SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

Data Analysis for the Quality, Safety & Oversight of the End Stage Renal Disease (ESRD), Transplant, and Organ Procurement Organization (OPO) Programs

STATEMENT OF WORK

I. Scope

The contractor will provide detailed data reports about End Stage Renal Disease (ESRD) facilities (commonly referred to as dialysis facilities), Transplant Programs, and Organ Procurement Organizations (OPOs) in formats that are useful to the Centers for Medicare & Medicaid Services (CMS), states, health care providers, and the general public. These reports will include summaries of patient characteristics, facility characteristics, patient outcomes, and facility practice patterns. These reports will include comparative state, network, regional, and national statistics as appropriate. These reports will be used by CMS in overseeing the quality and safety of the ESRD, Transplant and OPO Programs.

For the Dialysis Facility Reports (DFRs), the contractor will use data from a variety of sources to create the summary reports to be used to provide Federal, state and facility oversight of dialysis facilities. Data from all available sources, including the CMS Central Data Repository (CDR), claims forms, eligibility forms, clinical data sources, facility inventories, death forms, and survey and certification forms will be updated, edited, validated, and utilized by the contractor to create a series of reports that will assist CMS, states, and other entities in monitoring the care provided by ESRD facilities. These reports will be risk-adjusted and facility, state, regional, and corporate-specific for each fiscal year. The reports shall include a rank-ordered Outcomes List of ESRD facilities for each state . The Outcomes Lists will be constructed from a composite of data elements that most validly and reliably identify facilities with potential problems.

The contractor will routinely revise the DFRs to ensure they are 1) aligned with the ESRD Survey process, 2) provide development of data sources and data tools to allow state surveyors convenient and timely access to more current dialysis facility quality outcomes, 3) use state surveyor and other DFR user feedback to determine the need for revisions. The contractor will provide guidance on using advanced technologies and incorporate plans to integrate emerging technologies associated with Electronic Health Records (EHRs).

The contractor will prepare Transplant Program reports and OPO reports. The data for these reports will be obtained from the Scientific Registry of Transplant Recipients (SRTR) of the Health Resources and Services Agency (HRSA),

the Centers for Disease Control and Prevention (CDC), and Multiple Cause of Death (MCOD) databases. This data will be used in the calculation of annual OPO performance measure scores as required by the CMS regulations at 42 CFR §486.318.

The contractor shall provide the above-referenced reports during the contract base year and throughout all option years, in accordance with the Schedule of Deliverables (SOD) and as directed by the COR.

A. Background

1. ***Background for ESRD Dialysis Facility Reports:***

In 1997, Congress passed the BBA. Section 4558(b) of the BBA, Renal Dialysis Related Services, Implementation of Quality Standards, directs the Secretary of Health and Human Services to develop and implement a method to measure and report the quality of renal dialysis services provided under the Medicare program under title XVIII of the Social Security Act.

CMS was assigned responsibility for the development and implementation of the requirements of §4558(b) of the BBA. To do so, CMS developed facility, state, and regional specific Dialysis Facility Reports that are used by CMS and the states to focus their review of ESRD facilities on improving both the quality of care in dialysis facilities and enhancing the monitoring of health and safety aspects of that care.

Since 2008, there have been two significant changes in CMS ESRD oversight and reimbursement regulations that are aimed at advancing the quality of dialysis care. First, in 2008, CMS implemented the ESRD Conditions for Coverage (CfCs). These regulations significantly enhance the patient safety and governance requirements for dialysis facilities. For example, the 2008 CfCs require each ESRD facility to develop and maintain an ongoing, data-driven Quality Assessment and Performance Improvement (QAPI) program that monitors its operations and services and measures and tracks specific quality indicators. Second, the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008 changed the Medicare reimbursement system for ESRD services. The new reimbursement system, implemented in 2011, required CMS to establish a new monitoring system for ESRD facilities that includes ongoing monitoring of specific measures and values and ties each facility's payment to these facility and patient-specific measures.

Promoting high-quality care in dialysis facilities requires a data-driven ESRD survey process, which ensures that minimal standards for health and safety are met by dialysis providers. Reliable facility, state, and regional-specific reports, which contain data elements, are the most relevant and useful for evaluating the quality of care and predicting non-compliance with health and safety standards.

The number of patients receiving dialysis treatment for ESRD continues to climb in the United States, with numbers reaching over 487,000 patients as of December 31, 2019. The social and financial cost of treating these patients is significant. Most of the financial cost for treatment of ESRD is reimbursed through CMS, which has also been charged with oversight and assurance of the quality of care provided to ESRD patients. Variation has been reported in both patient outcomes and in quality measures of care for the providers of ESRD care, and concerns have been raised about the quality of care at some ESRD facilities by patients, state surveyors, and other reports and studies.

CMS has engaged the services of a contractor to perform analyses of data pertaining to the services provided by ESRD facilities. The reports produced for this project will include direct measures of the quality of dialysis services and information about how the quality of dialysis services influence the outcomes of patients that use these services The contractor will also provide statistical summaries that will directly inform quality improvement and assurance efforts; and, a summary statistical outcome-oriented prediction model will be computed each year to help identify those facilities that are at higher risk for health and safety problems. These statistical summaries will be classified as Outcomes Lists.

2. *Background for the Transplant Programs:*

The CMS Conditions of Participation (CoPs) for Transplant Programs are located at 42 CFR §482.72 through §482.104. These regulations require CMS to provide oversight for transplant programs.

Data reports and technical assistance are required to follow the requirements set forth in the Transplant CoPs. The contractor will provide technical assistance and support to CMS in support of the data and reports provided to CMS to assist with oversight of transplant programs.

3. *Background for the Organ Procurement Organizations Program*:

The CfCs for OPOs are located at 42 CFR §486.301 through §486.360. These regulations require CMS to provide oversight for OPOs.

The contractor will provide data needed by CMS for providing oversight of OPOs. The base data will be gathered from multiple sources that the contractor shall have access to and follow the previous formats described in the SOW to create detailed reports and analyses to oversee the OPOs.

The contractor will also provide technical assistance to CMS in support of the data and reports provided for oversight of the OPOs. The data reports and technical assistance provided must meet the requirements set forth in the CfCs for OPOs.

B. Purpose

The purpose of this project is to promote high quality care for dialysis and transplant patients, and OPOs through the analysis and use of data from reliable sources and advanced survey technologies. Specific purposes for each task are as follows:

1. ***Dialysis Facility Reports:***

   To develop and distribute detailed dialysis facility data reports for use by CMS, State Survey Agencies (SAs), dialysis facility providers, and the public in determining the quality of dialysis care delivery.

2. ***Data Reports and Technical Assistance for Transplant Programs*:**

   To provide data that will allow CMS to oversee the safety, quality, performance, and outcomes of transplant programs through surveillance and certification.

3. ***Data Reports and Technical Assistance for Organ Procurement Organizations (OPOs):***

   To provide the data that will allow CMS to oversee the safety, quality, performance, and outcomes of OPOs through surveillance and certification.

C. Quality Assurance

1. *Contractor Quality Requirements*

The contractor shall be responsible to have in place an internal quality control system, to ensure quality in all products, the work it produces and performance under this contract. The contractor shall demonstrate its internal quality assurance program such that each product delivered meets or exceeds industry standards.

2. *Government Quality Assurance*

CMS shall review the work in progress with the contractor on a monthly basis via teleconference calls and reports. The dates and times of the progress meetings shall be established mutually between the COR and the contractor. Discussion will include a status update on work in progress and identification of areas where work needs to be adjusted.

The CMS program staff/Government task leaders will review draft and final reports described in the Statement of Work and the Schedule of Deliverables and provide comments and guidance to the contractor upon receipt.

II. Requirements

A. General Requirements

1. This is a firm fixed price contract.

2. Independently, and not as an agent of the Government, the contractor shall furnish all of the necessary services, qualified personnel, materials, equipment, supplies, facilities and support not otherwise provided by the Government, as needed to perform the requirements of the Statement of Work.

3. No additional Government property shall be provided to the contractor for this effort.

4. All work under this procurement shall be performed for CMS under the general guidance and monitoring of the CMS COR. All work is subject to the COR's approval. Specialized Government Task Leaders may be assigned to specific tasks within this contract.

5. The contractor shall set up and facilitate conference calls as needed. Detailed minutes of each conference call shall be compiled and distributed to the COR for review.

6. The contractor shall provide all major deliverables to the COR in media compatible with government word processing software, e.g., Microsoft Word or another format agreed upon in conjunction with the COR.

7. The contractor shall perform validation or ensure the data to be used has been properly validated before performing the required analytical, statistical and other analyses and preparing any required and ad hoc reports.

8. Data reports shall be developed utilizing the most reliable available data and effective statistical and analytical methodologies to create facility-specific profiles for ESRD dialysis facilities, Transplant Programs, and Organ Procurement Organizations. The contractor shall keep abreast of the data environment for these three provider types and to update and improve upon these reports, as necessary. As needed, the contractor expeditiously responds to inquiries about data integrity and computations under its purview. The contractor provides timely information regarding issues regarding data integrity and access that potentially impact deliverables.

9. The final reports shall be delivered in two formats: (1) electronic, in a format compatible with government word-processing software (for text) or government spreadsheet software (for tables); and (2) electronic, in HTML (Hypertext Markup Language) format for posting on the CMS Web site.

10. The contractor will post the requested ESRD deliverables to a CMS-approved contractor website or post them to a CMS-government website at the descretion of the COR.

11. Data tables must be in HTML format as well. Charts and graphics must be in gif format. Data files (spreadsheets, databases) must be made available as comma-delimited or flat files, with proprietary file formats (Excel, Access) available as alternative downloads.

The COR may require a Portable Document Format (.PDF) version of the entire deliverable in addition to the above. Detailed guidelines for the creation of Internet-ready content are available on CMS's Web site at www.cms.gov.

11. The contractor shall ensure that the database and all electronic and information technology deliverables to CMS, including reports, user's manuals, drafts and final copies shall be compliant with Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d). This law helps to ensure that Federal employees and members of the public with disabilities have access to data and information. When applicable, the Section 508 standards in Section VII: Section 508 Requirements apply to the content, communications material, and all deliverables identified in the SOW.

B. Tasks to be Performed

TASK 1: Project Management for All Tasks /Administrative

1.1. ***Contract Kick-Off Meeting***

A technical kick-off meeting between the CMS COR and the contractor project manager and one other key personnel (project manager's back-up contact person) will occur within two weeks of contract base and each option year award.

1.2. ***Project Management Plan***

The contractor shall submit a project management plan (PMP) that:

- Includes all tasks and aspects of the work to be performed under the contract.
- Describes how the required data will be obtained, validated and the reports prepared.
- States how the reports adhere to the parameters set forth in the SOW.
- Delineates all subtasks, taking into account the relationship of this project with other relevant renal data projects that are being undertaken by the Agency.

Deliverable: Project Management Plan
Due Date: October 31st of each contract year

1.3: ***Monthly Progress Reports***

The contractor shall submit monthly progress reports, which meet the

following requirements:

- The monthly progress reports, at a minimum, shall:
  - Include information about the requirements for all tasks included in the SOW.
  - Describe the activities conducted during the prior month, to complete the tasks outlined in the project management plan.
  - Summarize work accomplished during the previous month.
  - Describe schedule performance broken down by tasks, using the management plan as a reference point and explaining whether any variance is a problem for the project; if not, why not; and if so, what corrective action(s) will be taken.
  - Discuss problems encountered that may adversely affect contract performance.
  - Any problems or deviations from the timeline should be noted and discussed.
  - State the likelihood of missing deliverable due dates or slippage in performance of tasks and shall offer proposed solutions.
  - Summarize key decisions agreed upon between the contractor and the COR.
- The contractor shall submit the monthly progress reports in electronic format to the COR with an electronic copy to the respective PM.
- The monthly progress report shall be submitted with each monthly invoice.
- The monthly progress reports must be submitted to the CMS COR by the 15th day of each month.[1]

Deliverable: Monthly Progress Reports
Due Date: By the 15th day of each month

TASK 2 – End Stage Renal Disease Reports

The following tasks will be performed for Task 2.

2.1 : *Statistical Analyses of ESRD Deliverables*

[1] If the 15th day of the month falls on a weekend, holiday or other non-business day, the contractor shall have until the next business day to submit the progress report.

The contractor shall provide statistical analyses of the ESRD data. These statistical analyses shall include:

- Comparative and relationship statistics.
- Comparative analyses shall be made among facilities and states, networks, and regions.
- Relationship analyses shall be made among practice patterns, outcome data, and survey and certification data.

Deliverable: Statistical Analyses of ESRD Deliverables
Due Date: September 1st of each contract year

2.2 *: Data Review Report*

The contractor shall obtain, verify, and validate, to the extent possible, all data elements that are used to prepare and are included in the data reports.

This task includes:

- Identifying the best data source for each data element.
- Considering the availability of projected databases that may emerge during the contract period.
- Obtaining the data required to populate the data reports.
- Locating possible alternative sources for additional data elements.
- Determining the usability of data elements and validating the data before use to determine its accuracy.
- Determining which data elements are most valuable and pertinent for oversight of the dialysis facilities to include in the report.
- Determining which data elements should be added to or subtracted from the current ESRD Dialysis Facility Reports and Outcomes Lists to ensure their continued relevancy for evaluating quality of care and predicting non-compliance with health and safety standards.

In preparing the required reports, the contractor shall use all available CMS databases, including:

- CMS Central Data Repository (CDR)
- National Claims History, Standard Analytical Files, Physician/Supplier File
- Enrollment Database
- OPTN transplant file
- OPTN transplant follow-up file
- OPTN transplant waiting list file
- ESRD Annual Facility Survey
- CMS Certification and Survey Provider Enhanced Reporting system (CASPER)
- ESRD Facility Cost Reports
- Group Health Plan files

Deliverable: Data Review Report
Due Date: January 31st of each contract year

2.3 : *Report Design (Draft Report Templates for CMS Review and Approval)*

The contractor will routinely revise the reports to ensure they are:

- Aligned with the ESRD Core Survey process.

- Provide development of data sources and data tools to allow state surveyors convenient and timely access to more current dialysis facility quality outcomes.

- Use state surveyor and other user feedback to determine the need for revisions.

The contractor shall suggest a format for presenting data and information for each specific report. The suggested framework for displaying the information and the accompanying instructions shall be approved by the COR. The suggested format for using each report should include the following:

- Instructions for using the information and/or a description of the data and its meaning.

- The calculations necessary for the reports and layout of the display of the information.

- The recommended means for dissemination of updated dialysis facility information to state surveyors and CMS staff involved in oversight activities related to the Medicare ESRD Program.

Deliverable: Draft Guide to the Annual Individual DFRs
Due Date: January 31st of each contract year

Deliverable: Draft Guide to the State Profiles*
Due Date: January 31st of each contract year

Deliverable: Draft Guide to the Individual Quarterly Updates of the DFRs
Due Date: January 31st of each contract year

Deliverable: Draft Annual Individual DFR Template
Due Date: January 31st of each contract year

Deliverable: Draft Individual Quarterly Update to the DFR (QDFR) Template
Due Date: January 31st of each contract year
*The QDFR template is used for the DFR Pre-Survey Extract.

Deliverable: Draft State Profile Template*
Due Date: January 31st of each contract year
*The State template is used for the US Profiles.

2.4 : *Dialysis Facility Reports (DFRs)*

The DFRs are created to provide dialysis facilities, consumers, the public, CMS, and its affiliates with valuable information on patient characteristics, treatment patterns, hospitalization, mortality, waitlisting, and transplantation patterns in Medicare-certified dialysis facilities. Each report provides summary data on each facility's chronic dialysis patients for the most recent four years. Each row of a table in the report summarizes an item. The facility has a column for each time period, and in most cases, three columns for the corresponding geographical summaries, including averages for the facility's state, its ESRD Network, and the entire nation. With the exception of tables 14 and 15, which are only included if there are a certain number of eligible patients, the following tables are included in each facility's DFR.

- Table 1: Summaries for All Dialysis Patients Treated as of December 31st of Each Year
- Table 2: Characteristics of New Dialysis Patients
- Table 3: Mortality Summary for All Dialysis Patients
- Table 4: Hospitalization Summary for Medicare Dialysis Patients
- Table 5: Transplantation Summary for Dialysis Patients under Age 75
- Table 6: Waitlist Summary for All Dialysis Patients & New Dialysis Patients
- Table 7: Influenza Vaccination Summary for All Dialysis Patients
- Table 8: Anemia Management Summaries for Adult Dialysis Patients
- Table 9: Dialysis Adequacy Summaries for Adult Dialysis Patients
- Table 10: Mineral Metabolism Summaries for All Adult Dialysis Patients
- Table 11: Vascular Access Information for All Dialysis Patients and Access-Related Infection Summaries for All Medicare Patients
- Table 12: Comorbidities Reported on Inpatient Medicare Claims for Medicare Dialysis Patients Treated as of December 31st of Each Year

- Table 13: Facility Information
- Table 14: Selected Measures for Dialysis Patients under Age 18
- Table 15: Selected Measures for Nursing Home (NH) Dialysis Patients

The contractor shall collect, evaluate, and utilize available ESRD data to develop and prepare an annual DFR. This report must meet the following requirements:

- Include risk-adjusted measures.
- Are facility-specific.
- Include statistical tables, charts, and descriptive text summaries.

The purpose of these reports is to:

- Promote quality improvement in dialysis care.
- Allow CMS and the SAs to compare facility data with national and state dialysis facility data.
- Inform CMS, the SAs, dialysis providers, and the public about practice patterns and patient outcomes for each dialysis facility.

The contractor shall also provide technical assistance and support services for the dialysis facility report. Such support would include:

- Instructions for reviewing and understanding the report.
- Providing appropriate training related to the report.
- Attending appropriate workgroup and training meetings.
- Answering queries about the nature of the report.
- Responding to comments during the preview period.

The contractor shall also provide supporting documentation to the DFRs to help with interpretation and to provide transparency. Many of these documents are posted publicly while some are only provided to Network Directors and/or CMS. Such documentation would include:

- An example of a DFR using simulated data (Sample DFR).
- Downloadable file that includes all data included in the DFR for dialysis facilities.

- The list of variables included in the data files provided to Networks and in the data available for download on a secure website by authorized users, along with a brief description and the location within the data file.

- A list of all codes used to calculate measures reported in the DFR. This includes codes used to identify patient events (i.e., hospitalizations, readmissions, transfusions), dialysis adequacy codes for Kt/V, vascular access types and infections, prevalent comorbid conditions; and codes used to identify patient exclusions.

- Detailed methodology used to calculate select standardized measures.

- Model coefficients and tables of the baseline survival probabilities used in the calculation of the standardized measures reported in the DFR.

- Network-specific comma-delimited ASCII files with the statistics used to produce the DFRs.

- Network-specific lists of all facilities in each Network that are receiving a DFR, as well as lists that associate each Medicare provider number with a provider number in the DFR along with an explanation for how to identify the DFR corresponding to a particular Medicare provider number.

- DFR public use files (PUFs) that include all data elements contained in each Medicare-certified dialysis facility's DFR, based on at least 11 patients, for the fiscal year indicated. A facility-level file for download that includes all summaries included in the DFR (wide format), as well as socrata facility-, State -, and Network-specific files for the interactive website (long format) will be provided along with a data dictionary for the facility-level PUF.

Deliverable: DFRs released for Facility Preview (pdf)
Due Date: July 15th of each contract year for the July 15-August 15th preview period

Deliverable: DFR Downloadable File (csv)
Due Date: July 15th of each contract year

Deliverable: Guide to the DFRs (pdf)
Due Date: July 15th of each contract year

Deliverable: Sample DFR (pdf)
Due Date: July 15th of each contract year

Deliverable: Data Dictionary for DFR Downloadable File (xlsx)
Due Date: July 15th of each contract year

Deliverable: DFR Diagnosis Codes (pdf)

Due Date: July 15th of each contract year

Deliverable: Standardized Ratio of Emergency Department Encounters Occurring within 30 Days of Hospital Discharge (ED30) Diagnosis Codes (xls)
Due Date: July 15th of each contract year

Deliverable: Standardized Hospitalization Ratio (SHR) Diagnosis Codes (xlsx)
Due Date: July 15th of each contract year

Deliverable: Standardized Readmission Ratio (SRR) Diagnosis Codes (xlsx)
Due Date: July 15th of each contract year

Deliverable: SHR Technical Documentation (pdf)
Due Date: July 15th of each contract year

Deliverable: Standardized Mortality Ratio (SMR) Technical Documentation (pdf)
Due Date: July 15th of each contract year

Deliverable: Standardized Transfusion Ratio (STrR) Technical Documentation (pdf)
Due Date: July 15th of each contract year

Deliverable: First-year SMR Model Information (xls)
Due Date: July 15th of each contract year

Deliverable: SMR Model Information (xls)
Due Date: July 15th of each contract year

Deliverable: SHR Model Information (xls)
Due Date: July 15th of each contract year

Deliverable: SRR Model Information (xlsx)
Due Date: July 15th of each contract year

Deliverable: STrR Model Information (xlsx)
Due Date: July 15th of each contract year

Deliverable: Facility Map Explanation (pdf)
Due Date: July 15th of each contract year

Deliverable: Practice Patterns (pdf)
Due Date: July 15th of each contract year

Deliverable: Individual Network Facility Lists (xlsx and pdf)
Due Date: July 15th of each contract year

Deliverable: Facility List CCN Mapping Explanation (pdf)
Due Date: July 15th of each contract year

Deliverable: Network Data files (csv)
Due Date: July 15th of each contract year

Deliverable: Final DFRs with comments appended for State Surveying Agencies (SAs)
Due Date: September 1st of each contract year

Deliverable: DFR Public Use Files and Data Dictionary
Due Date: December 15th of each contract year

2.5 : *State Specific Profiles*

The contractor shall collect, evaluate, and utilize available ESRD data to develop and prepare annual State Specific reports. These reports include all tables included in the facility-level DFR except for Table 13 (Faciliy Information) and Table 14 (Pedatric summaries) and must meet the following requirements:

- Includes risk-adjusted measures.
- Are state specific.
- Include statistical tables, charts, and descriptive text summaries.
- Include a rank-ordered, facility-specific listing (Outcomes List) based upon a composite measure, potentially predictive of noncompliance with health and safety standards.
- Lists of all facilities in each state that are receiving a DFR, as well as lists that associate each Medicare provider number with a provider number in the DFR.

The purpose of these reports is to:

- Promote quality improvement in dialysis care.
- Allow CMS to compare national and state dialysis facility data.
- Inform CMS, the SAs, dialysis providers, and the public about practice patterns and patient outcomes for each state.

The contractor shall also provide technical assistance and support services for the reports. Such support would include:

- Instructions for reviewing and understanding the report.
- Providing appropriate training related to the report.
- Attending appropriate workgroup and training meetings.

- Answering queries about the nature of the report.

The contractor shall also provide supporting documentation to the State Profiles to help with interpretation and to provide transparency. Such documentation would include:

- An example of a State report using simulated data.
- State Profile Summary report that includes a table and maps of key statistics from the State Profile for each state. The maps give an overall view of mortality, hospitalization, transplantation, and practice patterns in the United States, while the table gives the specific values for each state.

Deliverable: Individual State Profiles (pdf)
Due Date: September 1st of each contract year

Deliverable: Individual Pre-Survey DFR Extracts (pdf)
Due Date: September 1st of each contract year

Deliverable: Guide to the Individual State Profiles (pdf)
Due Date: September 1st of each contract year

Deliverable: Sample State Profile Report (pdf)
Due Date: September 1st of each contract year

Deliverable: National Outcomes List (xlsx)
Due Date: September 29th of each contract year

Deliverable: State Profile Summary Report (pdf)
Due Date: September 1st of each contract year

2.6 ***Quarterly ESRD Dialysis Facility Reports***

The contractor shall collect, evaluate, and utilize available ESRD data to develop and prepare quarterly updates of the Dialysis Facility Reports that are a condensed, facility-specific, and focused on measures included in the ESRD Core Survey. These reports will provide timely updates of select measures reported in the annual DFR to those involved in the provision and quality of dialysis care.

This report provides a tool to compare patterns in death, and hospitalization counts, dialysis access, fluid management, anemia, dialysis adequacy, nutrition, mineral metabolism, transplantation, and summaries among nursing home patients to local and national averages. In addition, summaries included in the ESRD Core Survey that are updated once a year for the two most recent calendar years are also provided. Such comparisons help evaluate patient outcomes, which may enhance each facility's understanding of the clinical experience relative to other facilities in the state, Network, and nation.

The contractor shall also provide technical assistance and support services for the quarterly dialysis facility report. Such support would include:

- Instructions for reviewing and understanding the report.
- Providing appropriate training related to the report.
- Attending appropriate workgroup and training meetings.
- Responding to comments during the preview period.
- Answering queries about the nature of the report.

The contractor shall also provide supporting documentation to the QDFRs to help with interpretation and to provide transparency. Such documentation would include:

- An example of a QDFR using simulated data (Sample QDFR).
- Downloadable file that includes all data included in the QDFR for dialysis facilities.
- The list of variables included in the data files provided to Networks and in the data available for download on a secure website by authorized users, along with a brief description and the location within the data file.

Deliverable: Release of Quarterly Updates of the DFRs for Facility Preview (pdf)
Due Date: Quarterly (3)-November 1st (November 1-15 preview period), February 1st (February 1-15 preview period), and May 1st (May 1-15 preview period) of each contract year

Deliverable: Guide to the Quarterly Updates of the DFRs (pdf)
Due Date: November 1st, February 1st, and May 1st of each contract year

Deliverable: Sample QDFR Report (pdf)
Due Date: November 1st, February 1st, and May 1st of each contract year

Deliverable: QDFR Downloadable File (csv)
Due Date: November 1st, February 1st, and May 1st of each contract year

Deliverable: QDFR Downloadable File data dictionary (xlsx)
Due Date: November 1st, February 1st, and May 1st of each contract year

Deliverable: Final QDFRs with Facility comments released to State Survey Agencies (SAs)
Due Date: Quarterly (3)- December 1st (Q1), March 1st (Q2), and June 1st (Q3)

2.7 *Optional Task:* Dialysis in Nursing Homes Report

The contractor shall utilize their ESRD data and statistical expertise to develop and validate individual measures that will allow CMS to monitor and trend the prevalence of home dialysis in nursing homes.

The contractor shall produce an annual report stating the frequency of both hemodialysis and peritoneal dialysis performed for nursing home residents by year. The contractor shall develop a Nursing Home Dialysis Prevalence Annual Report, which provides national comparisons of patient clinical outcomes between nursing home and non-nursing home patients and follows use trends for home dialysis in nursing home patients, currently being utilized by a relatively small, but growing, fraction of the nursing home dialysis population.

Deliverable: Nursing Home Dialysis Prevalence Annual Report
Due Date: September 1st of each contract year

2.8 *Optional Task*: Dialysis for Acute Kidney Injury Annual Report

The contractor shall produce an Annual Report with metrics that allow CMS to monitor the frequency of dialysis for Acute Kidney Injury (AKI) in chronic dialysis facilities, assuming that appropriate information is available on Medicare dialysis facility claims to allow identification of AKI patients. This report is intended to help inform CMS decisions regarding the impact of AKI patients in the ESRD dialysis facility survey process.The report will include national trends over time in the treatment of AKI patients and descriptive information about the population nationally. Identification of these AKI treatments will be through designation of codes on outpatient Medicare dialysis facility claims for the AKI patients. The report will evaluate the frequency and distribution of AKI claims per patient and per facility for all facilities and by facility ownership type (hospital-based, freestanding, and hospital-satellite). In addition, the report shall compare the demographic characteristics (race, gender, age) of AKI patients vs. non-AKI patients and AKI claims vs. non-AKI claims and the outcomes for these patients (ESRD, death, recovered/lost to follow-up). The contractor will update the report annually.

Deliverable: Annual Report on AKI Patients Requiring Dialysis
Due Date: September 1st of each contract year

TASK 3 - Transplant Program Reports

The contractor shall provide the data needed by CMS to provide oversight to CMS-approved organ transplant programs. The contractor shall also provide technical assistance and support to CMS in support of the data reports provided.

More specifically, the following tasks will be performed under Task 3 of this contract.

3.1 : *Obtain Data*

The contractor shall obtain monthly data, program-specific statistics, data, and documentation from the Scientific Registry for Transplant Recipients (SRTR) to be able meet the terms of this task. CMS will facilitate this data transfer through an agreement with the Health Resources and Services Administration (HRSA). The contractor will validate and analyze said data to perform the required tasks.

Deliverable: Obtain Data (Documentation in Monthly Report)
Due Date: By the 15th day of each month

3.2 : *Initial Transplant Report*

The contractor shall submit monthly Initial Transplant Report (ITR). These reports must:

- Be in an electronic format.
- Be sent to the COR via email with a copy to the respective CMS Program Manager.
- Include all CoP requirements for the initial approval of a transplant program: transplant volume for the past 12 months, patient-survival and graft-survival outcomes from the most recent SRTR PSR release, OPTN data submission, and OPTN rate of removal from waiting list within one calendar day.
- Include a list of all transplant programs that are currently shown in the report, a list of transplant programs that have been removed from the report after CMS approval, and a list of transplant programs that have been included in the report for at least 18 months, and therefore can be removed once CMS confirms approval.
- Include SRTR data from the previous month, OPTN data from the current month, and SRTR PSR data from the most recent release (e.g., the March report would include SRTR data from February, OPTN data from March, SRTR PSR data from the most recent release, and would be due on April 15th).

Deliverable: Initial Transplant Report
Due Date: Monthly by the 15th of each month

3.3: *Performance-Based Composite Score Report (PBCSR)*

The purpose of this report is to drive CMS' survey and oversight activities for determining compliance with the Medicare CoPs for transplant programs. On behalf of CMS, SAs perform transplant program oversight activities based on a tiered prioritization system. The contractor will provide the PBCSR that will combine pre- and post-transplant measures that aim to comprehensively assess program processes, quality of care, and

outcomes. The PBCSR combines four individual metrics into a single performance score for individual transplant programs. The metrics include the SRTR's transplant rate ratio, offer acceptance ratio, one-year patient survival ratio, and one-year graft survival ratio, obtained from the July PSRs. This method uses a more holistic set of measures that reflect both pre- and post-transplant outcomes and accurately depicts transplant program performance in which program activities influence the metrics. Any contractor recommendations to update the composite score methodology, including the metrics, rankings, and which transplant program types to include must be included in the annual Project Management Plan deliverable and discussed in meetings with CMS staff. Annually, CMS will direct the contractor on which transplant program types and rankings to include in the PBCSR. CMS will use the PBCSR scores to prioritize transplant programs for recertification surveys.

The contractor must provide responses to CMS and CMS' stakeholders' questions regarding the methodology and PBCSR deliverables.

At a minimum, the PBCSR deliverables must include:

- **Transplant Performance-Based Composite Score Report** (xlsx): for each transplant program CMS determines to include in the composite scoring – provide the program name, program/organ type, state located, CCN, OPTN code, all metric scores, z-scores for each metric, composite score, and ranking;
- **Transplant Performance-Based Composite Score Methodology document** (Word): describes the metrics used in the scoring and statistical calculations;
- **Transplant Performance-Based Composite Score Detailed Measure Report** (xlsx): for each transplant program (i.e., those included in the composite scoring and those not included)- provide the transplant program name, program/organ type, age group, OPTN code, state located, date range for measure, SRTR PSR date, and the following based on current metric methodology (subject to change based on CMS' decision):
    - Transplant Rate: counts on waitlist at start, person years, transplant count, observed transplant rate, expected transplant rate, and transplant rate ratio
    - Offer Acceptance: number of offers, number of acceptances, expected number of acceptances, and offer acceptance ratio
    - One-year Patient Survival: total number of patients in PSR, observed deaths, expected deaths, patient standardized mortality ratio (observed/expected)
    - One-year Graft Survival: total number of patients in PSR, observed failures, expected failures, standardized graft failure ratio (observed/expected)

Deliverable: Transplant Performance-Based Composite Score Report
Due Date: July 31st of each contract year

Deliverable: Transplant Performance-Based Composite Score Methodology document
Due Date: July 31st of each contract year

Deliverable: Transplant Performance-Based Composite Score Detailed Measure

Report Due Date: July 31st of each contract year

3.4 ***Ad-hoc Transplant Reports***

The contractor shall produce additional reports that are required for the operation and implementation of the organ transplant program on an as-needed (ad hoc) basis, with approval from the COR.

Examples of such ad-hoc transplant reports may include, but are not limited to:

- Summaries of initial mitigating factors,
- Program reviews,
- Analyses of the outcomes for programs with particular sub-populations,
- Analyses of organ acceptance rates, and
- Analyses of outcomes over time.

Deliverable: Ad-hoc Transplant Reports
Due Date: Ongoing throughout contract, as approved by the COR

TASK 4 - Organ Procurement Organization Reports and Technical Assistance for (OPOs)

The contractor shall provide technical assistance and support to CMS in support of the data reports and policy development for oversight of the OPO Program.

The following tasks shall be performed under Task 4.

4.1 ***: Annual OPO Performance Reports***

The contractor shall produce annual performance reports based on the established methodology described in the final rule[2], for the following two performance measures established in the Organ Procurement Organization Conditions for Coverage[3]:

- Donation rate– calculated as the number of donors in the Donation Service Area (DSA) as a percentage of the donor potential.

- Transplantation rate - calculated as the number of organs transplanted from donors in the DSA as a percentage of the donor potential. The organ transplantation rate is adjusted for the average age of the donor potential.

The contractor will collaborate with CMS to develop a draft template to include the table

[2] https://www.cms.gov/files/document/112020-opo-final-rule-cms-3380-f.pdf

[3] https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-486/subpart-G/subject-group-ECFR7490c5a92daf2da/section-486.318

structure and other report elements for OPO individual reports and the public aggregated report. The reports will incorporate updates recommended by the contractor or requested by CMS and approved by the COR. The contractor will also submit an updated draft User's Guide for the OPO Annual Performance Reports, including all methodological or data related changes that arose during the ensuing year with the report templates. The User's Guide will provide a description of the components included in the OPO donation and transplant rates; detailed methodology for the OPO performance measures; an explanation of how each OPO is assessed; reporting periods for each annual report within the certification cycle; and instructions for obtaining the data used in the calculations. A finalized version of the User's Guide incorporating CMS comments will be submitted with the final public aggregated reports.

The contractor will provide OPO Interim Annual Individual Performance Reports for preview for interim assessment years and OPO Final Annual Individual Performance Reports for preview in the survey year (e.g., for 2026 survey cycle, there are interim assessments in 2023, 2024, and 2025 and the final assessment in 2026). There will be an individual report for each OPO and include the following tabs:

- Methodology: Brief description of methods for reference.
- Rates: Donation and transplant rates for the OPO, tier and rate categories that show how these rates compare to the cutoffs, and which tier the OPO falls into, along with data from the prior year for comparison. The total number of OPOs in each tier is also shown.
- Raw Data: Counts of potential donors, donors, and organs transplanted that went into calculation of rates for the OPO for each year.
- Donor List: List of donors for the OPO for each year, including the organs transplanted and age group of each donor.
- Counties and Waivers: List of counties included in the OPO's DSA and potential donor apportionment for counties where there is a hospital with a CMS-approved waiver to or from the OPO.

After CMS and the contractor receive OPO feedback on preview reports, the contractor will incorporate adjudicated changes as instructed by CMS and deliver finalized versions of the OPO Interim (or Final) Annual Individual Performance Reports to CMS.

Additionally, the contractor will prepare an aggregated report for public posting that shows outcome measures and tier status for all OPOs according to deliverable dates listed below [OPO Annual Public Aggregated Performance Report (interim in non-survey years, final in 2026)]. The public report will include the following tabs:

- Methodology: Brief description of methods for reference.
- YYYY Assessment: Donation and transplant rates for each OPO for each annual assessment period; tier and rate categories that show how these rates compare to the cutoffs; and which tier the OPO falls into. The total number of OPOs in each tier is also shown.
- YYYY--Waiver Counties: List of hospital assignments for counties with CMS-

approved waivers. There is a separate sheet corresponding to each annual assessment.

- Summary: Tier and rate categories for each OPO across all years included in the report.

Along with the Public Aggregated Performance Report, the contractor will provide maps of OPOs showing regional boundaries, tier status, and U.S. census population estimates for the current reporting year. In addition, a table providing U.S. census race and ethnicity data for all OPOs are included.

Deliverable: OPO Performance Report Draft Templates - Individual OPO and Public Aggregate Templates
Due Date: January 15th of each contract year

Deliverable: Draft OPO Performance Report User's Guide
Due Date: January 15th of each contract year

Deliverable: OPO Annual Individual Performance Reports - Preview*
Due Date: February 25th of each contract year

Deliverable: Final OPO Annual Performance Report User's Guide
Due Dates: March 31st of each contract year

Deliverable: Final OPO Annual Individual Performance Reports*
Due Date: March 31st of each contract year

Deliverable: OPO Annual Public Aggregated Performance Report*
Due Date: March 31st of each contract year

Deliverable: OPO Annual Performance Report Census and Tier Maps, and U.S. Census Race and Ethnicity Data*
Due Date: March 31st of each contract year

* Contingent on timely availability of external data (i.e. SRTR, CDC, inpatient mortality, and updated waiver data). If the MCOD file (or another data source) is late the contractor will submit an alternative timeline based on the following table, expedited as feasible, and mutually agreed upon.

Timeline with dates for some tasks. Specific dates change each year depending on where weekends fall. The minimum time needed for each step is indicated in the last column.

Task	Due Date	Minimum Time Needed
All data available	February 1	
Process data and produce		15 business days

individual preview reports		
Preview individual reports delivered to CMS	February 25	
CMS distributes preview reports		3 business days
OPOs review reports		10 business days
Contractor and CMS to resolve any discrepancies and create finalized individual and public report		10 business days
Final individual and public reports delivered to CMS	March 31	

4.2*: Technical Assistance and Ad-hoc OPO Reports*

The contractor shall provide technical assistance and reports to CMS in support of policy and regulation development, and program oversight.

The contractor shall work with CMS to define the criteria to be used for quality performance measures for OPOs.

The contractor shall perform data analysis and submit reports, which include, but are not limited to the assistance in the enforcement of survey findings and actions related to decertification and competitions processes, as determined by CMS.

The contractor shall participate in virtual sessions to provide information to CMS staff about the work performed or reports provided pursuant to the SOW and SOD.

Deliverable: Technical Assistance and Ad-hoc Reports
Due Date: Ongoing throughout contract, as approved by the COR

III. Schedule of Deliverables

The Contractor shall submit all required reports and deliverables in accordance with the following schedule. Reports and/or deliverables submitted under this contract shall be in accordance with the Statement of Work and financially broken down in the excel section of the monthly reports.

Task	Deliverables– Task 1	Due Date
1.1	Contract Kick-Off Meeting	TBD

1.2	Project Management Plan	October 31st each contract year
1.3	Monthly Progress Reports	By the 15th day each month

Task	Deliverables – Task 2	Due Date
2.1	Statistical Analysis of ESRD Deliverables	September 1st of each contract year
2.2	Data Review Report	January 31st each contract year
2.3	Draft Guide to the Annual Individual DFR	January 31st of each contract year
2.3	Draft Guide to the State Profiles	January 31st of each contract year
2.3	Draft Guide to the Individual Quarterly Updates of the DFRs	January 31st of each contract year
2.3	Draft Annual Individual DFR Template	January 31st of each contract year
2.3	Draft Individual Quarterly Update to the DFR (QDFR) Template	January 31st of each contract year
2.3	Draft State Profile Template	January 31st of each contract year
2.4	Dialysis Facility Reports (DFRs) released for Facility Preview (pdf)	July 15th of each contract year for the July 15-August 15th preview period
2.4	DFR Downloadable File (csv)	July 15th of each contract year
2.4	Guide to the DFRs (pdf)	July 15th of each contract year
2.4	Sample DFR (pdf)	July 15th of each contract year
2.4	Data Dictionary for DFR Downloadable File (xlsx)	July 15th of each contract year
2.4	DFR Diagnosis Codes (pdf)	July 15th of each contract year
2.4	Standardized Ratio of Emergency Department Encounters Occurring within 30 Days of Hospital Discharge (ED30) Diagnosis Codes (xlsx)	July 15th of each contract year

Task	Deliverables – Task 2	Due Date
2.4	Standardized Hospitalization Ratio (SHR) Diagnosis Codes (xlsx)	July 15th of each contract year
2.4	Standardized Readmission Ratio (SRR) Diagnosis Codes (xlsx)	July 15th of each contract year
2.4	SHR Technical Documentation (pdf)	July 15th of each contract year
2.4	Standardized Mortality Ratio (SMR) Technical Documentation (pdf)	July 15th of each contract year
2.4	Standardized Transfusion Ratio (STrR) Technical Documentation (pdf)	July 15th of each contract year
2.4	First-year SMR Model Information (xlsx)	July 15th of each contract year
2.4	SMR Model Information (xlsx)	July 15th of each contract year
2.4	SHR Model Information (xlsx)	July 15th of each contract year
2.4	SRR Model Information (xlsx)	July 15th of each contract year
2.4	STrR Model Information (xlsx)	July 15th of each contract year
2.4	Facility Map Explanation (pdf)	July 15th of each contract year
2.4	Practice Patterns (pdf)	July 15th of each contract year
2.4	Individual Network Facility Lists (xlsx and pdf)	July 15th of each contract year
2.4	Facility List CCN Mapping Explanation (pdf)	July 15th of each contract year
2.4	Network Data files (csv)	July 15th of each contract year
2.4	Final DFRs with comments appended for State Surveying Agencies (SAs)	September 1st of each contract year
2.4	DFR Public Use Files and Data Dictionary	December 15th of each contract year

Task	Deliverables – Task 2	Due Date
2.5	Individual State Profiles (pdf)	September 1st of each contract year
2.5	Individual Pre-Survey DFR Extracts (pdf)	September 1st of each contract year
2.5	Guide to the Individual State Profiles (pdf)	September 1st of each contract year
2.5	Sample State Profile Report (pdf)	September 1st of each contract year
2.5	National Outcomes List (xlsx)	September 29th of each contract year
2.5	State Profile Summary Report (pdf)	September 1st of each contract year
2.6	Release of Quarterly Updates of the DFRs for Facility Preview (pdf)	Quarterly (3)-November 1st (November 1-15 preview period), February 1st (February 1-15 preview period), and May 1st (May 1-15 preview period) of each contract year
2.6	Guide to the Quarterly Updates of the DFRs (pdf)	November 1st, February 1st, and May 1st of each contract year
2.6	Sample QDFR Report (pdf)	November 1st, February 1st, and May 1st of each contract year
2.6	QDFR Downloadable File (csv)	November 1st, February 1st, and May 1st of each contract year
2.6	QDFR Downloadable File data dictionary (xlsx)	November 1st, February 1st, and May 1st of each contract year
2.6	Final QDFRs with Facility comments released to State Survey Agencies (SAs)	Quarterly (3)- December 1st (Q1), March 1st (Q2), and June 1st (Q3)
2.7	Optional Deliverable: Nursing Home Dialysis Prevalence Annual Report	September 1st each contract year
2.8	Optional Deliverable: Annual Report on AKI Patients Requiring Dialysis (Contingent on updated dialysis claims data including appropriate condition code)	September 1st each contract year

Task	Deliverable – Task 3	Due Date
3.1	Obtain Data (Documentation in Monthly Report)	Monthly – by 15th day of each month
3.2	Initial Transplant Report	Monthly – by the 15th day of each month
3.3	Transplant Performance-Based Composite Score Report	July 31st of each contract year
3.3	Transplant Performance-Based Composite Score Methodology document	July 31st of each contract year
3.3	Transplant Performance-Based Composite Score Detailed Measure Report	July 31st of each contract year
3.4	Ad-hoc transplant reports	Ongoing throughout contract, as requested by the COR

Task	Deliverables – Task 4	Due Date
4.1	OPO Performance Report Draft Templates - Individual OPO and Public Aggregate Templates	January 15th of each contract year
4.1	Draft OPO Performance Report User's Guide	January 15th of each contract year
4.1	OPO Annual Individual Performance Reports - Preview	February 25th of each contract year
4.1	Final OPO Annual Performance Report User's Guide	March 31st of each contract year
4.1	Final OPO Annual Individual Performance Reports	March 31st of each contract year
4.1	OPO Annual Public Aggregated Performance Report (Interim in non-survey years, Final in 2026)	March 31st of each contract year
4.1	OPO Annual Performance Report Census and Tier Maps, and U.S. Census Race and Ethnicity Data	March 31st of each contract year
4.2	Technical Assistance and OPO Ad-hoc Reports	Ongoing throughout the contract, as requested by the COR

IV. Central Data Repository (CDR)

To eliminate rogue/unauthorized IT systems and to be better stewards of taxpayer funds, CCSQ has established a Guiding Principle for Data, which mandates the use of the CDR data and infrastructure for performing IT contracts and other authorized solutions.

The CCSQ Information Systems Group (ISG) supports CCSQ Data & Analytics modernization tasks that focus on Bringing Users to the Data. These tasks supported the creation of a CDR in the CCSQ QualityNet Cloud and the implementation of the CCSQ Analytics Platform. The CDR offers convenient, secure, compliant, and timely access to CCSQ Quality data. The CDR provides access to other data domains (e.g., Claims, Beneficiary, Provider). The CCSQ Analytics Platform includes analytic tools with various data wrangling, data visualization, basic statistics, and advanced modeling capabilities.

A list of currently available analytics tools can be found here:
https://qnetconfluence.cms.gov/display/DATA/CAP+Analytics+Tools

It is expected that any contractor utilizing the CDR will have in-house expertise to include, but not limited to R, Python, SQL, and PySpark languages. CMS requires that any existing SAS Code shall be rewritten into a modern open-source language such as those listed above.

Goals of Data & Analytics Modernization include:

- Improving Data & Analytic experiences for CCSQ users
- Modernizing current analytic platforms and data repositories
- Improving data timeliness
- Reducing data duplication
- Simplifying/automating data access request process
- Maturing data governance
- Increasing data quality, security, and privacy
- Increasing collaboration and data sharing for internal/external stakeholders.

The CDR enables support contractors to connect external systems, tools, and data not currently available within the CDR. Systems, tools, and data must be compliant with CMS/CCSQ regulations.

Data should only be exported from a source System of Record (SOR) or the CDR if approved by Contract Officer Representative (COR), an ISG ISSO, and the CCSQ Federal Data and Analytic Lead.

VI. Section 508 Requirements

Section 508 of the Rehabilitation Act, as amended by the Workforce Investment Act of 1998 (P.L. 105-220) requires that when Federal agencies develop, procure, maintain, or use information and communication technology (ICT), it shall be accessible to people with disabilities. Federal employees and members of the public who have disabilities must have access to, and use of, information and data that is comparable to people without disabilities.

Item that contains ICT: Reports

Reports

E205 Electronic Content

E205.1 General. Electronic content shall comply with E205.

E205.2 Public Facing. Electronic content that is public facing shall conform to the accessibility requirements specified in E205.4.

E205.3 Agency Official Communication. Electronic content that is not public facing shall conform to the accessibility requirements specified in E205.4 when such content constitutes official business and is communicated by an agency through one or more of the following:

- A. An emergency notification;
- B. An initial or final decision adjudicating an administrative claim or proceeding;
- C. An internal or external program or policy announcement;
- D. A notice of benefits, program eligibility, employment opportunity, or personnel action;
- E. A formal acknowledgement of receipt;
- F. A survey questionnaire;
- G. A template or form;
- H. Educational or training materials; or
- I. Intranet content designed as a Web page.

E205.4 Accessibility Standard (WCAG 2.0). Electronic content shall conform to Level A and Level AA Success Criteria and Conformance Requirements in WCAG 2.0 (Incorporated by reference, see 702.10.1).

E206 Hardware

E206.1 General. Where components of ICT are hardware and transmit information or have a user interface, such components shall conform to the requirements in Chapter 4.

E301 General

E301.1 Scope. The requirements of Chapter 3 shall apply to ICT where required by 508 Chapter 2 (Scoping Requirements), 255 Chapter 2 (Scoping Requirements), and where otherwise referenced in any other chapter of the Revised 508 Standards or Revised 255 Guidelines.

E302 Functional Performance Criteria
302.1 Without Vision. Where a visual mode of operation is provided, ICT shall provide at least one mode of operation that does not require user vision.

302.2 With Limited Vision. Where a visual mode of operation is provided, ICT shall provide at least one mode of operation that enables users to make use of limited vision.

302.3 Without Perception of Color. Where a visual mode of operation is provided, ICT shall provide at least one visual mode of operation that does not require user perception of color.

302.4 Without Hearing. Where an audible mode of operation is provided, ICT shall provide at least one mode of operation that does not require user hearing.

302.5 With Limited Hearing. Where an audible mode of operation is provided, ICT shall provide at least one mode of operation that enables users to make use of limited hearing.

302.6 Without Speech. Where speech is used for input, control, or operation, ICT shall provide at least one mode of operation that does not require user speech.

302.7 With Limited Manipulation. Where a manual mode of operation is provided, ICT shall provide at least one mode of operation that does not require fine motor control or simultaneous manual operations.

302.8 With Limited Reach and Strength. Where a manual mode of operation is provided, ICT shall provide at least one mode of operation that is operable with limited reach and limited strength.

302.9 With Limited Language, Cognitive, and Learning Abilities. ICT shall provide features making its use by individuals with limited cognitive, language, and learning abilities simpler and easier.

503 Applications

503.1 General. Applications shall conform to 503.