

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Health Care Financing Administration

### 42 CFR Parts 484 and 488

[HCFA-3006-IFC]

RIN 0938-AJ10

### Medicare and Medicaid Programs: Reporting Outcome and Assessment Information Set (OASIS) Data as Part of the Conditions of Participation for Home Health Agencies

**AGENCY:** Health Care Financing Administration (HCFA), HHS.

**ACTION:** Interim final rule with comment period.

**SUMMARY:** Section 4602(e) of the Balanced Budget Act of 1997 authorizes the Secretary to require that home health agencies (HHAs) submit any information that the Secretary considers necessary to develop a reliable case mix system. This interim final rule with comment period requires electronic reporting of data from the Outcome and Assessment Information Set (OASIS) as a condition of participation for HHAs. Specifically, this rule provides guidelines for HHAs for the electronic transmission of the OASIS data set as well as responsibilities of the State agency or HCFA OASIS contractor in collecting and transmitting this information to HCFA. This interim final rule also sets forth rules concerning the privacy of patient identifiable information generated by the OASIS. The requirements of this interim final rule with comment period are necessary to establish a prospective payment system for HHAs and to achieve broad-based, measurable improvement in the quality of care furnished through Federal programs.

**DATES:** *Effective Date:* February 24, 1999. *Applicability Date:* Regulations at § 484.20 are applicable for testing of the HHA's transmission system and encoding of OASIS data on March 26, 1999, and for reporting of the HHA's OASIS data on April 26, 1999.

*Comment Period:* Comments will be considered if we receive them at the appropriate address no later than 5:00 p.m. on March 26, 1999.

**ADDRESSES:** Mail written comments (one original and three copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA-3006-IFC, P.O. Box 7517, Baltimore, MD 21244-1850.

If you prefer, you may deliver your written comments (one original and

three copies) to one of the following addresses:

Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201; or Room C5-09-26, 7500 Security Boulevard, Baltimore, MD 21244-1850.

For information on ordering copies of the **Federal Register** containing this document and electronic access, see the beginning of the **SUPPLEMENTARY INFORMATION**.

**FOR FURTHER INFORMATION CONTACT:** Tracey Mummert, (410) 786-3398 or Mary Weakland, (410) 786-6835.

#### **SUPPLEMENTARY INFORMATION:**

#### **Comments, Procedures, Availability of Copies, and Electronic Access**

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA-3006-IFC. Comments received timely will be available for public inspection as they are received, generally beginning approximately three weeks after publication of a document, in Room 445-G of the Department's offices at 200 Independence Avenue SW, Washington, DC, Monday through Friday of each week from 8:30 a.m. to 5:00 p.m. (Phone (202) 690-7890).

For comments that relate to information collection requirements, mail a copy of the comments to: Health Care Financing Administration, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Room N2-14-26, 7500 Security Boulevard, Baltimore, MD 21244-1850, Attn: John Burke HCFA-3006-IFC; and, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Allison Herron Eydt, HCFA Desk Officer.

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## **I. Background**

### *A. General*

Home health services are covered for the elderly and disabled under the Hospital Insurance (Part A) and Supplemental Medical Insurance (Part B) benefits of the Medicare program and are described in section 1861(m) of the Social Security Act (the Act). These services must be furnished by, or under arrangement with, an HHA that participates in the Medicare program, and must be provided on a visiting basis in the beneficiary's home.

Section 1861(o) of the Act specifies certain requirements that a home health agency must meet to participate in the Medicare program. (Existing regulations at 42 CFR 440.70(d) specify that HHAs participating in the Medicaid program must also meet the Medicare conditions of participation (COPs)). In particular, section 1861(o)(6) of the Act provides that an HHA must meet the COPs specified in section 1891(a) of the Act and any other COPs that the Secretary finds necessary in the interest of the health and safety of HHA patients. Section 1861(o)(8) of the Act provides that an HHA must meet additional requirements that the Secretary finds necessary for the effective and efficient operation of the home health program.

Section 1891 of the Act sets forth the conditions that HHAs must meet to participate in the Medicare program. Specifically, section 1891(a) of the Act establishes specific requirements for HHAs in several areas, including patient rights, home health aide training and competency, and compliance with applicable Federal, State, and local laws. Under section 1891(b) of the Act,

the Secretary is responsible for assuring that the COPs, and their enforcement, are adequate to protect the health and safety of individuals under the care of an HHA and to promote the effective and efficient use of Medicare funds. In accordance with sections 1864 and 1891(c) of the Act, State agencies generally conduct surveys of HHAs to determine whether they are complying with the COPs.

Under the authority of sections 1861(o), 1871, and 1891 of the Act, the Secretary has established in regulations the requirements that an HHA must meet to participate in Medicare. These requirements are set forth at 42 CFR part 484, Conditions of Participation: Home Health Agencies. The COPs apply to an HHA and the services furnished to each individual under the care of the HHA, unless a condition is specifically limited to Medicare beneficiaries.

Section 1864 of the Act authorizes the use of State agencies to determine providers' compliance with the COPs. Responsibilities of States in ensuring compliance with the COPs are set forth in regulations at 42 CFR part 488, Survey, Certification, and Enforcement Procedures.

#### *B. New Legislation and Related Regulations*

Section 4603 of the Balanced Budget Act (Public Law 105-33 (BBA)), enacted on August 5, 1997, amended the Act to require the Secretary to establish a prospective payment system for home health care. Although the implementation of a prospective payment system will be delayed until all related systems achieve year 2000 compliance, we will still need to begin receiving the data to be used for standardizing the payment amounts as soon as possible. The BBA reformed the payment system for Medicare home health services to achieve \$21.2 billion in savings by the year 2002. These reductions were undertaken as part of the overall strategy to balance the federal budget and extend solvency of the Medicare trust fund. The payment reform for home health services includes an interim payment system (IPS) with reduced cost limits and eventual implementation of a prospective payment system for HHAs. Details of the IPS can be found in the March 31, 1998 **Federal Register** at 63 FR 15718. The IPS will generally result in overall reduced payments to HHAs. Our objective in implementing the provisions of section 4603 of the BBA is to develop a payment system that promotes HHA efficiency while assuring that providers who serve patients with

high care needs are reimbursed within statutory dictates.

In order to implement this prospective payment system, it is necessary that we have data from HHAs to develop a reliable case-mix adjuster system. Section 4602 of the BBA provides that, for cost reporting periods beginning on or after October 1, 1997, the Secretary may require HHAs to submit additional information that the Secretary considers necessary for the development of a reliable case-mix system. We intend for the Outcome and Assessment Information Set (OASIS), a data set comprised of patient care items developed for the purpose of measuring patient health care outcomes in HHAs, to be the vehicle through which information for the case-mix system is collected. Thus, as discussed below, to facilitate the implementation of the prospective payment system and to gather data that can be used to evaluate and develop plans to improve outcomes of care in HHAs, we are publishing two regulations in this issue of the **Federal Register**. Specifically, we are publishing a final rule titled, "Comprehensive Assessment and Use of the OASIS as Part of the Conditions of Participation for Home Health Agencies," which requires that HHAs complete a comprehensive assessment for each patient and that they incorporate the OASIS into their comprehensive assessment process. In addition, as discussed in detail below, in this interim final rule with comment period, we are requiring that HHAs electronically report data from the OASIS to the State agency or other entity designated by HCFA (HCFA OASIS contractor).

#### **II. Provisions of This Interim Final Rule With Comment Period**

In this regulation we are requiring Medicare-approved HHAs and those HHAs that are required to meet Medicare conditions (including Medicaid HHAs and managed care organizations providing home health services to Medicare and Medicaid beneficiaries) to, with certain exceptions, report via electronic transmission their OASIS data to a database established by HCFA within each State. These reporting requirements are consistent with the collection requirements also published today in this issue of the **Federal Register**.

In addition to requirements for HHAs, this interim final rule with comment period includes responsibilities of the State agencies and HCFA OASIS contractors, which have been approved by HCFA to maintain an OASIS

database. Finally, to ensure confidentiality of patient identifiable data generated by the OASIS, we are setting forth requirements for State agencies, HCFA OASIS contractors, and HHAs regarding the release of this information.

#### *A. Section 484.20 Condition of Participation: Reporting OASIS Information*

We are adding a new § 484.20, Condition of Participation: Reporting OASIS Information, to provide that HHAs must report OASIS data on all patients except those specified in the preamble to the regulation describing collection of OASIS data, that is, "Comprehensive Assessment and Use of the OASIS as Part of the Conditions of Participation for Home Health Agencies," mentioned previously. This new COP at § 484.20 will consist of four standards, which are discussed in detail below.

In 1988, we entered into a contract with the Center for Health Services and Policy Research at the University of Colorado Health Sciences Center to develop, test, and refine a system of outcome measures that could be used for outcome-based quality improvement in HHAs. The results of subsequent studies have shown that the collection of precise information on the health status of patients at different points in time can be used in a variety of ways. Once reported to a central database, the compiled, aggregate results of the collection of OASIS data can be used by the HHA to determine how it is performing in terms of patient outcomes compared with other HHAs. The term most often linked with the use of OASIS data to improve quality of care is "outcome-based quality improvement" or OBQI. The OASIS data set is but one of several components of OBQI.

Other components of OBQI include using outcome and case mix reports within an agency to improve quality, evaluate effectiveness of practice, and better manage care to enhance outcomes and control costs and utilization. Outcome reports will be generated by the State agency or HCFA OASIS contractor and will contain data related to patient outcome and case mix findings based on the patient-level data submitted by the HHA. For example, outcome reports may provide information relative to hospitalization rates, medication management, and patient functional status within an HHA. These data will be displayed relative to the individual HHA, along with data representing local and national trends. When outcome reports become available, we expect that each

HHA will be able to use them in its own quality assessment and performance improvement program. HHAs will be able to examine specific care domains and case mix of patients, compare current performance to past performance, and compare their aggregate outcomes to national reference values, that is, the aggregate outcomes from all HHAs. The HHA could then compare its performance with other HHAs locally, regionally, and nationally. This information will be advantageous not only to Medicare beneficiaries and other home care clients, but also to the home care industry in demonstrating its effectiveness. For example, as a result of collecting OASIS information and submitting it to a central data base for evaluation, the University of Colorado has data indicating a statistically significant decrease in rate of re-hospitalization among HHA patients when the agency incorporates outcome reports into its OBQI program.

Outcome reports will most likely be available to HHAs from State agencies on a yearly basis, based on OASIS data that HHAs report to the State. These data will be used to establish and maintain a national database, based on the data from outcome reports. To generate outcome reports that are statistically valid, it is necessary that HHAs transmit a sufficient number of data points. Results of the OASIS demonstration project suggest that reports be based on the collection of data over a year's time. We estimate that outcome reports will begin to be made available no less than one year from the date HHAs are required to begin reporting their OASIS data. We expect that the outcome reports will be made available at least annually thereafter.

In addition, we, along with State agencies, will be able to use the outcome reports to identify opportunities for improvement in national or local priority areas, such as a project to improve medication management for beneficiaries generally or to shorten the time necessary to achieve a clinically important patient outcome. Therefore, the benefit of reporting OASIS data is two-fold. We not only meet our statutory requirements for establishing a prospective payment system for home health but also gather data that can be used at a national level to evaluate and develop plans to improve outcomes of care in the Medicare and Medicaid home health benefit. We believe that computerized patient assessment data would be a valuable resource to monitor trends in patient care in the home health industry. In addition, a national

data base would provide important insights into the structure of the industry and use of resources to achieve positive patient outcomes.

In our companion regulation concerning collection of OASIS data items, time frames for completing OASIS data sets are described for the comprehensive assessment (5 days from start of care), routine update of the comprehensive assessment (two calendar months from start of care), and discharge from a hospital admission, that is, resumption of care (48 hours). Specific time frames for completion of OASIS data were not described for discharge, including discharge to the community, transfer to an inpatient facility (with or without agency discharge), and death at home, nor were comments received relative to these time frames. For consistency in encoding (entering data into a computer) and reporting data relative to these OASIS data sets, we expect that HHAs would complete the OASIS data set items for these time points within 48 hours of knowledge of their occurrence. We are seeking comment on the expectation that HHAs will complete these assessment updates within 48 hours. The reason for the requirement to complete these other assessment types within two calendar days is that the HHA can more readily assess specific information related to the patient's condition at that point in time and maintain a uniform platform for reporting all assessment types.

#### 1. Section 484.20(a) Standard: Encoding OASIS Data

At § 484.20(a), we require that HHAs encode and finalize data entry (lock) for all patients (except those specified in the preamble to the regulation describing collection of OASIS data, that is, "Comprehensive Assessment and Use of the OASIS as Part of the Conditions of Participation for Home Health Agencies") in the agency within 7 days of completing an OASIS data set.

Once the OASIS data set has been collected by the authorized clinical staff member at the specified time points described at § 484.55, HHAs may take up to 7 calendar days after collection to enter it into their computer systems. To enter the data, HHAs will operate the Home Assessment Validation Entry (HAVEN) software program and run the OASIS data set through the HCFA-specified edits in order to make it transmission-ready. This process involves using the HAVEN software to review the data for accuracy and consistency, making any necessary changes, and finalizing the data. We specify 7 days to encode, edit, and lock

the OASIS data because we believe that this is a reasonable amount of time to expect agencies to complete this task while ensuring accuracy of the data. The agency must enter the OASIS data and identify any information that does not pass the HCFA-specified edits, that is, any missing, incorrect, or inconsistent data. This is a simple process of entering a data set into a computer using software that mirrors the OASIS data items. Editing and locking are functions automatically performed using the HAVEN software. If HAVEN identifies data items in need of clarification or additional information, we believe that 7 days is a reasonable amount of time for staff entering data to contact and seek assistance from the qualified clinician who assessed the patient. It is preferable that the edits and corrections be made as close in time as possible to the assessment activity, since the clinician's recall of the patient assessment and the clinical notes that document the assessment are fresher at that point. Seven days is also consistent with the timeframe currently required by long-term care facilities encoding Minimum Data Set (MDS) information. We believe that keeping OASIS encoding consistent with MDS encoding would be simpler for providers and State agencies to manage than introducing a different set of timeframes. In addition, we expect that, in order to provide quality care, HHAs would assess patients and submit OASIS data in a timely fashion for data entry in order to prepare and maintain a current and viable plan of care. As such, we feel that it is reasonable to expect that HHAs will be able to encode, edit, and ready OASIS data for transmission within 7 days of the data's collection.

HHAs will have flexibility in the method used to encode their data. Once the assessment is completed and OASIS data items are collected by the qualified skilled professional (that is, the nurse or therapist responsible for coordinating or completing the assessment), data can be encoded directly by that skilled professional, by a clerical staff member from a hard copy of a completed OASIS, or by a data entry operator with whom the HHA may contract to enter the data. Non-clinical staff may not assess patients or complete assessment items; however, clerical staff or data entry operators may enter the OASIS data collected by the skilled professional into the computer. We note that in entering the data, HHAs must comply with requirements for safeguarding the confidentiality of patient identifiable

information. These requirements are discussed in detail below.

Once the OASIS information is encoded, HHAs will "lock" the data, that is, use their software to review and edit it to create a file that will be transmitted to the State agency or other entity approved to receive this transmission. The edits will include an electronic safety net to preclude the transmission of erroneous or inconsistent information, and required formatting for the data set items. The locking mechanism is necessary to ensure the accuracy of the patient assessment at the point in time that the assessment took place. The locking mechanism will prevent the override of current assessment information with future information.

## 2. Section 484.20(b) Standard: Accuracy of Encoded OASIS Data

Section 484.20(b) requires that the encoded OASIS data accurately reflect the patient's status at the time the information is collected. As research has shown that the patient status changes over time, the data must accurately represent a patient's status at selected points in time. Before transmission, the HHA must ensure that data items on its own collection record match the encoded data that are sent to the State. We expect that once the qualified skilled professional completes the OASIS using either a hard copy of the instrument or an electronic method, the HHA will develop a means to ensure that the data put into the computer and transmitted to the State agency or HCFA OASIS contractor reflect the data collected by the skilled professional. The HHA might appoint staff to audit OASIS records after input as part of the HHA's overall quality assurance program. In addition, the State survey process for HHAs may include review of OASIS data collected versus data encoded and transmitted to the State.

## 3. Section 484.20(c) Standard: Transmittal of OASIS Data

**General requirements.** At § 484.20(c), we require that the HHA electronically transmit to the State agency or HCFA OASIS contractor, at least monthly, accurate, completed, encoded, and locked OASIS data for each patient. This time frame allows for transmission more frequently as determined by the HHA. We also provide that the data must be transmitted in a format that meets the requirements specified in the data format standard at § 484.20(d). Thus, data collected, encoded and locked in February will need to be transmitted in March. We believe that a monthly 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. We provide flexibility for the HHA in that we do not specify a date on which HHAs must transmit the data. Therefore HHAs are free to develop monthly schedules for transmitting the data that best suit their needs. In addition, we provide that HHAs may send OASIS data to the State agency or HCFA OASIS contractor more frequently than monthly if they choose to do so.

We note that the HHA must transmit the Clinical Record Items section of the OASIS, which identifies the patient, with each data set. The Clinical Record Items section includes information such as agency identification, patient identification, and start of care date. The Clinical Record Items are a key aspect of an OASIS data set that will allow the HHA, State agency or HCFA OASIS contractor, and HCFA to track all data sets collected on individual patients within the episode of care. Many elements in the Clinical Records Items section may be completed initially by clerical staff as part of the intake/referral process; but should be verified by the clinician doing the assessment.

As we continue to develop our system to maintain the OASIS data base, the items in the Clinical Record Items section may change to accommodate growth. No substantive changes have been made to the clinical data items published in the **Federal Register** on March 10, 1997, although minor changes have been made to the numbering system to accommodate electronic reporting. We refer you to the HCFA webpage (<http://www.hcfa.gov/medicare/hsqb/oasis/oasishmp.htm>) for changes necessary to comply with OASIS reporting requirements. The current version of OASIS is a proposed information collection requirement pending OMB approval. We have summarized the Paperwork Reduction Act process below and have described the timeframes associated with that process. As an alternative to Internet access, which is the most efficient method of obtaining the current version of the OASIS, agencies may contact their State agency or HCFA regional office home health representatives to request a paper copy of the data set for review. Any future changes to OASIS will be submitted to OMB to review pursuant to the Paperwork Reduction Act of 1995, will be available electronically on the HCFA website, and, when approved by OMB, available

in hard copy from the National Technical Information Service ((703) 487-4650).

In addition to OASIS data, HHAs will transmit information that identifies the location and description of the HHA sending data and the identity of the person submitting the data to the State agency or HCFA OASIS contractor. This information is referred to as the header record. Header information is not information requested by the OASIS data set. Rather, it is information required to support the transmission process. At the end of the transmission file, a record concerning the number of records being transmitted is required to complete the transmission process. This information is referred to as the trailer record. When the HHA is ready to transmit its data to the State, it will use the HAVEN software to add the selected records to be sent with the header and trailer records to create an export file. The export file is then transmitted to the State by the HHA.

HHAs should use standard communication software to dial-up to the State agency or HCFA OASIS contractor, transmit the export file, and receive validation information. HHAs should have a system that supports dial-up communications for the transmission of OASIS data to the State. The communications capability must meet our specification related to transmission of OASIS data. More detailed instructions on the process for data submission will be made available in the near future. This dial-up link will eventually serve as a means of communicating information such as reports, notices, and documents between HHAs and the State agency without requiring additional hardware or software.

HHAs must transmit the OASIS data using a private dial-up network based on a direct telephone connection from the HHA. The telephone communication provides a secure source of transmission, with interception of information being prohibited by Federal and State law. The information is transmitted via a modem at the HHA and received at the State communications server where the file is validated. The State agency or HCFA OASIS contractor will provide to the HHAs in their State specific instructions and phone numbers of the lines available for transmission.

Once transmitted, the State agency or HCFA OASIS contractor validates the information while the HHA remains on-line to ensure that some basic elements conform to HCFA requirements, such as proper format and HHA information. Once these file checks are complete, a

message indicating whether the file has been accepted or rejected is sent back to the HHA's terminal via the agency's communication link. If the submission passes the initial validation check, the record is 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 in the header or trailer record. A record may be rejected for a variety of reasons, for example, the provider identification name or number submitted may be incorrect or does not match the name or number at the State, or the number of records indicated in the trailer record does not match the actual number of records submitted. The HHA will need to make the corrections and re-submit the submission file to the State.

**Initial transmission requirements.** In order to initiate transmission of OASIS data to the State agency or HCFA OASIS contractor, we are including the requirement that HHAs make a successful transmission of test data to the State agency or HCFA OASIS contractor during the test transmission period. The initial test should include both 1) a transmission of any start of care or resumption of care OASIS data that passes HCFA edit checks; and 2) a validation report back from the State confirming transmission of data. We require that HHAs successfully transmit

test data to the State agency or HCFA OASIS contractor beginning March 26, 1999, and no later than April 26, 1999. This test data will not be included in the national repository.

On or after April 26, 1999 we expect that HHAs will send to the State agency or HCFA OASIS contractor all OASIS data collected on existing patients under the care of the HHA on March 26, 1999. The data should include the start of care; follow-up of the start of care; resumption of care; discharge to the community; transfer to an inpatient facility (with or without agency discharge); and death at home OASIS assessment items. Specifically, on patients admitted to the HHA on or after March 26, 1999 the data should include a start of care assessment and any other OASIS data collected in accordance with the requirements at § 484.55. For patients already under the care of the HHA as of March 26, 1999 the data may not include a start of care data set, but must include any OASIS data collected in accordance with the requirements at § 484.55 (follow-up, resumption of care (following an inpatient stay), transfer to inpatient facility (with or without agency discharge), or discharge (including death at home)). As stated above, OASIS data should be reported on all HHA patients except those specified in the regulation describing collection of OASIS data, that is, "Comprehensive Assessment and Use of

the OASIS as Part of the Conditions of Participation for Home Health Agencies." Specific directions for coding these assessments for initial transmission will be included in the State training and manual instructions. On or after, April 26, 1999 and at least monthly thereafter, HHAs will transmit OASIS updates on those patients included in the initial transmission as well as comprehensive assessment OASIS data and updates on any patients admitted to the HHA on or after March 26, 1999.

To further clarify the OASIS effective dates schedule, we offer the following chart based on the assumption that this regulation and the companion regulation describing collection of OASIS data, "Comprehensive Assessment and Use of the OASIS as Part of the Conditions of Participation for Home Health Agencies," are published November 16, 1998. While the publication date of the OASIS regulations differs from the one used in this example, the effective dates in the following chart are based on an assumed publication date. HHAs are cautioned to substitute the actual publication date into the formulas listed below to derive the actual effective dates in addition to reading the discussion of effective dates above. When these regulations are published, we will post the publication date and effective dates on the OASIS webpage.

#### OASIS COLLECTION AND REPORTING TIMELINE

Publication date	Collection begins (11/16/98 + 30 days) <sup>1</sup>	Encoding begins (11/16/98 + 60 days) <sup>2</sup>	HHA tests transmission system (11/16/98 + 60 through 90 days)	HHA begins reporting OASIS data (11/16/98 + 90 days and monthly thereafter) <sup>3</sup>
11/16/98 .....	12/16/98 .....	1/15/99 .....	1/15/99 through 2/14/99 .....	2/14/99 and monthly thereafter.

<sup>1</sup> HHA collects start of care, resumption of care, follow-up, discharge to the community, transfer to an inpatient facility (with or without discharge) and death at home OASIS data on all patients under the care of the HHA as of 12/16/98.

<sup>2</sup> HHA collects and encodes start of care, resumption of care, follow-up, discharge to the community, transfer to an inpatient facility (with or without discharge) and death at home OASIS data on all patients under the care of the HHA as of 1/15/99. For patients admitted to the HHA before 1/15/99, it is not required to encode start of care data.

<sup>3</sup> HHA reports (transmits to the State agency or HCFA OASIS contractor) all OASIS data collected and encoded from 1/15/99 through 2/14/99 and monthly thereafter. Monthly transmissions should include all OASIS data collected and encoded in the previous month.

#### 4. Section 484.20(d) Standard: Data Format

At § 484.20(d) we specify that the HHA must encode and transmit data using the software available from HCFA or software that conforms to HCFA standard electronic record layout, edit specifications, and data dictionary and includes OASIS data items specified in § 484.55(e). To meet the data format requirements, HHAs will be able to use the HAVEN software developed by HCFA, or other vendor's software that conforms to HCFA standardized electronic record formats, edit

specifications, data dictionaries, and that passes standardized edits defined by HCFA. The HAVEN software can be used for several purposes. HHAs will be able to use HAVEN to encode OASIS data, maintain agency and patient-specific OASIS information, and create export files to submit OASIS data. HAVEN will provide comprehensive on-line help to users in encoding, editing and transmitting these data sets. Additionally, we have developed a hotline to support this software product.

HAVEN will alert the individual who is encoding the data to use the correct screen for the specific type of

assessment record required. We suggest that as HHAs plan for implementation, those HHAs using paper copies of OASIS data sets consider a way to differentiate among the various subsets of OASIS data. For example, agencies who were involved in the demonstration pilot studies used different colored paper for each subset of the OASIS instrument. We caution HHAs that the HAVEN system will provide only the minimum requirements to encode and format the data. 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 vendors are encouraged to use the HAVEN software as a minimum system until they have developed their own software to accommodate HCFA specifications and other applications useful for HHAs. If the HHA uses software other than HAVEN it must conform to HCFA standardized electronic record formats, edit specifications, and data dictionaries. The software must also include the OASIS data items specified in § 484.55(e).

HCFA will provide standardized training to State agencies or HCFA OASIS contractors, who, in turn, will provide training to HHAs in each State in advance of the implementation date of this interim final rule. This training, which will include the OASIS User's Manual, will focus on how to use the HAVEN software to encode and format data, how to transmit data, and how to interpret the validation reports.

The required OASIS data set will be available on our website located at <http://www.hcfa.gov/medicare/hsqb/oasis/oasishmp.htm> at all times. HHAs will be able to access the website and download the required OASIS data set 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). We expect the required OASIS to vary slightly from that published in the March 10, 1997, proposed rule; however, there are no changes in the core data items that were published in the proposed rule. Items in the Clinical Records Items section of the OASIS are being updated to accommodate electronic reporting. In addition, the HAVEN software is available on the HCFA website and can be downloaded at no charge to HHAs and used to report OASIS data. This website includes the data specifications, data dictionaries, OASIS data set, and the OASIS User's Manual for the OASIS data set, HAVEN software and HHA data submission. We will also post other educational materials for HHAs on the website. We intend for the website to provide direct access for HHAs, State agencies, HCFA OASIS contractors, software vendors, professional organizations, and consumers. We encourage vendors and agencies to regularly review the website for information related to the computerization of OASIS and other HCFA-related home health issues. We will continue to promote processes for assuring accuracy in the software. In the

future, an alternate version of the OASIS may be required. HHAs will be directed to the HCFA website for the applicable version of the OASIS data set. Once the data set is approved by OMB, HHAs may also obtain hard copies from the National Technical Information Service at ((703) 487-4650).

#### *B. Exemption for HHAs in Research and Demonstration Projects*

Some HHAs participating in OASIS research and demonstration projects may be using other data collection sets, which have been approved by the Secretary. HHAs in research and demonstration projects may be exempt from the requirement to use the OASIS as part of the comprehensive assessment and reporting process for the duration of the project. These determinations will be made on a case-by-case basis. Whether an HHA participating in a research or demonstration project is exempt from the requirements of the final rules requiring collection and reporting of OASIS data will depend on several factors including, the nature of the demonstration project, the data set used, payment implications for the HHA, quality concerns, and burden issues.

At completion or termination of the studies, we will work on a case-by-case basis with these HHAs to transition them into compliance with the general collection and reporting requirements for HHAs that are required to meet the Medicare home health COPs.

#### *C. Section 484.11 Condition of Participation: Release of Patient Identifiable OASIS Information*

We are adding a new § 484.11 Condition of Participation: Release of Patient Identifiable OASIS Information. Section 484.11 provides that the HHA or agent acting on behalf of the HHA must ensure the confidentiality of all patient identifiable information contained in the clinical record and may not release patient identifiable OASIS information to the public. We believe that this provision will ensure that access to all OASIS data (hard copy as well as electronic data) will be secured and controlled by the HHA, State agency or HCFA OASIS contractor. We also specify that an agent acting on behalf of the HHA in accordance with a written contract between the HHA and the agent may not use or disclose the information. The agent may only use or disclose 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.

#### *D. Section 488.68 State Agency Responsibilities for OASIS Collection and Database Requirements*

Under section 1891(b) of the Act, the Secretary 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 for ensuring compliance with the COPs are set forth at part 488, Survey, Certification, and Enforcement Procedures.

Under the authority referenced above, we are adding a new § 488.68, State agency OASIS collection and data base responsibilities. This section provides that the overall responsibility for fulfilling requirements to operate the OASIS system will rest with the State agency or other entity designated by HCFA. The State may enter into an agreement with the State Medicaid agency, another State component, or a private entity to perform day-to-day operations of the system, or HCFA may contract with an entity directly, in the event the State is unable or unwilling to perform these operations. 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 HCFA. 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). Section 488.68 also specifies State agency and HCFA OASIS contractor responsibilities with regard to the OASIS system, which are discussed in detail below.

##### **1. Section 488.68(a) Establish and Maintain the OASIS Data Base**

At § 488.68(a), we provide that the State agency or other entity designated by HCFA must use a standard system developed or approved by HCFA to collect, store and analyze data generated by OASIS. The system developed to compile the Minimum Data Set (MDS) assessments (the HCFA standard State system) has already been procured, installed, and used to collect MDS data. We are currently modifying the standard State system to accommodate OASIS data transmitted by HHAs. The standard State system currently includes a database, communication, supporting

files, print servers for client workstations, local and wide area data networks, and application software for performing all aspects of MDS related functions and tasks. This system may also be utilized to reconfigure data into reports that can be used by State surveyors to focus facility surveys and improve quality of care.

We are providing States with the software and any additional hardware needed to support the standard State system. In several States the home health component of the survey agency is a separate entity that is governed separately and sometimes located in a different geographical location from the agency that currently supports the standard State system. In these States, HCFA will fund the purchase and installation of a computer work station to provide these separate agencies access to OASIS data. As part of the survey responsibilities, § 488.68(a) also provides that States will be responsible for basic system management responsibilities such as hardware and software maintenance, system backup, and monitoring the status of the database.

We also set forth requirements for modification of the HCFA standard State system. Specifically, the State agency must obtain HCFA approval before modifying any parts of the system. The State agency or HCFA OASIS contractor may not modify any aspect of the standard State system that pertains to the standard HCFA-approved OASIS data items, standard HCFA-approved record formats and validation edits, and standard HCFA-approved agency encoding and transmission methods.

## 2. Section 488.68(b) Analyze and Edit OASIS Data

At § 488.68(b), we provide that the State agency or HCFA OASIS contractor is responsible for analyzing and preparing OASIS data for HCFA to retrieve. Upon receipt of data from an HHA, we require that the State agency or HCFA OASIS contractor edit the data as specified by HCFA, and ensure that the HHA resolves errors within the limits specified by HCFA. At least monthly, the State agency or HCFA OASIS contractor must make available for retrieval by HCFA all edited OASIS records received during that period, according to formats specified by HCFA, and correct and retransmit rejected data as needed. We will electronically retrieve OASIS data from the HCFA standard State system into a central repository at HCFA for analysis.

Finally, we require that the State agency or HCFA OASIS contractor

analyze the data and generate reports as specified by HCFA. This responsibility includes generating the outcome reports discussed above for use by the HHA as well as for the State's own use in focusing onsite inspection activities associated with the home health survey process. The OASIS data will significantly improve each State's ability to identify areas of potential quality concerns and will facilitate partnership between States and industry in identifying opportunities to improve care. In addition to the responsibility for generating outcome reports, the State will issue validation reports once OASIS data is received in their systems. Validation reports provide timely feedback to HHAs as to whether the OASIS data they sent has been accepted or rejected, along with reasons why.

## 3. Section 488.68(c) Ensure Accuracy of OASIS Data

We are requiring at § 488.68(c) that, as part of the survey process, the State agency review an HHA's records to verify that OASIS data collected is consistent with OASIS data reported to the State agency or HCFA OASIS contractor. In keeping with § 484.20(b), which requires that the HHA's encoded OASIS data accurately reflect the patient's status at the time the information is collected, we expect that the HHA will develop a means to ensure that the data input into the computer and transmitted to the State agency or HCFA OASIS contractor reflects the data collected by the skilled professional. As discussed earlier, methods to ensure accuracy of OASIS data may include appointing staff to audit OASIS records after input as part of the HHA's overall quality assurance program. The State agency may include a review of the HHA's quality assurance documentation as part of the overall determination of compliance with OASIS related COPs.

## 4. Section 488.68(d) Restrict Access to OASIS Data

To secure and control access to patient identifiable information, we are requiring at § 488.68(d) that the State agency or HCFA OASIS contractor be responsible for restricting access to OASIS data. Specifically, we require that the State agency or HCFA OASIS contractor must assure that access to data is restricted except for transmission of data and reports to HCFA, transmission of data and reports to the State agency component that conducts surveys for purposes related to this function, and transmission of data and reports to other entities only when authorized by HCFA.

We also specify that patient identifiable OASIS data may not be released to the public by the State agency or HCFA OASIS contractor except to the extent it is permitted to do so under the Privacy Act of 1974. Disclosure may be made under the Privacy Act for "routine uses," that are compatible with the purpose for which the information was collected. These routine uses are described in the Privacy Act System of Records, which will be published in the near future. Consistent with these provisions, the State agency or HCFA OASIS contractor is not permitted to release patient identifiable information to the public but may release aggregated data.

## 5. Section 488.68(e) Provide Training and Technical Support for HHAs

The State agency will play a key role in providing educational and technical resources to the HHA to implement the automation of the OASIS data set. Therefore, at § 488.68(e), we require the State agency or HCFA OASIS contractor to provide training and technical support for HHAs. Specifically, we require the State agency or HCFA OASIS contractor to provide HHAs in each State with training on the administration and integration of the OASIS data set into the facility's own comprehensive assessment system. We also specify that the State agency is responsible for instructing each HHA on the use of software to encode and transmit OASIS data.

The State agency staff who operate the HCFA standard system will provide training to designated staff in HHAs on the use of the free HCFA software that will allow the HHAs to encode and format OASIS data for transmission to the State or HCFA OASIS contractor. In a similar manner, HCFA will provide standardized instructions for using the free software, as well as instructions for data submission which will be available electronically on the HCFA website. The designated trainer in the HHA should train HHA staff responsible for collecting OASIS information using a standard training curriculum and manual, which will be provided by HCFA. A User's Manual is available electronically on the HCFA website, and will be available in hard copy from the National Technical Information Service ((703) 487-4650).

States' responsibilities for training and supporting HHAs in the implementation of the OASIS and automation of the OASIS database will likely include the following tasks:

- Training HHAs on OASIS data set administration;



- Providing training and technical support to HHAs in integrating the OASIS items into the HHA's own comprehensive assessment system;
- Answering questions on the clinical aspects of OASIS and providing information to HHAs on the use of the OASIS data in determining prospective payment rates for HHA patients;
- Providing training to other State agency staff in using OASIS data and outcome reports for survey activities;
- Training HHAs on the submission of OASIS data to the State;
- Interpreting validation reports;
- Providing information relative to hardware and software requirements for HHAs to consider when purchasing computer equipment;
- Assisting with training HHAs on encoding and transmitting OASIS data to the State agency, including providing support for transmission of test data during startup, supporting callers requesting technical assistance, providing passwords to HHAs, answering questions about the computer edits and reports; and
- Participating in an annual update on the OASIS and home health prospective payment system project.

To promote national consistency in OASIS systems for States, we have requested that each State designate one or two individuals to support the several tasks involved in this project. These individuals, the State OASIS Educational Coordinator and State Automation Coordinator, will be funded by HCFA through the Medicare survey and certification program.

### III. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments that we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

### IV. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed and the terms and substance of the proposed rule or description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment

procedure is impracticable, unnecessary, or contrary to the public interest.

The primary reasons for waiving the proposed rulemaking process are two-fold. First, in the interest of creating budgetary savings, Congress explicitly authorizes the Secretary under section 4602(e) of the BBA to collect whatever data the Secretary deems necessary to implement a revised home health payment structure to be implemented in the very near future. We cannot issue a proposed rule followed by a final rule and be timely with the implementation of the revised home health payment system within the timeframes contemplated by Congress. No later than April 26, 1999, we must begin receiving OASIS data in order to revise the payment system as required by section 4603 of the BBA. Currently, HHAs are receiving payment for services via an interim payment system and will continue to receive payment for services via the interim payment system until the new payment system is developed and implemented.

Second, we believe it is consistent with public interest not to delay implementation of a prospective payment system by publishing a proposed rule. Publication of this rule as final is necessary to begin the flow of data to HCFA in order to establish, in the very near future, a system of payment for home health agencies using case mix adjusters. Finalizing this rule is in the best interest of the public because affording notice and opportunity for comment would extend the time home health agencies are reimbursed under the current interim payment system while delaying the implementation of the prospective payment system.

In addition, delaying the OASIS reporting process would postpone the implementation of a variety of survey and quality measures designed to protect and promote patient health and safety. Therefore, we find good cause to waive the notice of proposed rulemaking and to issue this final rule on an interim basis. We are providing a 60-day comment period for public comment.

### V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, agencies are required to provide a 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection

should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- Whether the information collection is necessary and useful to carry out the proper functions of the agency;
- The accuracy of the agency's estimate of the information collection burden;
- The quality, utility, and clarity of the information to be collected; and
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are, however, requesting an emergency review of this interim final rule with comment period. In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we are submitting to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection and reporting of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR Part 1320, to ensure the timely availability and reporting of data as necessary for the development of a reliable case mix adjuster that we require for the establishment of a prospective payment system for home health services in compliance with sections 4602 and 4603 of the BBA. We cannot reasonably comply with normal clearance procedures because public harm is likely to result if the agency does not enforce the inclusion of OASIS elements into an HHA's comprehensive assessment requirement early enough to permit training and to enable the HHA to collect and report reliable OASIS data for the period beginning on April 26, 1999. As mentioned above, delaying the OASIS reporting process would delay the implementation of a variety of survey and quality measures designed to protect and promote patient health and safety. In addition, this time frame is necessary because a key aspect of creating a prospective payment system based on agency cost experience is the need to "standardize" the rates by adjusting the agency costs for their case mix. In effect, case mix needs to be adjusted out of the basic payment rates, then, relevant to admissions, built back into the rates on an agency-specific basis. We believe the most reliable way to accomplish this result is by using data from existing agencies. Because the prospective payment system must be implemented as soon as possible, we will need to begin receiving the data to be used for standardizing the prospective payment amounts.



The immediate publication of rules requiring the collection and reporting of OASIS data and OMB approval of these requirements pursuant to the Paperwork Reduction Act of 1995 are essential because these data are required for the development of the home health prospective payment system, required by statute in October of 2000. Because OASIS data will form the basis for the case mix adjustment component of the prospective payment system, national OASIS data must be used in the extensive statistical analyses needed to calculate standardized prospective payment rates and estimate their impact. The process of rate development must take place in the early spring of 1999 for incorporation in a proposed rule. The proposed rule regarding the home health prospective payment system must be published by the fall of 1999 to allow for necessary comments and revisions prior to the publication of a final rule in the summer of 2000. Given the lag time between the publication of the OASIS rules and the receipt of viable national data by HCFA, we are already at the point where only two months of national data will be potentially available for use in the proposed rule and less than a year of data for the final rule. Further delays would reduce the amount of national data available for development of the prospective payment rates and thus seriously undermine the project plan aimed at implementation of the prospective payment system on October 1, 2000.

We note that the information collection requirements and associated burden referenced in this regulation are primarily concerned with the "reporting" of OASIS data. The collection requirements and related burden associated with the "collection" of OASIS data are referenced in a separate final rule published today in the **Federal Register** and approved under OMB control number 0938-0365. Also worth noting is the fact that HCFA-R-39 (0938-0365), "Home Health Medicare Conditions of Participation Information Collection

Requirement as Outlined in Regulation 42 CFR 484," is currently being revised to include the OASIS data set as displayed at <http://www.hcfa.gov/medicare/hsqb/oasis/oasishmp.htm>. As an alternative to Internet access, which is the most efficient method of obtaining the current version of the OASIS, agencies may contact their State agency or HCFA regional office home health representatives to request a paper copy of the data set for review.

The current version of OASIS is a proposed information collection requirement pending OMB approval. We have summarized the Paperwork Reduction Act process below and have described the timeframes associated with that process. We are asking not only for approval of OASIS but also reapproval of the COPs previously included in HCFA-R-39 and approved under the OMB control number indicated above.

HCFA is requesting OMB review and approval of this collection within 16 working days from the date of publication of this regulation, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individuals designated below within 15 working days from the date of publication of this regulation.

During this 180-day approval period, we will publish a separate **Federal Register** notice announcing the initiation of an extensive 60-day agency review and public comment period on these requirements. We will submit the requirements for OMB review and an extension of this emergency approval.

We are soliciting public comment on each of these issues for the provisions that contain information collection requirements as summarized below:

**Section 484.11 Condition of Participation: Release of Patient Identifiable OASIS Information**

Section 484.11 states that the HHA may release patient identifiable information to an agent acting on behalf of the HHA only in accordance with a written contract between the HHA and

the agent. As such, the agent agrees not to use or disclose the information except to the extent the HHA itself is permitted to do so.

The burden associated with this record keeping requirement is the time and effort for the HHA to maintain a copy of the written agreement. We estimate that each HHA will maintain one written agreement which will take 2 minutes. We estimate that there will be 2,623 written agreements (25% x 10,492 HHAs x 1 agreement) which will each take 2 minutes for a total annual burden of 88 hours.

**Section 484.20 Condition of Participation: Reporting OASIS Information**

Section 484.20 states that HHAs must electronically report all OASIS data collected in accordance with § 484.55 and the requirements contained in this section.

The burden associated with meeting § 484.20 is the time and effort for the HHA to electronically report all OASIS data collected in accordance with § 484.55 and the requirements contained in this section. We estimate that each HHA will take 121.50 hours on an annual basis (486 admissions per year x 2.5 assessments x 6 minutes to review, enter, transmit and perform a 15-minute monthly data audit) to comply with § 484.20. We estimate that the total annual burden for 10,492 HHA's will be 1,274,778 hours. As noted above, the requirements and associated burden imposed by this section relate only to the "reporting" burden. The burden associated with the "collection" of OASIS data is contained in the regulation HCFA-3007-F which is published as a separate final rule in this issue of the **Federal Register**.

The table below indicates the annual number of responses for each regulation section in this interim final rule with comment period that contains information collection requirements, the average burden per response in minutes or hours, and the total annual burden hours.

ESTIMATED ANNUAL BURDEN

CFR section	Responses	Average burden per response	Annual burden hours
484.11(b) .....	2,623	2 minutes .....	88 hours
484.20 .....	10,492	121.50 hours	1,274,778 hours
Total .....	.....	.....	1,274,866 hours

We have submitted a copy of this interim final rule with comment period to OMB for its review of the information collection requirements. These requirements are not effective until they have been approved by OMB. A notice will be published in the **Federal Register** when approval is obtained.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, E-mail your request, including your address, phone number, and HCFA form number(s) and/or OMB numbers referenced above, to [paperwork@hcfa.gov](mailto:paperwork@hcfa.gov), or call the Reports Clearance Office on (410) 786-1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information collection and recordkeeping requirements must be mailed and/or faxed to the designees referenced below, within 15 working days from the date of this publication in the **Federal Register** to:

Health Care Financing Administration,  
Office of Information Services,  
Security and Standards Group,  
Division of HCFA Enterprise  
Standards, Room N2-14-26, 7500  
Security Boulevard, Baltimore, MD  
21244-1850 Attn: John Burke HCFA-  
3006-IFC Fax number: 410-786-0262

and,

Office of Information and Regulatory  
Affairs, Office of Management and  
Budget Room 10235, New Executive  
Office Building Washington, D.C.  
20503 Attn.: Allison Herron Eydt,  
HCFA Desk Officer Fax numbers:  
202-395-6974 or 202-395-5167

## VI. Regulatory Impact Statement

### A. General

We have examined the impacts of this interim final rule with comment period as required by Executive Order 12866, the Regulatory Flexibility Act (RFA) (Pub. L. 96-354), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). The RFA requires agencies to analyze options for regulatory relief for small businesses. For purposes of the RFA, most hospitals, and most other providers, physicians, and health care suppliers are small entities, either by nonprofit status or by having revenues

of \$5 million or less annually. For purposes of the RFA, most HHAs are considered small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis for an interim final rule with comment period that may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds. We are not preparing a rural impact statement since we have determined, and the Secretary certifies that this interim final rule with comment period would not have a significant economic impact on the operations of a substantial number of small rural hospitals. However, we have provided a detailed discussion on the costs and various benefits of reporting OASIS data in tables, I and II in Section B. Costs associated with OASIS reporting, and in accompanying explanations.

Section 202 of the Unfunded Mandates Reform Act requires agencies to prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an annual expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million (adjusted annually for inflation). As discussed in detail in the cost benefit analysis below, we estimate that the amount of the unfunded mandate associated with this interim rule with comment period will result in an annual expenditure of less than \$100 million to these governmental and private sectors. Therefore, we believe the law does not apply.

We are requiring that all Medicare-certified HHAs and HHAs that are required to meet Medicare conditions of participation (for example, Managed Care and Medicaid HHAs), assess their patients using the standardized, outcome oriented data set known as OASIS. OASIS was developed through extensive research and validated in a multi-State demonstration project. As discussed in detail in a separate rule on OASIS data collection published today in the **Federal Register**, this defined set of core data items was developed largely for the purpose of measuring and risk adjusting patient-level outcomes in home health care and as such, is explicitly tailored to home care. Data reported from the OASIS will allow HHAs to integrate a quality assurance and performance improvement measurement system approach into

their practices and, as discussed above, will also be used to support the Medicare HHA prospective payment system.

The Balanced Budget Act of 1997 requires HCFA to develop a prospective payment system for home health. A prospective payment system pays providers based on the predicted costs of care, giving providers the incentive to provide care efficiently. In the home health prospective payment system, beneficiaries will be classified into case mix groupings based on their predicted resource use, with each group having a specific payment rate.

In developing a sound classification system, HCFA must account for the factors that would influence the beneficiary's use of services. In the case of the hospital prospective payment system, this was done using Medicare claims data linked to diagnosis data. Because the majority of inpatient services are attributed to the medical diagnosis, Medicare claims provide enough information to classify patients for hospital payments.

Post-acute care services such as home health and skilled nursing facility services are influenced in part by the medical diagnosis. However, other factors have a strong influence in the use of post-acute care, such as the severity of illness and functional abilities. Therefore, a more comprehensive data source is needed for proper patient classification. Because Medicare claims provide information only about diagnosis, age, gender, and race, a claims-based grouping would not adequately classify beneficiaries into payment groups.

The first attempt to design a prospective payment system for post-acute services was the case of skilled nursing facilities. Under this payment system, HCFA has used data from both claims and the Minimum Data Set (MDS) to classify patients into payment groups. Similarly, HCFA plans to use OASIS data in addition to claims data to construct the home health prospective payment system. A classification system that takes into account severity of illness as well as functional abilities will help to ensure adequate payment for high-cost beneficiaries. At this time, there is no other viable data source that would provide this information other than OASIS. If HCFA does not use OASIS data to identify case mix groups, then, on average, prospective payment amounts could be too low for beneficiaries who need assistance with many activities of daily living and too high for beneficiaries who need less assistance.

The Balanced Budget Act of 1997 also requires the amounts paid for each case mix group under the prospective payment system to be based on a standardized payment rate. HCFA is designing the case-mix classification system based on OASIS and claims data from a stratified sample of 90 HHAs. Standardization requires removing the effect of case mix and wage variation from payment levels for these 90 HHAs and from national payment levels. This helps to ensure that if resource use varies from region to region, payments in the prospective payment system are adjusted accordingly. This process requires the same information that is used to classify patients into payment groups. Therefore, we must collect OASIS data from HHAs before HCFA can set standardized payment rates for a prospective payment system.

The OASIS instrument has been in development for the past ten years. A large number of home health agencies have participated in its development and testing. The instrument has demonstrated its validity and reliability as an assessment and outcome measurement tool. We share the industry's interest in the adoption of a useful and appropriate instrument with as little disruption to existing HHAs operations as possible. We also share the industry's interest in minimizing unnecessary paperwork and record keeping burdens, while at the same time, ensuring quality of care for beneficiaries. Paperwork and record keeping requirements must be cost effectively integrated into HCFA's survey and enforcement processes (both from the balanced perspectives of the public and private sectors), and must maximize available information technologies. In particular, we may reevaluate OASIS data and reporting needs for patient reassessments. We solicit public comment on appropriate refinements to reassessment data requirements and any other aspects of OASIS that can be improved as the result of program experience.

In addition to its use as the basis for prospective payment, OASIS will assist agencies in improving their performance through outcomes-based assessment. The quality component of OASIS is crucial to ensuring that beneficiaries receive needed services under the home health prospective payment system.

OASIS is one of several components of the outcome-based quality improvement (OBQI) approach that has produced documented positive impacts on the clinical status of HHA patients. The outcome data encapsulated in OASIS allows HHAs to improve quality, evaluate the effectiveness of its care,

and better manage care to enhance outcomes and control costs and utilization. Key features of the OBQI approach are the collection of patient/client data at regular intervals; the aggregation and comparison of agency outcomes on a yearly basis and nationally; changing care associated with poor outcomes; and reinforcing care for exemplary outcomes. Outcome measures are defined as a quantification of a change in patient health status between two or more time points and in OBQI, outcome measures are computed using OASIS data from start of care and from subsequent time points or discharge. HCFA commissioned a demonstration study to evaluate the clinical outcomes associated with the application of OBQI/OASIS. The Center for Health Services and Policy Research at the University of Colorado has preliminary findings associated with an outcome-based quality improvement study. Preliminary results from the study, yet unpublished, suggest that risk-adjusted hospitalization rates declined from approximately 31 percent to 28 percent (about a 10 percent rate of decrease) from the first to second years of OBQI application. The demonstration findings also showed an improvement in other health status outcomes. OBQI, properly implemented and maintained, is capable of assisting HHAs enhance patient outcomes. However, in order to realize the full benefits of using OASIS data, the information needs to be computerized and configurable as an analytical tool. Implementation of this rule will allow this goal to be realized.

The OASIS data transmitted by HHAs and States to HCFA will improve the delivery of quality care to patients receiving services from HHAs in the following ways. The database will enable the State agencies and us to provide HHAs with reports of aggregated State and national patient outcome measures and trends. These reports will allow HHAs to compare themselves to similar providers and develop improvement activities, where the need is identified. By establishing internal quality assurance analyses derived from the computerized data, HHAs will be able to evaluate the effectiveness of various components of their home health care delivery systems. The evaluations will lead to identification of best clinical practices and interventions, optimal personnel staffing, and optimal length and type of services for each agency and its patients.

Access to this electronic data will provide information that will benefit both the policy and operational components of Federal and State government. The system has the

potential of providing consumer groups with outcome and quality information for making health care decisions. States will have access to timely OASIS data that will improve their ability to focus on-site inspection activities associated with the home health survey process. Since we require OASIS data for almost all home health patients regardless of payer source, the database will allow for comparison of outcomes of most patients receiving home health services. The OASIS data will significantly improve each State's ability to identify areas of potential quality concerns in an effective and efficient manner, and will facilitate partnership between States and industry in identifying opportunities to improve care. At both the Federal and State level, information from the OASIS system will provide a valid and reliable tool for evaluating and improving the efficacy of survey and certification activities. The quality of peer profiling will be made available from the State agency to allow the HHA to compare itself against its peers. If the HHA needs assistance with ways to improve its activity, the State agency or other consultative group will be able to provide guidance in this iterative process.

We note that OASIS data will become part of the same information system that is being designed to collect and report beneficiary specific outcomes of care and provider performance data across a multitude of delivery sites. Currently, as required in § 483.315(h), States are collecting and reporting assessment data on residents in all Medicare and Medicaid certified nursing homes through the use of the MDS. As OASIS data becomes part of this standard State system, we will have data on the second piece of the post-acute care continuum. The systems and staffing infrastructure to collect OASIS and MDS information have already been established at each State survey agency, as well as within HCFA itself, so that State costs associated with electronically collecting OASIS data from HHAs will be on an incremental basis.

#### *B. Costs Associated With OASIS Reporting*

##### *General*

We anticipate that both HHAs and States will incur some incremental costs from reporting OASIS information. We estimate total start-up costs of \$11.4 million, which represents only costs incurred by HHAs (we will be supplying the OASIS software directly to States and States already have the requisite hardware). This includes as much as \$5.2 million in Medicare program costs.

We also estimate total ongoing annual costs of about \$25.0 million, which includes \$22.0 million in costs for HHAs and \$3.0 million in costs for States. Approximately \$10.1 million of the \$22 million will be reimbursable by Medicare annually. The annual administrative cost for States of \$3.0 million will be absorbed within HCFA's program management appropriation. We will be supplying OASIS software directly to States and States already have the requisite hardware. However, the benefits associated with computerizing the OASIS far outweigh the additional costs of automating the data.

The preceding represents our estimates of the individual costs associated with this effort. These figures are based on our best estimates of actual burden to existing HHAs and are without the benefit of actual cost data documenting the incremental costs associated with the reporting of OASIS data. Any adjustments to Medicare cost limits would necessarily be based on cost data rather than estimates. In addition, these costs are based on the assumption that implementation will be in fiscal years 1999 and 2000. On August 11, 1998, we published in the **Federal Register** a notice with comment period that set forth the schedules of per-visit and per-beneficiary limitations for HHA costs (63 FR 42912). In that notice, we included an OASIS offset adjustment factor to the per visit limitations to address costs incurred with OASIS implementation. While we based this adjustment on the best data we had available, we are concerned that we may not have captured all relevant costs, particularly ongoing and automation costs. In part, this is because our data are based on agencies whose costs in this regard may not have been fully representative of agency costs in general. In the above notice, we asked for specific comments on ongoing and automation costs associated with OASIS reporting. We also asked for cost data that would impact subsequent decision making on future cost limit notices. In this interim final rule, we are requesting comments on the adequacy of estimated initial and on-going costs associated with the automation of OASIS data. Because the comment period for the notice referred to above closed on October 13, 1998, we will consider comments on cost limit adjustments based on the estimates we have included in this rule in future cost limit notices. However, we will only consider such comments on cost limit adjustments if they relate to the provisions of this interim final rule,

specifically those associated with the incremental cost of OASIS implementation.

We have used this approach of accepting comments on cost limit adjustment in response to this interim final rule because we would not consider re-opening the previous comment period. The issues in the August 1998 notice on the interim payment system are much broader than the payment adjustment for OASIS related costs. Consequently, the comments we received were almost entirely directed to the broader issues. In fact, we received only two comments suggesting additional factors to be considered in assessing costs associated with OASIS. We expect a great deal more comments relative to this issue in response to this interim rule with comment period, which focuses entirely on OASIS related concerns.

#### Home Health Agencies

Upon publication of this rule, each HHA that is required to meet the Medicare Conditions of Participation must electronically transmit OASIS data to its respective State survey agency or HCFA OASIS contractor. Most costs associated with computerizing the OASIS will be related to hardware and software. The costs presented below are based on the profile of an average HHA, where applicable, since certain costs (such as a computer) are constant regardless of the size of the agency. We define an average size HHA as having 18 clinicians and other service practitioners and 486 admissions per year.

At the current time, we estimate that approximately 50 percent of the 10,492 Medicare certified HHAs as of March 1998, or 5,246 agencies, already possess the requisite hardware needed to support automation of the OASIS. This estimate is based on a national survey conducted by the Joint Commission on Accreditation for Healthcare Organizations. We note that many HHAs currently contract with outside entities to electronically bill fiscal intermediaries for Medicare services. We anticipate that, similarly, many HHAs will choose to contract for the encoding and transmitting of the OASIS data as well. Therefore, these HHAs will not be incurring any costs associated with procuring the hardware needed to support this effort. Nonetheless, for the purpose of the estimates in this rule, we have assumed that all 50 percent of the HHAs without computer equipment will opt to purchase the requisite hardware.

#### Reimbursement for Costs

- Medicare

The BBA has mandated us to develop a prospective payment system for home health services based on units of payment. Until the HHA prospective payment system is in effect, the BBA also required that we implement an interim payment system (IPS) for home health, which began on October 1, 1997. This interim payment system established two sets of cost limits for home health agencies. Details of the IPS can be found in the March 31, 1998, **Federal Register** (63 FR 15718) and in the August 11, 1998, **Federal Register** (63 FR 42911). The IPS will generally result in overall reduced payments to HHAs. We anticipate that HHAs will incur some costs associated with the implementation of OASIS data collection and reporting. However, as stated above, we are evaluating comments on the August 11, 1998 payment notice setting forth HHA cost limitations that included an OASIS offset adjustment factor to the per visit limitations. This payment notice addresses costs incurred with the incremental costs of OASIS implementation.

The implementation of this interim final rule with comment period will be accomplished by HHAs in existence, and participating in HCFA programs. HHAs that apply for and receive Medicare certification in the future will be expected to comply with the current COPs regarding comprehensive assessment of patients prior to certification. Therefore we would not expect HHAs that are certified in the future to have start-up costs related to revising their comprehensive assessments.

- Medicaid

States have flexibility in designing their payment methodology for home health services that are reimbursable under the Medicaid program. The payment methodology can recognize provider costs or it can recognize a certain rate that the State is willing to pay. The State agency has a choice to either determine a negotiated rate with the HHA or to set a standard rate for all HHA providers. In this case, the HHA has the option of accepting the rate, or not. To the extent that an HHA incurs costs in computerizing the OASIS (such as, the acquisition of hardware or software, staff training, or additional staffing), the provider may take the costs into account when establishing its rates for home health services. The State Medicaid agency can also take the costs into consideration in reimbursing the provider. Therefore, we do not believe that these costs will serve as a barrier to new, viable HHA entrants.

The following tables show our estimates of national costs for OASIS reporting.

TABLE I.—NATIONAL START-UP COSTS FOR OASIS REPORTING

FY	Number of agencies incurring start-up costs	Start-up costs (in millions) <sup>5</sup>	Medicare costs (in millions)	Costs to other sources (in millions) <sup>3</sup>
1999 and 2000 <sup>1</sup>	10,492	\$11.4 <sup>4</sup>	\$5.2	\$6.2
2001	0	0	0	0
2002	0	0	0	0
2003	0	0	0	0

TABLE II.—NATIONAL COSTS FOR OASIS REPORTING

FY	Number of HHAs	Total on-going costs (in millions) <sup>5</sup>	State Admin Costs (in millions) <sup>2</sup>	On-going Costs @ \$2,097 per HHA (in millions)	Medicare Costs (in millions)	Costs to Other sources (in millions) <sup>3</sup>
1999 <sup>1</sup>	10,492	\$25.0	\$3.0	\$22.0	\$10.1	\$11.9
2000 <sup>1</sup>	10,492	25.0	3.0	22.0	10.1	11.9
2001	10,492	25.0	3.0	22.0	10.1	11.9
2002	10,492	25.0	3.0	22.0	10.1	11.9
2003	10,492	25.0	3.0	22.0	10.1	11.9

Tables I and II reflect estimates of total costs versus incremental costs. These costs are based on the following assumptions:

<sup>1</sup> Implementation will be in Fiscal years 1999 and 2000.

<sup>2</sup> Expected to be absorbed within HCFA's program management appropriation.

<sup>3</sup> Medicare will reimburse HHAs for their reasonable start-up and ongoing costs, subject to cost limits, based on the estimate that approximately 46% of HHA patients are Medicare beneficiaries. This estimate is reflected in Table I by indicating that 46% of \$11.4 million (or \$5.2 million) will be reimbursable by Medicare for start up costs. This estimate is also reflected in Table II by indicating that 46% of \$22.0 million (or \$10.1 million) will be reimbursable by Medicare for annual ongoing costs. These estimates may be overstated to the extent that reasonable cost determinations and application of cost limits reduce this expense. The remaining 54% of the start-up costs, or \$6.2 million in Table I, and the remaining 54% of the ongoing costs in Table II, or \$11.9 million annually may be absorbed by a combination of the Medicaid program, private insurers, and beneficiaries. Because approximately 23% of HHA patients are Medicaid beneficiaries, we expect HHAs to try to have the Medicaid programs absorb up to 23% of the \$11.4 million in start-up costs or \$2.6 million. Subtracting \$2.6 million from the remaining \$6.2 million start-up costs leaves \$3.6 million in start-up costs to be passed along to private insurers and beneficiaries. In a similar way, we expect HHAs to have the Medicaid programs absorb up to 23 per cent of the annual \$22.0 million in ongoing costs, or \$5.1 million. Subtracting \$5.1 million from the remaining \$11.9 million annual ongoing costs leaves \$6.8 million in annual ongoing costs. However, after implementation, ongoing costs become part of the HHA's base history.

<sup>4</sup> See Table I—Estimated start-up costs include \$170.00 for training expenses x 10,492 HHAs (\$1.8 million). We estimate approximately \$1,829 per HHA to purchase computers x 5,246 HHAs because an estimated one half of the 10,492 HHAs already have the necessary computer equipment (\$9.6 million). Therefore, \$1.8 million + \$9.6 million = \$11.4 million.

<sup>5</sup> The total of start up costs and ongoing costs equals \$61.4 million. This is based on an estimated start up cost of \$11.4 million for Fiscal years 1999 and 2000, and ongoing costs of \$25 million per year, for those two years.

• **Hardware:** We estimate total hardware costs associated with automating the OASIS to be approximately \$1,829 for a typical HHA, which includes the computer and communications components capable of running OASIS software and transmitting OASIS assessments, and a laser printer. This estimate is based on the most recent cost data available for a system that includes an Intel Pentium processor. This system typically would use Windows 95 or Windows NT 4.0, and include at least 32 megabytes of RAM, 2 gigabytes disk space, a 3.5 floppy disk drive, CD-ROM drive, a color SVGA monitor, a mouse, a laser printer, and a 56 kbps modem connected to a dedicated telephone line. The cost estimate is based on the optimal system we anticipate that many HHAs will choose to purchase. However, at a minimum, HHAs should

have at least a 486–50 personal computer in a Windows 3.1 environment with 8 megabytes of RAM, at least 100 megabytes of available hard disk space, a VGA color monitor, keyboard, mouse, a 3.5 floppy drive, and a laser printer. All HHAs should have at least a 28.8 kbps modem for telecommunications of the data, as well as web browser software that supports dial-up communications for the transmission of HHA assessment data to the State. The communications capability must meet our specifications related to transmission of OASIS data.

• **Software:** HHAs have the option of purchasing data collection software that can be used to support other clinical or operational needs (for example, care planning, quality assurance, or billing) or other regulatory requirements for reporting patient information. However, HCFA has developed an OASIS data

entry system (that is, Home Assessment Validation and Entry, or "HAVEN") that is available to HHAs at no charge through HCFA's website at <http://www.hcfa.gov/medicare/hsqb/oasis/oasishmp.htm>. HHAs may also request HAVEN on CD-ROM. Therefore, HHAs who plan to use HAVEN will need either Internet access (for example, a dial-up Internet Service Provider (ISP) account) or a CD-ROM drive in order to obtain and install the software.

HAVEN will offer users the ability to collect OASIS assessments data in a database and transmit the data in a HCFA-standard format to State databases. The data entry software will import and export data in standard OASIS record format, maintain agency, patient, and employee information, enforce data integrity through rigorous edit checks, and provide comprehensive on-line help. It is recommended that the

Windows operating system be operated at a screen resolution of 800x600 for HAVEN. While HAVEN will operate at 640x480 resolution, the data entry forms will not be completely visible on the screen, and the user will need to scroll to view some of the variables.

- **Supplies:** Supplies necessary for collection and transmission of data, including forms, diskettes, computer paper, and toner, will vary according to the size of the agency, the number of patients served, and the number of assessments conducted. We anticipate that an average HHA with 486 admissions per year will incur approximately \$250 in costs for supplies.

- **Maintenance:** There are costs associated with normal maintenance of computer equipment such as the replacement of disk drives or memory chips. Typically, such maintenance is provided through extended warranty agreements with the original equipment manufacturer, system retailer, or a firm that provides computer support. These maintenance costs are estimated to average no more than \$100 per year.

- **Training:** HHA staff will require training on encoding assessments and compiling OASIS data for electronic submission. One person in each agency should be trained in data entry and data transmission procedures and requirements. We expect that this initial training will require about 5.5 hours of staff time, and will cost an average HHA about \$170 based on an average hourly rate of \$12.50 for technical staff. This cost also includes travel expenses and travel time, since facility staff may need to travel to a centralized training site within the State (we anticipate that training will be provided in multiple sites in the State once the system is implemented). We expect that the State survey agencies will supply this training.

- **Data Entry:** HHAs have flexibility in choosing the method used to collect OASIS data, but the method must comply with our requirement for safeguarding the confidentiality of clinical records. HHAs must collect and transmit OASIS data to the State survey agency, at a minimum, on a monthly basis. The data may be entered directly by a technical staff member from a paper document completed by a clinical staff member, or by a data entry operator under contract to the HHA to key in data. Additionally, HHAs must allow time for data validation, preparation of data for transmission, and correction of returned records that failed checks at the State data-editing level. We estimate that an average HHA with 486 admissions per year will incur an

annual data entry cost of \$1,557 per year, based on an estimate of 2.5 assessments per admission and an hourly rate for data entry costs of \$12.50. This cost includes data review and entry, as well as a (recommended) 15 minute monthly data entry audit for quality assurance purposes.

- **Ongoing Data Transmission:** HHAs will fund the cost of transmitting OASIS data to their respective State agencies. HHA staff must also manage the data transmission function, correct communications problems, and manage report logs and validation reports transmitted from the State. We estimate that it will take about one additional hour of staff time to perform data transmission related tasks each month, including running a data edit check program. This staff time will cost an average size HHA about \$150 per year based on an hourly rate of \$12.50.

Some States will opt to provide their HHAs with a toll-free line to use in transmitting their data. However, in the States that choose not to do so, we estimate that an average HHA will incur about \$36 per year to electronically report its OASIS data to the State.

#### States

We expect that overall responsibility for fulfilling requirements to operate the State OASIS system will rest with the State survey agency. OASIS data will be maintained on the standard State systems that currently house the MDS assessments being reported by all certified nursing homes. HCFA has already procured and installed this system in each State survey agency. It is currently being used to collect the MDS data and to configure reports that will be used by the State surveyors to better focus surveys. However, there are some States in which responsibility for the long term survey and certification functions are located in different components of the State agency than the home health survey and certification functions. HCFA will fund the purchase and installation of a computer work station in these States, so that the non-long term care surveyors will have direct access to the OASIS data.

Since HCFA has already deployed computer hardware and software to the States to operate the MDS automated system, the entity operating the MDS system will also be responsible for day-to-day operations of the OASIS system. In most cases, the State is operating the system itself. However, several States have exercised their option to enter into an agreement with either the State Medicaid agency, another State component, or a private contractor to perform the day-to-day operations of the

MDS system. Just as we required for MDS data, prior to entering an agreement with a subcontractor to extend support for OASIS data, a State must receive approval from its respective HCFA regional office if the State OASIS system is to be operated by an entity other than the survey agency. If the State system is operated by an entity other than the State survey agency, the State must ensure that the survey agency has suitable access to this system to fully support all OASIS-driven functions that the State will require of the survey agency (for example, quality indicator reporting and survey targeting). The State is also responsible for maintaining OASIS data for retrieval by HCFA to a central repository to be established by HCFA.

States will use OASIS data primarily to focus the home health survey process and to provide HHAs and consumers with OASIS-driven information. As previously mentioned, the OASIS information will be maintained on the already existing MDS system which currently includes a database, communication, supporting file(s), and print servers for client workstations; local and wide area data networks; and application software for performing all aspects of MDS related functions and tasks. This system has been designed and developed within a broad class of systems known as Client/Server architecture.

We are providing the OASIS system to States primarily for use in the survey and certification program. As such, most Federally reimbursable costs incurred by the States for automating the OASIS will be funded through the Medicare survey and certification program. However, some States could also choose to use OASIS data in administering their Medicaid programs. When that is the case, Federal reimbursement is applicable to the extent that a State uses the OASIS for administering its Medicaid program. As a result, it may be appropriate for a State to allocate some OASIS costs to its Medicaid administrative cost claims.

When a State does use OASIS in administering its Medicaid programs, it should apportion Federal costs associated with automating the OASIS and operating the data system between the Medicare survey and certification program and the Medicaid program (as administrative costs, when applicable). The State should apportion OASIS costs to these programs based on the State's determination of each program's utilization of the OASIS system. The Federal financial participation rate for costs apportioned as Medicaid administrative costs is 50 percent. When

the State licensure program benefits from the automation of the OASIS, the State should also share in the OASIS automation costs.

- **Hardware:** As previously discussed, States already have the systems infrastructure in place to support the requirement to collect OASIS data from their certified HHAs. However, HCFA will fund the purchase and installation of a computer work station in those States in which the long term care and non-long term care surveyors work in different offices. We anticipate that these States will require a Pentium 233 workstation with 8 gigabyte hard drive and a 15 inch monitor. This system will run on Windows NT 4.0 and include a network card for LAN connections.

- **Software:** HCFA will provide each State with a standard suite of software applications to perform all OASIS-related functions, including receipt and validation of OASIS records, posting of records to the master repository, and analytical applications to be used to inform and support the home health agency.

The OASIS system, in most cases, will be operated by personnel within the designated State agency. We will require the State systems to perform the full gamut of OASIS system responsibilities including receiving, authenticating, and validating the records received from HHAs, providing feedback to the HHAs, storing the OASIS records in a permanent database within the State system, creating system management reports and logs, generating provider performance reports, and retransmitting validated OASIS records from each State agency to a national OASIS repository maintained by HCFA. When a State develops its own customized OASIS applications, the costs of developing and maintaining these additional software applications (and any related hardware components) will not be Federally funded.

- **Operational Staff Time:** The systems infrastructure that will collect and configure the OASIS data from HHAs is already in place in all States. We expect that States will hire or reassign the technical staff required to support the system. However, HCFA recognizes that there will be incremental staff time required to support the additional technical activities associated with maintaining additional provider passwords and a larger database, as well as fulfilling the provider/vendor education and support role. We are requesting that each State assign an OASIS automation coordinator who will be our key contact within each State for managing OASIS system issues. States have already

named an MDS automation coordinator, and we anticipate that in many cases, this same individual will also be supporting OASIS.

HCFA will fund additional staffing costs based on the incremental time requirements associated with the computerization of OASIS. We have ranked States into three groups based on the number of HHAs in each State and will fund staffing costs depending on the number of HHAs within each State. We will fund an additional .5 full time equivalent (FTE) staff time for a State with less than 100 HHAs; we will fund an additional 1.0 FTE for a State with 101–250 HHAs; and, we will fund an additional 1.5 FTE for a State with greater than 251 HHAs. These additional FTEs represent both the incremental technical time needed to support OASIS, as well as the duties of the OASIS Automation Coordinator whose duties will include training providers to encode data in the HCFA standard format, to create export files, and to use the communications software to dial into the State database; error tracking and resolution of HHA provider data problems; and other data management responsibilities such as cleaning and aggregating the data prior to transmission to HCFA and system backup and archiving. We estimate that the incremental staffing costs for both technical staff and the OASIS Automation Coordinator will be about \$44,000 for an average size State with responsibility for 101–250 HHAs.

- **Supplies:** States can expect about \$600 per year in incremental OASIS-related costs for products that are consumed, such as printer toner, paper, and back-up tapes.

- **Training:** We plan to centralize training of State personnel who will be responsible for administrative and technical aspects of OASIS operations. With our technical support and guidance, States will work closely with the HHA provider community in providing information on specific requirements related to the submission of OASIS assessments to the State repository.

In order to promote national consistency in OASIS system operations and troubleshooting, we will request the OASIS coordinators to attend a national multi-day training session. We will also convene at least one national meeting of the OASIS coordinators each year. We will use this forum to present new information, gather suggestions for system improvements, exchange ideas on OASIS system operations, administration and troubleshooting issues, and to discuss objectives for future system development and

refinement. States will be expected to work with their HHA provider community to educate them on automating the OASIS. We anticipate annual training costs associated with training for an average size State to be about \$5,600 which includes travel costs associated with both the centralized training and educating the HHAs and vendor community on computerization requirements.

- **Data Transmission:** States will incur data communication costs both in receiving OASIS data from HHAs and transmitting validation reports back to the HHAs. These costs have two basic elements:

- (1) Fixed monthly line fees of approximately \$23.00 per line per month. The number of lines required varies from 8 to 48 according to the number of HHAs supported by a State. On average, a State's fixed line costs will be \$2,208 per year.
- (2) Line connect and long distance charges of approximately \$.03 per assessment for the monthly connection times associated with transmitting error logs and edit reports back to the HHAs. This translates into an average connection cost of \$7,665 per year per State.

### C. Conclusion

As discussed in detail above, HHAs and States will bear some incremental costs associated with this proposal. However, we believe that these costs are well justified when considered within the context of the anticipated increased quality of care for HHA patients, as well as the potential uses of the automated data by the HHAs, the States, and us. The foregoing estimates may actually overstate anticipated costs because they do not take into account cost-savings to be achieved by improving HHAs' management information systems, as well as potential improvements in patients' overall health status. Nor do they represent the savings inherent in future improvements to the survey and certification process, and specifically, a more focused, uniform approach by both the States and us in assessing quality of care in the nation's HHAs. We note that we have received feedback from many of the HHAs that chose to participate in the HCFA-sponsored OASIS Demonstration Project that has been underway for the past several years. These HHAs have indicated that the value of the information they have received about their individual performance has well outweighed the incremental cost associated with collecting and reporting the data.

In accordance with the provisions of Executive Order 12866, this regulation



was reviewed by the Office of Management and Budget.

### List of Subjects

#### 42 CFR Part 484

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

#### 42 CFR Part 488

Administrative practice and procedure, Health facilities, Reporting and recordkeeping requirements.

42 CFR Chapter IV is amended as follows:

A. Part 484 is amended as follows:

### PART 484—CONDITIONS OF PARTICIPATION FOR HOME HEALTH AGENCIES

1. The authority citation for part 484 continues to read as follows:

**Authority:** Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh))

#### Subpart B—Administration

2. Section 484.11 is added to subpart B to read as follows:

#### § 484.11 Condition of participation: Release of patient identifiable OASIS information.

The HHA and agent acting on behalf of the HHA in accordance with a written contract must ensure the confidentiality of all patient identifiable information contained in the clinical record, including OASIS data, and may not release patient identifiable OASIS information to the public.

3. Section 484.20 is added to subpart B to read as follows:

#### § 484.20 Condition of participation: Reporting OASIS information.

HHAs must electronically report all OASIS data collected in accordance with § 484.55.

(a) *Standard: Encoding OASIS data.* The HHA must encode and be capable of transmitting OASIS data for each agency patient within 7 days of completing an OASIS data set.

(b) *Standard: Accuracy of encoded OASIS data.* The encoded OASIS data must accurately reflect the patient's status at the time of assessment.

(c) *Standard: Transmittal of OASIS data.* The HHA must—

(1) Electronically transmit accurate, completed, encoded and locked OASIS data for each patient to the State agency or HCFA OASIS contractor at least monthly;

(2) For all assessments completed in the previous month, transmit OASIS data in a format that meets the

requirements of paragraph (d) of this section;

(3) Successfully transmit test data to the State agency or HCFA OASIS contractor beginning March 26, 1999, and no later than April 26, 1999; and

(4) Transmit data using electronic communications software that provides a direct telephone connection from the HHA to the State agency or HCFA OASIS contractor.

(d) *Standard: Data Format.* The HHA must encode and transmit data using the software available from HCFA or software that conforms to HCFA standard electronic record layout, edit specifications, and data dictionary, and that includes the required OASIS data set.

B. Part 488 is amended as follows:

### PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

1. The authority citation for part 488 is revised to read as follows:

**Authority:** Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)).

#### Subpart B—Special Requirements

2. Section 488.68 is added to subpart B to read as follows:

#### § 488.68 State Agency responsibilities for OASIS collection and data base requirements.

As part of State agency survey responsibilities, the State agency or other entity designated by HCFA has overall responsibility for fulfilling the following requirements for operating the OASIS system:

(a) *Establish and maintain an OASIS database—* The State agency or other entity designated by HCFA must—

(1) Use a standard system developed or approved by HCFA to collect, store, and analyze data;

(2) Conduct basic system management activities including hardware and software maintenance, system back-up, and monitoring the status of the database; and

(3) Obtain HCFA approval before modifying any parts of the HCFA standard system including, but not limited to, standard HCFA-approved—

(i) OASIS data items;

(ii) Record formats and validation edits; and

(iii) Agency encoding and transmission methods.

(b) *Analyze and edit OASIS data.* The State agency or other entity designated by HCFA must—

(1) Upon receipt of data from an HHA, edit the data as specified by HCFA and ensure that the HHA resolves errors within the limits specified by HCFA;

(2) At least monthly, make available for retrieval by HCFA all edited OASIS records received during that period, according to formats specified by HCFA, and correct and retransmit previously rejected data as needed; and

(3) Analyze data and generate reports as specified by HCFA.

(c) *Ensure accuracy of OASIS data.*

The State agency must audit the accuracy of the OASIS data through the survey process.

(d) *Restrict access to OASIS data.* The State agency or other entity designated by HCFA must do the following:

(1) Ensure that access to data is restricted except for the transmission of data and reports to—

(i) HCFA;

(ii) The State agency component that conducts surveys for purposes related to this function; and

(iii) Other entities if authorized by HCFA.

(2) Ensure that patient identifiable OASIS data is released only to the extent that it is permitted under the Privacy Act of 1974.

(e) *Provide training and technical support for HHAs.* The State agency or other entity designated by HCFA must—

(1) Instruct each HHA on the administration of the data set, privacy/confidentiality of the data set, and integration of the OASIS data set into the facility's own record keeping system;

(2) Instruct each HHA on the use of software to encode and transmit OASIS data to the State;

(3) Specify to a facility the method of transmission of data to the State, and instruct the facility on this method.

(4) Monitor each HHA's ability to transmit OASIS data.

(5) 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

(6) Carry out any other functions as designated by HCFA necessary to maintain OASIS data on the standard State system.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.778, Medical Assistance Program)

Dated: November 3, 1998.

**Nancy-Ann Min DeParle,**

*Administrator, Health Care Financing Administration.*

Dated: December 15, 1998.

**Donna E. Shalala,**

*Secretary.*

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