CHAPTER 2

REGULATORY OVERVIEW

A. SERIES OF REGULATIONS

The current requirements for the collection, encoding, and transmission of OASIS data that home health agencies are expected to follow have evolved through a series of regulations, beginning in 1999. The initial regulations were published in the *Federal Register*, Vol. 64, No. 15, on January 25, 1999. The first rule presented here includes the requirement for a comprehensive patient assessment, including OASIS items, to be conducted at specific points in the home care episode. The second rule addresses the reporting of these data to the HHA's State agency. This chapter also incorporates the changes to the OASIS data collection and reporting requirements as published in the *Federal Register*, Vol. 64, No. 117, June 18, 1999; modifications to the regulations for the OASIS System of Records (*Federal Register*, Vol. 66, No. 248, December 27, 2001); and the recently updated reporting regulation (*Federal Register,* Vol. 70, No. 246, December 23, 2005).

B. COMPREHENSIVE ASSESSMENT AND OASIS REGULATION

In 1999, the Centers for Medicare & Medicaid Services (CMS) revised the Conditions of Participation (CoP) that home health agencies (HHAs) must meet to participate in the Medicare program. Specifically, this added rule states that each patient receive from the HHA a patient-specific, comprehensive assessment that identifies the patient's need for home care and that meets the patient's medical, nursing, rehabilitative, social, and discharge planning needs. The rule requires that as part of the comprehensive assessment, HHAs use a standard core data set, the "Outcome and Assessment Information Set" (OASIS), when evaluating adult, nonmaternity patients. Additionally, the OASIS meets the condition specified in §1891(d) of the Social Security Act, which requires the Secretary to designate an assessment instrument for use by an agency in order to evaluate the extent to which the quality and scope of services furnished by the HHA attain and maintain the highest practicable functional capacity of the patient as reflected in the plan of care. These components were identified as an integral part of CMS' efforts to achieve broad-based improvements in the quality of care furnished through Federal programs and in the measurement of that care.

1. Condition of Participation: Comprehensive Assessment of Patients

This condition underscores CMS' view that systematic patient assessment is essential to improving quality of care and patient outcomes. A comprehensive assessment of the patient, in which patient needs are identified, is a crucial step

in the establishment of a plan of care. In addition, a comprehensive assessment identifies patient progress toward desired outcomes or goals of the care plan. By creating a separate condition for the assessment process, CMS emphasizes the importance of this cornerstone of patient management.

As stated in the CoP, each patient is to receive from the HHA a patient-specific, comprehensive assessment that accurately reflects the patient's current health status and includes information that may be used to demonstrate the patient's progress toward achievement of desired outcomes. The comprehensive assessment must: (1) identify the patient's continuing need for home care; (2) meet the patient's medical, nursing, rehabilitative, social, and discharge planning needs; and (3) for Medicare patients, identify eligibility for the home health benefit, including the patient's homebound status. The comprehensive assessment must also incorporate the exact use of the current version of the OASIS data set, which is found on the CMS OASIS web site at http://www.cms.hhs.gov/oasis; click on "Data Set."

CMS expects that HHAs will collect OASIS data in the context of a comprehensive assessment on adult Medicare or Medicaid patients (age 18 or over) receiving skilled health services from the HHA, except prepartum and postpartum patients. Patients receiving skilled health services, whose care is reimbursed by other than Medicare or Medicaid, must receive comprehensive assessments, but the collection of OASIS data is not required. For patients receiving only personal care services, regardless of payer source, a comprehensive assessment also is required, but not the collection of OASIS data. Patients who receive only services such as homemaker, chore, or companion services do not require the comprehensive assessment.

Five standards are contained in the Comprehensive Assessment CoP. Following are the requirements for each standard.

a. Standard: Initial Assessment Visit

The initial visit is performed to determine the immediate care and support needs of the patient. This visit is conducted within 48 hours of referral or within 48 hours of a patient's return home from an inpatient stay, or on the physician-ordered start of care date.

The initial assessment visit is intended to ensure that the patient's most critical needs for home care services are identified and met in a timely fashion. It is critical to patient health and safety that the patient not be left unattended in the home when home health services are needed, and it is CMS' expectation that the HHA will deliver services when the physician

orders them. For Medicare patients, this initial assessment determines eligibility for the Medicare home health benefit, including homebound status.

The initial assessment visit must be conducted by a registered nurse unless rehabilitation therapy services are the only ones ordered by the physician. Under the Medicare home health benefit, any one of three services (skilled nursing, physical therapy or speech-language pathology) can establish program eligibility. If rehabilitation therapy services are the only services ordered by the physician, the initial assessment may be made by the appropriate rehabilitation skilled professional if the need for that service establishes eligibility for the home health benefit. The law governing home health eligibility prevents occupational therapy from establishing eligibility for the Medicare home health benefit at the initial assessment, though once eligibility is established, then continuing occupational therapy could establish eligibility for a subsequent episode (meaning that the occupational therapist could complete the Recertification assessment). If no skilled service is delivered at this initial assessment, this visit will not be considered the SOC nor is it considered a reimbursable visit for the Medicare home health benefit.

Note that for payers other than Medicare, the occupational therapist may complete the initial assessment if the need for occupational therapy establishes program eligibility.

The comprehensive assessment is not required to be completed at the initial assessment visit, although the HHA may choose to do so. If a skilled service is delivered at the initial assessment visit, thus establishing the SOC, the comprehensive assessment may be initiated at this visit and completed within the time frames discussed below, depending on agency policy.

b. Standard: Completion of the Comprehensive Assessment

The comprehensive assessment must be completed in a timely manner, consistent with the patient's immediate needs, but no later than five calendar days after the start of care.

This requirement does not preclude a home health agency (HHA) from completing the comprehensive assessment during the SOC visit, and many HHAs currently operate in such a manner. This time frame provides operational flexibility to the HHA while maintaining patient safety in ensuring that all patient needs will be identified within a standard time period.

c. Standard: Drug Regimen Review

The drug regimen review requirement was moved from the former plan of care requirements to the assessment requirement to reflect the true nature and purpose of this activity. Under this requirement, the comprehensive assessment must include a review of all medications the patient is currently using to identify any potential adverse effects and drug reactions, including ineffective drug therapy, significant side effects and drug interactions, duplicate drug therapy, and noncompliance with drug therapy.

While patients receive their drug regimen from the physician, review of this regimen is an integral part of the comprehensive assessment. In addition, this review is an important safeguard for patients who may receive medications from a variety of physicians and pharmacies.

d. Standard: Update of the Comprehensive Assessment

The comprehensive assessment, which includes the OASIS data set items for Medicare and Medicaid patients, must be updated and revised as frequently as the patient's condition requires, but not less frequently than every 60 days beginning with the start of care date; within 48 hours of the patient's return home from an inpatient facility stay of 24 hours or more for any reason except diagnostic testing; and at discharge. For purposes of this requirement, we consider discharge to mean discharge to the community, transfer to another facility, or the death of the patient.

The update of the comprehensive assessment must include completion of all designated data items of the OASIS for that time point, plus any others determined necessary by the HHA to comprise a complete assessment. It is only by performing an assessment that the clinician can determine if a change in treatment or plan of care is warranted. Therefore, a comprehensive assessment also is required when there is a major decline or improvement in a patient's health status, noted as a significant change in condition.

An inpatient facility admission as an event is generally a predictor of a change in the patient's health status and therefore should be captured in the OASIS data. In addition, because patients frequently improve rapidly upon returning home from an inpatient facility, it is important for the HHA to assess the patient's true needs as quickly as possible after discharge from the inpatient facility. Therefore, the comprehensive assessment is required within 48 hours of the patient's return to the home from an inpatient facility admission of 24 hours or more for any reason other than diagnostic tests.

Follow-up assessments must be completed every 60 days that a patient is under care. For Medicare and Medicaid patients, when a follow-up assessment is due, it must be completed no earlier than four calendar days before, and no later than the day marking the end of the 60-day period (i.e., day 56 through day 60 of the period).

e. Standard: Incorporation of the OASIS Data Set

The OASIS data set must be incorporated into the HHA's own assessment, exactly as written. Both the language and the groupings of the OASIS items must be maintained. Integrating the OASIS items into the agency's own assessment system in the order presented in the OASIS form would facilitate data entry of the items into data collection and reporting software. However, HHAs may integrate the items in such a way that best suits the agency's own assessment.

The OASIS data set is not intended to constitute a complete comprehensive assessment instrument. Rather, the data set comprises items that are a necessary part of a complete comprehensive assessment and that are essential to uniformly and consistently measure patient outcomes. An HHA can use the data set as the foundation for valid and reliable information for patient assessment, care planning, service delivery, and improvement efforts.

The OASIS items are already used in one form or another by virtually all HHAs that conduct thorough assessments, and simply adding the OASIS data set to the rest of the HHA's paperwork would be burdensome and duplicative. Therefore, we expect HHAs to replace similar assessment items with OASIS items in their assessment forms to avoid lengthening the assessment unnecessarily.

In determining how to meet the OASIS collection requirements, HHAs should consider the effort and resources needed to modify their own HHA forms versus the cost and utility of a commercially available comprehensive assessment form that includes OASIS items. If the HHA chooses to make the necessary modifications itself, it should evaluate its current assessment forms and processes, using the need to change as an opportunity to improve efficiencies in the assessment process. Upon national implementation, CMS chose to retain the Mxxxx numbers for each OASIS data item to allow for easy recognition of the "required" OASIS item in the HHA comprehensive assessments. An HHA thus can be sure that clinicians and data entry staff can recognize these required items. Several HHAs in the OASIS demonstrations dramatically decreased assessment times by streamlining and integrating forms and processes. We also encourage

HHAs to pilot their forms and processes in order to test them before distributing them agencywide.

The requirement that HHAs collect standardized OASIS data represents both a change in practice and an opportunity for HHAs to examine their processes for additional efficiencies and improvements. CMS intends that the OASIS become one of the most important aspects of the HHA's activities in providing patient care. We believe that these requirements will result in improved patient outcomes, more efficient HHA practice, and recognition of the value of home health services.

C. DATA REPORTING REGULATION

Section 4602(e) of the Balanced Budget Act of 1997 authorizes the Secretary of the Department of Health and Human Services to require that home health agencies 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 the State agency (or other entity designated by CMS) as a condition of participation for HHAs. The interim final reporting rule with comment was published in January 1999 concurrently with the "Comprehensive Assessment and Use of the OASIS as Part of the Conditions of Participation for Home Health Agencies" described earlier.

This rule provides guidelines for HHAs for the electronic transmission of the OASIS data as well as responsibilities of the State agency or contractor 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 requirements of this interim final rule with comment period were necessary to establish the prospective payment system for HHAs and to achieve broad-based, measurable improvement in the quality of care furnished through Federal programs.

The reporting regulation focuses on two Conditions of Participation 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

- CFR Title 42 §488.68 outlining the State agency responsibilities for OASIS collection and database requirements.

In the Volume 64, No. 117, June 18, 1999, *Federal Register*, publishing the effective dates for collection, encoding, and transmission, other protections for patient-level data privacy were included. This notice included the provisions:

- Each patient must receive a statement of privacy rights on admission to the HHA.

- The "routine uses" of OASIS data under the Privacy Act are limited, so that patient-identifiable information will only be used where statistical information is not sufficient.

- Delay in the requirement to collect, encode, and transmit OASIS data on patients receiving personal care-only services until further notice.

The final reporting regulation for OASIS was published in the Volume 70, No. 246, December 23, 2005, *Federal Register*. This final rule incorporated revisions in response to public comments received on the interim final rule with comment period (originally published in January 1999). The final rule's effective date is June 21, 2006. New and updated requirements for reporting OASIS data are included here as part of the relevant standards.

1. 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. 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.” Beginning June 2006, 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 electronic record layout, edit specifications, and data dictionary), the agency will review each assessment and edit it for transmission to the State agency. 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 (i.e., 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 which

document the assessment are better at a point in time closer to the assessment activity than if the 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 or hand-held 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.

Nonclinical staff may not assess patients or complete assessment items; however, clerical staff or data entry operators may enter into the computer the OASIS data collected by the skilled professional. In entering the data, HHAs must comply with all requirements for safeguarding the confidentiality of patient identifiable information.

Once the OASIS data are encoded, HHAs use their software to review and edit the data prior to transmission to the State agency. When editing he 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. 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 State. 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 the State agency (or CMS contractor) exactly reflect the data collected by the skilled professional. HHAs must continue to conduct data quality audits on a routine basis as outlined in the *OASIS Implementation Manual*, Chapter 12. In addition, the State survey process for HHAs may include review of OASIS data collected versus data encoded and transmitted to the State.

c. Standard: Transmittal of OASIS Data

CMS requires that the HHA electronically transmit the accurate, completed, and encoded OASIS data to the State agency (or CMS contractor) within 30 days of the completion of the assessment (M0090 Date Assessment Completed). 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). CMS believes that this time frame for transmitting the data will minimize the burden on the HHA associated with frequency of transmission, maintain uniform assessment reporting time frames, and maintain a clear reporting time frame that eliminates the variation of days in a month. Therefore, HHAs are free to develop schedules for transmitting the data that best suit their needs. HHAs must use CMS-specified electronic communications protocols to contact the State agency or CMS contractor, transmit the export file, and receive validation information. Effective July 1, 2000, those HHAs required to submit OASIS data must do so using browser software to access the State system via the Medicare Data Communications Network, which provides a direct telephone connection for submission and interim reports. Once transmitted, the State agency or CMS contractor validates the information while the HHA remains on-line to ensure that some basic elements such as format and HHA information conform to CMS requirements. Once these file checks are completed, a message indicating whether the file has been accepted or rejected is sent back to the HHA's terminal and appears on its computer screen. If the submission passes the initial validation check, all records are checked for errors or exceptions to the data specifications, and a Final Validation Report is generated. If the submission is rejected, a message is sent to the HHA along with the rejected submission file for correction. A file or individual record may be rejected for a variety of reasons, (e.g., the provider identification name or number submitted may be incorrect, or the number of records indicated in the trailer record does not match the actual number of records submitted). The HHA must make the corrections and resubmit the file to the State.

A new paragraph was added to this standard in the December 2005 final rule requiring HHAs to use a CMS-assigned branch identification number (where applicable) to identify branch-specific assessment information in a uniform fashion nationwide. This paragraph 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 Regional Home Health Intermediary (RHHI) when all of the four following conditions are met.

- After the OASIS assessment is complete and transmitted to the State
- Once 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
- 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 being established as the primary HHA for the beneficiary.

d. Standard: Data Format

To meet the data format requirements, HHAs may use software developed by CMS, the Home Assessment Validation Entry (HAVEN) system, or other vendor's software that conforms to CMS standardized electronic record formats, edit specifications, and data dictionaries. The HAVEN software can be used for several purposes. HHAs can use HAVEN to encode OASIS data, maintain agency and patient-specific OASIS information, and create export files to submit OASIS data. HAVEN provides comprehensive on-line help to users in encoding, editing, and transmitting these data sets. HAVEN 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. The number for home health providers is 877-201-4721 available 7AM to 7PM, CT.

HAVEN 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. We caution HHAs that the HAVEN system

provides only the minimum requirements to encode data, transmit the data, and receive validation reports. We will support these functions and applications; however, we do not intend to provide any other applications related to care planning, financial information, durable medical equipment, medications, or personnel issues. Software developers are encouraged to use the HAVEN software as a minimum system 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 HAVEN, it must conform to CMS standardized electronic record formats, edit specifications, and data dictionaries. The software must also include the various OASIS data sets.

The required OASIS data set is available on our OASIS web site located at http://www.cms.hhs.gov/oasis; click on "Data Set." HHAs can access the web site and download the required OASIS data set for each data collection time point, i.e., 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 the HAVEN software at the same web site that can be downloaded at no charge to HHAs and used to report OASIS data. In addition to the software and the OASIS data set documentation available, this site includes the data specifications, data dictionaries, user's manual for the OASIS data set, HAVEN manual, HHA data submission manual, contact information for each state's OASIS Education Coordinator and OASIS Automation Coordinator, and access to OASIS Questions and Answers. We will also post other educational materials for HHAs on the web site. We intend the web site to provide direct access for HHAs, State agencies, CMS contractors, software vendors, professional organizations, and consumers. We encourage vendors and agencies to regularly review the web site for information related to the computerization of OASIS and other CMS-related home health issues. We will continue to promote processes for ensuring accuracy in the software. In the future, revised versions of the OASIS may be required. HHAs will be directed to the CMS web site for the applicable version of the OASIS data set. HHAs may also obtain hard copies from the National Technical Information Service at 1-800-553-6847.

2. Condition of Participation: Release of Patient Identifiable OASIS Information

The HHA or an agent acting on behalf of the HHA must ensure that all patient identifiable information in the clinical record, including OASIS data, remains confidential and is not released to the public. The data, whether in hard copy or in electronic format, must be secured and controlled. 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. (Compliance with these privacy regulations became required on April 14, 2003. Further information on these requirements is found at http://www.cms.hhs.gov/hipaa.)

We specify 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. We believe 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.

3. State Agency Responsibilities for OASIS Collection and Database Requirements

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 a home health agency and to promote the effective and efficient use of public moneys. 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.

State agency OASIS collection and database responsibilities have been added to the other State responsibilities at 42 CFR §488. This section provides that the overall responsibility for fulfilling requirements to operate the OASIS system rests with the State agency or other entity under direct contract with CMS. The State may enter into an agreement with the State Medicaid agency, another State component, or a private contractor to perform day-to-day operations of the system, or CMS may directly contract with an authorized entity. These "CMS contractors" perform the duties on behalf of CMS or the State agency.

While these entities may actually perform all OASIS-related functions, the ultimate responsibility of the OASIS program rests with the State agency or authorized entity under contract directly to CMS. If the standard State system is operated by an entity other than the State agency, the State must ensure that it has suitable access to this system to fully support all OASIS-driven functions required of the State agency (for example, outcome-based quality improvement reports and survey specific data). The regulation specifies State agency and CMS contractor responsibilities with regard to the OASIS system.

As part of State agency survey responsibilities, the State agency or other entity designated by CMS has overall responsibility for fulfilling the following requirements for operating the OASIS system. The State agency or other entity designated by CMS must establish and maintain an OASIS database on the standard system developed or approved by CMS to collect, store, and analyze data; conduct basic system management activities including hardware and software maintenance, system back-up, and monitoring the status of the database; and analyze and report OASIS data to CMS. The State agency must edit the data on receipt from the HHA, as specified by CMS, and ensure that the HHA resolves errors within the limits specified by CMS. At least monthly, all edited OASIS records received during that period must be made available for retrieval by CMS.

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 State; monitor each HHA's ability to transmit OASIS data; provide ongoing technical assistance and general support to HHAs in implementing the OASIS reporting requirements specified in the Conditions of Participation for home health agencies; and carry out any other functions as designated by CMS necessary to maintain OASIS data on the standard State system.

D. 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. 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 prepartum and postpartum patients, 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. The assessment information contained in the System of Records is OASIS data. These data are obtained through a patient assessment that is conducted by a registered nurse or 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 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 Peer Review Organization (PRO), now termed 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 identifies the specific safeguards in place to ensure confidentiality of patient-level data. Please refer to this announcement for details.

FREQUENTLY ASKED QUESTIONS

1. Which patients of the HHA must receive the comprehensive assessment that includes OASIS items?

All Medicare or Medicaid patients receiving skilled care from the Medicare-certified HHA must receive the comprehensive assessment at the specified time points. The only exceptions to this requirement are:

a. those patients younger than 18 years of age,
b. prepartum or postpartum patients, or
c. those patients receiving ONLY nonskilled services such as personal care, homemaker, chore, or companion services.

2. Where can I obtain the HAVEN software?

The HAVEN software is available on the CMS OASIS web site

http://www.cms.hhs.gov/oasis; click on "HAVEN"

It can be downloaded at no charge to the HHA. In addition to the software, data specifications, data dictionaries, the HAVEN manual, and the HHA data submission manual are available.

3. To whom do the comprehensive assessment and OASIS requirements apply?

The comprehensive assessment and OASIS data collection requirements apply to Medicare-certified home health agencies (HHAs), and, to Medicaid home health providers in states where those agencies are required to meet the Medicare Conditions of Participation. The comprehensive assessment and OASIS data collection requirement currently applies to all Medicare and Medicaid patients receiving skilled care, including care reimbursed by Medicare and Medicaid managed care organizations, with the following exceptions: 1) patients under the age of 18; 2) patients receiving maternity services; 3) patients receiving only chore or housekeeping services. OASIS requirements have been delayed for patients receiving only personal care (nonskilled) services. The data encoding and transmission requirement also applies to Medicare and Medicaid patients only. A detailed explanation of the current requirements appears on the CMS OASIS web page at

http://www.cms.hhs.gov/oasis; click on "Regulations."

FREQUENTLY ASKED QUESTIONS

4. How do the regulations apply to Medicaid HHA programs? Do the OASIS regulations apply to HHAs operating under Medicaid waiver programs?

The regulations apply to HHAs that must meet the home health Medicare Conditions of Participation. An agency that currently must meet the Medicare conditions under Federal and/or State law will need to meet the Conditions of Participation related to OASIS and comprehensive assessment. If an HHA operates under a Medicaid waiver, and in that State it is required by State law that HHAs must meet the Medicare Conditions of Participation in order to operate under the Medicaid waiver, then OASIS applies. If an HHA operates under a Medicaid waiver, and in that State it is not required under State law that the HHA must meet the Medicare Conditions of Participation in order to operate under the Medicaid waiver, then OASIS does not apply. HHAs should be aware of the rules governing HHAs in their States.

Currently, OASIS requirements apply to Medicare and Medicaid patients receiving skilled HHA services as indicated under Q1 above, i.e., patients under the age of 18, patients receiving maternity services, and patients receiving only chore/housekeeping services are excluded.

5. We are an HHA that also provides hospice services. Do the comprehensive assessment and OASIS requirements apply to our hospice patient population? What if they are receiving "hospice service" under the home care agency (not the Medicare hospice benefit)? Would OASIS apply?

HHA Conditions of Participation are separate from the rules governing the Medicare hospice program. Care being delivered to a patient under the Medicare home health benefit needs to meet the Federal requirements put forth for home health agencies which includes OASIS data collection and reporting. Care being delivered to a patient under the Medicare hospice benefit needs to meet the Federal requirements put forth for hospice care. These requirements do not include OASIS data collection or reporting. However, if a Medicare patient is receiving terminal care services through the home health benefit, OASIS applies.

FREQUENTLY ASKED QUESTIONS

6. A branch of our agency serves non-Medicare patients. Can you elaborate on whether we need to do the comprehensive assessment with OASIS for these patients? We do serve Medicaid patients from this branch -- does this make a difference?

If an agency is required to meet the Medicare Conditions of Participation, then all of the conditions apply to that agency including the comprehensive assessment and OASIS data collection conditions. Whether the agency has different programs (or different branches operating under a single provider number) that serve different patient types does not matter. All patients receiving skilled care or personal care must receive the comprehensive assessment at the appropriate intervals; patients receiving only chore or housekeeping services are excluded from this requirement. OASIS data collection, data encoding, and data transmission requirements apply for Medicare and Medicaid skilled care patients only as indicated in the Federal Register announcements of June 18, 1999, and December 23, 2005.

Some States allow HHAs to establish completely separate entities for serving other than Medicare/Medicaid patients. If the separate entity does not have to comply with the Medicare Conditions of Participation and the individual State does not require Medicare compliance, then none of the conditions apply. To be considered a separate entity rather than a branch, several requirements must be met — including separate incorporation for tax and business purposes, separate employer IDs, separate phone numbers, separate staff, etc. If this separate entity does not meet the Medicare Conditions of Participation, then it is not Medicare-certified and can neither bill Medicare nor refer to itself as Medicare-certified in any context.

FREQUENTLY ASKED QUESTIONS

7. When a nurse visits a patient's home and determines that the patient does not meet the criteria for home care (e.g., not home-bound, refuses services, etc.), is the comprehensive assessment required? What about OASIS data collection?

This situation is addressed in the regulations for the initial patient assessment. If the patient is a Medicare patient and is determined to be not eligible for services, then the patient is not admitted for care and no comprehensive assessment or OASIS data collection are required. No data will be transmitted to the State agency. If other pay sources (which may not require that patients be homebound to receive home health benefits) are applicable, then the comprehensive assessment may apply as indicated under Q1 above.

8. Should we collect OASIS data on patients receiving therapy services under Medicare Part B?

If skilled therapy services are being provided under the Medicare home health benefit, the patient would receive the comprehensive assessment (with OASIS data collection) at the specified time points. This is true even if the therapy services are provided at a setting outside the patient's home simply because the required equipment cannot be made available at the patient's home. The key consideration is whether the care is being delivered as part of a home health plan of care.

If the patient is not under a home health plan of care, then the Medicare home health Conditions of Participation do not apply. This would be true if the patient was residing in an inpatient facility or the services were being provided under the Medicare outpatient therapy benefit.

FREQUENTLY ASKED QUESTIONS

9. Can you clarify the intent of and the difference between the "initial assessment" and the "comprehensive assessment?"

The initial assessment visit is conducted to determine the immediate care and support needs of the patient and, in the case of Medicare patients, to determine eligibility for the home health benefit including homebound status. If no skilled service is delivered, this visit will not be considered the SOC nor is it considered a reimbursable visit.

The SOC comprehensive assessment must be completed within five calendar days of the SOC date. In the interest of cost-effectiveness, many agencies have combined the initial assessment with the delivery of skilled service(s), assuming the patient is eligible for home care. This would make the initial assessment and the SOC the same date. Also in the interest of efficiency, many agencies also have encouraged clinical staff to complete the SOC comprehensive assessment at this visit. These protocols and procedures are a matter of agency choice and agency policy

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