractors who are in-charge of maintaining Network IT infrastructure. The plan allows for the prevention, assessment, and recovery operations in case of disasters and contains contact information. A copy of the plan and a set of back up data tapes are kept off site. This plan also allows for maintenance of Network #1 oversight as well as provision for assistance to dialysis facilities during disasters.

- **Development and Testing of ESRD Data and Data Systems**

Network of New England staff reviewed and provided comments on the ESRD Kidney Data Dictionary definitions, constraints, and valid values, on the business requirements and file specifications for the batch transmission of ESRD data. Network staff also participated in testing ESRD CROWNWeb.

- **Task Groups and Committees**

The Network #1 staff participates in task groups, committees, and beta testing of software before release. These committees meet by conference calls on a regular basis. The intent is to engage the end users of the software in the establishment of the business rules that are used in the software development as well as standardize the policies across 18 Network Organizations. One of the major quality improvement activities conducted in the past few years, the National Vascular Access Improvement Initiative, has several committees in which the Network staff is involved. Network #1 staff is also involved in the core data set project that consolidates all data elements required to conduct the program functions and provides clear definitions for each data element. One of the new major initiatives, CROWNWeb, the Network #1 staff are involved in many committees to create a Web based ESRD data system. In 2008 Network #1 was involved in planning committee for 2009 CMS meeting, CROWNWeb Gap Analysis, Attribution task group as well as several CROWNWeb related committees.

## – CROWNWeb

VISION, Network SIMS data bases and Central SIMS database will be replaced with CROWNWeb, a web based application. CROWNWeb will be implemented in a phased manner. The first phase will be rolled out in Feb of 2009 that consists of four Network organizations and eight dialysis facilities. When CROWNWeb is fully implemented, using CROWNWeb for data entry will be a requirement for ESRD facilities under the conditions for coverage.

**Network Staff Training:** In Preparation for full implementation of CROWNWeb in February 2009, Network of New England along with all other Network Organizations has received training in using CROWNWeb application.

**Facility Staff Training:** Network also participated in facility training conducted by the CMS contractor for Quality Infrastructure Support, Network 7.

**Registering Users to Access CROWNWeb Application:** Network registered facility users as security administrators. The security administrators not only can access CROWNWeb application but also can create other users at their facility. Creating two users as security administrators at each facility was Network's responsibility as well as making changes when there are changes to these users such as when the users leave the facility.

**Communication to Facilities Regarding CROWNWeb Implementation:** Network of New England communicated the information regarding CROWNWeb implementation to the facilities via Email and Fax broadcast. Network also presented the CROWNWeb information as a booth at the Network annual meeting in October 2008.

**Testing of CROWNWeb Application:** Network of New England also participated in several alpha testing's of CROWNWeb application.

**Enrolling Providers for Testing CROWNWeb Application:** Network of New England also enrolled providers to test the CROWNWeb application.

**Preparation of SIMS Database for Data Import into CROWNWeb:** In preparation for CROWNWeb implementation in 2009, data in SIMS is cleaned up so that the incompatibility between SIMS and CROWNWeb is reduced when data is imported into CROWNWeb. This includes running data clean up utilities, obtaining data from facilities on weekly basis instead of monthly basis, conducting a mock facility survey to balance patient data by provider as of December 2008 and running all the reports required for the facilities.

## ➤ Achieving Network #1 Goals in Data Management

Network #1 successfully met all data related deliverables to CMS for data processing, validation and CMS required forms submission compliance monitoring. Network #1 continues to support local providers using VISION. Network #1 also achieved its goals in providing support to develop data systems especially CROWNWeb in 2008 by participating in several alpha testing's providing gap analysis and providing suggestions for work around.