interest and incorporate a statement of the finding and the reasons for it into the notice issued.

We find it unnecessary to undertake notice and comment rulemaking because this notice merely provides technical corrections to the regulations. Therefore, we find good cause to waive notice and comment procedures.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: December 20, 2005.

Ann C. Agnew,

Executive Secretary to the Department.

[FR Doc. 05–24445 Filed 12–22–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

42 CFR Part 484

[CMS–3006–F]

RIN 0938–AJ10

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

AGENCY: Centers for Medicare and Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule makes revisions in response to public comments received on the January 25, 1999 interim final rule with comment period (64 FR 3748). The interim final rule requires electronic reporting of data from the Outcome and Assessment Information Set as a Condition of Participation for home health agencies.

DATES: *Effective Dates:* This final rule is effective on June 21, 2006.

FOR FURTHER INFORMATION CONTACT: Rebecca Donnay (410) 786–1428, Patricia Sevast (410) 786–8135, Steve Miller (410) 786–6656.

SUPPLEMENTARY INFORMATION:

I. Background

A. General Legislative Background

Home health services are furnished to Medicare beneficiaries 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, a home health agency (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 an HHA must meet to participate in the Medicare program. In particular, section 1861(o)(6) of the Act provides that an HHA must meet the Conditions of Participation (CoPs) specified in section 1891(a) of the Act, and any other CoPs that we find 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 many of the conditions that HHAs must meet to participate in the Medicare program. Specifically, section 1891(a) of the Act establishes requirements for HHAs with respect to patient rights, home health aide training and competency, and compliance with applicable Federal, State, and local laws. Under section 1891 of the Act, we are responsible for assuring that the CoPs, and their enforcement, are adequate to protect the health and safety of all individuals under the care of an HHA and to promote the effective and efficient use of Medicare funds.

Under the authority of sections 1861(o), 1871, and 1891 of the Act, we have established in regulations the requirements that an HHA must meet to participate in Medicare. These requirements are set forth at 42 CFR part 484, Home Health Services. The CoPs apply to an HHA as an entity and the services furnished to all individuals under the care of the HHA, unless a condition is specifically limited to Medicare beneficiaries. Existing regulations in § 440.70(d) specify that HHAs participating in the Medicaid program must also meet the Medicare CoPs.

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. 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 at 42 CFR part 488, Survey, Certification, and Enforcement Procedures.

B. Legislation and Related Regulations

Section 1861(o) of the Act, as amended by section 4603 of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), enacted on August 5, 1997, requires us to establish a Home Health Prospective Payment System (HHPPS) for services on or after October 1, 1999. Section 5101 of the Omnibus Consolidated and Emergency Supplemental Appropriations Act for 1999 (OCESAA) (Pub. L. 105–277), enacted on October 21, 1998, delayed the implementation date of the HHPPS until October 1, 2000.

In order to implement the prospective payment system, it was necessary that we have data from HHAs to develop a reliable case-mix adjustor system. Section 4602 of the BBA provided that, for cost reporting periods beginning on or after October 1, 1997, we may require HHAs to submit additional information that we consider necessary for the development of a reliable case-mix system. The Outcome and Assessment Information Set (OASIS), the assessment instrument developed to measure patient health care outcomes in HHAs, is also a vehicle through which information is collected and used for the case-mix system.

Thus, to facilitate the implementation of the prospective payment system and to gather data to be used to evaluate and develop plans to improve outcomes of care in HHAs, we published two regulations in the **Federal Register** on January 25, 1999. The final rule, Comprehensive Assessment and Use of the OASIS as Part of the Conditions of Participation for Home Health Agencies (64 FR 3764), requires that HHAs complete a comprehensive assessment for each patient, and that they incorporate the OASIS into their current patient assessment process. In addition, we published an interim final rule with comment period to require HHAs to electronically report data from the OASIS to the State survey agency, or other entity designated by us (64 FR 3748).

The June 18, 1999, notice (64 FR 32984) in the **Federal Register** entitled ''Mandatory Use, Collection, Encoding, and Transmission of Outcome and Assessment Information Set (OASIS) for Home Health Agencies (HHAs)'', announced the effective dates for the mandatory use, collection, encoding, and transmission of OASIS data for all Medicare/Medicaid patients receiving skilled services. This notice also described the development of a new OASIS System of Records (SOR). We indicated that for patients receiving only personal care services, regardless of payer source, requirements for OASIS and the transmission of those data would be delayed until further notice. In addition, the notice announced that for non-Medicare/non-Medicaid

patients receiving skilled services, there would be no encoding and transmission of OASIS data until further notice.

Until recently, HHAs were required by § 484.55 to perform a comprehensive assessment on non-Medicare/non-Medicaid patients receiving skilled services using OASIS even though they were not required to encode and transmit OASIS data collected on these patients. Section 704 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), enacted on December 8, 2003 (Pub. L. 108–173), however, temporarily suspended the collection of OASIS data on an HHA's non-Medicare/non-Medicaid patients required by § 484.55 until we reported to the Congress how OASIS information on non-Medicare/non-Medicaid patients was and could be used by large HHAs, including the value of collecting OASIS information by small HHAs compared to the administrative burden. We are also required by the MMA to publish final regulations regarding the collection and use of OASIS information. On December 11, 2003, we issued a survey and certification memorandum (S&C–04–12) instructing State survey agencies (SAs) that: (1) Effective December 8, 2003, and until further notice, SAs must not cite any deficiency for an HHA's failure to include the OASIS data set as part of the patient-specific, comprehensive assessment for non-Medicare/non-Medicaid patients otherwise required by § 484.55; and (2) any pending survey findings related to an HHA's omission to collect OASIS data on non-Medicare/non-Medicaid patients will be suspended.

After the January 25, 1999, and June 18, 1999, **Federal Register** publications, we expected that HHAs would incorporate the OASIS data set into their own agency assessment process, and that all patients receiving skilled services from Medicare-approved HHAs would be assessed at certain times, incorporating the specified OASIS data items. HHAs would encode and transmit OASIS data to the State agency, and HHAs would use the validation feedback reports, data management system reports, the Outcome-based Quality Monitoring (OBQM) reports, and the Outcome-based Quality Improvement (OBQI) reports generated by the State for agency improvement.

Since the effective date of the OASIS requirements, HHAs nationwide have been actively working to meet these goals. State OASIS Educational Coordinators (OECs) report that most HHAs have successfully incorporated the OASIS data set into their own agency assessment process and have trained their own staff in implementing OASIS. HHAs are assessing Medicare and Medicaid patients receiving skilled care, and are encoding and transmitting these assessments to the State agency. In most cases, HHAs are using the OASIS State system feedback reports to improve data collection and submission. Most clinicians and other agency staff have developed skills for tasks associated with OASIS data collection, data entry, and transmission. By using the many resources we have made available to providers (for example, State-sponsored training, Home Assessment Validation Entry (HAVEN), telephone and e-mail help lines, comprehensive User's Manuals, and the CMS OASIS Web page) agencies have, for the most part, successfully implemented OASIS.

An analysis of OASIS data in the CMS national repository shows that nearly all of the HHAs expected to submit OASIS data have done so. Over 56.4 million assessments have been submitted by HHAs from every State since August 1999. Currently, the State survey and certification agencies are contacting HHAs that have not submitted OASIS data and are initiating standard monitoring and enforcement procedures.

Over the next several years, home health agencies are encouraged to take steps toward the adoption of electronic medical records (EMRs) that will allow for reporting of clinical quality data from the electronic record directly to a CMS data repository. CMS intends to begin working toward creating measures specifications and a system or mechanism, or both, that will accept the data directly. The Department is presently working cooperatively with other Federal agencies in the development of Federal health architecture data standards. CMS encourages home health agencies that are developing systems to conform them to both industry standards and any Federal health architecture data standards, and to ensure that they would capture the data necessary for quality health measures. Ideally, such systems will also provide point-of-care decision support that enables high levels of performance on the measures. Home health agencies using EMRs to produce data on quality measures will be held to the same performance expectations as home health agencies not using EMRs. We are exploring requirements for the submission of electronically produced data and other options to encourage the submission of such data.

II. Provisions of the Interim Final Rule With Comment Period and Discussion of Public Comments

In the January 25, 1999, interim final rule with comment period (64 FR 3749), we generally mandated that all HHAs participating in Medicare and Medicaid (including managed care organizations providing home health services to Medicare and Medicaid beneficiaries) report their OASIS data to the database we established within each State via electronic transmission. The interim final rule required State agencies and the CMS OASIS contractors to maintain OASIS databases according to our specifications. To ensure confidentiality of individual patient-identifiable data collected for OASIS databases, we set forth requirements for State agencies, CMS OASIS contractors, and HHAs regarding the release of this information. We received approximately 200 public comments on the interim final rule (64 FR 3748), which we address below.

A. Section 484.11, Condition of Participation: Release of Patient-Identifiable OASIS Information

At § 484.11, Condition of Participation: Release of Patient-Identifiable OASIS Information, we require that the HHA, or an agent acting on behalf of the HHA, 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 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 use or disclose data only to the extent that the HHA itself is permitted to do so.

Comment: Many commenters were concerned about the confidential nature of OASIS data that are transmitted and questioned how we will ensure the protection of collected and reported patient-identifiable information.

Response: Confidentiality of medical information is not a new requirement. Health information, by its very nature is sensitive and private. Because the privacy of patient-identifiable information is one of our major priorities we have taken exhaustive steps to ensure the privacy of this information by making the provision a condition of participation to emphasize its seriousness. We endeavor to ensure that access to an agency's OASIS data (hard copy or electronic data) is adequately controlled by the HHA. Under this requirement, the HHA must ensure the confidentiality of all patient-

identifiable OASIS information contained in the clinical records, and may not release it for any reason other than for its intended purpose in conducting the business of the agency. As with any other medical information maintained by the agency, HHAs must have policies and procedures governing the confidentiality of OASIS data. In addition, we note that HHAs that are covered entities must comply with the requirements of the Privacy and Security Rules issued under the Health Insurance Portability and Accountability Act of 1996 (HIPPA).

Ensuring confidentiality of OASIS data includes mechanisms such as having policies and procedures for assigning and maintaining passwords—that *must* be kept secure—for access to HAVEN and for transmitting OASIS data to the State agency. This CoP also allows HHAs to choose to encode and transmit OASIS data to the State agency itself, or to contract with an outside entity (agent or vendor) to fulfill these requirements. Experience indicates that there are a number of secure methods that can be used to send OASIS data to vendors. Some examples of secure methods are to use a courier service, the United States Postal Service, or fax. However, use of fax transmissions must comply with section 2202.16 of the State Operations Manual, which provides guidelines for fax transmission of OASIS data.

Agents or vendors acting on behalf of the HHA, such as a data entry and submission vendor, are bound by the same confidentiality rules as the HHA. OASIS data must be used only as a matter of agency business. As such, a written contract must be in place that, among other things, defines the nature of agency business with regard to OASIS data. Violations that compromise data confidentiality by an entity that is contracted with the HHA are the responsibility of the HHA, and will constitute a condition-level finding of non-compliance.

Once the HHA data reach the State agency, there are additional safeguards in place to protect the confidentiality of the OASIS data. The HHA OASIS system is designed to conform to applicable law and policy governing the privacy and security of Federal automated information systems. These include, but are not limited to: The Privacy Act of 1974, Computer Security Act of 1987, the Paperwork Reduction Act of 1995, the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the Clinger-Cohen Act of 1996, the Federal Information Security Management Act of 2002, the Department's Privacy and Security Rules, and OMB Circular A–130 (revised), Appendix III, ''Security of Federal Automated Information Resources.'' We have prepared a comprehensive system security plan as required by the OMB Circular. This plan conforms fully to guidance issued by the National Institute for Standards and Technology (NIST) in NIST Special Publication 800–18, ''Guide for Developing Security Plans for Information Technology Systems.''

Some of the specific methods that we are using to ensure the security of the HHA OASIS system and the information within it are described below.

We have safeguards for authorized users and monitors these users to ensure against excessive or unauthorized use. Personnel having access to the system have been trained in the Privacy Act and systems security requirements. Employees who maintain records in the system are instructed not to release any data until the intended recipient agrees to implement appropriate administrative, technical, procedural, and physical safeguards sufficient to protect the confidentiality of the data and to prevent unauthorized access to the data.

In addition, we have physical safeguards in place to reduce the exposure of computer records and, thus, achieve an optimum level of protection and security for the HHA OASIS system. For computerized records, we have established safeguards in accordance with HHS standards and NIST guidelines; for example, security codes will be used, permitting access to authorized personnel exclusively. System security procedures are established in accordance with HHS, Information Resource Management Circular #10, HHS Information Systems Security Program Policy of December 15, 2004; CMS Information Systems Security Policy, Standards and Guidelines; and OMB Circular No. A–130 (revised) Appendix III.

Comment: One commenter was particularly concerned about patients' social security numbers. The commenter stated that social security numbers should not be used as an identifier for medical records stored by the government. Other commenters were concerned about reporting information collected from the OASIS that pertains to a patient's psychological profile and lifestyle.

Response: We have endeavored to put many physical, technical, and procedural safeguards in place to protect health information. Only those individuals with a legitimate need for this information will be allowed to have access. States and HHAs must take similar precautions. The transmission of all identifiable health information will be secure at all times if it is transmitted according to the requirements outlined in this final rule, which strictly controls access to prevent any unauthorized use. In addition, health information (including OASIS) is encoded and transmitted from providers to State agencies over closed loop telephone lines. In July 2000, in response to industry concerns, we made available the Medicare data communication network (MDCN) communications link from each HHA to its respective State health agency to allow the HHAs to submit OASIS data and retrieve reports. The MDCN, both hardware and software, allows direct dial-up access to the State agency by each registered MDCN user in each HHA. This supersedes use of the current dial-up connection process, which previously was the only way HHAs could submit OASIS data and retrieve reports. This new system allows each HHA to control all aspects of encoding, submitting, and receiving reports according to its policy and promotes a higher level of personal security with individual user IDs. There will be no additional cost to the HHA for the use of this dial-up service. Multiple users in an agency will be able to access the State agency with individual MDCN user IDs. In order to verify that the person trying to access the information is authorized, several safeguards are in place. For example, in the OASIS State system, a person must enter a user ID and password at three different checkpoints before access is permitted. There is no ''back door'' into the system that would allow unauthorized or illegal access.

Comment: A few commenters suggested that we eliminate OASIS questions that solicit sensitive financial information on patients, and remove the requirement for information to be reported to CMS.

Response: We believe commenters were referring to OASIS item M0160, ''Financial Factors.'' We have never required the collection or transmission of OASIS item M0160. In addition, we established a Regulations Reform Advisory Committee to further reduce regulatory burden. As a result of earlier recommendations from that committee, we have eliminated this item from the OASIS instrument. In addition to the OASIS item related to financial factors, we have also eliminated the following items from the OASIS instrument: M0310, ''Structural Barriers'; M0320, ''Safety Hazards'; M0330, ''Sanitation Hazards'; and M0600, ''Patient Behaviors.'' Earlier versions of HAVEN (5.0 and earlier) currently allow

encoding of these items for HHA use, but will automatically prevent transmission at the source. As part of the assessment process, HHAs may continue to collect the information. However, if HHAs transmit the information, it will not be stored in the State's system.

B. Section 484.20, Condition of Participation: Reporting OASIS Information

In § 484.20, Condition of Participation: Reporting OASIS Information, we require HHAs to report to CMS OASIS data collected on all patients. This requirement applies to all patients except prepartum and postpartum patients, patients under the age of 18, patients not receiving skilled health care services, and non-Medicare/non-Medicaid patients. As stated above, on June 18, 1999, we published a notice (64 FR 32984) that delayed the applicability of the collection requirements to patients receiving only personal care services and delayed the requirement to encode and report collected OASIS data on non-Medicare/non-Medicaid patients until further notice. Currently, the policy to delay the applicability of the collection requirements to patients receiving only personal care services and to delay the requirement to encode and report collected OASIS data on non-Medicare/non-Medicaid patients remains in effect. There is also a temporary suspension on the collection of OASIS data on non-Medicare/non-Medicaid patients effective December 8, 2003, under section 704 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub L. 108–173) (MMA).

General Comments on Reporting OASIS Data

We received several comments in support of our efforts to collect and report OASIS data for the purpose of tracking the quality of patient outcomes.

Comment: One commenter stated that many nurses, because of the substantial demands of their jobs, have not been able to devote sufficient time to assessing a patient's health care needs, compromising the quality of the care provided. The commenter believes that OASIS enables nurses to more thoroughly assess their patients' needs. The commenter also stated that OASIS is ''the best thing created by CMS.'' The commenter also noted that OASIS data could indicate that some patients actually need home care and may also reveal abuses of the Medicare program.

Response: We appreciate the positive comment. In addition to using OASIS to develop the HHPPS, in the quality measurement and improvement system, and in the Survey and Certification program, we plan to use OASIS to support our program integrity efforts as we administer the Medicare program.

Comment: Several commenters supported the principle of having HHAs collect and report OASIS data for quality outcome measurement and stated that they were looking forward to using the data. Commenters believed that OASIS would have positive results in identifying standards of care industry-wide, in addition to offering State-specific information concerning the care patients received. Other commenters stated that the industry has many questions regarding OASIS and its use and asked that we continue to provide clear and precise guidelines for OASIS reporting requirements.

Response: We appreciate the endorsement and support for OASIS, and we believe that OASIS data will assist HHAs in improving the quality of their services. We recognize that agencies may continue to require guidance on collecting and reporting OASIS information. Therefore, we will continue to provide guidance and updated information to HHAs via state-sponsored training, telephone, and e-mail help lines and by posting relevant information on our Web site.

Comment: One commenter acknowledged the usefulness of OASIS outcome data for both HHAs and CMS but questioned the connection between CMS obtaining data and translating those data into useable information to improve care.

Response: We appreciate the supportive comments. Since April 1999, HHAs have collected, encoded, and reported OASIS information. The reports generated from the information are outcome-based and used for quality improvement. For some time, these Outcome Based Quality Improvement and Outcome Based Quality Monitoring (OBQI/OBQM) reports have been used for comparative analyses. These reports are shared with HHAs for use in their quality monitoring and improvement activities.

For example, through a contract with the Center for Health Services Research, University of Colorado, we implemented the Medicare Home Health Quality Assurance (MEQA) demonstration to determine the feasibility of, and establish the methodology for, implementing OBQI programs in HHAs. Under the demonstration, 50 HHAs nationwide collected OASIS data at regular intervals for all adult patients. We computed outcome measures using OASIS data and provided risk-adjusted outcome reports for specific patient conditions (focused reports) and for all adult patients (global reports). We provided instruction to HHAs in using outcome reports to target areas for improvement or reinforcement. We implemented and monitored a plan of action for behavioral change while using yearly outcome reports to determine if targeted outcomes improved. Data from the reports during the MEQA demonstration indicate that there has been a 25 percent rate of reduction in hospitalizations over the length of the demonstration and 80 percent of participating HHAs experienced a significant improvement in targeted outcomes.

In the Home Health Outcome Based Quality Improvement (HH–OBQI) System Pilot Project, five Quality Improvement Organizations (QIOs) found similar levels of improvement in targeted outcomes to those levels experienced in the MEQA demonstration. The pilot project tasked QIOs in five States (Maryland, Michigan, New York, Rhode Island, and Virginia) with helping HHAs nationwide to identify opportunities to use the quality reports for improvement of home health quality of care for Medicare beneficiaries. These five QIOs serve as a coordinating body to oversee the establishment of a national HH OBQI System for home health care. The five QIOs, using OASIS outcome reports and their own analysis of OASIS data, the five QIOs distribute information and guidance to all other QIOs participating in the HH OBQI System. The other QIOs, in turn, provide education, consultation, and other technical assistance to HHAs in developing and managing outcome-based, continuous quality improvement programs.

Comment: Several commenters stated that OASIS should only be used for Medicare patients, so as not to destroy its usefulness for the HHPPS. Commenters were concerned that the quality of OASIS data would be adversely affected if collected and reported on patients from such diverse programs as Medicare, Medicaid, Medicaid waiver patients, and non-Medicare/non-Medicaid patients.

Several commenters specifically stated that OASIS should be re-evaluated for Medicaid patients, patients under Medicaid Home and Community-Based Waiver programs, and patients receiving ''personal-care-only'' services. One commenter stated the belief that the OASIS demonstration projects did not include patients receiving personal-care-only services. A few commenters suggested that we limit OASIS reporting to only a core set of

data elements needed for the development of the HHPPS.

Response: We received many comments regarding the application of OASIS to HHA populations. Collecting OASIS data on all patients for quality and assessment purposes does not affect the integrity of the HHPPS. Limiting reported OASIS data only to items under consideration for HHPPS will harm the integrity and risk adjustment of quality indicators (as discussed in the July 3, 2000 final rule for HHPPS) and eliminate the ability to evaluate the effects of HHPPS on quality or to improve HHPPS over time.

With regard to the quality of OASIS data, the intent of OASIS is to ensure that HHA patients are receiving quality care. However, we recognize the assessment needs for patients requiring personal-care-only services may be different than for patients who require skilled services, such as nursing and rehabilitative therapy. To address these concerns and further research the issues, we have delayed the requirement for agencies to use OASIS for the personal-care-only population until further notice. We published the notice of the delay (64 FR 32984) on June 18, 1999. We are continuing this delay until we determine an appropriate balance between the advantages of collecting OASIS data from this population of patients and the reported burdens on providers.

In addition, MMA, which was enacted on December 8, 2003, temporarily suspends the collection of OASIS data on an HHA's non-Medicare/non-Medicaid patients until further notice. HHAs may continue to incorporate OASIS items into their patient-specific, comprehensive assessment of non-Medicare/non-Medicaid patients for their own use but are no longer required to do so.

The inclusion of Medicaid waiver patients in the collection and reporting of OASIS data is a decision that may be made by individual States. Medicare-approved HHAs must report OASIS data for all other patients (that is, other than the previously discussed exceptions, and those for whom collection is delayed). The requirements governing who may provide services under waiver programs are left to each state's discretion. We do not require Medicaid waiver patients to be served by Medicare-approved HHAs, and States may choose providers that do not meet Medicare requirements (including the collection and reporting of OASIS data) to furnish services to individuals in State waiver programs.

Comment: Many commenters asked that we clarify our policy concerning a patient's refusal to answer a question. Commenters were concerned that agencies would be penalized if a patient refused to answer an OASIS question and stated that because of the patient's refusal, there would be no OASIS information to be reported to us.

Response: There is no Federal requirement that an HHA deny services to a home health patient if the patient refuses to allow clinicians to conduct a comprehensive assessment, refuses to answer any question during the comprehensive assessment, or refuses to allow the release of any information from the comprehensive assessment to us. However, for Medicare and Medicaid patients, the collection and transmission of OASIS data is required to meet the home health CoPs and for payment.

Doctors, nurses, and therapists are trained to do assessments of their patients as part of their routine care whether the patient is cooperative or not. Patient assessments are critical for providers to know if patients' needs are being met or if their health conditions are improving. It is important to understand that HHAs will continue to perform comprehensive assessments of their uncooperative clients. OASIS is a standardized data format for nurses and other home health professionals for assessing patients' needs, developing the appropriate plan of care, assessing that care over the course of treatment, and learning how to improve the quality of care over time. While patients may refuse to answer a direct question (or indeed, may provide an inaccurate or a misleading response), clinicians are taught to assess patients to the best of their ability. However, State surveyors are obligated to assess the HHA's performance of its data collection responsibilities. If an agency has an unusually high rate of patients refusing to answer assessment questions, it may warrant a review of the process the HHA is using to conduct assessments.

An HHA will have the opportunity to respond to any deficiencies cited by the surveyor in the HHA's plan of correction. CMS and its agents (State survey agencies) expect HHAs to comply with these regulations and will work with agencies to achieve compliance. We expect agencies to make a good faith effort to use OASIS. During initial implementation, which lasted until the end of 1999, we did not cite deficiencies unless an HHA was doing nothing to comply with the OASIS collection and reporting requirements. Beginning in 2000, we shifted from a more ''global'' approach of determining overall compliance to a more specific consideration of each requirement. Now each OASIS requirement is reviewed for compliance exactly as it is written, in the same manner as all other existing home health requirements. We took this action because proper OASIS data collection and reporting has payment and quality implications.

1. Section 484.20(a), Standard: Encoding and Transmitting OASIS Data

We have revised § 484.20(a) to require HHAs to encode and electronically transmit to the State agency or CMS OASIS contractor accurate and complete OASIS data for each applicable agency patient within 30 calendar days from the date the assessment was completed (that is, the date entered at OASIS item M0090). We have removed the ''lock'' requirement that appeared at § 484.20(c)(1) to allow HHAs the option of making corrections to OASIS data at any time without edit warnings. Since HHAs will now be able to make corrections to transmitted OASIS data at any time, we determined that there is no compelling reason to require HHAs to encode OASIS data within a specific timeframe. Therefore, we are no longer requiring HHAs to encode OASIS data within 7 days of completing an OASIS data set. Instead, HHAs will have 30 calendar days from the date the assessment was completed to both encode and transmit completed OASIS data to the State agency or CMS OASIS contractor. In other words, once the qualified clinical staff member has collected the OASIS data set at the time specified in § 484.55, HHAs may take up to 30 calendar days after collection to: (1) Enter it into their computer systems using the Home Assessment Validation Entry (HAVEN) software or the vendor software meeting our data submission specifications; (2) electronically transmit the accurate, complete, and encoded data to the State agency or CMS OASIS contractor; and (3) establish HHA policy which will be in compliance with the instructions within the OASIS Implementation Manual Chapter 1, page 1.4, which require that HHAs develop ''policies and procedures establishing the necessary data entry and transmission mechanisms and, very importantly, develop and maintain appropriate data quality monitoring activities.''

The changes in § 484.20(a) do not alter the need for HHAs to ensure that the data items on the patients clinical record match the encoded data that are sent to the State (see OASIS Implementation Manual, Chapter 12, pages 12.1 and 12.2). HHAs must also continue to conduct data quality audits on a routine basis as outlined in the

OASIS Implementation Manual, Chapter 12, pages 12.1 and 12.2.

Currently, OBQI/OBQM reports are available 2 months after submission of completed assessments. However, many HHAs are requesting that the OBQI/OBQM reports be more timely. Now that we are requiring HHAs to both encode and transmit completed OASIS data within 30 calendar days, we expect the reports to be available 30 days sooner. Currently, 50 percent of the HHAs transmit OASIS assessments by the 16th day after completion, and the majority of HHAs (75 percent) transmit assessments by the 30th day after completion. HHAs must continue to comply at all times with requirements for safeguarding the confidentiality of patient-identifiable information.

Comment: Several commenters were concerned about the resources required to encode and transmit OASIS data. One commenter stated that the increased time to complete data entry adds to difficulties in meeting the 7-day encoding requirement. Another commenter suggested that the requirement be extended to 14 days, especially for rural providers.

Response: After reviewing comments, we agree with commenters' concerns about the 7-day time frame for encoding. Therefore, we will allow HHAs 30 calendar days after the assessment is completed to encode and transmit OASIS data items. We have revised this timeframe based on industry concerns and the need to confirm the accuracy of their data. We believe this revised timeframe will be less burdensome for HHAs. These 30 calendar days are in addition to the time frames currently allowed for collection of the OASIS items set forth at § 484.55. We are providing the revised timeframe of 30 calendar days for agencies to encode their OASIS data, resolve any outstanding data collection issues, and transmit the accurate and completed OASIS data. We assigned time frames that we believe best represent a balance between efficient, timely data collection and entry, and the burden placed on the HHA. As this process evolves, we will continue to explore techniques to make the reporting process as efficient as possible.

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 of the assessment. 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 HHAs to devise a method to track this process that includes comparison of data collected at the time of the assessment to data entered after the initial assessment. We expect agencies to use their validation reports to confirm proper data submission or to identify areas for improving data submission.

Comment: Several commenters expressed concern that we did not include time spent calling the professionals responsible for the assessment to obtain clarification of assessment data if there are errors found during encoding in our estimate of the costs associated with OASIS reporting. Commenters also stated that a registered nurse or other full-time employee would need to manage the paper work and computerization of OASIS.

Response: We agree with commenters that HHAs may need to designate a staff person to coordinate the OASIS data collection and reporting systems. The burden estimate took this into account in the January 25, 1999 final rule (64 FR 3748). Some agencies may be able to assign these duties to current staff, while others may decide they need to hire additional personnel, at the HHA's discretion. This person could have a clinical or computer background.

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

In existing § 484.20(c)(1), we required HHAs to electronically transmit to the State agency or CMS OASIS contractor accurate, completed, encoded, and locked OASIS data for each applicable patient at least monthly. Now that we are combining the requirement to electronically transmit OASIS data with the requirement to encode OASIS data in § 484.20(a) and removing the ''lock'' requirement, we have removed existing § 484.20(c)(1) and redesignated § 484.20(c)(2) through § 484.20(c)(4) as § 484.20(c)(1) through § 484.20(c)(3), respectively.

Newly designated § 484.20(c)(1) requires HHAs to transmit the OASIS data in a format that meets the data format standard specified at § 484.20(d). Newly designated § 484.20(c)(2) requires HHAs to transmit successfully test data to the State agency or CMS OASIS contractor. Newly designated § 484.20(c)(3) requires HHAs to transmit data using electronic communications protocols as directed by us. As of July 1, 2000, those HHAs that are required to submit OASIS data for submission and interim reports must do so via the MDCN, which replaces the previous dial-up connection for submission and interim reports. In January 2004, we started requiring HHAs to use a CMS-assigned branch identification number (where applicable) to identify branch-specific OASIS assessment information in a uniform fashion nationwide. This process is described below.

During the development stage of OASIS implementation, the National Association for Home Care (NAHC), engaged in a series of teleconferences with its member HHAs to solicit suggestions about OASIS data entry software. HHAs proposed that the outcome reports be made available at the branch level, rather than limited to data that represent the agency as a whole. NAHC transmitted its concerns to us, and, in response, we agreed to create a field in the HAVEN data entry software to allow HHAs to enter a self-defined number that identifies the assessment information sent to the State agency by a branch office.

An analysis of OASIS data submitted by HHAs to State agencies nationwide, from the period July 1999 to January 2000, shows that 1.8 million of the 4 million assessments submitted included identifying information for branches. We were encouraged that so many HHAs wanted to identify assessment information submitted by their branches. Subsequently, we determined that assignment of unique branch identification numbers would facilitate HHAs' ability to receive outcome reports specific to their branches.

Providing HHAs with the outcome reports specific to their branches will help both the State agency and HHAs to monitor the quality of care being furnished to branch patients. The State agency, after reviewing the specific branch outcome reports, will be better able to target scarce survey resources when conducting HHA surveys. Branch-specific information will also allow the parent HHA to use its own objective performance criteria to assess and improve patient services, outcomes, and satisfaction at the branch level.

As a result of input from the home health industry, we revised the OASIS data set to accommodate branch identifications. The new items developed are: (M0014) Branch State and (M0016) Branch ID. The State in which the branch is located is the two-letter postal service abbreviation where the agency branch is located. For the Branch ID, rather than continuing to allow HHAs to enter a self-defined number that identifies the assessment information that the branch sent to the State agency, we have standardized the identification numbering system for HHA branches to ensure that these assessments will be linked to the proper branch. This national numbering system links each branch number to the parent HHA provider number by numbering

each branch with the same Federally assigned provider number as the parent with two modifications. There is a ''Q'' between the State code and four-digit provider designation plus three more digits for a 10-character branch identifier. The last three digits allows us to assign up to 999 branches to one parent HHA with branch identification numbers being used only once. If an HHA branch closes, we will terminate its unique branch identification number and will not re-use it to identify another branch of that HHA or subunit. For example, an HHA in a state has three branches. The parent agency's Medicare provider number is 017001. The branches are assigned the branch identification numbers 01Q7001001, 01Q7001002, and 01Q7001003. We have made a corresponding revision to the regulation text by adding a new paragraph § 484.20(c)(4).

On the OASIS B–1 (10/1998) data set, which we used to implement OASIS data collection and reporting initially, the fields ''Branch State'' and ''Branch ID'' are optional. On the December 2002 version of the OASIS B–1 data set, which is being used for OASIS collection and reporting as of January 1, 2004, ''Branch ID'' is required for submission of all assessment records completed by a branch. We expect HHA branches to place their CMS-assigned branch identification number on each OASIS assessment at M0016, and subsequently encode and transmit the assessment to the State agency. We have added the requirement to include branch identification numbers in § 484.20(c)(4).

Comment: One commenter was concerned that HHA branch offices are not allowed to transmit their own OASIS data to the State. The commenter stated that the interim final rule is silent regarding this policy, but according to our Web site, branch offices are required to deliver OASIS assessment data to the parent for transmission to the State agency. The commenter stated that this practice would generate mistakes, thus compromising OASIS data. The commenter suggested that HHA branch offices be allowed to transmit their own OASIS data via a dial-up connection to the State agency using the same OASIS ID code and password as the parent agency.

Response: The HAVEN data entry software was originally designed for single submission by the parent HHA for security reasons. The State survey agency assigned one specific user identification and password to each parent HHA in the State. Moreover, the previous data management program could not accommodate separate user identification numbers and passwords to all existing HHA branches. Based on industry concerns, and in response to their needs to permit submission by branches, we installed in each HHA, a communication link to the State agency for submission of OASIS and the retrieval of reports. The MDCN was installed in all HHAs in July 2000, to allow direct dial-up access to the State agency by each registered MDCN user in each HHA. This was a change to the previous system, which allowed the dial-up connection to be used only for submission of OASIS data and retrieval of reports. There was no additional charge to the HHA for the use of this MDCN dial-up service. Multiple users in an agency, including branch users, are now able to access the State agency with individual MDCN user IDs. This system allows the branch to control all aspects of encoding, submission, and receiving reports, according to the parent HHA policy, and promotes a higher level of personal security with the assignment of individual user IDs.

We have begun to assign identification numbers to every existing branch of a parent HHA and subunit. The identification system has been implemented nationally and uniquely identifies every branch of every HHA certified to participate in the Medicare home health program. It also links the parent to the branch. Having a system to identify branches gives us the capability of associating survey results with individual HHA branches. Also, by including the branch identification number on OASIS assessments, we will have the capability of developing outcome reports that will help HHAs differentiate and monitor the quality of care delivered by their agencies down to the HHA branch level.

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

At § 484.20(d), we specify that HHAs must encode and transmit data using the software available from CMS or software that conforms to CMS standard electronic record layout, edit specifications, and data dictionaries and includes OASIS data items specified in § 484.55(e). To meet the data format requirements, HHAs may use the HAVEN software developed by CMS, or use other vendors' software if it conforms to our standardized electronic record formats, edit specifications, data dictionaries, and can pass [CMS-defined] standardized edits. The HAVEN software is made available to all HHAs free of charge, either via download from the Internet or by requesting a compact disc (CD). Agencies can call the HAVEN help line at 1–877–201–4721 to order a HAVEN CD and/or to ask any other HAVEN-related questions they may have.

The required OASIS data set is available at all times on our Web site located at *http://www.cms.hhs.gov/oasis.* HHAs may access the Web site and download the required OASIS data set for each data collection time point. HHAs may also obtain hard copies of the OASIS data set from the National Technical Information Service (NTIS) at 1–800–553–6847.

Comment: Several commenters stated that the HAVEN computer screen is extremely slow and that HHA staff spend time waiting for screen response. The commenter believes that the slowness of the software directly relates to an increase in agency cost. One commenter stated that while HAVEN is free, it does not meet the needs of every agency, nor can every agency access the Internet. This commenter also stated that some agencies are opting to scan the hard copy assessments, because it is more cost effective. However, the commenter stated that HAVEN does not allow for scanning. One commenter stated that their agency convened a taskforce to prepare for OASIS. The taskforce recommended that the agency not use CMS HAVEN software because the software did not have the ability to track outcomes internally.

Response: HAVEN is a tool designed solely for entering, creating, and maintaining OASIS data files for transmission to the State survey agency. HAVEN is not a tool for developing outcome reports. Rather, the files created by HAVEN are part of the process that we use to develop these reports. Outcome reports will be available to all agencies, free of charge. HHAs can electronically access the OBQI/OBQM reports in a manner similar to the submission process.

While HAVEN will operate on older systems, we continue to recommend that agencies use a computer system compatible with the current industry standard. We have always cautioned that HAVEN may not perform as well on older computer systems as it would if run on a newer or more powerful system. Finally, some of the slowness may be due to multiple simultaneous users. Newer versions of HAVEN are released to accommodate multiple simultaneous use. Although we provide HAVEN as a tool to assist agencies in complying with the requirements, agencies may use vendors' products or develop software that meets their own unique needs in addition to meeting OASIS regulatory requirements. Vendor products, however, must meet our

minimum data, format, and transmission specifications.

Comment: One commenter suggested the need to enter the same data multiple times was a flaw in the software that could be reduced if HHAs allowed software vendors to interface, or to map data entry so that one entry would satisfy both data sets.

Response: We believe the commenter may be referring to the situation that requires duplicate entry into an HHA's original claims and assessment software, and then re-entry of the same data into the HAVEN software. Since HAVEN software is available free of charge, our experience is that vendors of the original claims and assessment software are now incorporating the HAVEN software into their own software so that duplicate entry will no longer occur.

In addition, we implemented the patient tracking sheet (PTS) for HHAs nationwide on December 16, 2002. With implementation of the PTS, HHAs no longer need to re-enter the information from 18 common patient demographic items collected at the start of care and on subsequent assessments. These items only need to be updated as appropriate.

C. Section 488.68,State Agency Responsibilities for OASIS Collection and Database Requirements

Under section 1891(b) of the Act, we must assure that processes are in place to protect the health and safety of individuals under the care of an HHA and to promote the effective and efficient use of public moneys. Section 1864 of the Act authorizes the use of State agencies to determine a provider's compliance with the CoPs. State responsibilities for ensuring compliance with the CoPs are set forth in part 488, and entitled ''Survey, Certification, and Enforcement Procedures.'' We did not receive any public comments on this section. Nevertheless, we have summarized the provisions of § 488.68 as set forth in the January 25, 1999, interim final rule below.

In accordance with the provisions referenced above, we added a new § 488.68, State agency responsibilities for OASIS collection and data base requirements. This section provides that the overall responsibility for fulfilling requirements to operate and maintain the OASIS system rests with the State agency or other entity that we designate. The State may delegate this responsibility to the State agency, another State component, or enter into an agreement with a private entity to operate the system, or we may contract with an entity directly, if the State is unable or unwilling to perform these operations. If the 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 it (for example, outcome-based quality improvement reports and survey-specific data).

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

In § 488.68(a), we require that the State agency or other entity that we designate must use a standard system developed or approved to collect, store, and analyze CMS data generated by OASIS. To meet this requirement, we are using the system developed to compile the Minimum Data Set (MDS) assessments (the CMS standard State system), which has already been procured, installed, and utilized. 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 that States must meet if they seek modification of the standard State system. Specifically, State agencies must obtain our approval before modifying any parts of the system. The State agency or CMS OASIS contractor may not modify any aspect of the standard State system that pertains to the standard CMS-approved OASIS data items, standard CMS-approved record formats and validation edits, and standard CMS-approved agency encoding and transmission methods. It also cannot maintain patient data on the system that we do not require to be reported on the OASIS State system.

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

In § 488.68(b), we provide that the State agency or CMS OASIS contractor is responsible for analyzing and preparing OASIS data for us to retrieve. Upon receipt of data from an HHA, we require that the State agency or CMS OASIS contractor edit the data as specified by us, and ensure that the HHA resolves errors within the time limits we specify.

We also require that the State agency or CMS OASIS contractor analyze the data and generate outcome reports as we specify. In addition to the responsibility for generating outcome reports, the State system issues validation reports once OASIS data are received in the system, to provide feedback to HHAs as to whether the OASIS data they sent has been accepted or rejected, and if rejected, the reasons why.

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

In § 488.68(c), we require the State agency to review an HHA's records to verify that the records are consistent with the OASIS data reported to the State agency or CMS OASIS contractor as part of the survey process. In keeping with § 484.20(b), which requires that HHAs' encoded OASIS data accurately reflect the patient's status at the time the information is collected, we expect that HHAs will develop a means to ensure that the data input into the computer and transmitted to the State agency or CMS OASIS contractor reflects the data collected by the appropriate skilled professionals. We expect HHAs to devise a method to track this process, which should include the comparison of data collected at the time of the assessment to data entered after assessment. We expect HHAs to use the validation reports created by the State agencies to confirm proper data submission or to identify areas for improving data submission. We suggest that HHAs retain final validation reports for about 12 months, or until the next OBQI report is available.

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

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

We also specify that patient-identifiable OASIS data may not be released to the public by the State agency or CMS OASIS contractor except to the extent it is permitted under the Privacy Act of 1974 and the HHS Privacy Rule, 45 CFR Parts 160 and 164. In the June 18, 1999 SOR (64 FR 32992), and subsequently revised notice published December 27, 2001 (66 FR 66903), we outlined the provisions governing the disclosure of the information we collect. Consistent with the provisions in those notices, the State agency or CMS OASIS contractor is not permitted to release patient-identifiable information to the public but may release provider-specific aggregated data that do not contain individual patient identifiers.

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

In § 488.68(e), we require the State agency or CMS OASIS contractor to provide training and technical support for HHAs. Specifically, we require training on the administration and integration of the OASIS data set into the HHA's own assessment process. 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 (or contractors) who operate the CMS standard system will provide training as needed to designated HHA staff on the use of the software that we provide. In a similar manner, we will continue to provide standardized instructions for using the free software and submitting information on our website. The designated trainer in the HHA should train HHA staff responsible for collecting OASIS information, as needed, using a standard training curriculum and manual, which we provide. A User's Manual is available electronically on our website and is available in hard copy from the National Technical Information Service by calling 1–800–553–6847.

III. Provisions of the Final Rule

In this final rule, we are adopting the provisions as set forth in the interim final rule with comment period with the following revisions:

- We have revised the standard in § 484.20(a), Encoding and transmitting OASIS data, to allow 30 days from the date the assessment is completed for the agency to encode and submit OASIS data.
- We have removed the requirement in § 484.20(c)(1), which required HHAs to electronically transmit accurate, completed, encoded, and locked OASIS data for each patient to the State agency or CMS OASIS contractor at least monthly. This removes the ''lock'' requirement, which was required at implementation. Experience has indicated that the lock function is no longer necessary.
- We have redesignated the requirement in § 484.20(c)(2) as § 484.20(c)(1). This requirement provides that OASIS data must be transmitted in a format that meets the data format standard specified in § 484.20(d).
- We have redesignated the data submission requirement at § 484.20(c)(3) as § 484.20(c)(2) and have removed the reference to a specific time frame of March 26, 1999 to April 26, 1999. When the January 25, 1999, interim final rule was published, we assumed that no agencies were reporting OASIS information, and all would need to establish connectivity via a test transmission to the State agency before submission of the required data. Now that we are beyond the effective date when all existing agencies were expected to transmit required data, a test transmission is only required when an HHA that is not currently Medicare-approved applies for approval. As such, we expect that HHA to meet all of the Medicare home health CoPs, including demonstrating that it is collecting and can transmit OASIS data, before receiving its Medicare approval. States will work with agencies on a case-by-case basis to issue a temporary user identification number and password for the new HHA to demonstrate compliance.
- We have redesignated the requirement in § 484.20(c)(4) as § 484.20(c)(3). This requirement provides that HHAs must transmit data using electronic communications software that provides a direct telephone connection from the HHA to the State agency or CMS OASIS contractor.
- We have added a new paragraph § 484.20(c)(4) to include the CMS-assigned branch identification number as applicable.

IV. Collection of Information Requirements

The information collection requirements contained in § 484.20 of this document are subject to the PRA; however, these information collection requirements are currently approved under OMB control number 0938–0761 ''Medicare and Medicaid Programs Use of the OASIS as Part of the CoPs for HHAs,'' with a current expiration date of June 30, 2006. The currently approved collection authorizes HHAs to collect and transmit OASIS data.

V. Regulatory Impact Statement

We have examined the impact of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This rule does not reach the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6 million to $29 million in any 1 year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined that this rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 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 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined that this rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. This rule will have no consequential effect on the governments mentioned or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. Since this regulation does not impose any costs on State or local governments, the requirements of E.O. 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 484

Health facilities, Health Professions, Medicare, Reporting and Recordkeeping Requirements.

■ For reasons set forth in the preamble, CMS amends 42 CFR part 484 as follows:

PART 484—HOME HEALTH SERVICES

■ 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 484.20 is amended by revising paragraphs (a) and (c) to read as follows:

§ 484.20 Condition of participation: Reporting OASIS information.

* * * * *

(a) *Standard: Encoding and transmitting OASIS data.* An HHA must encode and electronically transmit each completed OASIS assessment to the State agency or the CMS OASIS contractor, regarding each beneficiary with respect to which such information is required to be transmitted (as determined by the Secretary), within 30 days of completing the assessment of the beneficiary.

* * * * *

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

(1) For all completed assessments, transmit OASIS data in a format that meets the requirements of paragraph (d) of this section.

(2) Successfully transmit test data to the State agency or CMS OASIS contractor.

(3) Transmit data using electronics communications software that provides a direct telephone connection from the HHA to the State agency or CMS OASIS contractor.

(4) Transmit data that includes the CMS-assigned branch identification number, as applicable.

* * * * *

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

Dated: May 20, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Approved: September 12, 2005.

Michael O. Leavitt,

Secretary.

[FR Doc. 05–24389 Filed 12–22–05; 8:45 am]

BILLING CODE 4121–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 64

[CG Docket No. 03–123; FCC 05–203]

Telecommunications Relay Services and Speech-to-Speech Services for Individuals With Hearing and Speech Disabilities

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Commission concludes that its current rules regarding eligibility criteria for compensation from the Interstate Telecommunications Relay Services (TRS) Fund do not reflect advances in the way that TRS is offered, particularly with respect to the two Internet-based forms of TRS, Video Relay Service (VRS) and Internet-Protocol (IP) Relay. Therefore, the Commission amends its rules to permit common carriers desiring to offer VRS and IP Relay service and receive compensation from the Interstate TRS Fund (Fund) to seek certification from the Commission. In doing so, the Commission largely adopts the proposal set forth in the *Second Improved TRS Order's NPRM.* Through this action, the certification procedure will permit common carriers desiring to offer only VRS and/or IP Relay, and not the other forms of TRS, to receive compensation from the Fund without having to meet one of the existing three eligibility criteria set forth in the Commission's rules. Also in this document, the Commission addresses a related issue raised in Hands On Video Relay Services, Inc.'s (Hands On) petition for reconsideration of the *2004 TRS Report and Order,* which challenges the Commission's dismissal of Hands On application for certification as a VRS provider eligible for compensation from the Fund. Because the Commission adopts a new eligibility rule that permits Hands On to seek certification as a VRS provider eligible for compensation from the Fund without being part of a certified state TRS, the Commission concludes this issue is moot. Also, in this document, the Commission seeks approval from the Office of Management and Budget (OMB) for any Paperwork Reduction Act (PRA) burdens contained in this document that will modify OMB Control No. 3060–1047. The revised PRA burdens are related to new rules permitting common carriers seeking to offer VRS or IP Relay service, that are not part of a certified state program or have not contracted with an entity that is, to qualify for compensation from the Fund through a Commission-level certification process.

DATES: Effective January 23, 2006, except for § 47 CFR 64.605 (a)(2), (c)(2), (e)(2), (f)(2), and (g), which contains information collection requirements that have not been approved by the Office of Management and Budget (OMB). The Commission will publish a document in the **Federal Register** announcing the effective date. Written comments on the Paperwork Reduction Act (PRA) information collection requirements must be submitted by the general public, Office of Management and Budget (OMB), and other interested parties on or before January 23, 2006.

ADDRESSES: You may submit PRA comments identified by [CG Docket Number 03–123 and/or OMB Control Number 3060–1047], by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.
- Federal Communications Commission's Web site: *http://www.fcc.gov/cgb/ecfs/.* Follow the instructions for submitting comments.
- E-mail: Parties who choose to file by e-mail should submit their comments to Leslie Smith at *Leslie.Smith@fcc.gov* and to Kristy L. LaLonde at *Kristy_L.LaLonde@omb.eop.gov.* Please include the CG Docket Number 03–123 and/or OMB Control Number 3060–1047 in the subject line of the message.
- Mail: Parties who choose to file by paper should submit their comments to Leslie Smith, Federal Communications Commission, Room 1–A804, 445 12th Street SW., Washington, DC 20554, and to Kristy L. LaLonde, OMB Desk Officer, Room 10234 NEOB, 725 17th Street, NW., Washington, DC 20503.
- People with Disabilities: Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by e-mail: *FCC504@fcc.gov* or phone (202) 418–0539 or TTY: (202) 418–0432.

FOR FURTHER INFORMATION CONTACT: Thomas Chandler, Consumer & Governmental Affairs Bureau, Disability Rights Office at (202) 418–1475 (voice), (202) 418–0597 (TTY), or e-mail at *Thomas.Chandler@fcc.gov.* For additional information concerning the PRA information collection requirements contained in the document, contact Leslie Smith at (202) 418–0217, or via the Internet at *Leslie.Smith@fcc.gov.* If you would like to obtain or view a copy of this revised information collection, you may do so