APPENDIX E – DATA REPORTING REGULATIONS

DATA REPORTING REGULATION

Section 4602(e) of the Balanced Budget Act of 1997 authorizes the Secretary of the Department of Health and Human Services (HHS) to require that home health agencies (HHAs) submit any information that the Secretary considers necessary to develop a reliable case mix system for the purposes of implementing a prospective payment system for HHAs. To fulfill this mandate, CMS implemented a regulation requiring electronic reporting of OASIS data for Medicare and Medicaid patients to a centralized data submission system maintained by CMS as a condition of participation for HHAs. This rule provides guidelines for HHAs for the electronic transmission of the OASIS data as well as responsibilities of the provider in collecting and transmitting this information to CMS. Rules concerning the privacy of patient identifiable information generated by the OASIS were also set forth.

The reporting regulation focuses on the Conditions of Participation (CoP) for the HHA at Code of Federal Regulations (CFR):

- CFR Title 42 §484.20 - Reporting OASIS information and CFR Title 42 §484.11 - Release of patient identifiable OASIS information, and

42 CFR 484.20 Condition of Participation: Reporting OASIS Information

There are four standards in the Reporting OASIS Information CoP. In these standards, we address the following requirements:

a. §484.20(a) Standard: Encoding OASIS Data

Once the comprehensive assessment has been completed and OASIS data collected, HHAs enter the OASIS information into the computer system, which we call “encoding.” All the time points of the OASIS assessments have a uniform time frame of thirty days from the date the assessment is completed (M0090— Date Assessment Completed) for encoding and submitting the data. Once the OASIS data are encoded (in software available from CMS, or other software that conforms to the CMS standard data submission specifications), the agency will review each assessment and edit it for transmission to a centralized data submission system. During this preparation period, the HHA must run a software application that subjects each patient data set to the CMS edit specifications and makes it transmission-ready. The agency must correct any information that does not pass the CMS-specified edits (e.g., data is missing, incorrect, or inconsistent). Staff entering data may need to contact the qualified clinician who assessed the patient for assistance in making those corrections. The clinician’s recall of the patient assessment and clinical notes that document the assessment are more accurate if the review occurs soon after the assessment than if edits and corrections are delayed.

HHAs have flexibility in the method used to encode their data. Data can be encoded directly by the skilled professional who conducts the assessment into a laptop, hand-held, or tablet computer, by a clerical staff member from a hard copy of the completed assessment, or by a data entry operator or service with whom the HHA may contract to enter the data. Any of these are acceptable methods of meeting the regulatory reporting

requirements for OASIS. However, the HHA is ultimately responsible for meeting the reporting requirements as well as maintaining patient confidentiality.

Once the OASIS data are encoded, HHAs use their software to review and edit the data prior to data submission. When editing the data prior to transmission, it is important to remember that the edits include an electronic safety net to preclude the transmission of erroneous or inconsistent information and enforce the required formatting for the data set items. When transmitted, the patient assessment data are stabilized at the time point of the assessment, preventing the override of current assessment information with future or past information.

b. §484.20(b) Standard: Accuracy of Encoded OASIS Data

The encoded OASIS data must accurately reflect the patient's status at the time the information is collected. Before transmission, the HHA must ensure that data items on its own clinical record match the encoded data that are sent to the centralized data submission system. We expect that once the qualified skilled professional completes the assessment, the HHA will develop a means to ensure that the OASIS data input into the computer and transmitted to a centralized data submission system exactly reflect the data collected by the skilled professional. Appendix B contains recommendations for conducting data quality audits on a routine basis and includes information from the original *OASIS Implementation Manual* (Chapter 12) (archived but available at the following link (download Part I Chapters: http://www.cms.hhs.gov/HomeHealthQualityInits/14_HHQIOASISUserManual.asp#TopOfPage). In addition, the State survey process for HHAs may include review of OASIS data collected versus data encoded and transmitted to the State.

c. §484.20(c) Standard: Transmittal of OASIS Data

CMS requires that the HHA electronically transmit the accurate, completed, and encoded OASIS data to a centralized data submission system within 30 days of the completion of the assessment (M0090 Date Assessment Completed). As long as the submission time frame is met, HHAs are free to develop schedules for transmitting the data that best suit their needs. Data must be transmitted in a format that meets the requirements specified in the data format standard (i.e., conforming to the CMS standard electronic record layouts, edit specifications, and data dictionary). HHAs that are required to submit OASIS data must do so using a secure connection to a network maintained by CMS or its contractor. Once transmitted, the data submission is validated and feedback is provided to the HHA as to whether the submission file(s) has been accepted or rejected and whether each submitted record meets the data format and edit requirements. An entire submission or individual records may be rejected for a variety of reasons. The HHA must make corrections and resubmit the data for any assessments that are rejected. If an assessment record causes non-fatal warning messages to be generated, the HHA may elect to submit a corrected assessment record but is not required to do so.

HHAs must use a CMS-assigned branch identification number (where applicable) to identify branch-specific assessment information in a uniform fashion nationwide. This procedure finalized a process that began in January 2004, uniquely identifying every branch of every HHA certified to participate in the Medicare home health program. The

system links the parent to the branch HHA and gives CMS the capability of monitoring the quality of care delivered by agencies down to the HHA branch level.

For Medicare fee-for-service patients, the transmitted OASIS data also are utilized for billing. The HHA can submit a Request for Anticipated Payment (RAP) to their Medicare Administrative Contractor (MAC) when all of the four following conditions are met:

- After the OASIS assessment is complete, locked or export ready, or there is an agency-wide internal policy for establishing that the OASIS data is finalized for transmission to the centralized data submission system,
- A physician's verbal orders for home care have been received and documented,
- A plan of care has been established and sent to the physician, and
- The first service visit under that plan has been delivered.

An episode will be opened on Common Working File (CWF) with the receipt and processing of the RAP. RAPs, or in special cases claims, must be submitted for initial HH PPS episodes, subsequent HH PPS episodes, or in transfer situations to start a new HH PPS episode when another episode is already open at a different agency. HHAs should submit the RAP as soon as possible after care begins to assure they are established as the primary HHA for the beneficiary.

d. §484.20(d) Standard: Data Format

To meet the data format requirements, HHAs may use software developed by CMS or other vendor's software that conforms to CMS standardized electronic record formats, edit specifications, and data dictionaries. The CMS software can be used for several purposes. HHAs can use CMS software to encode OASIS data, maintain agency and patient-specific OASIS information, and create export files to submit OASIS data. The CMS software provides comprehensive on-line help to users in encoding, editing, and transmitting these data sets. The CMS software can also be used as a core program by HHAs and software vendors for developing their own software that supports OASIS reporting requirements, while also supporting or developing programs that meet other agency needs. Additionally, CMS maintains a toll-free help line to support this software product. For questions about HAVEN software, please call the HAVEN Help Desk at 1-877-201-4721 from 7:00 a.m. to 7:00 p.m. Central Time or send e-mail to help@qtso.com.

The CMS software alerts the individual who is encoding the data to use the correct screens for the specific type of assessment record required. HHAs using paper copies of assessment instruments must differentiate among the various subsets of OASIS data, i.e., specialized forms for particular assessment time points. HHAs are cautioned that the CMS software provides only the minimum requirements to encode data, apply mandatory edits, and prepare data files for transmission. CMS will support these functions and applications. However, CMS does not intend to provide any other applications related to care planning, financial information, durable medical equipment, medications, personnel, or claims submission. Software developers are encouraged to use the CMS software to meet minimum requirements until they can ensure that their own software will accommodate CMS specifications and other applications useful for HHAs. If the HHA uses software other than software developed by CMS, it must conform to CMS standardized electronic data submission specifications.

The current OASIS Data Set and Manuals can be found at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/index.html. HHAs can download the required OASIS data set documents by clicking on "OASIS-C1." There is one document that includes all items in the data set, and additional documents for each data collection time point: start of care; resumption of care following an inpatient facility stay; follow-up; discharge (not to an inpatient facility); transfer to inpatient facility (with or without agency discharge); and death at home. In addition, CMS provides OASIS data entry and data management software at. The software can be downloaded at no charge to HHAs and used to encode OASIS data and create data files ready for submission to CMS. Data submission specifications, data dictionaries, the HHA data submission manual, contact information for each state's OASIS Education Coordinator and OASIS Automation Coordinator, and a link to OASIS Questions and Answers are located at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/OASIS/index.html. Other educational materials for HHAs will be posted on the website. The site is intended to provide direct access for HHAs, State agencies, CMS contractors, software vendors, professional organizations, and consumers. Vendors and agencies are encouraged to regularly review the website for information related to the computerization of OASIS and other CMS-related home health issues. CMS will continue to promote processes for ensuring accuracy in the software. In the future, as OASIS is revised, HHAs will be directed to the CMS OASIS website for the current version of the OASIS data set.

42 CFR 484.11 Condition of Participation: Release of Patient Identifiable OASIS Information

The HHA or an agent acting on behalf of the HHA must ensure that all protected health (patient-identifiable) information in the clinical record, including OASIS data, remains confidential and is not released to the public. The data must be secured and controlled, whether in hard copy or in electronic format. In addition to the provisions of this Condition of Participation, all HHAs must adhere to the provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) to ensure patient confidentiality and the security of patient information. (Further information on these requirements is provided on-line at http://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/HIPAAGenInfo/index.html?redirect=/hipaageninfo/.)

CMS specifies that the HHA who chooses to secure the services of an agent to complete the OASIS regulatory reporting requirements must secure a written contract between the HHA and the agent to not use or disclose the information. The agent may only release data to the extent the HHA itself is permitted to do so. It is believed that this CoP will act as a safeguard against the unauthorized use of a patient's clinical record information, regardless of the form or storage method.

State Agency Responsibilities for OASIS Collection

Under section 1891(b) of the Social Security Act, the Secretary of the Department of Health and Human Services must assure that processes are in place to protect the health and safety of individuals under the care of an HHA and to promote the effective and efficient use of public monies. Section 1864 of the Act authorizes the use of State health agencies to determine a provider's compliance with the CoPs. State responsibilities in ensuring compliance with the CoPs are set forth at Part 488, Survey, Certification, and Enforcement Procedures.

The State Agency must ensure that access to data is restricted (except for the transmission of data and reports to CMS) to the State Agency component that conducts surveys for purposes related to this function, and to other entities if authorized by CMS. The State Agency must ensure that patient identifiable OASIS data are released only to the extent permitted under the Privacy Act of 1974 and the Administrative Simplification provision of the HIPAA Act of 1996. The System of Records supports the HHA/OASIS database.

The State Agency provides training and technical support for HHAs. The State Agency or other entity designated by CMS must instruct each HHA on the administration of and integration of the OASIS data set into the facility's own record keeping system; instruct each HHA on the use of software to encode and transmit OASIS data to the centralized data submission system; monitor each HHA's ability to transmit OASIS data; and provide ongoing technical assistance and general support to HHAs in implementing the OASIS reporting requirements specified in the Conditions of Participation for HHAs.

Privacy Act System of Records Notice

The Privacy Act System of Records (SOR) Notice was first published in the *Federal Register*, Vol. 64, No. 117, June 18, 1999, and was updated in the Vol. 66, No. 248 *Federal Register*, published on December 27, 2001 and Vol. 72, No. 218 *Federal Register,* published November 13, 2007. The original notice describes the purpose of the new SOR (a national database) and identifies the statutory authority for creation and maintenance of the system and appropriate routine uses of the data. Clinical assessment information for all Medicare or Medicaid patients receiving the services of a Medicare- or Medicaid-approved HHA except for those receiving HHA services for pre- and post-partum conditions, patients less than 18 years of age, and patients receiving exclusively personal care or non-health care services (i.e., chore or homemaker services) is included in the System of Records (SOR). The assessment information contained in the SOR is the OASIS data set. These data are obtained through a patient assessment that SOR conducted by a registered nurse or qualified therapist. To determine the type of care needed by a patient, HHAs perform an assessment of each patient's physical and emotional status. HHAs will continue to do these assessments, but now they will report a portion of that assessment to CMS to perform several critical functions, such as calculating the appropriate amount to pay for home health services, and to ensure that HHAs are providing the highest quality of care for the entire agency and for each individual patient. Home health patients are one of the most vulnerable populations because services are provided in the home where it is difficult to oversee the quality of services provided. OASIS data allow CMS to measure how well HHAs care for their patients through the development of performance profiles for each agency.

Consistent with the HIPAA Privacy and Security Rules, the Privacy Act permits CMS to disclose information without an individual's consent if the information is to be used for a purpose that is compatible with the stated purpose(s) for which the information was collected. This disclosure is known as "routine use." Several routine use disclosures have been identified for OASIS data. These data may be disclosed only to:

- The Department of Justice, court, or adjudicatory body when CMS is involved in litigation or when CMS' policies or operations could be affected by the outcome of the litigation.

- A third party with whom CMS has contracted to assist in accomplishing CMS functions relating to purposes of the System of Records.

- Another Federal or State Agency, agency of a State Government, or established by State law, for purposes of evaluating and monitoring the quality of home health care and contributing to the accuracy of CMS' health insurance operations.

- A Quality Improvement Organization (QIO), to assist in performing specific functions relating to assessing and improving HHA quality of care.

- An individual or organization for research, evaluation, or epidemiological activities related to health.

- A member of Congress or a Congressional staff member in response to an inquiry of the Congressional Office made at the written request of the constituent about whom the record is maintained.

The December 27, 2001, *Federal Register* notice added a seventh use disclosure:

- National accrediting organizations with approval for deeming authority for Medicare requirements for home health services, allowing these organizations to target potential or identified problems during the accreditation review process.

The June 18, 1999, *Federal Register* notice also identified the specific safeguards in place to ensure confidentiality of patient-level data. Please refer to this announcement for details.

Deficit Reduction Act of 2005 Requirement for Reporting Quality Data and Public Reporting for Quality Measures

In 2005, the Deficit Reduction Act (DRA) Section 5201(c) (2) was passed by Congress and added section 1895(b) (3) (ii) (V) to the Social Security Act requiring each HHA to submit to the Secretary such data that the Secretary determines are appropriate for the measurement of health care quality for 2007 and each subsequent year. Section 5201 (c)(v) requires a payment adjustment if an HHA does not submit data for the reporting year, "the home health market basket percentage increase applicable for such year shall be reduced by 2 percentage points." The two percent reduction would begin to apply to annual payment updates beginning on January 2007 and each year thereafter. For calendar year (CY) 2010, the data will be will based on OASIS submissions from 7/1/2008 through 6/30/2009.

The law also requires the Secretary to establish procedures for making data submitted available to the public and ensures the HHA has the opportunity to review the data prior to the data being made public. HHAs currently have pre-publication access to their own agency's quality data (which the contractor updates periodically). CMS proposes to continue this process, to enable each agency to know how it is performing before public posting of data on the Home Health Compare website. CMS also publishes an annual Preview Report in the fall of each year (available to home health agencies on the Casper Reporting system and posted the QTSO memorandum in the OASIS State Welcome Page in their folders to advise agencies of the preview reports and how to access them).

The Secretary of the Department of HHS has determined that the OASIS information collection best meets the requirements of this statutory mandate. Continuing to use the OASIS instrument ensures that providers will not have an additional burden of reporting through a separate mechanism and that the costs associated with the development and testing of a new reporting

mechanism can be avoided. Therefore, OASIS assessment submissions are monitored by CMS to evaluate compliance with the quality reporting requirements. HHAs that meet the reporting requirements are eligible for the full home health market basket percentage increase. The specific manner is which CMS determines whether an HHA is in compliance with this requirement is laid out in the yearly Prospective Payment Rule. The most recent rule, which applies to CY2014, is available at http://www.gpo.gov/fdsys/pkg/FR-2013-12-02/pdf/2013-28457.pdf