
**Measure & Instrument Development and Support
(MIDS)**

Statement of Work

IDIQ

SECTION C – DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

C.1 STATEMENT OF WORK

CHAPTER 1. SCOPE

1.A. – Background

The Centers for Medicare and Medicaid Services (CMS) is the federal agency tasked with overseeing a variety of health care programs, including Medicare and Medicaid. It strives to ensure that the American public receives the highest quality of care, consisting of personalized, prevention-oriented, and patient-centered care, based on evidence about the benefits and costs applicable to each individual patient.

The current health care system does not consistently deliver high-quality care for every patient at every opportunity, resulting in gaps in the quality of care provided for different population groups. Therefore, CMS recognizes the opportunity available to improve the health care system by closing such gaps, thereby further increasing the quality of care for our population.

One way that CMS will carry out its obligation to drive improvement in the health care system is through the development and use of quality measures and related activities. Quality measures are already widely used in several quality reporting programs, including the Hospital Inpatient Quality Reporting Program (IQR) and the Quality Payment Program (QPP). Quality measurement and quality reporting programs are also statutorily required or authorized for settings such as Hospices, Long-term Care Hospitals (LTCHs), Inpatient Rehabilitation Facilities (IRFs), PPS- exempt Cancer Hospitals (PCHs), Psychiatric Hospitals, Hospital Outpatient Departments, and Ambulatory Surgical Centers (ASCs) as well as value-based purchasing programs for hospitals, Skilled Nursing Facilities (SNFs), and physicians, and End Stage Renal Disease (ESRD) centers. Other ways in which CMS carries out its obligation is through the standardization of core health assessment information in CMS's post-acute care's patient assessment instrument data, as required under the Improving Medicare Post-Acute Care Transformation Act (IMPACT) of 2014.

CMS seeks to utilize this contract mechanism to develop, implement, and align measures that fill critical gaps for quality priorities. These include measures relating to clinical quality of care, care coordination, population/community health, safety, person- and caregiver-centered experience and outcomes, and efficiency and cost reduction. The tasks under this Statement of Work (SOW) shall be performed under an Indefinite Delivery Indefinite Quantity (IDIQ) contract. Such work shall be performed by one or more Measure and Instrument Development and Support (MIDS) Contractors.

The IDIQ SOW of this MIDS IDIQ contract encompasses all of the fundamental activities that may be required of a MIDS Contractor. However, given the nature of an IDIQ contract, no work will be performed or specifically assigned under this IDIQ SOW. Rather, this IDIQ SOW outlines scope of the work that may be performed only; individual Task Orders (TOs) under the MIDS IDIQ will be awarded for specific duties as the need arises and these TOs authorize expenditures and accomplish SOWs (see below Section G - Contract Administration, for details on TO procedures).

TOs may be awarded by CMS for some or all of the activities identified in this IDIQ SOW. Each TO will contain an individual SOW containing detailed requirements to be performed within the scope of this IDIQ SOW. For example, a TO may be issued for all, or part, of the activities identified in this IDIQ SOW under an individual TO SOW that may read, “The Contractor shall perform all of the requirements of the IDIQ SOW as the maintainer of the Outcome and Assessment Information Set (OASIS).” Alternatively, a TO may be issued for some of the activities, such as, “Coordinate with Post-Acute Care MIDS Contractors to assure Congruent Measure Application.”

1.B. – Purpose

The purpose of this MIDS IDIQ SOW is to procure the services of one or more Contractors by establishing the fundamental activities that may be awarded in subsequent individual TOs. Further, the purpose of the MIDS IDIQ SOW is to develop outcome, process, structural, cost, and composite quality measures suitable for endorsement by a consensus endorsement entity (CBE) and reflective of quality care across settings, including, but are not limited to, psychiatric hospitals, ambulatory care services, physician providers, accountable care organizations, nursing homes, home health agencies, hospice programs, LTCHs, IHRs, PCHs, acute care hospitals, and ASCs. Its purpose is also to support the collection of data that could be used to trend quality related to patient care for those patients that receive services across settings, as well as other uses related to cross-setting analysis. Such quality care measures would include any aspect of care that is consistent with the Institute of Medicine’s (IOM) Six Aims of Care (safety, timeliness, efficiency, effectiveness, equitability and patient centeredness) and is consistent with current CMS quality priorities.

The Contractor shall explore the dimensions of the measurement in order to generate results that inform the public about how well a provider ensures patient safety, manages symptoms, mitigates poor outcomes, facilitates population health, and enhances coordinated and patient-centered care, with respect to the IOM’s Six Aims of Care. This contract also includes the identification or development of the data elements and items necessary to implement data collection for the proposed measures across settings, as well as the data collection vehicles. Particularly, this is intended to support the modification and/or development of standardized patient/resident assessment instruments (RAIs) for the collection of data and for interoperable exchange, as laid out in the IMPACT Act of 2014.

This IDIQ SOW further seeks to provide a contracting mechanism to promote the quality of care by emphasizing major strategies for improving care, as noted in the following actions:

- Conduct business through partnerships within CMS, across other Federal and State agencies, other CMS contractors, and non-Governmental entities if requested;
- Publish information for various purposes with varying audience requirements (e.g., diverse audiences that may include the general public, patients/caregivers, professionals, providers, purchasers) so as to convey both general information pertaining to quality reporting and general programmatic education, and more complex technical information pertaining to programmatic requirements, and quality measurements;

- Promote payment adjustments and incentives that express a commitment to quality care and reward improved care outcomes and processes, and does not inadvertently lead to negative unintended consequences;
- Promote the integration of health information technology (HIT) (includes both standards promotion and payment for HIT results) into quality measurement programs;
- Become an active partner in developing and applying knowledge about effective health care technologies to bring innovations to care delivery more efficiently, and to monitor the effectiveness of such federally funded technologies on outcome improvement;
- Promote cross-setting outcome measurement development;
- Implement Health and Human Services (HHS)/CMS's quality measurement strategic approach;
- Optimize measure development and alignment and application at the conceptual as well as data specification level;
- Enable program monitoring and evaluation for multiple purposes to include identifying unintended consequences; identification of measures that have "topped out" and are candidates for retirement/removal; program integrity; new gaps in quality;
- Enable transparency through public reporting; and,
- Reduce provider burden.

CHAPTER 2. GENERAL REQUIREMENTS

2.A. - Basic Requirements

The MIDS Contractor shall:

1. Furnish the necessary services and qualified personnel (defined as personnel with the skills and expertise to follow the best practices relevant to the work of the project), facilities, equipment, materials, and supplies not otherwise provided by the Government as needed to perform the requirements set forth in this IDIQ SOW and indicated in each individual TO.
2. Provide CMS, and other federal agencies as applicable with complete, timely, and accurate information on all actions upon request.
3. Perform requirements as defined in the IDIQ SOW and future TOs in accordance with (IAW) applicable federal laws, regulations, and manuals.
4. Continuously evaluate the effectiveness of all actions. For example, CMS continually looks for innovation and improved processes when developing clinical quality measures (CQMs). As more CQMs are developed and used in CMS programs, the goal is to be more lean, agile and nimble. This includes developing accurate, well-tested CQMs efficiently with diminishing defects, better measures, and not necessarily more measures.
5. Report IAW the deliverables stated throughout this SOW and in any future TO as applicable.

2.B. - Fundamental Activities

Development, revision, and/or maintenance of assessment instrument data items, data collection vehicles, and performance measures (and their corresponding manuals, public outreach and coordination of data elements and measures with other MIDS Contractors) comprise the fundamental activities of future TOs under the MIDS contract. Although the following sections represent fundamental measures-related activities, they are not meant to be sequential and many of these activities overlap and/or occur in parallel depending on the type of MIDS contract/measures developed.

Additionally, other MIDS TOs performed by MIDS Contractors may require quality measurement program support activities such as public reporting and analytical support. These types of TOs, if needed, will not require all the processes, deliverables, and tools described in *The Blueprint for the CMS Measures Management System (MMS)* (the Blueprint), described in detail in Section 2.C.2 (Measures Management). Detailed information on the CMS MMS may also be found at: https://www.cms.gov/MMS/19_MeasuresManagementSystemBlueprint.asp.

The data items produced under the MIDS contract allow for the application of and standardization of data elements used in data collection vehicles. Such data elements may be deployed in the multiple assessment instruments, which may also serve as data collection vehicles, for clinical quality measures. These assessment instruments, e.g., data collection vehicles or standardized data item sets, could include, but are not limited to: the LTCH Continuity Assessment Record and Evaluation (CARE) Data Set; the Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI); the OASIS; the Minimum Data Set (MDS), and the CARE for multiple providers. Any updates and future standardized data item set shall also be included. Such data collection sets provide for data element standardization and usability of the data elements in any setting requiring the submission of a standardized data for quality measurement.

A patient-centered approach is critical to improving the quality of care in our country. In order to truly drive improvements in patient outcomes and experience with the health care system, CMS and others must design performance measures that address the needs and values of patients and the people who care for them. Therefore, development of measures, whether they are used for quality improvement, public reporting or value-based purchasing, must be directly informed by patients. Under this IDIQ SOW, all TOs for measure development shall include explicit incorporation of the patient perspectives and preferences in measure development through patient and/or caregiver participation on Technical Expert Panels (TEPs). While participation by patient or consumer advocacy organizations may also be desirable, this IDIQ SOW will require participation by actual patients and caregivers, not just the organizations who represent them.

2.C. – Coordination

Broadly, CMS builds its measure development and maintenance work on six quality priorities: clinical quality of care, care coordination, population/community health, safety, person- and caregiver-centered experience and outcomes, and efficiency and cost reduction. These focus areas shall drive measure development, selection, and maintenance.

The MIDS Contractor's success in developing and supporting accurate and reliable quality measures, assessment instruments and standardized data item sets depends on a well-coordinated working relationship between CMS components and external stakeholders. CMS may direct that the MIDS Contractor and its partners collaborate and communicate frequently and regularly to keep each other apprised of potential areas of improvement, and to avoid duplicating efforts. CMS may also direct the MIDS Contractor to work and coordinate with, to the extent feasible, external entities, such as those described in the following sections.

The MIDS Contractor shall anticipate CMS' requirement for burden reduction measure simplification, strategic alliance with cross-setting measurement and outcome improvement using a focused approach that will seek to harmonize measurement concept and measurement application across appropriate settings as reflected by the measurement specifications and data elements required to establish and calculate the measures. CMS is working to align, harmonize, and prioritize measure development and maintenance activities across programs and settings. CMS convenes a number of working groups to review measures or measure sets to determine where opportunities exist for alignment and harmonization. CMS is also actively engaged with various workgroups at HHS and the "National Consensus Development and Strategic Planning for Healthcare Quality Measurement" contractor, National Quality Forum (NQF)-convened Measures Application Partnership (MAP) and National Priorities Partnership (NPP).

The MIDS Contractor must align their Project Management Plan (PMP) with CMS rulemaking schedules and relevant statutory timelines, such as time lines related to the pre-rule-making process required under Section 3014 of the Patient Protection and Affordable Care Act (ACA), rulemaking, Paperwork Reduction Act (PRA) submission, the Blueprint, data submission specification development, and integral deadlines and timelines related to public engagement and web-based postings.

2.C.1. - Other MIDS Contractors

The MIDS Contractor shall coordinate with other MIDS Contractors, as directed by the TO Contracting Officer Representative (COR), to accurately and reliably measure and reflect the level of quality care being provided throughout the health care system. If directed, the MIDS Contractor shall utilize all available tools [e.g., Measures Management Contractor, Quality Information Evaluation System (QIES), the National Data Base, the Chronic Conditions Warehouse, National Claims History, Measures Authoring Tool, etc.] to ensure coordination and prevent duplication of efforts. As a part of its coordination activities, the MIDS Contractor shall participate in information sharing sessions, such as Program/Contractor Status or Updates.

2.C.2. – Measures Management

CMS developed a standardized approach for developing and maintaining the quality measures used in its various quality initiatives and quality reporting programs, known as the MMS. The MMS, overseen through a MIDS TO, is this system composed of a set of business processes and decision criteria that CMS-funded measure developers (or Contractors) follow when developing, implementing and maintaining quality measures. The major goal of the MMS is to provide

critical information to the measure developers to help them produce high caliber quality measures that are appropriate for accountability purposes. The MMS was developed to help CMS develop quality measures which can be used to evaluate health care delivery and which can be applied to use in various public reporting and quality programs as well as in value- based purchasing initiatives. The full MMS set of business processes and decision criteria are documented in or described in the Blueprint.

The Blueprint is updated annually by the Measures Manager, given the evolving nature of the quality measurement environment. CMS uses the standardized processes documented in the Blueprint to ensure that the resulting measures form a coherent, transparent system for evaluating quality of care delivered to its beneficiaries. The Measures Management Contractor will provide consultation regarding the application of the Blueprint. CMS may direct the MIDS Contractor to review and comment on the proposed Blueprint updates and work collaboratively with the Measures Management Contractor to integrate the processes detailed in the Blueprint into the activities as specified in future TOs. The MIDS Contractor shall work with their COR, Subject Matter Experts (SMEs) and the Measures Management Contractor to ensure they are working IAW the most up-to-date Blueprint processes, tools, and forms. This ongoing activity includes participating in monthly measures contractor measure development and maintenance coordination meetings to ensure that measures contractors are following vital steps of the MMS Blueprint for harmonization purposes.

Please note: There is a restriction to the MMS TO. Given the purpose of the MMS, the MMS contractor may not hold a CMS TO for quality measure development. However, the MMS contractor may hold a non-measure development MIDS TO that allows the contractor to maintain impartiality to the development process (ex. Education and outreach or annual report). CMS will evaluate TOs on a case by case basis to determine if there is a conflict of interest.

2.C.3. – State Agencies for Survey and Certification

The MIDS Contractor upon direction of the COR, shall work with State Agencies responsible for quality monitoring, data transmission, receipt and/or analysis in order to coordinate all instrument activities.

2.D. - Project Management

2.D.1. - Project Management Plan (PMP)

For awarded TOs, the MIDS Contractor will be required to develop and submit an integrated PMP that defines the necessary steps (flowchart of activities), milestones, dates, deliverables, dependencies, critical path, and resources needed to execute the contract work as well as a tracking method to update regularly (via dashboard or other as indicated by the TO). This may include but not be limited to the Blueprint activities for measure and patient assessment instrument development, the Information Technology (IT) development life cycle pertaining to data collection item set development, PRA submission, policy-based decisions, public engagement, including the pre-rule-making process required under Section 1890(A) of the Social Security Act (review by the NQF-convened MAP), in order to meet successful program

deliverables. The PMP also provides constraints of the project and addresses how the MIDS Contractor proposes to perform the work described under the TO. All project plans shall be modified and updated continuously after the initial submissions to reflect any major changes in the project.

The Contractor shall identify, under Key Personnel, a professional project manager, who has the skills and expertise to follow best practices for the management of a project including the development of a formal work breakdown structure (WBS), timeline, project milestones, critical path, and risk factors. The project manager shall be responsible for collaborating *weekly* with CMS' Project Management Oversight Point of Contact, to indicate actions, refinement and progress relative to this contract's tasks and team responsibilities.

The MIDS Contractor shall specifically be responsible for identifying all dependencies both in relation to what is dependent upon the MIDS Contractor's project work, and what the MIDS Contractor is dependent upon to carry out its deliverables. The MIDS Contractor shall identify where some project efforts are fully dependent, while others may be attended to in a parallel fashion. This strategic monitoring is essential to ensure the integration of the various activities necessary to meet the complex requirements involved in actualizing all facets of the various CMS programs in their totality, e.g., the Blueprint requirements, rulemaking, training, assessment instrument modification, requirements gathering, PRA submission, data submission specifications, 508 requirements, manual development, etc. noting that some CMS programs may require all aspects of programmatic development while others may be exempt from some aspects (e.g. the MIDS does not require a PRA package to be developed).

In developing the PMP, the MIDS Contractors that are developing measures shall adhere to the following high level steps:

1. Environmental scan (includes data analysis, literature review, etc.)
2. Identify risk and mitigation strategies
3. Quality measure development and maintenance, suitable for Consensus Entity Endorsement
4. Instrument/item development (includes refinement of existing data items or instruments)
5. Field testing/validation
6. Implementation and production
7. Data collection vehicle/assessment tool/standardized data item set development

All measure and assessment development and maintenance-related work shall follow the processes specified in the Blueprint. The Contractor shall dedicate sufficient number of well-qualified staff and labor hours to coordinate their contract activities with the CMS Measures Management Contractor in fulfilling all activities identified in the Blueprint. As directed in the TO, the Contractor may be required to provide the Measures Management Contractor with updates on the progress and status of all measure activities during the regularly scheduled project team call including minutes and agendas.

Deliverable 2-1 (Draft PMP): The MIDS Contractor shall submit a draft PMP during the first 5 calendar days following the award of the TO

Deliverable 2-2 (Final PMP): The MIDS Contractor shall submit a final PMP during the first 15 calendar days following the award of the TO

The draft plan shall include the information described above and shall be submitted in electronic format and hard copy (hard copy only if requested) no later than 5 calendar days after TO award. The final plan shall be submitted no later than 15 calendar days after the TO award. The Contractor will utilize the PMP to inform and ascertain critical work paths, and guide decisions related to deliverable requirements.

The MIDS Contractor will provide an updated project plan after these initial submissions to reflect any major changes in the project. A major change is defined as an issue or an event that shifts the work or plan by more than 2 business days. When changes are identified, a draft plan shall be submitted for review within 3 business days of identifying the change. CMS will provide comments within 5 business days and the final plan will be due 5 business days after receipt of CMS comments. If CMS comments are not received within 10 business days, the draft plan becomes final.

The draft PMP shall minimally include the following:

1. Details of the work to be performed
2. Key staff types devoted to each activity, if appropriate, and time allocation for each
3. Key bi-directional dependencies
4. Unique CMS requirements as applicable to each program
5. Key milestones signifying successful completion of each activity and periodic internal assessment/progress reports planned
6. Activity interdependency and critical path for completion

The MIDS Contractor shall maintain a working PMP which is updated with revisions or changes on a regular basis, at least monthly. All changes to the PMP must be reviewed and approved by the COR.

2.D.2. - Kickoff Meeting

Deliverable 2-3 (Kickoff Meeting): Under an awarded TO, a Kickoff Meeting shall be held no later than 30 calendar days after the TO award unless otherwise negotiated with the COR.

At the Kickoff Meeting, the MIDS Contractor shall work with CMS personnel to develop a PMP. The MIDS Contractors shall invite the Measures Management Contractor and Measures Manager COR or arrange for a separate meeting with the Measures Management Contractor to review Blueprint processes, forms, and tools. The MIDS Contractor shall be responsible for providing meeting minutes and deliverables for all activities no later than 3 business days following each meeting.

The Kickoff Meeting minutes shall include, at a minimum, the following information:

1. A list and timeline of all deliverables necessary to ensure completion of the activities described in the TO SOW.
2. Reporting expectations
3. Other general TO expectations and milestones

2.E.- Deliverables

Timely deliverables are critical to the success of the MIDS contract. Timely is defined as the deliverables being received by all parties by the due date referenced in the deliverable schedule in a manner that complies with CMS data security policy, especially if the deliverables contain personal health data or confidential data. Due dates will include the preliminary due dates needed for CMS review of draft documents and collaboration with other various agencies and CMS components. **All** deliverables shall meet 508 compliance guidelines.

For email deliverable submissions, the received date is the date the deliverable is emailed by the MIDS Contractor to the recipient(s). Hard copy mail delivery (if requested by the COR) is considered received on the date it arrives in the hands of the recipient(s). If deliverables are required in both electronic and hard copy, the email copy must be submitted by the due date. If the MIDS Contractor anticipates problems with a deliverable, it should take steps to forward the deliverables earlier than the due date so that problems can be resolved prior to the due date.

Deliverable 2-4 (Submittal of all Deliverables): The MIDS Contractor shall submit to their COR, at the end of the TO year, an electronic package in an agreed upon format containing all the deliverables listed in the TO SOD.

2.F. – Ad Hoc Requests

Deliverable 2-5 (Ad Hoc Requests): CMS may need information on an ad hoc basis regarding its Contractors' activities. The MIDS Contractor shall provide such information upon request.

For measures developed using complex statistical methodologies, the MIDS Contractor shall have staff with graduate-level training in advanced statistical methods, and working knowledge in CMS claims, patient assessment and/or survey data, and work experience in federally-funded national studies on topics related to health outcomes, health care costs and utilization, and quality. Additionally the Contractor should have technical writers to ensure that requested deliverables are well-written and clear. Examples of ad hoc requests may include but not be limited to responding to reports in publications or other sources (e.g., the impact of \$4 retail prescriptions on the validity of claims- based measures), trend reports of exclusion use, and activities which support other Contractors as directed by CMS. The number of ad hoc requests will be identified at the TO level.

<u>Deliverables in Chapter 2:</u>
Deliverable 2-1 (Draft PMP)
Deliverable 2-2 (Final PMP)

Deliverable 2-3 (Kickoff Meeting)
Deliverable 2-4 (Submittal of all Deliverables)
Deliverable 2-5 (Ad Hoc Requests)
Deliverable 2-6 (To Be Determined (TBD), if necessary)
Deliverable 2-7 (TBD, if necessary)

CHAPTER 3. INFORMATION GATHERING

Under an awarded TO, the MIDS Contractor shall be required to gather and analyze data and information relating to activities specified in the TO SOW in the form of an environmental scan and empirical data analysis of all pertinent data/information sources.

Information gathering is the first step in the development of new measures or the maintenance of existing measures or can be used for other purposes related to measure or program evaluation and implementation. Information gathering shall provide a significant knowledge base that includes quality goals, the strength of scientific evidence (or lack thereof) pertinent to the topics/condition of interest for the specific TO, as well as information with which to build a business case for the development of a measure(s) or for maintaining a measure(s). Refer to the Blueprint for additional information related to information gathering. Relevant steps shall be followed for the patient/RAI modifications, for example, in relation to the modification of assessment instrument data elements in the SNF/Nursing Facility RAI MDS.

For such TOs, the MIDS Contractor must initially gather a variety of information and conduct analysis to assess the concept or domain discussed in the TO SOW for the measures to be developed or maintained to determine the following four criteria that have been adopted from the IOM: importance/relevance, scientific soundness, usability/actionability, and feasibility.

Example Blueprint requirements associated with information gathering as specified under an awarded TO may include:

Deliverable 3-1 (Information Gathering Report): Information Gathering Reports shall include a summary report of the Environmental Scan and Empirical Data Analysis and other information.

Deliverable 3-2 (List of Potential Measures): List of potential measures

Deliverable 3-3 (Measure Information Form (MIF)): Documentation on MIF (Note: Contractors begin to fill in some of the fields in the MIF)

Deliverable 3-4 (Measure Justification Form (MJF)): Documentation on MJF (Note: Contractors begin to fill in some of the fields in the MJF)

Deliverable 3-5 (Business Case Development): Development of the business case for measure concepts, topics, and/or candidate measures.

3.A. – Environmental Scan

This can be done via various methods, such as literature review, clinical performance guideline search, interviews, or other activities. At a minimum, for the development of new measures and patient assessment data elements, the scan shall identify current applicable measures and data elements that might be appropriate for the specific TO, through research with the following sources: employers, commercial plans, managed care plans, Tricare, NQF, MedPac, IOM,

Institute for Health care Improvement (IHI), Veterans Health Administration (VHA), Department of Defense (DOD) and the NPP.

In conducting the scan, consideration should also be given to the CMS Quality Measurement Task Force Goals, as well as Medicare top volume and top cost conditions. As specified in the TO, the Contractor may be required to conduct a literature review and scan the Internet for relevant sites, peer-reviewed journal articles, gray literature, competing measures, and other reliable sources of information relating to the topic.

The Contractor may be expected to conduct an additional environmental scan of existing performance measures for the purposes of developing measures that facilitate high quality care, such as those that measure quality related to safety and adverse events, health care acquired conditions, such as health care-associated infections, and those that measure quality related to patient-centered care, such as symptom management, care coordination, and readmissions. The Contractor may include, in the establishment of measures and the modification of assessment instruments, any aspect that will be used to drive high quality care. It is important that such measures be consistent with the IOM's Six Aims of Care: safety, timeliness, efficiency, effectiveness, equitability and patient centeredness. The Contractor shall explore the dimensions related to quality, in various ways, in order to generate performance measures that inform the public about how well a provider manages patient care, e.g., care coordination, ensuring safety and symptom management, with respect to the IOM's Six Aims of Care.

The Contractor shall prepare a report of the Environmental Scan activities conducted to document their findings. Activities shall include, but are not limited to:

1. Search for related or similar measures (and data elements) as well as competing measures, and identify opportunities for harmonization and alignment.
2. Clinical guidelines pertinent to the clinical domain or topic specified in the SOW.
3. Studies that document the success of particular measures in the same or similar health care setting or domain covered in the SOW.
4. Scientific evidence to support the clinical leverage points, such as importance, on which measures can be based.

3.B. –Expert Input

CMS may direct the MIDS Contractor to solicit input from a variety of sources as a step in the development of new measures, evaluation/maintenance of existing measures, or for other purposes, as directed by a specific TO. Input may be solicited from industry-related professional organizations and associations, clinical, and technical experts through such means as stakeholder groups, Open Door Forums, structured interviews, Listening Sessions, etc. Input should, where appropriate, specifically include clinical expertise and SMEs from within the Federal Government agencies, e.g., the Department of Veterans Affairs (VA), Centers for Disease Control and Prevention (CDC), DOD as well as from the public sector.

Deliverable 3-6 (Expert Input Report): The Contractor shall summarize the input referenced in the above paragraph in the Expert Input Report.

3.C. - Data Analysis

If data is available, the Contractor may be directed to conduct an empirical data analysis to provide statistical or other evidence to support the selection of the topics, conditions, or potential measures and to assist in the development of the business case for the topics, conditions or measures. Data analysis is conducted to achieve several objectives. These activities may include, but are not limited to:

1. Provide analysis to inform CMS policy decisions.
2. Provide the evidence that informs inclusion or exclusion criteria related to population groups or geographical regions into measure/item specifications.
3. Provide evidence for the identification of specific clinical topics, and performance measurement needs.
4. Provide evidence/justification for the business case to select or develop measures.
5. Provide data validation plan, or directly apply specific strategies that will ensure accuracy in reporting.
6. Provide evidence of evaluation factors that may influence measure performance, such as health literacy and social and demographic factors.

3.D. – Summary Report

Under the awarded TO, the Contractor shall provide a narrative report of the information gathered (Information Gathering Report - Deliverable 3-1), to include, but is not limited to (specific requests may be made upon each TO award):

- Summary Report of Environmental Scan findings
- Input from technical experts or other stakeholders
- Empirical Data Analysis findings
- Business Case for the concept, topic, condition, and/or potential measure(s).

3.E. – Reporting Information Gathering Costs

When reporting Information Gathering costs following an awarded TO, the MIDS Contractor shall include any hours and associated costs dedicated to pre-measure/item development that includes data analysis, literature review, etc. and/or other activities meeting the characteristics described in IDIQ SOW Chapter 3 (Information Gathering) and included in the specific TO.

<u>Deliverables in Chapter 3:</u>
Deliverable 3-1 (Information Gathering Report)
Deliverable 3-2 (List of Potential Measures)
Deliverable 3-3 (MIF)
Deliverable 3-4 (MJF)
Deliverable 3-5 (Business Case Development)
Deliverable 3-6 (Expert Input Report)
Deliverable 3-7 (TBD, if necessary)
Deliverable 3-8 (TBD, if necessary)

CHAPTER 4. QUALITY MEASURE DEVELOPMENT & REEVALUATION

The Quality Measure Development Activity represents those activities associated with refining, enhancing, developing, or modifying only performance measures to include ratios, rates, and/or composite measures.

4.A. – Quality Measure Development

Under an awarded TO, the MIDS Contractor shall develop performance measures including electronic Clinical Quality Measures (eCQMs) based on the domains/concepts/priorities defined in each TO SOW. The Contractor shall utilize the Blueprint to guide measure development and maintenance. As part of this process, measures must undergo public input as noted therein. Based on the results of the information gathered, measures that are specific and relevant to the domains/concepts/priorities described in the TO SOW shall be developed. The Contractor shall work with their COR, appropriate SMEs, and the Measures Management Contractor to ensure they are working IAW the most up-to-date Blueprint process, tools, and forms.

New Measure Development/Adaptation of Existing Measures

Please note for the information provided in this section: Some of the criterion does not apply to certain types of measures. CMS requires the application of NQF's most recent version of measure criteria for each of the subsets of measures, which can be accessed at www.qualityforum.org.

The following criteria shall be considered during the process of new measure development/adaptation of existing measures. These criteria align with the measure evaluation criteria below, established by a CBE, including, but is not limited to, the CBE currently under contract with the Secretary under §1890 of Title XVIII of the Social Security Act. However, to note, Contractors must reference the Blueprint for additional information and the most current criteria:

1. Impact, Opportunity, Evidence—Importance to Measure and Report: extent to which the specific measure focus is evidence-based, important to making significant gains in quality, and improving health outcomes for a specific high-impact aspect of care where there is variation in or overall less-than-optimal performance. *Measures must meet all three sub-criteria to pass this criterion and be evaluated against the remaining criteria.*

a. **High Impact** – The measure focus addresses:

1. A specific national health goal/priority identified by HHS or the NPP convened by the CBE;
- OR**
2. A demonstrated high-impact aspect of health care (e.g., affects large numbers of patients and/or has a substantial impact for a specific population segment; leading cause of morbidity/mortality; high resource use (current and/or future); severity of illness; and severity of patient/societal consequences of poor quality).

AND

- b. **Performance Gap** – demonstration of quality problems and opportunity for improvement, i.e., data demonstrating considerable variation, or overall less- than-optimal performance, in the quality of care across providers and/or population groups (disparities in care).

AND

- c. **Evidence to Support the Measure Focus** – The measure focus is a health outcome or is evidence-based, demonstrated as follows:
- **Health outcome:** a rationale linking a specific health outcome to processes or structures of care.
 - **Intermediate clinical outcome, Process, or Structure:** a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence that the measure focus leads to a desired health outcome.
 - **Patient experience with care:** evidence that the measured aspects of care are those valued by patients and for which the patient is the best and/or only source of information OR that patient experience with care is correlated with desired outcomes.
 - **Efficiency:** evidence for the quality component as noted above.
- d. **Measure focus is supported by the quantity of evidence, strength of evidence, and consistency** of results in the body of evidence.
- **Quantity of Body of Evidence:** total number of studies (not articles or papers)
 - **Quality of Body of Evidence:** certainty or confidence in the estimates of benefits and harms to patients across studies in the body of evidence related to study factors including: study **design** or flaws; directness/indirectness to the specific measure (regarding the population, intervention, comparators, outcomes); imprecision (wide confidence intervals due to few patients or events). Study factors include: a) Study designs that affect the strength of evidence may include, but are not limited to: the design and implementation of randomized controlled trials (RCTs), which, in theory, control for both observed and unobserved confounders, and the design and implementation of non-RCTs (observational studies), which tend to vary in the level of control for observed confounders, b) Study designs that may bias estimates of effect include, but are not limited to: lack of allocation concealment; lack of blinding; lack of adjustments (sampling or statistical) for large losses to follow-up; failure to adhere to study protocols; stopping early for benefit; and failure to report important outcomes.
 - **Consistency of Evidence:** Stability in evidence related to both the direction and magnitude of clinically/practically meaningful benefits or harms to patients (benefit over harms) across studies.
2. **Reliability and Validity—Scientific Acceptability of Measure Properties:** extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the

quality of care when implemented. ***Measures must meet the sub-criteria for both reliability and validity to pass this criterion and be evaluated against the remaining criteria.***

a. Reliability

- i. The measure is well defined and precisely specified so it can be implemented consistently within and across organizations and allow for comparability. Electronic Health Records (EHR) measure specifications are based on the quality data model (QDM).
- ii. Reliability testing demonstrates that the measure results are repeatable when assessed in the same population in the same time period and/or that the measure score is precise.
- iii. Reliability is ensured through the use of uniform, standardized data elements that are used to collect focused-assessment information (in a standardized format). Information collected using such data elements enables the calculation of a measure and ensure a consistent, systematic approach to information gathering. This allows for quality measurement implementation across settings at the data element level.

b. Validity

- i. The measure specifications are consistent with the evidence presented to support the focus of measurement under criterion 1c. The measure is specified to capture the most inclusive target population indicated by the evidence, and exclusions are supported by the evidence.
- ii. Validity testing demonstrates that the measure data elements are correct and/or the measure score correctly reflects the quality of care provided, adequately identifying differences in quality.
- iii. Exclusions are supported by the clinical evidence; otherwise, they are supported by evidence of sufficient frequency of occurrence so that results are distorted without the exclusion;

AND

If patient preference (e.g., informed decision-making) is a basis for exclusion, there must be evidence that the exclusion impacts performance on the measure; in such cases, the measure must be specified so that the information about patient preference and the effect on the measure is transparent (e.g., numerator category computed separately, denominator exclusion category computed separately).

- iv. For outcome measures and other measures when indicated (e.g., resource use):
 - An evidence-based risk-adjustment strategy (e.g., risk models, risk stratification) is specified; is based on factors that influence the measured outcome (but not factors related to disparities in care or the quality of care) and are present at start of care; and has demonstrated adequate discrimination and calibration.

OR

- Rationale/data support risk adjustment/stratification is not necessary or feasible.
- v. Data analysis of computed measure scores demonstrates that methods for scoring and analysis of the specified measure allow for identification of statistically significant and practically/clinically meaningful-differences in performance;

OR

There is evidence of overall less-than-optimal performance.

vi. If multiple data sources/methods are specified, there is demonstration they produce comparable results.

c. **Disparities: if disparities in care have been identified, measure specifications, scoring, and analysis allow for identification of disparities through stratification of results (e.g., by race, ethnicity, socioeconomic status, gender);**

OR

Rationale/data justifies why stratification is not necessary or not feasible.

3. Feasibility: the extent to which the required data are readily available or could be captured without undue burden and can be implemented for performance measurement (Note: not all measures programs receive incentives/adjustments for performance measurement).

- a. For clinical measures, the required data elements are routinely generated and used during care delivery (e.g., blood pressure, lab test, diagnosis, medication order).
- b. The required data elements are available in EHRs or other electronic sources. If the required data are not in EHRs or existing electronic sources, a credible, near-term path to electronic collection is specified.
- c. Susceptibility to inaccuracies, errors, or unintended consequences and the ability to audit the data items to detect such problems are identified.
- d. Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality, etc.) can be implemented (e.g., already in operational use, or testing demonstrates that it is ready for operational use).

4. Usability and Use: extent to which intended audiences (e.g., consumers, purchasers, providers, policymakers) are using or could use performance results for both accountability and performance improvement to achieve the goal of high quality and efficient health care for individuals or populations.

- a. Accountability and Transparency: demonstration that performance results of a measure are used or can be used in public reporting, accreditation, licensure, health IT incentives, performance-based payment, or network inclusion/exclusion.

AND

- b. Improvement: demonstration that performance results facilitate the goal of high quality efficient health care or credible rationale that the performance results can be used to further the goal of high quality efficient health care.

AND

- c. Benefits of the performance measure in facilitating progress toward achieving high quality efficient health care outweigh the evidence of unintended consequences to individuals or populations (if such evidence exists).

- 5. Harmonization:** extent to which either measure specifications are harmonized with related measures so they are uniform or compatible or the differences must be justified (e.g. dictated by evidence).
- a. Related measure: the measure specifications for this measure are completely harmonized with a related measure.
 - b. Competing measure: this measure is superior to competing measures (e.g. a more valid or efficient way to measure quality); OR has additive value as an endorsed additional measure (provide analyses if possible).
 - c. Application of measures across settings using standardized, uniform data elements for measures.
 - d. The Contractor will develop and update, as needed, the data collection vehicles/assessment instruments to ensure the implementation of measurement alignment, and measure application, per endorsement requirements. Such alignment shall include data element harmonization where applicable. They will ensure appropriate collaborative efforts with other MIDS Contractors, and others as directed, to ensure oversight of data element harmonization and subsequent updates.
- The Contractor may be required to use additional criteria as determined by CMS IAW the Blueprint and as specified in the TO. The Contractor shall consult with the Measures Management Contractor if the Contractor is required to use additional criteria.

4.A.1. - Technical Expert Panels (TEP)

Under an awarded TO, the MIDS Contractor shall, as appropriate, identify and recruit a group of nationally recognized experts in the relevant fields, including clinicians (physicians, pharmacists and registered nurses), statisticians, quality improvement experts, methodologists, consumers, experienced measure developers, and EHR vendors to work with the measure contractor to develop the technical specifications and business case for measure development, review testing results, and to identify potential measures for further development or refinement. Each TEP shall have at minimum of one patient or caregiver on its roster in order to provide input into quality issues that are important to patients. The Contractor, shall, in turn, propose the list of measures to CMS. Refer to the TEP section of the Blueprint.

The MIDS Contractor shall follow the Blueprint in convening a TEP to include, but not be limited to:

Deliverable 4-1 (TEP Composition Documentation Form): Convene a TEP by issuing a call for TEP on the CMS website. Select a balanced panel that specifically includes persons/caregivers, and clinical experts that may exist outside of the provider stakeholder groups.

IAW Deliverables 3-1, 3-2, and 3-6: Prepare and disseminate materials for the TEP.

Deliverable 4-2 (Measure Evaluation Report for Each Measure): Conduct the TEP meeting via conference call, WebEx or in person.

Deliverable 4-3 (Summary of TEP Evaluation of Measures): Document and summarize the TEP's review, input, discussions of the measures. Propose recommended set of measures to CMS.

Other Blueprint requirements associated with convening a TEP include:

1. Call for TEP member nominations.
2. TEP Nomination/Disclosure/Agreement forms.
3. TEP Charter.
4. TEP membership list.
5. Meeting materials and minutes.
6. Potential measures presented to the TEP.
7. Measure Evaluation reports.
8. If the MJF and MIF are modified after the TEP meetings, updated versions shall be submitted.
9. TEP Summary report, including list of candidate measures.

MIDS Contractors should refer to the Blueprint for additional specific information regarding TEPs.

4.A.2. – Public Comment

The public comment period specified in the Blueprint ensures that CMS measures are of the highest caliber possible by using a transparent process with balanced input from relevant stakeholders, including patients. The public comment period provides an opportunity for the widest array of interested parties to provide input on measures and assessment data elements under development and to provide critical suggestions not previously considered by the measure contractor or the TEP. Additionally, public comment is a requirement for both the modification of the post-acute care assessment instruments and the measures used in satisfaction of the IMPACT Act.

The federal rule-making process also includes a public comment period and provides an additional opportunity to obtain public feedback on CMS measures. The federal rule-making process is primarily used for measures utilized in quality reporting and pay for performance programs.

The Example Blueprint requirements applicable to soliciting public comments include, but are not limited to (MIDS Contractors should refer to the Blueprint for additional details):

1. Call for Public Comment
2. List of Stakeholders for Notification
3. MIFs and Measure Justifications for Candidate Measures
4. Verbatim Public Comments
5. Responses to Public Comment
6. Public display of outcome of measures related to the call for Public Comment
7. Public Comment Summary Report

4.A.3. – Standardized Measure Selection Criteria

All measures recommended for use by CMS will be reviewed against the following criteria:

1. Importance to Measure and Report

2. Scientific Acceptability of Measure Properties
3. Usability and Use
4. Feasibility
5. Harmonization

The MIDS Contractor may be required to use other criteria as determined by CMS and IAW the Blueprint and specified in the awarded TO. The Contractor shall consult with the Measures Management Contractor if the MIDS Contractor requires additional criteria.

4.A.4. – Technical Specification & Documentation

Under an awarded TO, the MIDS Contractor shall provide complete, detailed, and precise technical specifications for all measures, standardized data item sets and data collection vehicles developed. The Contractor shall develop measures specifications consistent with the processes described in the Blueprint while being mindful that the Blueprint is updated periodically to improve and streamline processes; thus, new forms and tools may be developed. The MIDS Contractor must work closely with the Measures Management Contractor to ensure they are working IAW most up-to-date forms and tools.

The contractor shall provide technical specifications and requirements to CMS's contractors/components supporting the data submission of such data, so that technical specifications can be developed, for provider and vendor use.

Example Blueprint requirements associated with the development of the measure technical specifications include, but are not limited to (MIDS Contractors should refer to the Blueprint for additional details):

IAW Deliverable 3-3: MIF - Several iterations of this form will be required as the measures are more fully specified over the course of measure development.

IAW Deliverable 3-4: MJF - Several iterations of this form will be required as the measures are more fully specified over the course of measure development.

For Contractors developing eMeasures, the Health Quality Measures Format (HQMF) document shall be used in lieu of the MIF (refer to the eMeasure Specifications section in the Blueprint for further details). Other requirements associated with the eMeasure Specifications section include application of the Measure Authoring Tool (MAT) and provision of the following:

- Machine readable file (.xml)
- Human readable file (.html)
- Web facing file
- eMeasure style sheet
- Link to the National Library of Medicine Value Set Authority Center
- MJF (required only for de novo eMeasures)

To complete these forms, the Contractor shall use the instructions in the Blueprint, most specifically the Technical Specification section, as well as other pertinent sections (eMeasures and Risk Adjustment section).

Deliverable 4-4 (Risk Adjustment Section of the MIF): The Contractor shall complete the Risk Adjustment section of the MIF. The Contractor shall use the instructions in the Blueprint in the Risk Adjustment Section to complete the section.

Deliverable 4-5 (Draft Documentation Set): The Contractor shall complete a Draft Documentation Set (or package) of draft MIFs and MJFs for a representative sample of measures in the set and submit to the COR and Measures Management Contractor for review and comment.

Deliverable 4-6 (Final Documentation Set): The Contractor shall complete a Final Documentation Set (or package) of MIFs and MJFs for all measures in the set and submit to the COR and Measures Management Contractor. The Contractor may be required to revise these forms based on the measure testing results, public comment, or feedback from the COR.

For quality measures that utilize a data collection vehicle or standardized data item set, the Contractor shall provide, or work in collaboration to provide:

1. The technical submission specifications and requirements for the data elements used in the data collection vehicles or standardized data item sets, and apply the most up-to-date, federally-adopted uniform standards for the electronic exchange of clinical health information to all data elements, data collection instruments and quality measures developed under the MIDS IDIQ SOW. These uniform standards may include, but are not limited to, Health Level 7 (HL7), Laboratory Logical Observation Identifier Name Codes (LOINC), HIPAA transactions and code sets, RxNORM, SnoMED.
2. The contractor shall consult with the CMS COR and appropriate SMEs to determine if additional collaboration/coordination with other HHS components, such as the Division of Health Information Technology (DHIT) at CMS and DHIT's Contractors or the Office of the National Coordinator for Health Information Technology (ONC), shall be needed to identify and apply the most up-to-date, federally-adopted uniform standards for electronic data exchange. Such coding will be provided for public use.
3. Provide justification, and supporting evidence as needed for CMS-based Change Control Boards, e.g., CMS'S Data Element Library's CMS Assessment Library Data Council (CALDC) when there are data element changes, or when new data element inclusions are required, or requested.
4. Support the development or modification of data collection vehicles, e.g., the technical submission specifications, and the sub-specifications, such as those that pertain to the quality measurement data elements collected via such a vehicle.
5. Support, as appropriate and required, standardized (uniform) data elements for use across assessment instruments, e.g. the MDS and the other post-acute care assessment instruments.
6. Technical specifications shall include data submission specifications that provide the data logic necessary to ensure that data responses given in the measurement's construct are logical and consistent. This supports the measurement's construct and logical "underpinning" data that is collected as information and determines what is used in the measure's actual construct. The Contractor shall provide all documents, e.g. the measurement technical specifications, and the technical submission specifications and

sub-specifications manual(s), for public display.

7. For eCQMs, measure developers shall follow the NQF guidance or the guidance of other CMS Contractors to assess the current state of feasibility testing for new and retooled eMeasures and identify a set of principles and criteria for adequate feasibility testing. Note that the NQF guidance may evolve over the life of the contract, and shall be re-examined regularly.

4.A.5. Consensus-Based Entity (CBE) Endorsement

To the extent feasible, CMS uses measures that have been endorsed by the CBE under contract with the Secretary pursuant to § 1890 of Title XVIII of the Social Security Act.

Deliverable 4-7 (CBE Endorsement Submission Materials - Draft): The MIDS Contractors shall submit a draft of the CBE measure submission materials and all necessary attachments to CMS and the Measures Management Contractor for review and comment.

Deliverable 4-8 (CBE Endorsement Submission Materials - Final): Once the draft submission is approved, CMS will submit the required documentation to the CBE for all the measures in the set.

The CBE Requirements can be found at <http://www.qualityforum.org/>. The Contractor shall be actively involved with the endorsement process, including taking the initiative to reach out to the CBE to seek technical assistance, feedback, and clarification, and provide substantive responses to inquiries and requests regarding the measures from the CBE Steering Committee activities in a timely manner. If directed to do so by the Contractor's COR, the Contractor may be asked to revise measure specifications multiple times. For additional information on the Consensus Development Process (CDP), refer to the CBE Section in the Blueprint.

Requirements associated with CBE include, but are not limited to (MIDS Contractors should refer to the Blueprint for additional details):

1. Developers with measures for endorsement are asked to respond by email that includes:
 - Title and description of each measure they intend to submit for evaluation.
 - The name of the submitting organization and/or developer.
 - The name, email address, and phone number of the contact person.
2. Measure Contractors must submit their measures via an online Measure Submission Form. The online form is available on the CBE Web site and allows users to:
 - Gain secure access to the submission form from any location with an Internet connection.
 - Save a draft version of the form and return to complete it at their convenience.
 - Print a hard copy of the submission form and/or electronically save the submission form for reference.
3. When appropriate, the Contractor shall provide the rationale for measurement expansion to additional settings, to include rationale as it pertains to appropriateness, feasibility, validity,

and reliability of measures, and demonstrate the application of standardized data elements to such additional settings when appropriate.

4. In expanding measures to other settings, the Contractor shall include rationale from publicly available resources such as Government Accountability Office (GAO), the Office of the Inspector General (OIG) and the Medicare Payment Advisory Commission (MedPAC) reports, as appropriate. The Contractor shall also provide a discussion on whether there is a need for developing a different attribution approach for the settings in question, and a detailed description of potential options for attribution approaches.
5. The Contractor shall present and support CMS measures during NQF Steering Committee and CSAC reviews, and shall be fully prepared to provide technical information needed to defend the endorsement of CMS measures.
6. After the NQF has completed its CDP, the measure contractor will meet with the Contractor's COR and appropriate SMEs and the Measures Management Team to discuss the results of the CDP, why CMS measures were not endorsed (if any were not), identify lessons learned regarding both the NQF process and CMS MMS processes.

4.B. – Quality Measure Reevaluation

Under an awarded TO, the MIDS Contractor shall conduct a measure reevaluation based on the domains/concepts/priorities defined in each TO SOW. Depending on the type of measure reevaluation needed (comprehensive, update, or ad hoc), the Contractor shall utilize the Blueprint to guide measure reevaluation. The Contractor shall work with their COR, CMS SMEs, and the Measures Management Contractor to ensure they are working IAW the most up-to-date Blueprint process, tools, and forms.

Types of measure reevaluations: update, comprehensive, and ad hoc.

4.B.1.- Measure Update Reevaluation

Deliverable 4-9 (Maintenance Reevaluation): The MIDS Contractor shall produce a limited review of the precision of the measure's specifications focused on ensuring that the procedure, diagnostic, and other codes (CPT, ICD-10- CM, LOINC, etc.) used within the measure are updated when the coding sets are updated. This measure update may be done annually or semiannually. Feedback received regarding the measure's specifications, reliability, and validity—including the reliability and validity of the measure's constituent data elements—shall be reviewed and addressed at this time. If a paper measure is retooled to an e-measure, the e-specifications are submitted during the measure update process.

4.B.2. - Comprehensive Reevaluation

Deliverable 4-10 (Comprehensive Reevaluation): The MIDS Contractor shall conduct a thorough review of the measure, done no less than every three years, generally IAW the

requirements of the CBE. A Comprehensive Reevaluation of the literature, measure performance rates, and all feedback received regarding the measure is conducted at this time.

4.B.3. - Ad Hoc Reevaluation

Deliverable 4-11 (Ad Hoc Reevaluation): The MIDS Contractor shall conduct a limited review of the measure based on new and urgent information evidence that may have a significant, adverse effect on the measure or its implementation.

4.B.4. Technical Expert Panel

IAW Deliverable 4-1: The MIDS Contractor shall, as appropriate and in consultation with CMS, convene a TEP IAW section 4.A.1 of this chapter.

4.B.5. Standardized Measure Selection Criteria

All measures recommended for use by CMS will be reviewed against the following criteria:

1. Importance to Measure and Report
2. Scientific Acceptability of Measure Properties
3. Usability and Use
4. Feasibility
5. Harmonization

4.B.6. Technical Specification & Documentation

The MIDS Contractor shall provide complete, detailed, and precise technical specifications for all reevaluated measures including SAS codes or other codes/algorithms to calculate the measures as necessary. The Contractor shall evaluate the measures consistent with the processes, forms, and tools described in the Blueprint. The MIDS Contractor must work closely with the Measures Management Contractor to ensure they are working IAW most up-to- date forms and tools. The MIDS Contractor shall use:

Deliverables associated with the three types of measure reevaluation and maintenance activities including:

- a. **IAW Deliverable 3-3**: All maintenance reviews require updated MIFs (including algorithm)
- b. **IAW Deliverable 3-4**: All maintenance reviews require updated MJFs
- c. Measure updates require:
 - o **IAW Deliverable 3-3**: A document summarizing changes made, such as Release Notes if not included in the updated MIF.
 - o CBE Annual Update online submission (whether or not any change was made to the measure).
 - o CBE submission documentation for any material changes to the measure.
- d. Comprehensive Measure Reevaluations also require:
 - o **IAW Deliverables 3-3 and 4-4**: A document summarizing changes made (such as Release Notes), if not included in the updated MIF.

- IAW **Deliverable 3-4:** An updated MJF documenting the environmental scan results, any new controversies (e.g., conflicting medical evidence) about the measure, and any new data supporting the measure.
 - **IAW Deliverable 4-9:** An updated Maintenance Reevaluation report reflecting the experience of the measure compared to the measure evaluation criteria.
 - In the years when an endorsed measure is not being re-evaluated for continued endorsement, measure stewards shall submit the online annual update form to the CBE.
 - CBE endorsement maintenance documentation (at the time of CBEs next scheduled three-year maintenance review).
- e. Ad hoc measure reviews also require:
- **IAW Deliverable 4-11:** Updated Ad Hoc Reevaluation reports, if the review results in a change to the measure's strengths and/or weaknesses.

IAW Deliverable 4-10: The Contractor shall complete a draft set (or package) of these materials for a representative sample of measures and submit to the COR and Measures Manager Contractor for review and comment.

IAW Deliverable 4-6: The Contractor shall complete a Final Documentation Set (or package) of these materials for all measures in the set submit to the COR and Measures Manager Contractor. The Contractor may be required to revise these forms based on the measure testing results or other activities.

- f. **Deliverable 4-12 (Public Description of Quality Measures):** Public Description of Quality Measures
- g. Other forms as required

To complete these forms, the Contractor shall use the instructions in the Blueprint, most specifically Volume 2, Measure Maintenance.

4.C. – Reporting Quality Measure Development/Reevaluation Costs

When reporting Quality Measure Development and/or Reevaluation costs, the MIDS Contractor shall include any hours and costs dedicated to refining, enhancing, calculating, developing, or modifying quality measures to include specifications, ratios, rates, and/or composite measures, and/or other activities meeting the characteristics described in IDIQ SOW Chapter 4 (Quality Measure Development and Reevaluation) and included in the specific TO.

<u>Deliverables in Chapter 4:</u>
Deliverable 4-1 (TEP Composition Documentation Form)
Deliverable 4-2 (Measure Evaluation Report for Each Measure)
Deliverable 4-3 (Summary of TEP Evaluation of Measures)
Deliverable 4-4 (Risk Adjustment Section of the MIF)
Deliverable 4-5 (Draft Documentation Set)
Deliverable 4-6 (Final Documentation Set)
Deliverable 4-7 (CBE Endorsement Submission Materials - Draft)
Deliverable 4-8 (CBE Endorsement Submission Materials - Final)

Deliverable 4-9 (Maintenance Reevaluation)
Deliverable 4-10 (Comprehensive Reevaluation)
Deliverable 4-11 (Ad Hoc Reevaluation)
Deliverable 4-12 (Public Description of Quality Measures)
Deliverable 4-13 (TBD, if necessary)
Deliverable 4-14 (TBD, if necessary)

CHAPTER 5. INSTRUMENT/ITEM DEVELOPMENT

The Instrument/Item Development Activity represents those activities associated with developing, implementing, modifying, refining, or enhancing, data items/elements within a data collection instrument as well as ensuring data element consistency, when able, across the settings that use data collection vehicles.

5.A. Development of Data Collection Tool/Assessment Instrument & Associated Instructions

Under an awarded TO, The MIDS Contractor shall develop, or contribute to the development of data collection vehicles, such as data sets that are health assessment-based instruments and/or question banks, and which include data element items that are based on quality measurement domains, concepts, and priorities defined in each TO SOW. The Contractor shall work collaboratively with other CMS components or entities in the development or modification of such data collection tools, e.g., to standardize patient assessment instrument data elements as required under the IMPACT Act. Specifically, data elements used for quality measurement collection, or quality measurement and data element testing, should be considered for use in a standardized manner across settings so as to ensure measurement alignment, where able, at the data element level, regardless of setting.

Data collection sets shall be relied upon to ensure the use of standardized data elements, in part to enable interoperable exchange of such data. Therefore, the data element collection vehicles and data sets, such as a patient/resident health assessment-based instruments, shall be approached, in their development and modification, for the applicability of the data elements across the continuum of care settings, severity, population, etc. and shall provide the requisite data properties to calculate the quality measure(s) developed (see Chapter 4). In addition to the data elements providing for a standardized approach to data collection, the development of the data collection vehicles shall be considered for not only their ability to collect the data elements that will provide what is required to calculate the measure, they should also provide the additional data elements necessary to provide the ability to perform internal consistency determinations of the measure's data, as well as other functions such as data validation, and reliability testing and activities such as payment, care planning, longitudinal analysis by providers, informing transitions in care and enabling safe care coordination. The data collection vehicles should be developed, and maintained, with their potential use as a primary source, or as part of the medical record, when appropriate. Data elements may be required for purposes beyond quality measurement data collection, such as for identifying social factors, disparities and gap analysis, payment, Medicare certification, and care planning.

Deliverable 5-1 (Data Collection Tools/Assessment Instruments, Manuals or Instructions, and Updates): The MIDS Contractor shall develop, revise and, or, maintain Data Collection Tools/Assessment Instruments, Manuals or Instructions, and Updates , as appropriate, associated with data collection instruments or patient/RAIs, e.g., the MDS RAI Manual, the Long-Term Care (LTC) Facility RAI User’s Manual, the OASIS Manual, the LTCH CARE Data Set Quality Reporting Program Manual, Hospice Item Set Manual, etc.

The Contractor may be directed to provide support to data-related standardization boards in efforts related to data element changes to the instruments. The Contractor shall work collaboratively with other CMS components when manual sections or chapters require revision/updating, or provide input, in such sections or chapter’s sections as required and requested.

5.B. – Standards

The MIDS Contractor shall incorporate appropriate CMS-specified standards in defining data elements or for the transmission of data where applicable, into all data collection or assessment instruments or/data items developed/identified under this MIDS IDIQ.

5.C. – Data Collection Tool/Assessment Instrument Updates:

5.C.1. – Updates

IAW Deliverable 5-1: _The Data Collection/Assessment Instruments, Manuals, Instructions, and Updates shall include, but are not limited to:

- a. A crosswalk of existing to new/revised data items.
- b. A cross walk of data elements that may differ at the data element level but are congruent, and are (or will be) used in a common quality measure, e.g. data elements in cross setting measures.
- c. Data elements used to calculate measures.
- d. Data elements that are used to support those data elements used directly in measures, e.g., pain assessment evaluation data elements that are used to lead to a pain measure score that is used in a measure’s construct.
- e. Provide data logic, such as the data sub-specifications, associated with data elements used to support the data elements used in the measure calculation.
- f. Skip patterns associated with responses.
- g. Coding response options and/or requirements.
- h. Specifications related to frequency of data collection, e.g. once and random, quarterly, annually, admission, intermittent, discharge, etc.
- i. Provide and update a table, or matrix, that designates the exact use of each data element, and on which assessment.
- j. Routine review of data element reliability, and validity, and recommended changes.
- k. Consideration given to the use of a tested form design.
- l. Provide PRA submission documents as required for data collection implementation.

- m. Ensure public input with regard to data element development, and as appropriate rule making.
- n. Follow the Blueprint Process in data element development and implementation where appropriate.
- o. Ensure adequate provider training on assessment instrument modifications and new measures.

5.C.2. Summary Report

Deliverable 5-2 (Summary Report of New/Revised Data Collection Instruments or Data Items): The Summary Report of New/Revised Data Collection Instruments or Data Item shall include, but is not limited to, the following:

- a. Annotated description of all of the data elements and their purpose/function, e.g., payment items, quality measurement-related items, care planning and/or protocol triggers, etc. with the inclusion of all of the uses of a particular data element when the data element is used for more than one purpose (e.g., for payment and quality measurement).

5.D. – Data Collection Instrument/Item Development Costs

When reporting Instrument/Item Development costs, the MIDS Contractor shall include any hours and costs dedicated to refining, enhancing, developing, or modifying data collection or assessment instruments or data items/elements within a data collection instrument or database, and/or other activities meeting the characteristics described in IDIQ SOW Chapter 5 (Instrument/Item Development) and included in the specific TO.

<u>Deliverables in Chapter 5:</u>
Deliverable 5-1 (Data Collection Tools/Assessment Instruments, Manuals or Instructions, and Updates)
Deliverable 5-2 (Summary Report of New/Revised Data Collection Instruments or Data Items)
Deliverable 5-3 (TBD, if necessary)
Deliverable 5-4 (TBD, if necessary)

CHAPTER 6. TESTING/VALIDATION

Measure testing enables a Contractor to assess the suitability of the measure's technical specifications, and acquire empirical evidence to help assess the strengths and weaknesses of a measure with respect to the evaluation criteria. This information can be used in conjunction with expert judgment to evaluate a measure and happens throughout the development process. Correctly conducting measure testing and analysis is critical to approval of a measure by CMS and endorsement by the CBE (currently NQF). To note, the same approach described in this section applies to data element development.

The Field Testing/Validation Activity represents those activities associated with testing for validity, soundness, specificity, reliability, feasibility, usability, and/or sensitivity of either a measure (see Quality Measure Development and Reevaluation – Chapter 4) or data instrument/instrument (see Instrument/Item Development – Chapter 5).

Data collection vehicles shall be capable of including the data elements necessary to expand, or develop, measures for use in other settings, or across settings, as well as provide for a standardized data collection approach. The data elements used for measures shall be optimally standardized such that they are able to be implemented in multiple (or across) settings, or are able to support existing measurement expansion, and cross setting implementation. The measure being expanded would apply the same data elements used in the measurement calculation, and the approach on how the response to those data elements are determined would remain intact ensuring reliability.

6.A. – Reliability and Validity Testing

Verification of the accuracy and reliability of data being reported to CMS is critical to:

1. Ensure clinically and appropriate assessment information.
2. Ensure accurate representation of quality of care outcomes.
3. Ensure the accuracy of publicly reported Quality Measures.
4. Ongoing surveillance in order to deter gaming of assessment data.
5. Support CMS planning and decision making within payment systems.
6. Support the expansion and development of measures across settings.

Under an awarded TO, the MIDS Contractor shall use data surveillance and analysis, onsite review, various education and communication strategies, and other sources of expert opinion in order to improve the accuracy and reliability of national CMS data across various stakeholder and provider communities.

Reliability is defined as the extent to which the measurement is reproducible and free from random error; random error (variable or chance error) is caused by chance factors and occurs in an unsystematic manner. Reliability is necessary but not a sufficient condition for validity. The use of standardized data collection vehicles, with standardized data elements, supports standardized data collection; ensuring reliability.

Validity is defined as the extent to which a measure achieves the purpose for which it is intended (i.e., to measure the quality of care or service). Validity relates to the use of, and a conclusion made from, the measure results - i.e., measure distinguishes between higher and lower levels of quality.

IAW Deliverables 4-4 and 6-3 (below): Additionally, depending on the measure, risk adjustment may also be part of the measure development process and may be conducted before and after reliability and validity testing if required. For previously-developed measures, using measures across settings may require additional risk analysis for risk adjustments to some settings that might not be needed in others. For example, measures for LTCHs may require additional or different risk adjustment for pressure ulcer development.

Risk adjustment factors may be setting specific and may need to be tested/developed when measures are developed to be setting-agnostic. For example, setting X needs these 3 covariates to be compared to other like settings, but setting Y only needs 2 of the 3 covariates. The measure construct is the same but with differing covariates.

The term risk adjustment refers to the statistical process used to identify and adjust for differences in population or setting characteristics (i.e., risk factors) before comparing outcomes of care. The terms risk adjusted outcome, risk factor, and risk adjustor are used to describe expressions related to a risk adjustment model. In contrast, the term risk stratification refers to the separate reporting of different groupings of data that may or may not be adjusted by a risk model.

Not all measures require risk adjustment. However, risk adjustment is necessary when measurement results are confounded by comorbidity, demographic characteristics, or other factors. When risk adjustment is required in the measure calculation, appropriate detail and guidance shall be included in the measure specifications.

The Blueprint references evidence-based risk-adjustment *strategies* that encompass both statistical risk models and risk stratification using language employed by the CBE (currently NQF). As part of a risk-adjustment strategy the CBE recommends using risk models in conjunction with risk stratification when use of a risk model alone would result in obscuring important health care disparities.

Within this framework of a risk adjustment strategy, the purpose of any measure risk adjustment model is to facilitate fair and accurate comparisons of outcomes across health care organizations, providers, or other groups, as well as reduce unintended consequences related to quality reporting. In developing health care measures, it is essential to examine the need and approaches for risk adjustment because risk factors before or during treatments may contribute to variations in outcomes regardless of the quality of care received, and adjusting for these risk factors can avoid misleading results in comparisons of provider performance. However, risk adjustment models for publicly reported quality measures should not obscure disparities in care associated with race, socioeconomic status, or gender. The exploration of a risk adjustment strategy (e.g., the use of a statistical risk adjustment model and if necessary, risk stratification for selected populations) is required for measures developed using the Blueprint. For a measure to be accepted by CMS and endorsed by NQF, the measure developer must demonstrate the appropriate use of a risk adjustment strategy. If a risk adjustment model or risk stratification is not used, a rationale and strong evidence must be provided. Consequently, it is the measure developer's responsibility to determine if variation in factors intrinsic to the patient should be accounted for before outcomes can be compared, and how to best apply these factors in the measure specifications. It is important to remember that risk adjustment does not itself provide the answers to study questions about measures, but instead, provides a method for determining the most accurate answers.¹ The purpose of this section is to provide guidance to CMS Measure

¹ Boston, MA. Management Decision and Research Center; Washington, DC: VA Health Services Research and Development Service in collaboration with Association for Health Services Research 1997, W84.AA1 R595 1997.

Contractors regarding the nature and use of a risk adjustment model in quality measurement.

Under an awarded TO, the measure developer must demonstrate the appropriate use of a risk adjustment strategy if one is required.

Example Blueprint requirements associated with measure testing include:

- **Deliverable 6-1 (Measure Testing Plan)**
- **Deliverable 6-2 (Measure Testing Summary Report)**
- **IAW Deliverable 3-3:** Updated MIF
- **IAW Deliverable 3-4:** Updated MJF
- **Deliverable 6-3 (Risk Adjustment Methodology Report)**
- **IAW Deliverables 3-3 and 4-4:** Updated MIF with completed Risk Adjustment Section for each measure

6.B. – Types of Testing

A measure shall be tested one or more times during the development process. Testing provides an opportunity to refine draft specifications before they are finalized; augment or re-evaluate earlier judgments about the measure's importance to measure and report, the scientific acceptability of measure properties, feasibility, and usability. Initial testing during development (sometimes referred to as pilot testing) is generally conducted within the framework of alpha and beta tests.

There are several types of tests that can be used to verify quality measures and/or data items/instruments. For the purposes of the MIDS Contractors, CMS will use the following definitions:

6.B.1. Alpha Testing (Formative Testing)

Alpha testing (also called formative testing) is of limited scope. These tests usually occur during the formative stage of measure development before detailed specifications are fully developed.

Under an awarded TO, the Contractor shall submit the design of each test to the COR for approval and Measures Management Contractor for information and technical feedback prior to implementing the test. The Contractor shall report the testing results to the COR and the Measures Management Contractor. Using the testing results, the Contractor shall revise the measures as needed and submit the revised MIF to the COR and the Measures Management Contractor.

6.B.2. Beta Testing (Field Testing):

Beta testing (also called field testing) generally occurs after the initial technical specifications have been developed, and is usually larger in scope than alpha testing. In addition to gathering further information about feasibility, beta tests serve as the primary means to assess scientific acceptability and usability of a measure. They can also be used to evaluate the measure's

suitability for risk adjustment/stratification, and expand prior evaluations of the measure's importance and feasibility. Careful planning and execution of beta testing facilitates reporting and documenting measure properties with respect to criteria used by CMS and the CBE.

Under an awarded TO, the Contractor shall submit the design of each test to the COR for approval and Measures Management Contractor for information and technical feedback prior to implementing the test. The Contractor shall report the results of the test to the COR and the Measures Management Contractor. Using the test results, the Contractor shall revise the measures as needed. The Contractor shall submit the revised measures in the MIF to the COR and the Measures Management Contractor.

6.C. – Reports from Testing:

The following Reports (Narrative and Summary) are required per activity conducted under the MIDS TOs:

Example Blueprint requirements associated with Measure Testing are:

1. **IAW Deliverable 6-1:** Measure Testing Plan
2. **IAW Deliverable 6-2:** Measure Testing Summary Report
3. **IAW Deliverable 3-3:** Updated MIF
4. **IAW Deliverable 3-4:** Updated MJF

6.D. – Reporting Testing/Validation Costs:

When reporting Testing/Validation costs, the MIDS Contractor shall include any hours and costs dedicated to testing and/or validation of measures or other activities meeting the characteristics described in IDIQ SOW Chapter 6 (Testing/Validation) and included in the specific TO.

<u>Deliverables in Chapter 6:</u>
Deliverable 6-1 (Measure Testing Plan)
Deliverable 6-2 (Measure Testing Summary Report)
Deliverable 6-3 (Risk Adjustment Methodology Report)
Deliverable 6-4 (TBD, if necessary)
Deliverable 6-5 (TBD, if necessary)

CHAPTER 7. REPORTS/APPROVAL PACKAGES

The Reports/Approval Packages activity represents those activities associated with providing a written progress report and other documented deliverables (see TO SODs), as well as packages intended for third-party stakeholders such as the CBE or Office of Management and Budget (OMB).

7.A. – Monthly Status Report:

Deliverable 7-1 (Monthly Status Report): A Monthly Status Report shall be submitted in electronic format and in hard copy (hard copy only if requested) no later than the 20th of each month for the prior month's activities. The COR and the MIDS Contractor shall agree upon the content and format of the Monthly Status Report. The report shall list all updates regarding each task, subtask, or deliverable and place emphasis on substantive information, progress and changes to the work, including:

- Achievements and accomplishments, including process improvement
- Upcoming milestones and events in the next 4 months (for example, if the Contractor submits the June monthly report, the upcoming milestones for the next 4 months would be those milestones in July through October)
- Any foreseeable issues or risks to the project work and timeline
- Lessons learned
- Workload Template Report
- Staffing Changes
 - i. Additions
 - ii. Deletions

7.B. – Workload Template Report:

Deliverable 7-2 (Monthly Workload Template Report): Monthly Workload Template Reports shall be submitted in electronic format and hard copy (hard copy only if requested) to the COR of each MIDS TO.

The Workload Template Report shall be submitted electronically no later than the 20th of each month for the prior month's activities. The report shall be related to the Cost Report and will provide a unit breakdown of costs incurred to the product or service delivered. The itemization of product or service provided will be reported by each Activity (under each TO – Business Proposal Activities).

7.C. - Cost Report:

Deliverable 7-3 (Cost Report): The Cost Report shall be submitted no later than the 20th of each month for the prior month's activities. The report shall include at a minimum:

1. A summary of costs incurred by each Activity (under each individual TO) during the previous month, in business proposal format;

Contractors will use the example template below to report the summary of costs. Contractors are encouraged to include additional information for their records and/or the CORs benefit.

<u>MIDS Invoice Template -</u> <u>CMS/CCSQ/OMVIG</u>					
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MONTH 2018 Cost by Task, Base (or Option) Year (June 1 - June 30, 2018)					
Contractor: CONTRACTOR NAME					
Contract #: HHSM-500-2018-XXXXXX					
Task Order #: HHSM-500-TXXXX					
Period of Performance: Month/Day/Year - Month/Day/Year					
Spending for month: Month-Year					
Task	Hours	Reported June 2018	Cumulative Reported Costs	Total Budget	Funds Remaining
Task 0: Project Management	XX	\$ 1,000.00	\$ 10,000.00	\$ 15,000.00	\$ 5,000.00
Task 1: Measure Planning	XX	\$ 500.00	\$ 5,000.00	\$ 5,500.00	\$ 500.00
Task 2: Measure Development and Maintenance	XX	\$ 20,000.00	\$ 200,000.00	\$ 220,000.00	\$ 20,000.00
Task 3: Technical Release Notes	XX	\$ 1,000.00	\$ 10,000.00	\$ 11,000.00	\$ 1,000.00
Task 4: Testing and Validation	XX	\$ 500.00	\$ 5,000.00	\$ 5,500.00	\$ 500.00
Task 5: Implementation	XX	\$ 1,000.00	\$ 10,000.00	\$ 10,000.00	\$ -
Task 6: Public Reporting	XX	\$ 1,000.00	\$ 10,000.00	\$ 15,000.00	\$ 5,000.00
Total Hours/Costs	XX	\$ 25,000.00	\$ 250,000.00	\$ 282,000.00	\$ 32,000.00
<i>Percent of Budget Spent (before fee)</i>					88.65%

2. A narrative report of expenditures by summary line item and/or each SOW section that exceed 10% above or below the estimated expenditures for the period of time that is being reported.
3. Cumulative costs incurred to date on the TO.
4. Funds remaining to be incurred on the TO.
5. Costs by labor category, labor hours, labor rates, travel, subcontracts, TEPs/conferences; and,
6. Itemization of Other Direct Costs (ODCs) incurred.

7.D. - Annual Self-Assessment Report:

The report will include:

1. **Deliverable 7-4 (Annual Self-Assessment Report):** The Annual Self-Assessment Report (CMS will provide the format to the MIDS Contractor one month prior to the due date) shall indicate details of the MIDS Contractor performance including descriptions of the Quality of Product or Service, Cost Control, Timeliness of Performance, and Business Relations (e.g.,

technical re-writes, delivery on time with minimal revisions, integrated project oversight in satisfaction of the COR, etc.).

2. Recommendations for areas that could be improved.
3. Identification of problems not anticipated throughout the year.
4. Recommendations and insights into resolution of the unanticipated problems.
5. Areas of innovation where the MIDS Contractor has exceeded the IDIQ SOW and/or TO requirements.

7.E. – Periodic Status Calls

Deliverable 7-5 (Periodic Status Calls): The MIDS Contractor shall facilitate Periodic Status Calls with CMS and other designated parties per TO SOW to update Contract activities.

Deliverable 7-6 (Periodic Status Call Minutes): The Contractor shall submit the Periodic Status Call Minutes within three (3) business days following each status call. The frequency of these calls shall be established in each TO SOW.

7.F.—Timeline Reports

The MIDS Contractor shall provide weekly, or as needed, timeline reports related to deliverables providing their status related to deadlines in a manner that informs CMS on work activities that may negatively impact dependencies, or be impacted as dependencies on other deliverables.

7.G. - Office of Management and Budget (OMB)/Paperwork Reduction Act (PRA) Submissions

Deliverable 7-7 (OMB/PRA Submission Materials): The MIDS Contractor may be directed to provide support and/or prepare forms, data, and information suitable for submission to OMB/PRA Submission Materials IAW the PRA (44 U.S.C. 3501 *et seq.*).

7.H. – Reporting Reports/Approval Packages Costs

When providing Reports/Approval Packages costs, the MIDS Contractor shall include any hours and costs with providing written progress or other documented deliverables, as well as packages intended for third-party stakeholders such as the CBE, OMB, or other activities meeting the characteristics described in IDIQ SOW Chapter 7 (Reports/Approval Packages) and included in the specific TO.

<u>Deliverables in Chapter 7:</u>
Deliverable 7-1 (Monthly Status Report)
Deliverable 7-2 (Monthly Workload Template Report)
Deliverable 7-3 (Cost Report)
Deliverable 7-4 (Annual Self-Assessment Report)
Deliverable 7-5 (Periodic Status Calls)
Deliverable 7-6 (Periodic Status Call Minutes)
Deliverable 7-7 (OMB/PRA Submission Materials)

Deliverable 7-8 (TBD, if necessary)
Deliverable 7-9 (TBD, if necessary)

CHAPTER 8. IMPLEMENTATION, PRODUCTION & ASSESSMENT

The Measure Rollout section in the Blueprint provides a framework that describes the major tasks involved in the implementation (i.e., rollout) of a measure at the national level. The Measure Production and Monitoring section of the Blueprint describes the tasks required for the ongoing use of the measure. The process of rolling out measures or implementing measures in CMS programs varies from one measurement set to another. Typically the implementation of measures in CMS programs is initiated through the Federal Rule making process, where measures are proposed, public comments solicited, and measures are finalized for specific performance and program/payment periods and/or for public reporting. Often, especially with complicated outcome measures, a dry-run is conducted to give providers an opportunity to review the detailed measure methodology and the measure performance rates and to give CMS a mechanism for evaluating the measure methodology before the measures are fully implemented in a CMS program.

CMS may also implement new or revised data collection vehicles and/or assessment instruments as a means to obtain the needed data for the calculation of measure rates to use for public reporting or pay for performance programs.

8.A. - Implementation of Measures or Data Collection Vehicles/Assessment Instruments:

8.A.1. - Measure Selection and Rule Making Process

CMS selects measures for implementation in its programs by using the Federal Rule Making process. The process begins via an annual pre-rulemaking activity by providing a list of potential measures to stakeholders via the MAP for review and comment prior to proposing the measure in a specific CMS payment or other rule. CMS will then propose measures in a Notice of Proposed Rule Making (NPRM) for a specific program and solicit comments from the public on the measure and program requirements. After the NPRM comment period ends, comments are reviewed and analyzed and CMS determines what measures to finalize in the Final Payment or other rule. As directed by the MIDS TO, the Contractor may be directed to assist CMS with the rulemaking process for a set of measures or other program requirements. The assistance may take the form of:

- Providing information about measures for the pre-rulemaking measure list;
- Providing language describing measures, methodologies, etc. that can be used to describe measures or program requirements in proposed rules;
- Developing rule proposals including but not limited to measures, assessment instrument modifications, form and manner, public reporting, regulatory text, and burden related sections of the rule;
- Monitoring, receiving, analyzing comments received during the NPRM comment period;
- Drafting responses to comments received during the comment period; and,
- Collecting and delivering all rule artifacts as required by Office of Strategic Operations and Regulatory Affairs (OSORA).

8.A.2. – Development of Rollout/Implementation Plan

Deliverable 8-1 (Timeline for Data Item and/or Quality Measure Implementation): The Contractor shall develop and provide technical support for a rollout/implementation plan for the implementation of new quality measures in a CMS program (e.g. quality reporting, pay for performance, public reporting, etc.). Refer to the Blueprint for activities to be considered in the rollout/implementation plan, to take into account such things as the rulemaking process, communication plans, training and education, outreach, dry runs, auditing or validation plans, appeals, etc. As directed by the TO, the Contractor may be directed to develop a rollout/implementation plan for a new or revised data collection vehicle or assessment instrument. The Measures Management Contractor shall be included in any implementation discussions.

8.A.3. - Coordination with Stakeholders

Deliverable 8-2 (Implementation Stakeholder Meetings): The Contractor shall coordinate, arrange, and/or actively participate in stakeholder meetings, open door forums, or other means by which to inform and educate the public of upcoming implementation of new or revised data collection vehicles/assessment instrument or the implementation of new measure or measure revisions.

Stakeholders include, but are not limited to:

- State Agencies
- Payment (Office of Financial Management (OFM))
- Public Reporting (Office of Communications (OC) Web and New Media Group)
- IT Infrastructure (Office of Information Services (OIS))
- IT Infrastructure (Center for Clinical Standards & Quality (CCSQ) Information Systems Group (ISG))
- Program Support (CCSQ Quality Improvement Group (QIG))
- Software Vendors
- Survey and Certification Group (SCG) in CCSQ
- The ONC
- Accrediting Organizations
- Providers

8.A.4. - Measure Dry Run

The dry run is usually conducted before the measure is implemented in a CMS program; however, not all measures require a dry run. When needed or directed by CMS, a dry run should be considered as an initial step in a measure rollout/implementation plan. In the dry run, data are collected from all relevant providers across the country, usually from clean data. Rates are calculated and shared with the providers, but not publicly reported or used for payment adjustment. The purpose of the dry run is to test all methodologies related to case identification/selection, data collection (for measures using medical records data) and measurement calculation. The dry run generally tries to accomplish:

- Verification that the measure design works as intended and begins to identify unintended consequences such as gaming or misrepresentation.
- Familiarizes relevant entities, such as CMS, Quality Improvement Organizations (QIOs), and the providers, with measure methodology and presentation of results. This provides CMS the opportunity to work with them to improve the usability of the reports before actual implementation and to identify and respond to questions and concerns.
- Identifies any issues with the report production process so that the production processes can be improved to avoid problems when the measure is implemented.
- Rates from a dry run are not publicly reported or used for payment or other reward systems, though the COR may decide to use them as the baseline measurement. The dry run shall not be a discrete step in the implementation of the measure. At the COR's direction, this step may be skipped. Skipping this step means that the first round of data collection and results reporting may serve as the *de facto* dry run.

Deliverable 8-3 (Question and Answer Support): The Contractor shall provide Questions and Answers Support for publicly reported measures that undergo a dry run and are then implemented for a length of period specified by CMS.

To note, the dry run may include a dry run for the modified assessment instruments if specified in the TO SOW.

8.A.5. – Other Implementation Activities

The MIDS Contractor may be directed to assist CMS in the development of auditing and validation plans, appeals process or other activities needed for the implementation and support of new measures or new/revised data collection vehicles or assessment instruments. Refer to the Blueprint for activities associated with these items.

8.B.- Measure Production

8.B.1– Roadmap

Deliverable 8-4 (Implementation Process Roadmap): The Contractor shall develop and carry out an Implementation Process Roadmap for the production of measures to be used as directed in specific MIDS TO.

8.B.2– Testing/Documenting /Producing Measure Calculations

Deliverable 8-5 (Measure Calculations/Results): As needed, the Contractor shall develop, review, and test codes for the calculation of measure results and document changes or updates to the codes, analyze the impact of these changes on measure results and report findings to the COR; communicate with measure developer regularly to understand the rationale and nature of codes and updates to the codes to ensure accuracy of measure results. Using developed specifications and the code (SAS or other code), the Contractor shall calculate measures based on data gathered, documenting the data processing and the quality assurance process of the data

processing and shall produce a file of the calculated measures by individual provider type, national, and state rates (as required) for dry run, public reporting, or for national implementation in pay for reporting or feedback programs.

8.C- Provide Support for Public Outreach

Provide direct and indirect support related to educational and training materials for the initial and ongoing implementation of measures or data collection vehicles or assessment instruments. This may include activities such as monitoring internal and external mailboxes, organizing, conducting and/or supporting Town Hall Meetings and listening sessions, conducting or coordinating training and/or developing training materials, reviewing and maintaining website textual content and downloadable files for all program websites, developing and modifying the participant feedback report, and establishing and/or providing Help Desk support.

Provide training, answers and support related quality measurement and program questions received in the manner indicated by the COR. Prepare for public announcement and posting information pertaining to measures, quality programs, data collection tools, etc.

8.D.– Program, Measures, and Initiative Assessment

Deliverable 8-6 (Program and Initiative Assessment Report): The MIDS Contractor shall evaluate measure sets used in current or upcoming quality initiatives, programs or priorities as detailed in the Measure Priorities Planning Section of the Blueprint, Volume 1 and:

1. Evaluate current measures and measure sets used in a quality program or initiative and recommend ways to accommodate cross-setting use if appropriate. Work with the alignment process across various CMS programs that utilize shared measures.
2. Provide recommendations for alternative ways to adapt and apply existing measures and measure sets to various care settings in the continuum of care.
3. Analyze the measure performance trends, determine if these are still the best or most relevant measures, and examine the nature and extent of unintended consequences that need to be addressed. Identify and conduct a gap analysis on existing measures to determine if new measures are needed.
4. Monitor the feedback and input provided on the measure, report this information to the COR. This analysis of the measures may include determining reporting and performance rates on the individual measures within the specific program that can be applied for payment adjustment and the impact on the value based modifier.

The MIDS Contractor may be directed to evaluate aspects of quality reporting, pay for performance, or public reporting programs. Examples of Blueprint requirements associated with Production and Monitoring are, but are not limited to (MIDS Contractors should refer to the Blueprint for additional details):

- Audit and validation reports.
- Audit and validation appeals reports.

- Preview reports, if required by the CMS program using the measure (usually, this is only required for measures being used in public reporting.).
- Periodic measure reports.
- Analysis of the measure results.
- Ad hoc reviews, as requested by CMS.
- Periodic environmental scans of journal literature, guidelines, and stakeholder feedback as directed by CMS.
- Program and Initiative Assessment.

8.E.– Reporting Implementation, Production, & Assessment Costs

When reporting Implementation, Production, & Assessment Activity costs, the MIDS Contractor shall include any hours and costs associated with implementing, producing and assessing measures or data collection vehicles or assessment instruments or other activities meeting the characteristics described in IDIQ SOW Chapter 8 (Implementation, Production, & Assessment) and included in the specific TO.

<u>Deliverables in Chapter 8:</u>
Deliverable 8-1 (Timeline for Data Item and/or Quality Measure Implementation)
Deliverable 8-2 (Implementation Stakeholder Meetings)
Deliverable 8-3 (Question and Answer Support)
Deliverable 8-4 (Implementation Process Roadmap)
Deliverable 8-5 (Measure Calculations/Results)
Deliverable 8-6 (Program and Initiative Assessment Report)
Deliverable 8-7 (TBD, if necessary)
Deliverable 8-8 (TBD, if necessary)

CHAPTER 9. PUBLIC REPORTING/COMPARE SITES

The Public Reporting/Compare Sites Activity represents those activities associated with coordinating with appropriate personnel (as directed by the COR and appropriate SMEs), Center for Medicare (CM), OC, or other components as directed by the COR and appropriate SMEs, to provide the descriptive language on quality measures for public reporting on CMS websites. Under an awarded TO, the MIDS Contractor shall coordinate and provide descriptive language and/or quality measure rates to achieve public reporting of new or revised quality measures IAW the TO SOW. Public Reporting activities include, but are not limited to the following (MIDS Contractors should refer to the Blueprint for additional details):

9.A. – Coordination with other CMS Components

Deliverable 9-1 (Compare Site Files and Measures): The Contractor shall provide coordination with other CMS components to assist in the development of a suitable Web report (such as work flow documents or displays, if one has not been developed already).

These departments may include:

- a. Public Reporting [OC Web and New Media Group]
- b. IT Infrastructure [OIS]
- c. IT Infrastructure [CCSQ ISG]
- d. Program Support [CCSQ QIG]
- e. Other CMS components

9.B. – Content Management/Support

The Contractor may be requested to provide website content management/support in the form of reviewing and maintaining website textual content, assistance in drafting language for CMS websites, conducting or participating in consumer testing of measures or other information posted or to be posted on CMS websites or other activities associated with the implementation or rollout of new measures/information on CMS websites.

9.C. Provider Preview

Deliverable 9-2 (Pre-Posting Preview Report): The Contractor shall develop a process for provider preview of the measurement results before they are publicly posted. This process includes a plan for providers to appeal their results within a length of period specified by CMS before the results are publicly posted. The Contractor shall staff or provide resources to a Help Desk to answer provider questions about measure methodology, access to confidential reports, interpretation of results, and requests for corrections. The Contractor shall provide the COR with a summary of topics of provider questions on a regular basis during the preview period. If errors in measure results are determined to be the results of CMS programming or computational problems, then the Contractor shall re-calculate, re-generate, and re-disseminate measure results to providers based on a timeline and process approved by the COR.

9.D. – Measure Implementation Algorithm

Deliverable 9-3 (Implementation Algorithm): The Contractor shall work with the COR, and CMS SME's to develop an algorithm in both graphic (e.g., flowchart) and written (i.e., text) format. The calculation algorithm is an ordered sequence of data element retrieval and aggregation through which numerator and denominator events or continuous variable values are identified by a measure and is documented in the MIF; refer to the Technical Specifications section of the Blueprint. This implementation algorithm will begin with the submission of data by the providers (for measures based on data abstraction) or the initiation of data collection (for measures based on administrative data) and end with the posting of the measures for public view on a Compare Web site.

9.E. – Measure File Production

Calculate quality measures, both by provider and nationally and prepare hospital and/or discharge-level data files of the measure rates and/or demographic information suitable for posting on CMS website.

9.F. – Communications Material

Develop communication materials to educate providers and other stakeholders on measure methodology, program goals, preview/review and correction processes, interpretation of measure results, contact information of Help Desks, etc. Upload materials approved by the COR onto a CMS website before the beginning of the preview/review and correction period. Update the materials before measure results are refreshed.

9.G. – User Acceptability Testing

Conduct user acceptability testing (UAT)/consumer testing to ensure accurate display of measure results; develop a plan for UAT for COR approval; report findings of UATs to the COR, communicate measure display problems with other CMS Contractors as needed/directed by the COR.

9.H. – Public Reporting Timeline

Work with relevant stakeholders to develop a public reporting timeline and data flow document for each quarterly release. Develop a public reporting annual timeline for each calendar year's release. Along with this, the Contractor shall develop and maintain a dashboard of measures to be publicly reported in a given calendar year.

9.I. – Reporting Public Reporting/Compare Site Costs

When reporting Public Reporting/Compare Site Activity costs, the MIDS Contractor shall include any hours and costs associated with coordination of efforts and content management/support for purposes of public reporting or other activities meeting the characteristics described in IDIQ SOW Chapter 9 (Public Reporting/Compare Sites) and included in the specific TO.

<u>Deliverables in Chapter 9:</u>
Deliverable 9-1 (Compare Site Files and Measures)
Deliverable 9-2 (Pre-Posting Preview Report)
Deliverable 9-3 (Implementation Algorithm)
Deliverable 9-4 (TBD, if necessary)
Deliverable 9-5 (TBD, if necessary)

CHAPTER 10. ACCESS TO SYSTEMS/DATA

10.A. - Data Use Agreement (DUA)

Deliverable 10-1 (DUA): As needed, the MIDS Contractor shall enter into a DUA with the CMS. The agreement shall delineate confidentiality requirements of the Privacy Act, implement security safeguards, and explain CMS's data use policies and procedures. The DUA serves as

both a means of informing the MIDS Contractor of these requirements and a means of obtaining their agreement to abide by these requirements. The DUA must be submitted to the COR no later than 30 days after the start of the TO.

To create a DUA, the MIDS Contractor shall complete the CMS DUA form and submit it to the COR for review. The COR will then coordinate with the CMS Privacy Officer for authorization and assigning of a DUA number. If additional data not identified in the DUA is required, a second DUA may also be required to obtain access to that information.

<u>Deliverables in Chapter 10:</u>
Deliverable 10-1 (DUA)
Deliverable 10-2 (TBD, if necessary)
Deliverable 10-3 (TBD, if necessary)

CHAPTER 11. QUALITY ASSURANCE AND PERFORMANCE EVALUATION

11.A – MIDS Contractor Quality Assurance Program

CMS will utilize a number of quality assurance procedures to ensure MIDS Contractor compliance with this contract. Examples include inspection of deliverables, review of reports, and onsite progress meetings, performance evaluations, etc. Government quality assurance will be addressed in each TO for MIDS Contractor activities identified herein.

11.A.1 - Cooperation/Coordination

The MIDS Contractor shall cooperate and coordinate with relevant stakeholders other than CMS as necessary. MIDS Contractor performance will be evaluated using measures including, but not limited to:

1. Demonstration of ongoing dialogue or meetings with appropriate and necessary parties;
2. Feedback from other entities;
3. Number and type of issues that arise and indicate communication, or lack of communication, between appropriate entities and the MIDS Contractor.

11.A.2 – Quality

The MIDS Contractor shall maintain the highest degree of quality for all activities performed throughout the period of performance of the contract. CMS will evaluate MIDS Contractor performance using measures including, but not limited to:

1. Completeness and accuracy of data analysis;
2. Completeness, timeliness, and accuracy of all deliverables.

11.B – MIDS Contractor Performance Evaluation

The MIDS Contractor shall successfully perform the specific requirements defined in this SOW, Medicare laws, regulations, manuals, instructions and any additional responsibilities assigned by the Contracting Officer (CO) under contract. The MIDS Contractor shall provide complete and

accurate information, as requested by CMS, in order for its performance to be effectively evaluated.

11.B.1. - Evaluation Overview

The Government will evaluate the MIDS Contractor's performance on an annual basis for each TO. The MIDS Contractor's performance evaluation covers a wide range of performance and will follow the National Institutes of Health's (NIHs) Contractor Performance criteria for:

- Quality of Product Service
- Timeliness of Performance
- Cost Control
- Business Relations

11.B.2 – Objectives

The objectives of the CMS MIDS Contractor Performance Evaluation Program are to:

- Measure and evaluate the MIDS Contractor's performance in quality measure and instrument development and refinement work;
- Identify opportunities to improve performance;
- Provide a fair and accurate system of review for CMS's use in ensuring effective and efficient Medicare program administration.

11.C – Evaluation

The CMS COR will conduct a review of the MIDS Contractor's performance with the COR, CO, and other CMS staff as required. CMS reserves the right to monitor any aspect of the MIDS Contractor's operation at any time and is not limited to those areas specifically stated or in the TO.

CMS will provide the MIDS Contractor with general information about the review process, but is not obligated to provide the Contractor with specific details relating to how the reviews will be conducted. The Contractor is expected to perform effectively and efficiently in all areas of its operations, including those areas not specifically evaluated. CMS may elect to evaluate performance for any or all activities performed by the MIDS Contractor.

11.C.1 - Performance Evaluation Process

CMS will continuously monitor the Contractor during the period of performance for this SOW. The purpose of the performance review is for CMS to assess the Contractor's overall performance to date.

The Contractor shall utilize the Contractor Performance Assessment Reporting System (CPARS) in order to execute annual and final Contractor performance evaluations. CPARS is a secure Internet website located at <http://www.cpars.csd.disa.mil/cparsmain.htm>.

Contractors may obtain CPARS training material and register for on-line training at <https://www.cpars.csd.disa.mil/webtrain.htm>. There is no fee for registration or use of the CPARS.

Dates are calculated from a 1 year anniversary date of receiving a TO and annually thereafter. For a TO with a period of performance less than 1 year, a performance evaluation process appropriately tailored to the TO will be developed and incorporated into the quality assurance section of the TO.

11.C.2 - Performance Evaluation Data Sources

Below are examples of some of the data sources that the Performance Evaluation Team (PET) may use in evaluating the Contractor's performance:

- Contractor Supplied Data - The MIDS Contractor shall prepare a self-evaluation that contains data on its performance specified by the PET. The data from the Contractor's self-evaluation will be considered as part of the annual performance evaluation.
- Chief Financial Officer (CFO) Audit - In addition to the financial reporting requirements required by CMS to comply with the CFO Act, CMS may periodically require the MIDS Contractor to have a financial or internal control audit performed by an external auditor.
- Internal Controls - CMS may periodically conduct internal control reviews of the MIDS Contractor. When these reviews are available, the PET will consider the information contained in them as part of its evaluation.
- PET Reviews - The PET may conduct primary reviews into any aspect of the MIDS Contractor's activities as part of the evaluation process. These reviews will be included as part of the annual performance evaluation.

11.D - Basic Performance Standards

The MIDS Contractor shall meet all the requirements outlined under this SOW and future TOs. Specific minimum performance requirements are listed for some activities. Where specific minimum requirements are not listed, the basic standard is assumed to be an accurate, timely, high-quality product that effectively performs its intended function. The PET may review performance on any and all requirements contained in this SOW that apply to the TOs that the MIDS Contractor has been awarded. Failure to meet the basic performance standards could result in administrative actions such as a reduction in work volume or other administrative actions.

<u>Deliverables in Chapter 11:</u>
Deliverable 11-1 (TBD, if necessary)
Deliverable 11-2 (TBD, if necessary)

CHAPTER 12. TRANSITION FROM INCUMBENT TO SUCCESSOR

12.A – General

During performance of this contract, should termination or non-renewal of an existing contract occur, CMS may require the Incumbent Contractor to provide transition services beginning at the earliest mutually agreeable date. During this period, the Incumbent Contractor shall work with the Successor Contractor, CMS staff, as well as other identified CMS Contractors to ensure continued operation of the MIDS Program.

Prior to commencement of transition, CMS will request a transition plan from the Incumbent Contractor. The Transition Plan shall provide adequate coverage to ensure uninterrupted service to the MIDS Program, be effectively and efficiently administered, and be completed within a reasonable timeframe.

The Successor and Incumbent Contractors shall cooperate fully, as directed by the COR, to ensure that all services continue without interruption.

12.B – Contract Phase-In Services

The Successor Contractor shall organize, host, and provide toll-free telecommunication lines for transition meetings. The Successor Contractor shall determine who attends the transition meetings, which may include, but is not limited to, the Incumbent Contractor, the CMS COR, other CMS personnel, and any other affected stakeholders. During these meetings, attendees may discuss, but are not limited to, the status of the major tasks, issues, deliverables, schedule, delays, problem resolution, and risk mitigation and/or contingencies. The Successor Contractor shall use its best efforts to ensure that all transition meetings reflect the coordination and cooperation of all parties.

12.C – Contract Phase-Out Services

At the end of the contract/task order, if a determination is made to terminate or not renew the Incumbent's contract/task order, the Incumbent Contractor shall provide transition/phase-in/phase-out support to the Successor Contractor selected by CMS (refer to Federal Acquisition Regulation 52.237-3 Continuity of Services).

12.D – Transition Plan

Deliverable 12-1 (Transition Plan):

At a minimum, the Transition Plan shall provide the following:

- Detailed methods that will be used to ensure a smooth transition from the Incumbent Contractor's operation to sole operation by the Successor Contractor.
- A milestone chart detailing the time lines and stages of transition from the effective date of contract performance until the Successor Contractor assumes sole responsibility for the MIDS Program work.

- Plans to communicate and cooperate with the Successor Contractor; Transition services will include transfer of Government-Furnished Property (GFP) or Contractor Acquired Property (CAP) (e.g., hardware, software, records/data) from the Incumbent Contractor to the Successor Contractor, or to CMS or another CMS Contractor. CMS may elect to require the transition of GFP/CAP as follows:
 1. Prior to procurement of an asset, the Incumbent Contractor shall propose a transition charge to be evaluated and negotiated by the CMS.
 2. A Successor Contractor or CMS will be afforded the opportunity to acquire Incumbent Contractor assets at a reasonable transition charge. All existing assets shall remain installed and usable by CMS through the transition of assets for their replacement by the Successor Contractor. In the event a decision is made not to procure the assets, the Incumbent Contractor has the responsibility to dispose of the assets as instructed by CMS.

<u>Deliverables in Chapter 12:</u>
Deliverable 12-1 (Transition Plan)
Deliverable 12-2 (TBD, if necessary)
Deliverable 12-3 (TBD, if necessary)