DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 484

[HCFA–3007–F]

RIN 0938–AJ11

Medicare and Medicaid Programs: Comprehensive Assessment and Use of the OASIS as Part of the Conditions of Participation for Home Health Agencies

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

ACTION: Final rule.

SUMMARY: This final rule revises the existing conditions of participation that home health agencies (HHAs) must meet to participate in the Medicare program. Specifically, this rule requires that each patient receive from the HHA a patient-specific, comprehensive assessment that identifies the patient's need for home care and that meets the patient's medical, nursing, rehabilitative, social and discharge planning needs. In addition, this final rule requires that as part of the comprehensive assessment, HHAs use a standard core assessment data set, the ''Outcome and Assessment Information Set'' (OASIS) when evaluating adult, non-maternity patients. These changes are an integral part of the Administration's efforts to achieve broad-based improvements in the quality of care furnished through Federal programs and in the measurement of that care.

EFFECTIVE DATE: These regulations are effective on February 24, 1999.

ADDRESSES: Mail written copies of comments related to information collection requirements to the following addresses:

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, Attention: John Burke HCFA–3007–F, 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, Attention: Allison Herron Eydt, HCFA Desk Officer, Fax number: 202–395–6974 or 202–395–5167

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FOR FURTHER INFORMATION CONTACT: Janice Stevenson at (410) 786–4882.

SUPPLEMENTARY INFORMATION:

I. Background

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 be provided on a visiting basis in the beneficiary's home. Services may include the following:

- Part-time or intermittent skilled nursing care furnished by or under the supervision of a registered nurse.
- Physical therapy, speech-language pathology, and occupational therapy.
- Medical social services under the direction of a physician.
- Part-time or intermittent home health aide services.
- Medical supplies (other than drugs and biologicals) and durable medical equipment.
- Services of interns and residents if the HHA is owned by or affiliated with a hospital that has an approved medical education program.
- Services at hospitals, SNFs, or rehabilitation centers when they involve equipment too cumbersome to bring to the 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.) In particular, section 1861(o)(6) of the Act provides that an HHA must meet the conditions of participation specified in section 1891(a) of the Act and such other conditions of participation as the Secretary finds necessary in the interest of the health and safety of patients of HHAs. 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 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 the Medicare program. These requirements are set forth at 42 CFR Part 484, Conditions of Participation: Home Health Agencies. Unless a condition is specifically limited to Medicare beneficiaries, the conditions of participation (COPs) apply to an HHA as an entity and to the services it furnishes to an individual under its care. 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. To implement this requirement, State survey agencies generally conduct surveys of HHAs to determine whether they are complying with the conditions of participation.

II. Provisions of the Proposed Rule and Discussion of Public Comments

On March 10, 1997, we published two proposed rules in the **Federal Register** that proposed significant changes to the HHA COPs. The first proposed rule, Conditions of Participation for Home Health Agencies (62 FR 11004), set forth broad based revisions to the COPs with the goal of eliminating cumbersome process regulations and focusing on outcomes of care. In the preamble to that proposed rule, we discussed in detail our rationale for revising the COPs and the principles underlying our

proposed revisions. Specifically, we stated that the revised COPs will promote a partnership between HCFA and the rest of the health care community, and are based on the belief that we should retain only those regulations that represent the most cost-effective, least intrusive, and most flexible means of meeting HCFA's quality of care responsibilities. Also, they rely on the principle that making powerful data available to consumers and providers can produce a strong nonregulatory force to improve quality of care. One of the most significant provisions of the HHA COPs proposed rule was the requirement that each patient receive from the HHA a patient-specific, comprehensive assessment that identifies the patient's continuing need for home care, and that meets the patient's medical, nursing, rehabilitative, social and discharge planning needs.

The second proposed rule published on March 10, 1997, Use of the OASIS as Part of the Conditions of Participation for Home Health Agencies (62 FR 11035), proposed that as part of the comprehensive assessment, HHAs use a standard core assessment data set, the ''Outcome and Assessment Information Set'' (OASIS), when evaluating adult, non-maternity patients. In the preamble to that rule, we discussed in detail the process we used to develop the OASIS including numerous definitional and methodological issues that had to be addressed before the OASIS was finalized. In addition, we also described expectations regarding the use of the OASIS both in the near future and in the long run. Both the proposal to revise the HHA COPs and the proposal requiring use of the OASIS are integral parts of the Administration's efforts to achieve broad-based improvements in the quality of care furnished through the Medicare and Medicaid programs and in the measurement of that care.

Subsequent to the publication of the two proposed rules discussed above, the Balanced Budget Act (Public Law 105–33 (BBA)) was enacted on August 5, 1997. It amended the Act to require the Secretary to establish a prospective payment system for home health services. 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. In order to implement this prospective payment system, it is necessary that we have data from HHAs to develop a reliable case mix adjustment system. Case mix adjustment modifies prospective payment rates to reflect the differences in the amount of services required by patients of different diagnosis and severity, and allows the payments to correspond more closely with expected resource use by patients. Section 4602(e) 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 to develop reliable case mix adjustments. We intend for the OASIS to be the vehicle through which information for the case mix adjustments is collected. Thus, to facilitate the implementation of the prospective payment system, in this final rule, we are setting forth only that portion of the proposed COPs concerning comprehensive assessment. In addition, we are finalizing the proposed rule that requires use of the OASIS. Specifically, as discussed in detail below, we are requiring that HHAs complete a comprehensive assessment for each patient and that they incorporate the OASIS into their comprehensive assessment process.

In addition to publishing this rule, in today's issue of the **Federal Register**, we are also publishing regulations that require HHAs to electronically report OASIS data as a condition of participation. 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 payment amounts. The publication of this final rule and the rule concerning reporting requirements for OASIS will allow us enough lead time to be assured that the data we collect are consistent and complete for the purposes of computing valid case mix adjusters. Only then can we be confident that resulting payment levels are proper. Should computations be flawed and payments improper, incentives would be distorted and patient care could quite possibly suffer.

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.

Our commitment to revising the COPs for HHAs to focus on patient-centered, outcome-oriented care remains unchanged. Once HHAs have become familiar with collecting and reporting OASIS data, we expect to publish a final rule that sets forth the remainder of the revisions to the HHA COPs, which we proposed in March, 1997. Following is a discussion of the provisions of the March 10, 1997 proposed rules concerning comprehensive assessment and use of the OASIS as well as our responses to public comments received on these issues. We will respond to comments concerning the other home health conditions, which were proposed in the March 10, 1997 **Federal Register**, in a separate rulemaking document.

A. Comprehensive Assessment

The Comprehensive Assessment of Patients COP reflects the patient-centered, interdisciplinary approach, and underscores our view that systematic patient assessment is essential to improving quality of care and patient outcomes. We believe that the comprehensive assessment requirements reflect standard practice for most HHAs. In addition, this condition requires HHAs to incorporate the use of OASIS in their comprehensive assessment.

We proposed to add a new § 484.55 to require that each patient receive from the HHA a patient-specific, comprehensive assessment that identifies the patient's need for home care and that meets the patient's medical, nursing, rehabilitative, social and discharge planning needs. For Medicare patients, identifying the need for home care would include assessment of the patient's eligibility for the home health benefit, including the patient's homebound status. (This verification of a patient's eligibility for Medicare home

health benefit including homebound status does not apply to Medicaid patients or private pay patients.) As a result of the utility of OASIS as a case mix adjuster, we have slightly modified the appropriate populations for whom the OASIS data should be collected. Because OASIS data is necessary for payment purposes, it must be collected for all Medicare beneficiaries except pediatric patients, including those groups for whom OASIS is not as useful for outcome measurement as for others. We expect HHAs will collect OASIS data on all patients served by the HHA *except* prepartum and postpartum patients, patients under 18, and patients who are not receiving personal care or health services (that is patients who are receiving only services such as housecleaning, cooking or laundry).

General Comments

Comment: One commenter expressed concern that the home care industry is facing many major changes at one time including revised COPs (which include a new set of standards requiring data driven performance improvement), implementation of OASIS, and the implementation of a prospective payment system that has not been designed to consider the costs of outcome measurement and performance improvement.

Response: We agree that change, even necessary change, is difficult, and we have endeavored to make the transition as smooth as possible. To that end, we published OASIS and the revised COPs in the **Federal Register** in March, 1997, to give HHAs and the industry an opportunity to begin familiarizing themselves with the data set and developing strategies for complying with the proposed COPs. We recognize that recent changes in the reimbursement system have made the implementation of the OASIS requirements a challenging prospect for some HHAs. However, as a result of the BBA, HCFA and HHAs are faced with the rapid implementation of a prospective payment system. As discussed above, OASIS data is critical to the development of case mix adjustments for the prospective payment system for HHAs, which has been mandated by the BBA. Without such data, there is a strong likelihood that HCFA could not obtain the case mix information that is absolutely essential for the establishment of a prospective payment system. Although we recognize that it may be difficult for HHAs to cope with the changes that would result from implementation of all the proposed COPs at one time, we cannot delay implementation of the OASIS requirements. Therefore, in this rule, we are finalizing only the condition that requires collection of OASIS information. The reporting requirements for OASIS data are published in a separate rule in today's issue of the **Federal Register**. We plan to finalize the remainder of the home health conditions in a later rulemaking document. We believe this approach will give HHAs the opportunity to concentrate on OASIS implementation.

Comment: One commenter suggested that assessment and care planning are intertwined and should remain together in a single COP.

Response: We believe that assessment and care planning are sequential steps in patient management, as one cannot develop a care plan without first assessing the patient. By creating a separate condition for the assessment process, we emphasize the importance of this cornerstone of patient management. We provide specific assessment requirements to support not only care planning, but also data critical to the development and operation of a prospective payment system.

Comment: One commenter stated the belief that the requirement to assess Medicare patients' homebound status when identifying patients' need for home care is restricting. The commenter further stated the belief that requiring a patient to be homebound in order to obtain Medicare benefits limits them to the point of institutionalizing them. Another commenter pointed out that the homebound criteria is not a requirement for non-Medicare patients. The commenter recommended that this be clearly stated in the surveyor interpretive guidelines.

Response: We recognize the commenters' concerns. However, sections 1814(a)(2)(C), and 1835(a)(2)(A) of the Act require a physician to certify that an individual be homebound, or confined to the home, in order to receive Medicare coverage for home health services. This requirement is consistent with the statute, and promotes program integrity because it requires HHAs to evaluate the Medicare patients' eligibility for the home health benefit. We agree that homebound status and other Medicare eligibility requirements do not apply to patients served by the HHA who are not receiving Medicare home health benefits. Therefore, we have revised the introductory text of § 484.55 to clarify that the HHA must verify the patient's eligibility for the Medicare home health benefit including homebound status only for Medicare home health beneficiaries. Verification of a patient's eligibility for Medicare home health benefit including homebound status does not apply to Medicaid patients, beneficiaries receiving Medicare outpatient services or private pay patients. Because the comprehensive assessment may not be completed at the time of the initial assessment visit, we have also revised paragraphs (a) and (b) to require the HHA to assess the patient's eligibility for the home health benefit at the initial evaluation visit, and at the time the comprehensive assessment is completed. In addition, we will ensure that HCFA guidance and surveyor training reflect this distinction in accordance with the commenter's request.

Comment: Many commenters favored the comprehensive assessment, but requested clarification on the sequence of the assessment process as specified in § 484.55.

Response: We believe that commenters found the structure of the condition confusing, as the requirements proposed at § 484.55(a) addressed drug regimen review as part of the comprehensive assessment, § 484.55(b) addressed the initial assessment visit, and § 484.55 (c), (d) and (e) returned to the subject of the comprehensive assessment. To improve clarity, we have revised the regulation to place assessment requirements in sequential order within the condition. We have also shortened the title of the proposed standard at § 484.55(c), Standard: Time frame for completion of the comprehensive assessment to Standard: Completion of the comprehensive assessment, in order to focus on the activity of completing the comprehensive assessment, rather than to focus on the timing of the activity. To further clarify the condition, we are removing language at § 484.55(d), which requires that the comprehensive assessment meet the needs of the patient and include information on the patient's progress toward clinical outcomes. We have incorporated this requirement into the introductory text of § 484.55.

The comprehensive assessment COP requires that a patient receive an initial assessment in order to determine the immediate care and support needs of the patient. The initial assessment visit corresponds to the registered nurse initial evaluation visit required under the skilled nursing condition of participation at § 484.30. The initial assessment visit is intended to ensure that the patient's most critical needs for home care services are identified and met in a timely fashion. We do not require that a comprehensive assessment be completed at this visit, although the HHA may choose to do so. If the HHA does not complete the

comprehensive assessment during the initial visit, then the comprehensive assessment must be completed and updated according to the time points at § 484.55(b) and (d). Section 484.55(e) requires that OASIS items be incorporated into the HHA's comprehensive assessment.

Therefore, in order to avoid misunderstandings regarding the initial assessment, the comprehensive assessment and the OASIS, we have rearranged the sequence of the process in § 484.55 to read as follows: § 484.55(a) Initial assessment visit; § 484.55(b) Completion of the comprehensive assessment; § 484.55(c) Drug regimen review; § 484.55(d) Update of comprehensive assessment; and § 484.55(e) Incorporation of OASIS data items.

Standard: Initial Assessment Visit

The regulation for the initial assessment visit set forth at proposed § 484.55(b) (now § 484.55(a) in accordance with the reorganization scheme discussed above) required that a registered nurse perform an initial assessment visit based on physician's orders to determine the immediate care and support needs of the patient either within 48 hours of referral, within 48 hours after patient's return home, or within 48 hours of the physician-ordered start of care date. We proposed that when rehabilitation therapy services are the only services ordered by the physician, the initial assessment would be made by the appropriate rehabilitation skilled professional.

We solicited comments on the appropriateness of using competent individuals other than a registered nurse or appropriate therapist to perform initial patient assessments. We also invited comments on the feasibility of permitting the delegation of nursing responsibilities within the scope of State practice acts to competent individuals.

Comment: Several commenters questioned the requirement that the initial assessment be completed within 48 hours. Commenters stated that compliance would be difficult for home care providers who serve rural areas, especially for weekend therapy coverage. Some commenters suggested that the time frame be extended to 72 hours, others suggested it be left up to the HHA. One commenter questioned how HHAs would demonstrate that the patient was seen in the required amount of time. However, another commenter pointed out that if a patient receives a visit 48 hours after the physician orders those services to begin, then the HHA is not complying with the plan of care.

Response: The requirement for the initial assessment to be completed within a 48-hour time frame is imperative for the safety of the patient. As the complexity of the care needs of patients increase, so does the need for a comprehensive assessment of the patient, and the importance of the development and implementation of an effective care plan becomes paramount. In addition, HHAs are often providing services that were once exclusively provided in a hospital or other institutional settings (for example, chemotherapy, intravenous treatments, and care for patients dependent on respirators). Thus, HHAs are often caring for patients with severe and complex health care needs who require high-tech services. Patients who are discharged from the hospital or referred for home health services should not be left unattended in the home for any extensive period of time, unless the physician determines that a later start of care date is suitable. If the physician orders that the patient begin receiving home health services on a specific date, then it is reasonable to expect the HHA to comply with that order. If there is no start of care date ordered, or if access to the patient or provision of services are difficult to provide within 48 hours of referral or discharge from the hospital, then the HHA must communicate that difficulty to the physician. The physician can then establish a start of care date that is appropriate to meet the needs of the patient and is acceptable to the HHA.

We expect that HHAs will develop administrative processes to track admissions and timeliness of service, and see such attention as a positive outcome of this requirement. HHAs are free to choose the method that works for them, given the size and patient population of the HHA. We agree with the commenter that allowing the HHA to delay services for 48 hours after the physician orders services to begin would promote noncompliance with physician orders. As a result of this comment, we have revised the requirement at § 484.55(a)(1) to state that the initial assessment visit must occur either within 48 hours of referral, or within 48 hours of a patient's return home, or on the start of care date ordered by the physician. To further clarify, if the HHA is notified of a patient referral for home care on Monday, and the patient is discharged from the hospital on Wednesday, we would expect the initial assessment visit to occur by Friday, unless the physician specifies an earlier time. However, if the physician orders the start of care to begin on the following Monday (5 days after hospital discharge and 7 days after the referral), the initial assessment must be rendered on that day. We have also revised paragraph § 484.55 (a)(1) to remove language that requires the registered nurse to complete the initial assessment ''based on physician's orders''. We believe this language is unnecessary, since all visits to the patient are made based on physician orders.

Comment: One commenter indicated that most HHAs will not allow 48 hours or longer to complete the initial assessment. The commenter stated that paperwork requirements, which differ from State to State, mandate that all information be obtained and reduced to writing as quickly as possible in order to obtain the physician's signature on the document in the required time frames.

Response: In this final rule, we require specific time frames for the initial assessment visit and completion of the comprehensive assessment because we believe that these requirements are predictive of good patient care, and proactive for the prevention of harm to the patient. We recognize that States may have regulations that require completion of the assessment earlier. However, we do not preclude agencies from completing their assessments prior to the mandated timeframes.

Comment: Two commenters suggested that we consider patient choice and the patient's right to determine when the HHA will make the visit. A commenter offered an example of a patient who would have help at home until a designated point in time at which that help would cease. The commenter suggested that the patient should be able to request that home health services start as soon as help was no longer available.

Response: Section 1891(a)(1)(A) of the Act states that the patient has the right to be fully informed in advance about the care and treatment to be provided by the agency and the right to participate in planning care. Section 1861(m) of the Act requires that the individual receive services under a plan of care established and periodically reviewed by the physician. Therefore, we expect that the patient, the HHA and the physician will communicate in developing a plan of care that meets the patient's health needs, is considerate of the patient's concerns and can be delivered by the HHA. In the situation described by the commenter, we would expect that a later start of care date would be established by the physician if appropriate.

Comment: Several commenters disagreed with our proposed requirement that therapists can perform initial assessment visits. Commenters stated that, as the focal point for opening the case, the initial assessment should be performed only by a registered nurse, because the nurse has the broadest scope of clinical expertise. A few commenters stated that therapists, including occupational therapists, (but not therapy assistants) should be able to complete the initial assessment visit. Several commenters questioned who should complete the comprehensive assessment and asked that we clarify the requirement. One commenter stated that updates of the comprehensive assessment and completion of the OASIS at required intervals could be satisfactorily performed by a licensed practical nurse under RN supervision.

Response: We received many comments recommending both restriction (to registered nurses) and liberalization (to occupational therapists) of our current requirements. Section 484.30(a) states that the registered nurse make the initial evaluation visit; and, we agree that the broad scope of clinical expertise of the registered nurse is beneficial in conducting the initial evaluation. However, restricting the initial evaluation to the registered nurse only (when only a therapy service has been ordered by the physician) can be burdensome. In these instances, in an endeavor to allow flexibility, a physical therapist or speech language pathologist may conduct the initial evaluation visit in accordance with physician orders. This policy has been explained in interpretive guidelines, and is based on the proven ability of the physical therapist and/or speech language pathologist to conduct the initial visit.

At this time, we will make this policy explicit in regulation. As we have said above, the initial assessment visit and comprehensive assessment must be conducted by a registered nurse unless physical therapy or speech language pathology is the only required service for that patient. If that is the case, the physical therapist or speech-language pathologist can conduct these assessments. The staff requirements are the same for follow-up assessments and assessments at the time of transfers and discharges.

With regard to occupational therapists completing the initial assessment visit, we note that while Medicare pays for occupational therapy, eligibility for the Medicare home health benefit cannot be established based solely on the need for that service. The occupational therapist may complete the comprehensive assessment and its updates if the need for occupational therapy establishes program eligibility. The need for occupational therapy would not establish eligibility for the Medicare home health benefit, but could establish eligibility, for example, in some States under the Medicaid program. Conversely, the Medicare home health patient with multiple service needs can retain eligibility if, over time, the only remaining need is for occupational therapy. At that time, an occupational therapist can conduct the follow-up assessment as well as those associated with transfers and discharges. In the case of Medicaid patients, or Medicare patients receiving outpatient services, if the need for a single therapy service either establishes eligibility or allows eligibility to continue once it is otherwise established, the corresponding practitioner, (including a physical therapist, speech-language pathologist, or occupational therapist) can conduct any of the designated assessments.

We do not believe the comprehensive assessment can be completed by the licensed practical nurse in accordance with the COPs. The introductory text to § 484.55 requires that the comprehensive assessment meet the needs of the patient and include information on the patient's progress toward clinical outcomes. Thus, completing the comprehensive assessment involves an evaluation of the patient. In the current conditions of participation, patient evaluation is included in the duties of the registered nurse at § 484.30(a) and therapy services at § 484.32, but is not included in the duties of the licensed practical nurse at § 484.30(b). In response to comments, we have revised § 484.55(b)(2) to require that the registered nurse complete the comprehensive assessment.

Comment: Several commenters requested that we clarify the term ''appropriate therapist''. Commenters indicated that surveyors apply the Medicare restriction of occupational therapy as a qualifying skilled service to non-Medicare patients or those Medicare patients receiving outpatient services. Other commenters requested clarification regarding the inclusion of the occupational therapist as one of the disciplines to conduct the initial assessment visit.

Response: The appropriate therapist is the physical therapist or speech language pathologist; and, in some cases as indicated above, the occupational therapist. We have made this clarification in the regulatory text at § 484.55(a)(2). To further clarify, we have added a new paragraph (b)(3) to provide that the comprehensive assessment may be completed by the physical therapist, speech-language pathologist or occupational therapist if the need for occupational therapy establishes program eligibility.

Standard: Completion of the Comprehensive Assessment

At proposed § 484.55(c) (now § 484.55(b)) we specified the timeframe in which the HHA must complete the comprehensive assessment. We proposed that the HHA must complete the comprehensive assessment in a timely manner consistent with the patient's immediate needs, but no later than 5 working days after the start of care.

Comment: A few commenters questioned if the requirement for a comprehensive assessment with OASIS data applies to all payment sources, including managed care patients. Commenters also asked if managed care organizations (MCOs) will be responsible for supplying the follow-up to outcomes.

Response: The conditions of participation apply to the HHA, and thus to all patients served by the agency. Therefore, we would expect that managed care patients receive a comprehensive assessment, including OASIS items, where required in the COPs. With regard to MCO responsibility for follow-ups, we note that outcome reports generated from OASIS data will be sent directly to the HHA providing the services. At the discretion of the HHA, the HHA can work with the MCO to develop a plan for follow-ups to the outcome reports.

Comment: Several commenters disagreed with the requirement that the comprehensive assessment be completed within 5 working days after the start of care. Some commenters suggested the requirement be changed to 7 days. Other commenters disliked the term ''working days'', stating that every day is a working day for HHAs. These commenters suggested changing the requirement to 5 calendar days.

Response: We agree with commenters that the term ''working days'' may be misleading. HHAs provide care to patients in accordance with patient needs, and patient needs do not comply with the arbitrary limits of ''working days''. Therefore, we have revised § 484.55(b)(1) to change the term ''working days'' to ''calendar days'' in the requirement.

Comment: Two commenters requested that HCFA establish a standardized comprehensive assessment that must be used for all HHAs. The commenters felt

that this would improve efficiency for the HHA and the quality of patient assessment. Another commenter pointed out that HHAs must develop two comprehensive assessments; one for patients who require collection of OASIS items, and one for patients who do not need to have OASIS items included in their assessment. Commenters stated the belief that this can be confusing and potentially burdensome for the HHA.

Response: We do not believe that a standardized comprehensive assessment is necessary or useful to all HHAs. Our intent is that HHAs have the flexibility to use a comprehensive assessment that reflects the needs of their patient population. The standardized elements of the comprehensive assessment are the OASIS items that must be incorporated into the comprehensive assessment. We are aware that some provider, vendor and academic organizations have developed standard comprehensive assessments with the OASIS data set integrated into them. We expect that the availability of such standard assessments would be attractive to HHAs that do not want to develop their own. We do not require the HHA to develop different comprehensive assessments in order to accommodate OASIS data or varying clinical needs. The HHA is free to establish assessment policy and to develop the number and type of assessment forms that meet the individual HHA's needs.

Comment: One commenter stated that the OASIS follow-up must be completed by the same discipline that completed the initial OASIS to ensure reliability of the assessment.

Response: As discussed in the OASIS proposed rule, the University of Colorado has found the OASIS to be valid and reliable even when completed by different disciplines such as a nurse and physical therapist or speech language pathologist at subsequent time points. Therefore, we do not believe that the same discipline must complete the OASIS at every time point.

Standard: Drug Regimen Review

Under § 484.55(c) (proposed § 484.55(a)) drug regimen review, we proposed to incorporate the existing requirement concerning a drug regimen review from § 484.18(c). However, we clarify the requirements by eliminating the identification of ''adverse actions'' and ''contraindicated medications'' and substituting the more concise requirements of review for drug interactions, duplicative drug therapy and noncompliance with drug therapy. This modification narrows the scope of the drug regimen review, provides accountability, and focuses the assessment toward data predictive of a significant patient outcome. In this final rule, we are revising § 484.18(c), by removing the last sentence of the paragraph, which relates to review of the patient's medications. This requirement has been incorporated into § 484.55(c) (proposed § 484.55(a)).

Comment: Several commenters suggested that HCFA define the term ''drug regimen'' and questioned if this means all medications the patient is taking or only medication prescribed for an episode of treatment.

Response: We agree that the term ''drug regimen'' should be clarified. Therefore, we have revised this standard to reflect that drug regimen review is part of the comprehensive assessment of the patient and includes all medications the patient is using at the time of the assessment. This is an important safeguard for patients to evaluate compliance with drug therapy, to recognize and reduce the risk of complications from multiple medications, and prevent adverse drug interactions and unnecessary medication. If an adverse drug reaction should occur, the patient care provider should note the patient's side effects and or adverse reaction in the medical record, notify the patient's doctor, and, if possible, contact the pharmacy where the prescriptions were filled.

Comment: One commenter stated that the review of drugs, drug interactions, duplicative drug use, and noncompliance with the drug regimen is not necessary for patients receiving only aide services, as these patients are receiving their drug regimen from their physician and pharmacist.

Response: All patients, whether receiving skilled services or only aide services, receive their drug regimen from the physician. The drug regimen review is an integral part of the comprehensive assessment, and an important safeguard for patients who frequently receive medications from a variety of physicians and pharmacies. We believe that patients receiving aide services are likely to have multiple medications and therefore require this health and safety protection.

Comment: Several commenters stated that the standard concerning drug regimen review does not specify that the RN is responsible for the drug regimen review as part of the comprehensive assessment. Commenters were concerned that drug monitoring is beyond the scope of practice for therapists and stated that it should be the ongoing responsibility of the patient's physician and pharmacist in therapy-only cases. Another commenter stated that the therapist was capable of completing the drug regimen review and pointed out that therapists are currently doing so.

Response: Limiting the drug regimen review and completion of the comprehensive assessment to the registered nurse would be burdensome to the HHA, especially as the comprehensive assessment must be completed periodically. If a therapy-only patient admission has a drug regimen, we would expect the therapist to evaluate the patient's medications and patient knowledge during the initial assessment visit and bring any problems to the attention of the physician. We agree that management of drug therapy is the responsibility of the physician, regardless of whether the patient is receiving therapy-only services. We note that this is a continuation of our policy since regulations previously located at § 484.18(c) allowed the drug regimen review to be completed by the HHA nurse and therapist.

Standard: Update of the Comprehensive Assessment

Section 484.55(d) addresses the update of the comprehensive assessment. In this standard, we proposed to require that the comprehensive assessment must include information on the patient's progress toward clinical outcomes, and be updated and revised (1) as frequently as the patient requires but no less frequently than every 62 days from the start of care date, (2) when the patient's plan of care is revised for physician review, (3) within 48 hours of the patient's return home from the hospital, and (4) when the patient is discharged. The comprehensive assessment updates must include the appropriate OASIS items as indicated on the data set.

Comment: Several commenters objected to the requirement that the OASIS be completed for patients who are seen infrequently (for example, every two weeks, or monthly) in order to comply with the 57 to 62 day requirement. Commenters stated that this standard would require HHAs to provide additional skilled visits.

Response: In order to have data that is comparable across HHAs, OASIS data must be collected at uniformly defined time points including at recertification. We do not believe that this requirement will add to the number of skilled visits provided by the HHA. We understand that many HHAs arrange visit schedules to accommodate home health aide supervisory requirements and patient and care giver schedules. We would expect the HHA to similarly adjust the patient's visit schedule in order to

accommodate OASIS time points. As discussed in detail below, we have revised paragraph (d) by removing the proposed 62 day requirement. Instead, we provide that the comprehensive assessment must be completed every second calendar month beginning with the start of care date.

Comment: Several commenters objected to the requirement that the OASIS be completed within 48 hours of a patient's return home from a hospital, stating that this would be burdensome and duplicative of assessment information in the clinical progress notes. Other commenters stated that the comprehensive assessment and OASIS items should be completed after a hospital stay of 24 hours or more, as this would be more predictive of a significant patient event and less burdensome to the HHA. A few commenters questioned the sequence of events regarding collection of the OASIS data after the patient's return from the hospital.

Response: Hospitalization as an event is generally a good predictor of a deterioration in the patient's health status, and therefore should be captured in the OASIS data. HHAs that do not account for hospitalizations in their OASIS data collection may reflect poorer outcomes than those that do. Patients frequently improve rapidly upon returning home from the hospital, therefore it is important that the patient's health status at the time of discharge from the hospital be captured quickly. The 48-hour requirement is necessary, given the speed of changes in a patient's status after hospitalization. In addition, the importance of OASIS as a case mix adjuster makes it necessary, in the interest of the accuracy of patient data, for the HHA to assess the patient's true needs as quickly as possible upon discharge from the hospital. This standard is intended to ensure the timely and accurate assessment of patients who were not discharged from the HHA when they were admitted to the hospital, and have returned home.

We do not intend that the comprehensive assessment be duplicative of assessment information that is documented in the clinical progress notes. Rather, we expect the comprehensive assessment to *replace* assessment information that is transcribed in clinical progress notes. For example, if a nurse assesses and documents the status of a patient's surgical wound, ability to ambulate, presence of assistance in the home and ability to manage medications during the comprehensive assessment required upon return from a hospitalization, it is unnecessary, burdensome and counterproductive for the nurse to also document this information elsewhere in the clinical progress notes. We agree with the commenter that requiring that the comprehensive assessment (including the appropriate OASIS items) be completed after a hospital admission of 24 hours or more would be predictive of a significant patient event and less burdensome to the HHA. Therefore, we have revised § 484.55(d) to require that the comprehensive assessment (including administration of OASIS) be completed within 48 hours of the patient's return home from a hospital admission of 24 hours or more for any reason except diagnostic testing.

If home health care is resumed after a hospital admission (regardless of whether the patient was formally discharged from the HHA), the comprehensive assessment must include the OASIS items appropriate for assessment after a hospital admission. If the patient was not formally discharged from the HHA, the HHA should establish the next assessment time point at the end of the second calendar month interval that corresponds to the original start-of-care date. For example, if the start-of-care date is June 25th, the patient would be reassessed on August 25th.

If the patient is formally discharged from the HHA, the data collection proceeds on the basis of the new start-of-care date that followed the inpatient stay. For purposes of OASIS data collection, the HHA can establish its own internal policies regarding criteria for formal discharge versus interrupting home care services but maintaining the patient on the HHA admission roster.

Comment: Two commenters requested that HCFA define the update of the comprehensive assessment. The commenters asked if it is necessary to complete a full assessment and OASIS in the event that only one item has changed, if the patient has a planned re-hospitalization, or if the patient is chronically ill with frequent hospitalizations. Another commenter suggested that the HHA should only complete OASIS data related to the diagnostic or quality grouping of the patient, rather than all OASIS items.

Response: The diagnostic and quality groupings to which the commenter refers were made on aggregated patient data in the Medicare demonstration and discussed in the OASIS proposed rule (62 FR 11038). These groupings were created for research purposes and the HHAs in the demonstration did not vary OASIS data collection in order to accommodate these groupings. We believe the commenter misunderstood the purpose and utility of the quality groupings and the methodology of the Medicare demonstration. The update of the comprehensive assessment must, at a minimum, include completion of all follow-up data items of the OASIS and any changes in patient status. OASIS items must be re-assessed and documented regardless of whether the patient's status has changed.

It is only by doing an assessment that the caregiver can determine if a change in condition has occurred or if a change in treatment is warranted. For example, although a patient with testicular cancer may continue to be incontinent, other factors may change that would warrant a change in the care plan. Another example would be a diabetic patient who continues to require insulin therapy. An assessment would still be necessary to rule out any complications or other changes in the patient's physical or mental health that would warrant revision of the treatment plan.

For purposes of outcome measurement and case mix adjustment, it is important to capture stabilization of the patient's health as well as improved or deteriorated outcomes. Thus, the information must be collected in order to measure the patient's complete health status, not just to capture change. In addition, documentation of all the OASIS items is an important safeguard for data accuracy. In the Medicare demonstrations, HHAs with computer systems that allowed OASIS items to ''carry over'', rather than requiring re-entry every time, experienced poorer outcomes. Upon examination of the data, it was discovered that documenting OASIS by exception missed many of the subtle and interrelated improvements in the patient's health status. For the remainder of the comprehensive assessment that does not include the OASIS items, limiting documentation to the changes in the patient's assessment is acceptable. We have revised the introductory text of paragraph (d) to clarify that all updates and revisions of the comprehensive assessment include administration of the OASIS.

Comment: Several commenters expressed concern about the requirement for gathering OASIS data when the plan of care is revised for physician review, stating that this would require completion of a comprehensive assessment each time the physician's orders are changed. Other commenters stated that this requirement is duplicative of the requirement to update the assessment every 57–62 days.

Response: We agree with the commenter that the requirement at § 484.55(d)(2) is duplicative and have

eliminated it. It was not our intent to require the HHA to complete a comprehensive assessment whenever physician orders are changed, and therefore, the HHA is not required to complete the OASIS data set whenever the plan of care is revised. However, the HHA will still be required to complete a comprehensive assessment when there is a significant change (a major decline or improvement) in a patient's health status.

Comment: Commenters indicated that the completion of the OASIS should be based on the needs of the individual patient, rather than an arbitrary time frame.

Response: While the frequency of ongoing patient assessment is based on the needs of the individual patient, completion of the OASIS items at standardized time points is critical for comparable information and for a case mix system. To maintain a clear reporting timeframe that eliminates the variations of days in a month, we have revised the proposed 62 day requirement at paragraph (d)(1) to provide that the HHA must update the comprehensive assessment no less frequently than every second calendar month, beginning with the start of care date. The allowable completion dates for the first assessment and any subsequent follow-up assessments will be determined based on the start of care date. Follow-up assessments must be completed every two months that a patient is under care. For each month in which a follow-up assessment is due, it must be completed no earlier than five days before, and no later than one day before the calendar day on which care began. The new rule defines the completion date relative to the day of the month which marks every two-month anniversary of the start of care. Please note the following two examples:

Example 1: If the start of care date is March 1st, the first follow-up assessment must be completed between April 26th (five days before May 1st) and April 30th (1 day before May 1st). The second follow-up assessment must be completed between June 26th and June 30th.

Example 2: If the calendar day of the start of care exceeds the last day of a month in which a follow-up assessment is due, the completion dates are computed relative to the last day of the target month. For example, if the start of care date is December 31st, the first follow-up assessment must be completed between February 23 (five days before February 28th) and February 27th (one day before February 28th). This example assumes that the year is not a leap year. In a leap year, the completion date would fall between February 24th and February 29th.

Comment: One commenter suggested that the terms ''discharge'' and ''transfer'' be defined by HCFA in order to improve the accuracy of data. The commenter expressed concern over data accuracy issues, and encouraged HCFA to require accuracy of OASIS data collected.

Response: We agree that the term ''discharge'' should be clarified, since the COPs require update of the comprehensive assessment at discharge. For purposes of this requirement, the term ''discharge'' applies when the patient is officially released from home health care by the HHA, when the patient is transferred to another facility (such as a nursing home or hospital), or when the patient dies. If any of those events occur, then we would consider the patient to be discharged from the HHA and we expect the HHA to update the comprehensive assessment (including the appropriate OASIS items). A transfer occurs when the physician orders that the patient's care be assumed by another facility (for example, nursing home or rehabilitation hospital).

We also agree with the commenter that the data derived from the comprehensive assessment and OASIS will be meaningless unless they accurately reflect the patient's health status. Therefore, we have revised the introductory text at § 484.55 to require that the comprehensive assessment accurately reflect the patient's current status.

B. Use of the Outcome and Assessment Information Set (OASIS)

As discussed above, we published a proposed rule that proposed to require HHAs to incorporate the core standard assessment data set, called the ''Outcome and Assessment Information Set'' (OASIS), into their comprehensive assessment process. This proposed rule added a new paragraph (e), Standard: Incorporation of OASIS data items, to § 484.55. In the March 10, 1997 proposed rule (62 FR 11036), we discussed in detail the methods we used to develop and validate the OASIS items, as well as a demonstration project we established, which was conducted by the University of Colorado, to assess the value of the OASIS data set in targeting and guiding improvements in outcomes and satisfaction for HHA patients. In addition, we described both the short term and long term expectations for use of the data set. All public comments, including those comments received on the impact of the OASIS proposed rule have been summarized and are discussed below.

Standard: Incorporation of the OASIS Data Set

Section 484.55(e) provides that the HHA must incorporate the OASIS data set into its own assessment, using the language and groupings of the OASIS items. Integrating the OASIS items into the HHA's own assessment system in the order presented in the OASIS form would facilitate data entry of the items into data collection and reporting software. However, it is not mandatory that agencies integrate the items in any particular order. An HHA may integrate the OASIS items in such a way that best suits the agency's own assessment. OASIS data items include information regarding demographics and patient history, living arrangements, supportive assistance, sensory status, integumentary status, respiratory status, elimination status, neuro/emotional/behavioral status, activities of daily living, medications, equipment management, emergent care, and discharge. The OASIS data set includes only information necessary to measure outcomes of care. Our intent was not to develop a complete patient assessment but rather to identify standardized data elements that fit within the HHA's overall comprehensive assessment responsibilities; that is, the incorporation of the core standard assessment data set will complement the HHA's current approach to comprehensive assessment.

We intend that the OASIS become one of the most important aspects of the HHA's activities in providing patient care. By integrating a core standard assessment data set into its own more comprehensive assessment system, an HHA can use such a data set as the foundation for valid and reliable information for patient assessment, care planning, service delivery, and improvement efforts.

Comment: We received many comments in favor of OASIS, but some commenters were concerned about the length of the assessment process if OASIS items are included.

Response: We agree that the assessment would be lengthy if the OASIS is added to the HHA's routine assessment form. However, we emphasize the need to replace similar items/questions on the agency's own assessment. It is our understanding that some HHAs have simply appended the OASIS items to their current assessment without considering which OASIS items could replace similar items on the agency's assessment. Obviously this approach adds time to the assessment process, and renders the comprehensive assessment burdensome and

duplicative. We wish to make it clear that the OASIS is not intended to constitute a complete comprehensive assessment. Rather, the data set comprises items that are a necessary part of a complete comprehensive assessment and are essential to uniformly and consistently measuring patient outcomes. The OASIS items are already used in one form or another by virtually all HHAs that conduct thorough assessments. We therefore believe that HHAs should replace similar items with OASIS items to avoid lengthening the assessment unnecessarily. In fact, when OASIS items have been used to replace similar assessment items, HHAs in the demonstration project found that completing the integrated assessment adds little to no net time increase to the visit. In addition, HHAs have found it less burdensome to enter OASIS data items into a data collection software program when they are inserted in order into the HHA's comprehensive assessment. This approach increases the speed and accuracy of data entry.

Comment: Several commenters applauded HCFA's effort to bring about OASIS stating that, from experience, they had found that incorporating the OASIS data set into their assessment process has proven to be very beneficial in assisting health care professionals in identifying the medical necessity and services that patients require. Commenters stated the belief that the OASIS data set had been developed using sound scientific processes, and will provide a useful minimal set of data items for HHAs in assessing and demonstrating outcomes by promoting systemization and completeness.

Response: We agree with the commenters that OASIS data will be helpful to HHAs and assist them in planning and providing home health services. We appreciate the positive comments and support for OASIS.

Comment: Several commenters stated that OASIS should have been developed to be compatible with the Minimum Data Set (MDS) used in Nursing Homes and/or the Uniform Needs Assessment that is under development for use in hospitals. Commenters stated that such compatibility or a crosswalk is crucial as we strive to develop integrated systems and well coordinated care.

Response: The MDS and OASIS are different data sets, developed for different purposes, for different patient care settings, and to implement different statutory provisions. MDS was developed in 1990 to implement sections 1819(f)(6) (A) and (B) of the Act for Medicare and sections 1919(f)(6) (A) and (B) of the Act for Medicaid, which required nursing homes to perform a comprehensive assessment of long term care facility residents. The MDS was designed to function as a complete assessment to promote decision making, care plan development, and care plan implementation and evaluation. The structure of the MDS is designed to enhance resident care and promote the quality of a resident's life.

The OASIS data set was developed in 1993, in part to implement sections 1891(c)(2)(C) and 1891(d)(1) of the Act, which require as part of the home health assessment, a survey of the quality of care and services furnished by the agency as measured by indicators of medical, nursing, and rehabilitative care. OASIS is the designated assessment instrument (or instruments) for use by an agency in complying with the requirement. OASIS focuses on outcomes of care, and was developed as a system of outcome measures that could be used specifically for outcome-based quality improvement and evaluation in HHAs. OASIS, while helpful for patient assessment, is not a care planning tool, and was not designed to be a comprehensive patient assessment. In addition, research has shown that there may be several uses for OASIS data, one of which will provide HCFA with data for case mix adjustment and grouping in the development of the home health prospective payment system.

OASIS is the data set currently in use in many HHAs and is the fundamental data set being evaluated for case mix adjustments for the HHA prospective payment system. The OASIS data set reflects the care of the patient populations in the home setting, and MDS reflects the care and patient population of the nursing home setting. Therefore, it is unlikely that we can collectively attain perfect overlap between the MDS, OASIS, or other assessments under development. However, it is our goal to ultimately attain as much commonality across these data sets as possible so that patient health status might eventually be monitored across provider settings using a core set of data items within each data set.

HCFA is currently pursuing research that could ultimately help in developing an assessment instrument that can support a common assessment across settings. As our data sets are modified and improved over time, our goal is to incorporate common data elements and definitions within each of the instruments to the fullest extent possible. This will improve HCFA's and States' ability to track the characteristics and care needs of beneficiaries across the post-acute and long term care service continuum. Use of common data elements will also benefit patient care by facilitating transfer of information to the continuing care provider and minimizing providers' data collection burden.

We have already started the process of identifying areas in which increased coordination of data elements is possible as part of our uniform needs assessment instrument (UNAI) initiative. This activity entails review of the item labels, definitions and reliabilities for OASIS, the long term care minimum data set (MDS), and the MDS for post-acute care (MDS–PAC), which incorporates items common to the MDS and is currently being tested for potential implementation in rehabilitation hospitals. We expect to be able to identify some areas in which increased commonality is possible across OASIS and MDS items. Refined item labels and definitions will be available for use within the next versions of these instruments (e.g., construction of version 3.0 of the MDS will begin in mid-1999.)

Comment: Several commenters requested that we add items to the OASIS data set. Requests for additions included: data items tested during the development of the OASIS data set; discipline-specific services, interventions, the amount and frequency of visits and outcomes; various ostomies for elimination status; surgical and V-codes; and, additions to the answers listed for some items. Other commenters suggested that we change or eliminate answers for some items, or that we change the order of the OASIS items.

Response: At this time, any changes to the OASIS data set, or changes in the order of existing items, would require further validation and reliability testing, and revision of the outcome measures. However, HHAs are reminded that OASIS is a core data set of required items. While the OASIS items must be used as written, HHAs may choose to collect additional data on discipline-specific services, etc., as part of their comprehensive assessment, as long as the same OASIS items, and the same answer choices as appear in the current version of OASIS are incorporated into the agency's own assessment. We have revised § 484.55(e) to provide that the OASIS data items are determined by the Secretary and must be used as they appear, and as set forth in the current version of the OASIS.

Comment: One commenter expressed concern that client/caregiver learning ability is not addressed in OASIS, when

a great deal of HHA's staff time is spent teaching clients.

Response: OASIS is a data set for gathering data that provides valid, reliable information to measure selected home health outcomes. Due to the lack of scientific measures that capture teaching outcomes within the home health context, OASIS does not currently provide outcome data on clients' learning ability, nor is it intended to gather workload data on activities carried out by care givers. We agree that patient education is a frequent service that HHAs provide, and we remain interested in looking at pertinent measures at some point in the future. In the interim, HHAs are at liberty to add these kinds of items to their comprehensive assessment in order to capture those activities.

Comment: Several commenters stated that the OASIS primarily measures outcomes that reflect skilled services, and does not address the broad scope of patients served in home health. The commenter was concerned that OASIS is a work in progress, and questioned the appropriateness of mandating something that is not tested or finished.

Response: We agree that not all OASIS items address the needs of patients receiving supportive services or specialized populations (such as pediatric or maternal-child health), although many of the data items are useful for comparison and to risk adjust outcomes. However, contrary to this commenter's concern, OASIS has been extensively tested in the field for validity, reliability and case mix adjustment for almost a decade. Like any other data set (such as the MDS), the OASIS will evolve to meet changing program needs and to reflect changes in the health care environment and additional experience in program administration.

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.

Comment: One commenter was concerned that in the future, HCFA may wish to require the use of OASIS data for persons served in their new Medicaid Managed Long Term Care plan.

Response: The requirements at § 484.55 apply to HHAs that participate in the Medicare and Medicaid programs, and the patients served by that HHA. Requirements for Medicaid home and community-based waiver programs vary from State to State, and are addressed by the individual State.

Comment: A few commenters stated that the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the Community Health Accreditation Program (CHAP) data collection requirements should be considered, coordinated and approved by HCFA, which will minimize the data collection burden on HHAs. Commenters further stated that the relationship between JCAHO, CHAP and HCFA needs to be coordinated at the Federal level to ensure that data requirements are not duplicative, particularly since the goals of JCAHO, CHAP and HCFA are to foster and support a data driven quality assessment and performance improvement program in the home health care industry.

Response: HCFA has approved the deemed status option for use by HHA accreditation organizations (JCAHO and CHAP). This deemed status program ensures close coordination between HCFA and the HHA accrediting bodies. Once OASIS requirements become final, JCAHO and CHAP must adopt equivalent requirements for those HHAs that are accredited and certified in the Medicare program. In fact, JCAHO's ORYX measures, which have been approved by HCFA, contain the OASIS data set. CHAP has also incorporated OASIS into their accreditation program. In fact, in order for an accreditation organization to be granted deeming authority, its requirements must be comparable to those of HCFA. Therefore, there is no duplication of information.

Comment: One commenter suggested that Medicaid-eligible individuals' State/Medicaid ID number should be collected to allow analysis of data on dual eligible beneficiaries.

Response: The OASIS has a field that contains a patient ID number that is unique to the patient. HCFA requires OASIS data to be encoded and reported by the HHA, as provided in a separate rule in today's **Federal Register**, Reporting Outcome and Assessment Information Set (OASIS) Data as Part of the Conditions of Participation for Home Health Agencies (HCFA–3006–IFC). In the interim, this rule does not preclude HHAs and States from using Medicaid ID numbers to identify the patient.

Comment: One commenter requested that we clarify what is meant by the ''current'' version of OASIS. The commenter asked if we were referring to the OASIS–A, OASIS–B, or OASIS+.

Response: As stated in the preamble to the proposed regulation, we urge HHAs currently using various versions of the OASIS, including ''partial'' versions, to focus on the version of the OASIS published in the March 10, 1997 proposed rule. While the content of OASIS has not changed, there may be a few changes in coding and identifier items as a result of the OASIS reporting system. The version of OASIS approved by the Secretary and for which we are seeking OMB approval is available on HCFA's website on the Internet for HHAs to download 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 note that some HHAs participating in research and demonstration projects may be using other data collection data 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 process for the duration of the project. We intend to make these determinations on a case-by-case basis, depending on several factors including, the nature of the demonstration project, the data set used, payment implications for the HHA, quality concerns, and burden issues.

Comment: Several commenters questioned the collection of OASIS data for various types of patients. Some commenters recommended that the comprehensive assessment be collected only on patients who were medically unstable or require therapeutic treatment. Others suggested that HHAs not be required to collect OASIS information for patients receiving services for brief periods of time (with suggestions ranging from two to eight days), for limited services (such as dressing changes), for infrequent visits

(less frequently than every two weeks) and for long term patients. Commenters stated that the financial burden to the HHA outweighs the benefits of the data collected for these types of patients.

Response: We disagree. It is important that OASIS data be collected on the entire spectrum of patients seen by the HHA (stable and unstable, short-term and long-term, minimal services and extensive services, frequent visits and infrequent visits). Eliminating an entire subset of patients served by the HHA would harm the quality of care and services to beneficiaries, and skew the case mix adjuster system which could potentially result in undesirable payment incentives. In addition, we would expect HHAs to be interested in evaluating the quality, efficacy and efficiency of care delivered to all their patients.

Comment: Several commenters recommended that consideration be given to the type of patients for whom the OASIS is appropriate. Commenters stated that the proposed conditions recognize that the OASIS data set is not applicable to all populations served by the HHA (for 53 example, pediatric and maternal/child), and all services such as non-personal care, and educational services. Commenters suggested that we specify for whom OASIS data must be collected.

Response: OASIS data will be used for two purposes. Specifically, the data will be used as outcome measures to evaluate HHA quality of care, and to provide data for a case mix adjustment and grouping for the home health prospective payment system. When collection of the OASIS information was proposed, we required the data to be collected for those populations that were appropriate for outcome measurement. Therefore, in the preamble of the OASIS proposed rule, we discussed OASIS data collection for all patients except prepartum and postpartum patients, pediatric patients, and patients who are not receiving personal care or health services (that is, patients who are receiving only services such as housecleaning, cooking, or laundry). We did not exempt patients receiving educational services from OASIS collection, as patient teaching is a skilled service and patient education can affect outcomes of care such as medication management, pain management, or equipment management.

As a result of the BBA and the utility of OASIS as a case mix adjuster, OASIS must be collected on most patients, including public and private pay patients, *except* prepartum and postpartum patients, patients under age 18, and patients who are not receiving personal care or health services (that is, patients who are receiving only services such as cooking, housecleaning, or laundry services). Additionally, HHAs must collect OASIS data on both public and private pay patients because section 1891(b) of the Act requires the Secretary to assure that the COPs and other requirements are adequate to protect all individuals under the care of the HHA. As we gain experience with OASIS, we will consider adjusting the patient populations and/or data items collected, consistent with our statutory mandate.

Comment: One commenter had concerns regarding terminally ill patients for whom a decline in status (a poor outcome) is expected, and whether the HHA will be penalized because the outcomes show a decline over the course of care.

Response: For terminally ill patients, death is an expected outcome; thus, conclusions about the quality of care for a patient cannot be made solely on the basis of whether or not the patient improved. The OASIS collects information on the patient's prognosis regarding recovery from illness, functional status improvement and life expectancy, and outcome measures are adjusted to accommodate these patient characteristics. Thus, HHAs that care for a large number of patients with poor prognoses are not placed at a disadvantage when their performance is compared to another HHA that serves a healthier population. This process of adjusting for differences in patient characteristics (case mix adjustment) is an important aspect of the OASIS and is also an important function in a prospective payment system.

Comment: One commenter stated that it would be helpful to know what outcomes HCFA will want reported in the next set of rules, stating that it seems a waste of time for everyone to set a data reporting system, when HCFA may mandate electronic submission of the data. Another commenter expressed concern that there is no approved software for the OASIS data.

Response: As discussed above, as a result of the statutory requirement that we develop a prospective payment system for home health agencies, we expect that HHAs will begin reporting OASIS data to HCFA in the very near future, as specified in the interim final rule published separately in today's **Federal Register**. That regulation and subsequent implementing manuals will outline the hardware and software requirements for the transmission of OASIS data. Therefore, HHAs will be aware of the OASIS reporting requirements as they integrate OASIS data collection into the work of the HHA.

Comment: Two commenters expressed concern about patient privacy issues. One commenter stated that OASIS contains personal information that patients may be reluctant to provide. Another commenter expressed concern about the confidentiality of OASIS data being used for benchmarking among HHAs nationally. The commenter especially objected to the information being shared with managed care organizations.

Response: We expect HHAs to protect the confidentiality of patient-specific OASIS information in accordance with Federal and State privacy requirements, just as they would any other part of the patient record. The condition concerning patient rights at § 484.10 provides that the patient has the right to confidentiality of the clinical record. In addition, the condition concerning clinical records at § 484.48 requires HHAs to protect the clinical record against loss or unauthorized use. Health professionals and HHAs have always had access to personal information that is necessary to provide patient care, and we expect the HHA to vigorously address confidentiality concerns in compliance with State and Federal laws.

The OASIS data set contains assessment data that is normally collected by the HHA in the course of delivering services. Disclosure of this data must comport with both Federal and State privacy protections.

Comment: One commenter stated that there is a need for HHAs to track outcome data. Several commenters stated that OASIS appears well conceived, and expressed support for the creation of a national database for outcomes measurement and benchmarking.

Response: We appreciate support for our efforts to improve outcomes of care in home health. As stated previously in this preamble, and as a result of the BBA, we will develop the database supported by the commenters.

III. Provisions of the Final Rule

We are adopting the provisions of the HHA COPs proposed rule related to comprehensive assessment and the provisions of the OASIS proposed rule, with the following revisions:

Section 484.18

- We revised paragraph (c) by removing the last sentence of the paragraph, which relates to review of the patient's medication.

Section 484.55, Reorganization

- To clarify the condition, we have rearranged the order of the standards in § 484.55 as follows: § 484.55(a) Initial assessment visit; § 484.55(b) Completion of the comprehensive assessment; § 484.55 Drug regimen review; § 484.55(d) Update of the comprehensive assessment; and § 484.55(e) Incorporation of the OASIS data set.

Section 484.55, Introductory text

- We revised the introductory text to require that the comprehensive assessment must accurately reflect the patient's current health status; and, for Medicare patients, the home health agency must verify the patient's eligibility for the Medicare home health benefit, including homebound status at the time of the initial evaluation visit, and at the time of the completion of the comprehensive assessment.
- We have also incorporated into the introductory text language from paragraph (d), which requires that the comprehensive assessment include information regarding the patient's progress toward desired outcomes.

Section 484.55(a) (Proposed § 484.55(b))

- In response to public comments, we revised paragraph (a)(1) to provide that the initial assessment visit must occur either within 48 hours of referral, or within 48 hours of the patient's return home, or on the start of care date ordered by the physician.
- We added, at paragraph (a)(1), the requirement that for Medicare patients, the initial assessment visit must include a determination of the patient's eligibility for the home health benefit, including homebound status.
- We removed the proposed requirement at paragraph (a)(1) that the initial assessment visit must be performed based on physician's orders.
- We revised paragraph (a)(2) to clarify that when rehabilitation therapy service (speech language pathology, physical therapy, or occupational therapy) is the only service ordered by the physician, and if the need for that service establishes program eligibility, the initial assessment visit may be made by the appropriate rehabilitation skilled professional.

Section 484.55(b) (Proposed § 484.55(c))

- We revised the title of the standard to read ''Completion of the Comprehensive Assessment''.
- We revised paragraph (b)(1) to provide that the comprehensive assessment must be completed no later than 5 calendar days after the start of care date.
- We added a new paragraph, (b)(2), to provide that a registered nurse must complete the comprehensive assessment, and for Medicare patients determine eligibility for the Medicare home health benefit.
- We added a new paragraph (b)(3) to provide that when physical therapy or speech language pathology is the only service ordered by the physician, the physical therapist or speech language pathologist may complete the comprehensive assessment and that occupational therapists may complete the assessment when the need for occupational therapy establishes program eligibility.

Section 484.55(c) (Proposed § 484.55(a))

We revised this paragraph by removing the term ''drug regimen review'' and providing that a comprehensive assessment must include a review of all medications the patient is using at the time of the assessment.

Section 484.55(d) (Same Paragraph Designation as Proposed)

- For the purpose of clarity, we made editorial changes to this paragraph. Specifically, we incorporated language previously located in paragraph (d) into the introductory text of § 485.55 and we removed language from paragraph (d)(1) and included it in the introductory text for paragraph (d).
- We have revised the introductory text of paragraph (d) to clarify that all updates and revisions of the comprehensive assessment include administration of the OASIS, as frequently as the patient's condition warrants, due to a major decline or improvement in the patient's health status.
- We revised paragraph (d)(1) to provide that the HHA must update the comprehensive assessment every second calendar month beginning with the start of care date.
- We removed the proposed requirement at paragraph (d)(2) that the comprehensive assessment must be updated when the care plan is revised for physician review.
- We redesignated proposed paragraph (d)(3) as (d)(2) and proposed paragraph (d)(4) as (d)(3).
- We revised redesignated paragraph (d)(2) to provide that the comprehensive assessment must be completed within 48 hours of the patient's return home from a hospital admission of 24 hours or more for any reason other than diagnostic tests.

Section 484.55(e) (Same Paragraph Designation as Proposed)

- We revised this paragraph to provide that the OASIS data items determined by the Secretary must be incorporated into the HHA's own assessment and must include: clinical record items, demographics and patient history, living arrangements, supportive assistance, sensory status, integumentary status, respiratory status, elimination status, neuro/emotional/behavioral status, activities of daily living, medications, equipment management, emergent care, and data items collected at inpatient facility admission or discharge only.

IV. Regulatory Impact Statement

We generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA)(5 U.S.C. 601 through 612) unless we certify that a final rule will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, States and individuals are not considered small entities. HHAs, on the other hand, are considered small entities for the purposes of the RFA. Consequently, we are including a statement of impact on the effect that this final rule will have on HHAs. Also, we have discussed associated costs in detail in the Collection of Information Requirements section of this preamble. The impact associated with reporting of OASIS data will be in a separate rule in today's **Federal Register**.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis for any final rule that may have a significant impact on the operation 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 outside of a Metropolitan Statistical Area and has fewer than 50 beds. We are not preparing a rural impact statement since we have determined that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

We also have examined the impacts of this final rule as required by section 202 of the Unfunded Mandates Reform Act. 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 this preamble, we estimate that the amount of the unfunded mandate associated with this final rule 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.

In this final rule, under § 484.55, we are requiring HHAs to use the core assessment data set, the ''Outcome and Assessment Information Set'' (OASIS) as part of the agency's comprehensive assessment; specific timeframes for the initial assessment; completion of the assessment; and, interim updates to the patient assessment. We believe that these requirements, though process-oriented, are predictive of good patient care and safety, as well as necessary to prevent harm to the patient. Our rationale for these timeframes is that by definition, a new patient who is referred to a home health agency for initiation of services is at a point of immediate and serious need. Likewise, as the complexity of the care needs of patients increase, so does the need for comprehensive assessment of the patient. The importance of the development and implementation of an effective care plan becomes paramount.

We believe that the timeframe requirements pose little or no additional burden on the HHA since assessments at these intervals would in all likelihood be performed in the absence of regulations. However, the timeframes serve as a strong performance expectation for HHAs that may not have adequate resources. If too many patient referrals occur together, effective service delivery to some patients could be delayed by the HHA's inability to see the patient quickly and to complete the needed comprehensive assessment. Thus, if an HHA recognizes that its workload renders it incapable of assessing a patient upon referral, the HHA must contact the patient's physician to arrange an appropriate start of care date or to determine if the patient requires immediate service.

In the March 10, 1997 proposed rule, we solicited comments on whether the specific timeframe requirements in § 484.55 are reasonable and consistent with current medical practice, and whether the timeframes should be used as benchmarks to ensure the timeliness of the assessment components, and to protect patient health and safety. In this final rule, we have addressed comments regarding timeframes in section V.A. of this preamble.

The existing COPs contain several requirements that address the need for patient assessment, including most notably an extensive, detailed list of items that are required to be covered in a plan of care, such as pertinent diagnoses, mental status, and functional limitations. (See § 484.18(a).) In this final rule, we emphasize the importance of the comprehensive assessment by establishing ''Comprehensive assessment of patients'' as a separate COP. We have specified the desired outcome of the assessment (that is, the identification of a patient's care needs). We have required the use of a specific assessment data set (OASIS) and we are allowing HHAs the flexibility to determine how best to meet patients' care needs. We believe that most HHAs now perform a comprehensive assessment for most of their patients as a current accepted practice. We need to balance the possible short-term increase in costs or other administrative burden, if any, on the HHA with the long-term fundamental positive effect on patient health resulting from an organized and timely comprehensive assessment.

We anticipate that HHAs will incur some costs associated with the implementation of this final rule. It is unknown at this time exactly how many HHAs will receive an adjustment to the per visit limits associated with these costs, which was announced in a **Federal Register** notice on August 11, 1998. Only HHAs that have not already reached the per beneficiary limits will benefit from these adjustments through the HHA interim payment system. We estimate that approximately 70% of HHAs will not receive an adjustment for the costs associated with implementing this final rule. Because these HHAs have reached their per beneficiary limits, they will not be reimbursed by Medicare for the costs associated with OASIS collection start up activities. Those HHAs still below these limits will be reimbursed by Medicare. However, we also expect that the HHAs that will not be reimbursed by Medicare will, to varying degrees, be reimbursed by a combination of the Medicaid program, private insurers and beneficiaries. A table projecting the costs to HHAs for the implementation of the use of the OASIS is included at section V.C.3. of this preamble. 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 per visit and per beneficiary limitations for HHA costs (63 FR 42912). That notice included an OASIS offset adjustment factor to the per visit limitation to address these costs. In that notice, we asked for specific comments, including data, that would impact future decision making on HHA cost limitations. While, in the March 7, 1997 proposed rule, we indicated implementation in 1998 and an estimated start-up cost for 5 years, we now realize that implementation of the final rule will occur in fiscal years 1999 and 2000, and that the start-up costs associated with implementation of this final rule will be incurred by HHAs in existence, and participating in HCFA programs as of the effective date of the rule. Therefore, HHAs that are certified after the effective date of this final rule will not have established patient assessment protocols requiring change to meet the HCFA requirements. Accordingly, these HHAs will not have the corresponding start-up costs associated with a change of protocols. (See table 1 in section V.C. of this preamble.) We strongly believe that the benefits associated with the use of OASIS data will far outweigh its costs.

As discussed above, OASIS data will improve the delivery of quality care in the nation's HHAs in several ways. HHAs will find the information helpful in organizing care planning, and the increased specificity in patient assessment will assist agency staff to uniquely tailor a treatment plan to each individual patient. Also, this data will become an integral factor in the development of case mix adjusters for a home health agency prospective payment system, as authorized by sections 4602 and 4603 of BBA '97.

The Balanced Budget Act of 1997 requires HCFA to develop a prospective payment system (PPS) 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 PPS, 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 PPS. 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. 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 PPS 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 from past payment levels for these 90 HHAs and from national payment levels. This helps to ensure that if case mix changes over time, or if resource use varies from region to region, payments in the PPS 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 PPS.

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. In addition to its use as the basis for PPS, 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 PPS.

On a more global scale, once data from the OASIS are available in the form of standardized outcome reports, consumers, purchasers, providers, and HCFA will be able to use the information to evaluate quality of care across the full spectrum of HHAs. The home health industry can use the data for comparative performance assessment. HCFA and State survey agencies will be able to use the data on a continuous basis to identify providers that are not performing as well as others. This use will allow us to further progress in our efforts to develop a more efficient and targeted survey approach.

The impact of these final regulations will vary from HHA to HHA depending upon an HHA's current assessment process. The additional impact on HHA workload centers around collection of information and paperwork burden. There are no other requirements in this final rule that will impact HHAs. As discussed in detail and illustrated in the tables in section V.C. of this preamble, implementation requirements of § 484.55, will not have a significant overall effect on the economy.

Section 804(2) of Title 5, United States Code (as added by section 251 of Pub. L. 104–121), specifies that a ''major rule'' is any rule that OMB finds is likely to result in—

- An annual effect on the economy of $100 million or more;
- A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or
- Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic export markets.

Our estimation of the impact of this final rule does not meet the above definition of a major rule in Title 5, United States Code, section 804(2). Therefore it will not be forwarded to Congress for a 60-day review period.

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

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.

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we are submitting to OMB the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR Part 1320. This is to ensure the timely availability and reporting of data as necessary for the development of a reliable case mix adjuster that is required by section 4603(a) of BBA '97 for the establishment of a prospective payment system for home health services in compliance with sections 4602 and 4603 of BBA '97. 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 HCFA to collect reliable OASIS data for the period beginning on January 1, 1999. This timeframe is necessary because a key aspect of creating a prospective payment rate system based on agency cost experience is the need to ''standardize'' the rates. The overall objective of standardization is to ensure that when the standardized payment rate for an episode of care is adjusted by the case-mix and the wage index, the results are consistent with the costs in the data base used to construct the prospective payment amounts. That is, when the average standardized payment rates are multiplied by the appropriate wage and case mix adjustment factors, and summed for all relevant episodes, the sum is equal to the total costs in the original data base. We know of no reliable way to accomplish this result except by using data from existing agencies. Because the payment system must be implemented, we will need to begin receiving the OASIS data to be used for standardizing the payment amounts as soon as possible.

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 the BBA, in October of 2000. As stated earlier in this preamble, the process of rate development must take place in the early spring of 1999 for incorporation in a proposed rule. The home health prospective payment system proposed rule 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 prospective payment rate development and thus seriously undermine the project plan aimed at implementation of the prospective payment system on October 1, 2000.

This notice explicitly seeks OMB reapproval, with revisions, of HCFA–R–39 (OMB # 0938–0365), ''Home Health Medicare Conditions of Participation Information Collection Requirements as Outlined in Regulation 42 CFR 484'', with a current expiration date of 11/30/2000. It should be noted that this revision includes the OASIS protocol that was proposed in HSQ–238–P, ''Use of the OASIS as Part of the Conditions of Participation for Home Health Agencies'' (62 FR 11035). We are not only asking for approval of OASIS but also reapproval of the existing conditions of participation.

The version of OASIS approved by the Secretary and for which we are seeking OMB approval is available on HCFA's website on the Internet for HHAs to download 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. Any future changes to OASIS will be submitted to OMB to review pursuant to the Paperwork Reduction Act of 1995, will be available on the HCFA website, and, when approved by OMB, available in hard copy from the National Technical Information Service (NTIS) at (703) 487–4650.

We are requesting OMB review and approval of these collection requirements 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 addressees referenced in section V.A. of this preamble, within 15 working days from the date of publication of this regulation.

During this 180-day 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.

A. Responses to Public Comments on Collection of Information Requirements

Comment: Commenters suggested that the proposed requirement at § 484.55(d)(2) to update comprehensive assessment forms on patients each time the plan of care is revised, would be unnecessary, burdensome, and costly.

Response: HCFA specified in the proposed regulation at § 484.55(d)(2) that the comprehensive assessment must be updated whenever the plan of care is revised for physician review. However, after further consideration, we agree with the commenter that the requirement to update comprehensive assessment forms each time the plan of care is revised, at proposed § 484.55(d)(2), is unnecessary and accordingly, we have not included the requirement in this final rule.

Comment: Some commenters suggested that OASIS data collection requirements are excessive, both in terms of the number of items and the frequency that the assessment must be performed. Commenters stated that this could result in increased visits, particularly for rural public health agencies.

Response: Findings from the Medicare OASIS demonstration indicate that, after completion of the learning curve, this data collection requirement does not impose ongoing burden on HHAs. Currently, it is common practice for agencies to conduct ongoing assessments of patients. While the frequency of ongoing patient assessment is based on the needs of the individual patient, completion of the OASIS items, which may be only part of the assessment, must be done at standardized time points for comparable data and for the development of case mix adjusters for use in the creation of prospective payment rates. We also disagree that the data collection requirements will increase visits. We have specified timeframes for assessment that are intended to provide the HHA flexibility, and to diminish burden.

Comment: Several commenters stated concerns regarding increased paperwork burden and the associated cost of producing new forms to include the OASIS items.

Response: We acknowledge that developing and reproducing new forms that incorporate the OASIS into an HHA's own comprehensive assessment may create start-up costs for the HHA. Medicare OASIS demonstration data indicates that an agency may incur costs of approximately $280 to revise the start of care, assessment updates, and discharge forms. (See table 2 below.) Therefore, in our start-up cost estimates, we have now included a one time printing cost of $280 for the first year.

Comment: One commenter suggested that we have underestimated the time for the learning curve as it relates to the OASIS. The commenter stated that the HHA staff will not be proficient in using the OASIS data after only 5 uses as estimated in the proposed rule.

Response: We recognize that learning curves may vary from HHA to HHA, and person to person, and that some agencies may take longer than our estimates to become familiar with the OASIS. Therefore, we have adjusted our estimate of the number of uses required for the staff to become proficient with OASIS to eight uses. Findings from the Medicare OASIS demonstration indicate that use of the OASIS initially adds approximately 15 minutes per person more than the time taken for an HHA's existing assessment protocol. Then, rather than project a time savings after the first 8 uses, as some research seems to suggest, we have estimated neither a gain nor loss to the completion time.

Comment: Several commenters suggested that 2.5 minutes is an underestimation of the additional time necessary, above the HHA's routine patient assessment, for completion of the OASIS. Other commenters recommended that HCFA's estimate of an additional 2.5 minutes to complete OASIS items should be increased to 3 minutes.

Response: We believe that our original estimate of 2.5 additional minutes required to complete a comprehensive assessment that includes the OASIS is inaccurate. We have heard from agencies that participated in the OASIS demonstration about a time savings of 1 minute per assessment. The ease with which OASIS items can be assimilated into a comprehensive assessment process is apparent because all of the OASIS items are typically included in any effective, relevant comprehensive assessment of a patient.

Our analysis of data indicates that after the initial learning curve, ongoing OASIS data collection poses no additional burden above the routine patient assessment. In fact, agencies that participated in the Medicare OASIS demonstration required one minute less overall for completion of the patient assessment that included the OASIS than HHAs that did not use OASIS-incorporated assessments. However, as stated above, for the purpose of estimating burden on the provider community, we have not factored in the time savings mentioned above.

Comment: Several commenters requested that HCFA guarantee the availability of OASIS software prior to implementation of the requirements for the use of OASIS as part of the Medicare conditions of participation for home health agencies.

Response: The required OASIS form is available on our website at the following address: http://www.hcfa.gov/medicare/hsqb/oasis/oasishmp.htm. HHAs may access the HCFA website and download the required OASIS for each data collection time point. For example, data sets are available for start of care, resumption of care following an inpatient facility stay, follow-up, discharge (not to an inpatient facility), transfer to inpatient facility (with or without agency discharge), and death at home. In addition, HCFA will provide software on its website that can be downloaded and used to collect and report OASIS data. This software, the Home Assessment Validation Entry (HAVEN), will include the data specifications, data dictionaries, OASIS, a user's manual for the OASIS, the HAVEN manual, and the HHA submission manual. Other educational materials for the HHA will also be posted on the HCFA website. This medium was chosen, and will be supported by HCFA to provide for direct access by HHAs, State agencies, software vendors, professional organizations, and other 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 that we anticipate will evolve over time.

Comment: Many commenters agreed that the OASIS items are similar to those that most agencies assess for their patients and should impose a minimal burden once they have been successfully incorporated into an HHA's assessment process. However, commenters stated that HCFA underestimated the time necessary to integrate OASIS into existing assessment forms.

Response: We agree that OASIS items are similar to those that most agencies use for their patients and that the OASIS should impose only a minimal burden once successfully incorporated into the assessment process. We stated in the proposed regulation that for each HHA a clerical employee would take 16 hours to integrate the form. Ongoing research indicates that revising assessment forms to incorporate the OASIS items will require 12 hours of clinician expertise and involvement, and 4 hours of clerical assistance (for a total of 16 hours). Therefore, we have revised the estimates accordingly. Further discussion on the reassessment of the start-up requirements, along with corresponding revisions to the summary tables, are below in section V.C. of this preamble.

Various firms have developed an integrated clinical record (that is, OASIS items integrated with other items necessary for good clinical assessments) available for purchase. Based on an observation of the Medicare OASIS demonstration, approximately one half to two-thirds of agencies will purchase forms (to use ''as is'' or with minor modifications). Since an agency will have the option of purchasing integrated forms, or developing its own forms, we believe that the burden for the average agency to integrate the OASIS into its existing assessment forms will be less than the 16 hours we have estimated for inclusion of OASIS elements into assessment forms.

Comment: Many commenters expressed concern that HCFA substantially underestimated the time and cost required to train agency staff on implementing OASIS. Commenters also stated that the proposed rule referred to training only full time staff, did not consider the training of part-time or contracted staff, nor did it consider the cost of staff turnover.

Response: After careful consideration, we have re-estimated the time and cost involved in training agency staff on the implementation of OASIS. Based on additional information we received from the Medicare OASIS demonstration, we have determined that training for OASIS data collection is necessary for two categories of HHA employee, an agency coordinator and the clinical staff. We estimate that the agency coordinator, specified as the individual who conducts training or clinical supervision for clinical staff, will need to read the OASIS manual (4 hours) and attend an 8-hour training session (for a total of 12 hours to train the coordinator). We also estimate that each clinical staff member in the agency will require an average of 3 hours of training, to include practice and retraining, if indicated. Additionally, we expect that training on data collection in general, data collection for follow-up assessments, and data auditing will be included within the 3 hours of staff training. In light of the Medicare demonstration, we have also re-estimated the total number of training hours stated in the March 10, 1997 proposed rule for the clinical staff to 3 hours (3 hours per clinical staff member). The estimated average training costs for each HHA have been increased to $1659 (that is, $144 more than the estimate of $1515 in the proposed rule). Training for part-time and contracted staff was considered; however, we calculate amounts for staff as full-time equivalents which encompasses HHAs' flexible staffing practices. Training costs associated with staff turnover should be considered part of an agency's normal operating costs.

Comment: Several commenters stated that in the proposed rule, HCFA did not accurately address the burden as it applies to the cost of developing the necessary educational programs, or the costs associated with preparing training materials.

Response: As part of the ongoing operating costs, an agency that wants to develop training and educational programs is free to do so. However, we have not developed cost estimates for additional training because individual agency training policies and needs vary to such a great degree.

Comment: Several commenters stated that the proposed rule provided no transition time for incorporation of OASIS into an agency's comprehensive patient assessment, or to develop related policies and procedures.

Response: Although HCFA did not specify an exact transition period, as discussed above in this preamble, requirements for a comprehensive assessment as a COP for HHAs and for the incorporation of OASIS into an HHA's patient assessment were published in the March 10, 1997 **Federal Register** in separate proposed rules. This final rule will become effective 30 days after the date of publication in the **Federal Register**.

Comment: A few commenters indicated that the timeframes for implementation will be cost prohibitive. Commenters also stated, that HCFA's estimated national HHA cost of $50 million dollars, although reimbursable, suggests a waste of taxpayer money and would unnecessarily raise the cost of health care.

Response: Fifty million dollars is a misstatement of what we estimated in the March 10, 1997 proposed rule. Our

final estimates of start-up costs indicate that HHA costs will decrease with the implementation of OASIS. As stated above, in the August 11, 1998 notice, we included an OASIS offset adjustment factor to the per visit limitation to address the costs. In that notice, we solicited specific comments, including data, that would impact future decision making on this issue. We believe the benefits of using the OASIS far outweigh the burden since the OASIS will promote standardization of information on patients. We believe that an HHA can integrate a core standard assessment data set (OASIS) into its own more comprehensive assessment system, then use that data set as the foundation for valid and reliable information for patient assessment, care planning, and service delivery. Also, we are using the OASIS data set to comply with section 1891(d)(1) of the Act, which gives the Secretary the authority to designate an assessment instrument for use by HHAs. As discussed above, OASIS data will support the BBA '97 requirement that mandates the implementation of a prospective payment system for HHAs. Therefore, we need OASIS data to develop case mix adjusters for standardizing HHA prospective payment amounts. To this end, we believe the prospective payment system will save taxpayer dollars.

Comment: Commenters suggested that use of the HCFA–485 form in conjunction with the OASIS is duplicative. They questioned whether information from the HCFA–485 will be sent to HCFA for use in the OASIS data base, whether the HCFA–485 form will be changed to a standardized format to make the information more useful to HHAs, or whether the HCFA–485 form will be discontinued.

Response: The HCFA–485 form and the OASIS are designed to serve two different purposes. The HCFA–485 is the plan of care form developed for payment purposes. It contains a certification statement that must be signed by the patient's physician, and the HHA must continue to maintain the HCFA–485 in the patient's medical records. The OASIS does not provide for the physician certification needed to authorize payments to HHAs for covered services.

B. Condition of Participation: Comprehensive Assessment of Patients (§ 484.55)—Discussion and Summary

The HHA condition of participation for the comprehensive assessment of patients at § 484.55 requires that each patient receive a comprehensive assessment that incorporates the exact use of the current version of the OASIS as part of the HHA's patient assessment. The OASIS includes only information necessary to measure outcomes of care for quality indicators. Accordingly, our intent is not to develop a complete patient assessment, but rather to identify standardized data elements that fit within the HHA's overall comprehensive assessment responsibilities. Therefore, we require that HHAs use the current version of the OASIS as specified in § 484.55(e). We believe this requirement is necessary to build a valid, reliable, comparable data set of outcomes. As discussed in the proposed rule, and elsewhere in this preamble, the items on the OASIS have undergone rigorous validity and reliability testing so that trained individuals can have confidence in incorporating the data items as part of their comprehensive assessment of patients. As long as the HHA staff conduct assessments accurately and use the measurement criteria specified for each item, in any HHA, the validity and reliability extend to the comparability of the data acquired using the same items to collect information from other patients. Altering the items or using a different data set, destroys the essential validity and comparability of the data collected. HHAs may distribute the OASIS items within the agency's own comprehensive assessment system as long as the items remain within the groupings as they appear in the current version, and as specified by the Secretary.

We intend for the OASIS to become one of the most important tools of the HHA's quality assessment and performance improvement efforts. By integrating a core standard assessment data set into the HHA's own more comprehensive assessment system, HHAs can use the data set as the foundation for valid and reliable information for patient assessment, care planning, and service delivery. Also, HHAs can use the data set to build a strong and effective quality assessment and performance improvement program. We believe, except as discussed below, that these requirements pose little or no burden for well managed HHAs since a comprehensive assessment would in all likelihood be performed in the absence of regulations. However, we acknowledge that the timeframes required by § 484.55 serve as a strong performance expectation for HHAs.

In summary, the information collection requirements in this final rule ensure that HHAs increase the precision of patient assessments and continue to demonstrate whether they meet the conditions of participation in the Medicare and/or Medicaid programs. The frequency of the revised information collection in the Medicare home health conditions of participation remain on an ''as needed'' basis. The affected public continues to be businesses or other for-profit and not-for-profit institutions. Due to changes in the number of certified home health agencies, as of March 1998, the number of respondents has increased to 10,492.

Except for the specific information collection for the OASIS for which we are requesting emergency approval from OMB (as discussed in detail below) we do not anticipate an increase in burden as a result of incorporating § 484.55 Condition of participation: Comprehensive assessment of patients into the HHA conditions of participation. In section V.A. of this preamble, we address public comments on the collection of information requirements of the comprehensive assessment of patients COP combined with comments on the use of the OASIS. However, we are interested in obtaining comments on the changes from the proposed rule regarding the currently approved home health conditions of participation information collection requirements, as referenced in this regulation, and on modifications of the burden discussed in detail in this section and summarized in tables below.

C. OASIS—Discussion and Summary

As discussed in section III. of this preamble, final regulations at § 484.55 will require HHAs to use the OASIS as part of a comprehensive assessment of the patient. In the proposed rule, we stated that the burden from requiring HHAs to collect OASIS data could be divided into the two categories of activities: those activities required for startup, and those required for ongoing data collection. The first burden category of activities that are required for startup include incorporating the OASIS data into an HHA's clinical records, initial adaptation to use of the OASIS, and training agency staff. After the initial startup activities, we stated that the second burden category arose from the ongoing collection of the OASIS data. Based on data obtained from the Medicare demonstration, we have reconsidered our original estimates, in addition to making technical mathematical corrections. While the overall actual burden has not increased from the proposed rule, our reassessment indicates that since OASIS implementation will occur in fiscal years 1999 and 2000, the burden estimate for subsequent years is zero. After the initial startup costs, HHAs will

have become familiar with OASIS, and its use will then be a common business practice for HHAs.

1. Startup Activities: Time and Cost

We expect HHAs to incorporate the OASIS data into their clinical records to minimize the documentation burden by not having to complete different forms with similar questions, and to increase the precision of patient assessments. Once the data items are incorporated into the clinical records, information can easily be collected at start of care and at each follow-up time point (that is, every two calendar months; within 48 hours after the return home from a hospital admission; and at discharge).

• Inclusion of OASIS Elements Into Assessment Forms

The following estimates are based on the experience of HHAs that participated in the development of the home health quality indicators.

We define an average-size HHA as having 18 clinicians and other service practitioners and 486 admissions per year. We estimate that the time required by an average-sized HHA to integrate OASIS into the HHA's assessment forms is approximately 16 hours. This 16 hours includes 8 hours required to revise the initial assessment forms, 4 hours to revise the clinical record forms for follow-up visits, and post hospital admissions. Many items in the discharge follow-up are identical to the follow-up assessment and the assessment within 48 hours after hospital admission, but there are several data elements associated with discharge that will result in an additional 4 hours for revisions of discharge forms. Thus, the total burden for clinical record forms revision is estimated to be 16 hours per agency for integration of OASIS items for all 4 data collection time points. This estimate includes time associated with pilot testing the revised forms and subsequent revisions as necessary.

In the proposed rule, we based our estimates on the assumption that only clerical staff would integrate the OASIS data elements into an HHA's assessment forms. However, research from the Medicare OASIS demonstration indicates that revising forms will require both clinical involvement and clerical assistance. Therefore, we now estimate that the cost for an average-size HHA to revise the clinical records will be $339, based on 12 hours at an hourly rate of $24.05 for clinician time, and 4 hours at an hourly rate of $12.50 for clerical time ((12 hrs. × $24.05/hr.) and (4 hrs. × $12.50/hr.)). The total national hours for revisions of patient assessment forms are now estimated to be 167,872 hours based on 10,492 Medicare certified HHAs as of March 1998 (16 hrs. × 10,492 HHAs), with an associated national cost of $3.6 million ((12 hrs. × $24.05/hr. × 10,492 HHAs) and (4 hrs. × $12.50/hr. × 10,492 HHAs)).

• Printing Forms

The time required to revise clinical records to include OASIS items will vary for each agency, depending on the nature of their current documentation. For example, HHAs that have developed their own forms using word processing software may find it easier to merge or replace items than those agencies without that capability. We stated in the preamble to the proposed rule that most HHAs are accustomed to revising patient assessments periodically, as new assessment protocols become available or as new requirements are implemented by accrediting bodies or regulators. Thus, we did not estimate costs for printing at that time. However, based on the Medicare OASIS demonstration, research data has shown that the need to revise the start of care, assessment updates, and discharge forms may create startup costs. The inclusion of OASIS items may add up to three pages to some of the HHA start of care forms, and may also cause HHAs to revise assessment update and discharge forms. HHAs participating in the demonstration estimated an average of $280 in printing costs. Therefore, we have included an additional one time estimated cost of $280 for the first year to print the following forms:

New patient/start of care:	
500 forms × 3 additional pages × .03/page	$45.00
Follow-up:	
250 forms × 9 total pages × .03/page	67.50
Discharge:	
500 forms × 10 total pages × .03/page	150.00
Stapling Charges	17.50
Total	280.00

HHAs currently print their start of care assessment forms which, prior to the implementation of this rule, have not been required to include OASIS items. The average HHA conducts its comprehensive assessment using forms that may vary in length from HHA to HHA. Based on the Medicare OASIS demonstration, we are aware that in order to comply with HCFA policy, an agency may need to print the start of care forms when OASIS items have been integrated; the revised forms may increase the length of an HHA's assessment form by 3 pages. Therefore, we have estimated the cost to print an additional 3 pages. Once OASIS items are included in an HHA's clinical record forms, we believe the HHA will have only minor subsequent revisions for any future OASIS releases.

• Staff Training

In the proposed rule, we estimated 3.5 hours as the necessary training time per nurse (or other clinical staff within each HHA) for the new OASIS record keeping. We have revised this estimate to 3 hours based on research conducted through the Medicare OASIS demonstration. The 3 hours have been allocated for training on data collection for the initial assessment, data collection for assessment at follow-up, data collection at discharge, and data auditing. In the proposed rule, we provided a breakout of the training hours. However, since training needs may differ from agency to agency, we have not specified within this final rule, a breakout of how the 3 hours of training should be used.

Part of the training described above would include an emphasis on data accuracy to ensure the production of meaningful outcome reports. Other procedures to be used by the agency to monitor data accuracy (including interdisciplinary comparisons and record reviews) require training as they are implemented. Several approaches to data auditing could be explained in 30 minute training sessions. The projected 3 hours of training time for staff is expected to cost an average HHA with 18 clinicians approximately $1,299 (3 hrs. × $24.05/hr. × 18 clinicians). The projected 12 hours of training for the OASIS coordinator is expected to cost $360 per HHA (12 hrs. × $30.00/hr. × 1 coordinator). These estimates are based on an average hourly rate of $24.05 for the clinical staff and of $30.00 for the

OASIS Coordinator. The total national training burden is estimated to be 692,472 hours ((3 hrs. × 18 staff) and (12 hrs. × 1 coordinator) × 10,492) across all certified HHAs, at a cost of $17.4 million ((3 hrs. × $24.05/hr. × 18 clinicians) and (12 hrs. × $30.00/hr. × 1 coordinator) × 10,492 HHAs).

Once HHA staff are familiar with the OASIS items, OASIS data collection does not impose a burden above the current patient assessments. OASIS data are collected using a combination of staff observation and patient/care giver interviews. Initially, the OASIS data collection may take additional time until the HHA clinicians become familiar with the precision and format of the items. Estimates from providers using clinical records with integrated OASIS items on the ''learning curve'' indicate that the use of the OASIS initially adds approximately 15 minutes to the start of care assessment. However, as discussed above, after using the OASIS approximately 8 times, the additional time required to complete a comprehensive assessment that incorporates the OASIS into an HHA's existing patient assessment is eliminated. Thus, the total learning curve (of 8 uses until familiar with OASIS) for an average HHA is estimated to be 36 hours (8 uses × .25 hr. × 18 clinicians), at a cost of about $866 per HHA, based on an average hourly rate of $24.05 per clinical staff for 18 clinicians (36 hrs. × $24.05/hr.).

2. Data Collection

Most items included in the OASIS require information that the majority of HHAs currently gather during patient assessments. However, the OASIS employs a more precise scale. For instance, most HHAs assess a patient's ability to bathe in the course of an assessment, but use only three levels (independent, needs moderate assistance, or dependent). The OASIS item for bathing requires that the clinician assesses each patient's bathing ability on a more precise six-level scale.

In order to measure outcomes, OASIS data are collected at uniformly defined time points (start of care, every two calendar months, and within 48 hours after return to home from a hospital admission for any reason except diagnostic testing). Some data items are unique to only one point in time (for example, selected items are collected only at patient discharge), while other data are collected at every time point. By collecting data using uniform data items and time points, specific information on individual patients is comparable and can be aggregated to produce agency-level outcome reports that permit comparisons between different groups of patients.

Since the proposed rule was published in the **Federal Register** on March 10, 1997, we have collected data from the Medicare OASIS demonstration that prompts us to revise our previous estimate of ongoing costs for initial care, follow-ups, post hospital admissions, and discharges. The data indicates that after the initial learning curve, OASIS data collection on an ongoing basis poses no additional burden above an HHA's routine patient assessment. Instead, agencies that participated in the University of Colorado's OASIS Time Survey and that completed comprehensive assessments incorporating the OASIS required one minute less overall for completion of the assessment than did the agencies that completed comprehensive assessments that did not include OASIS. Therefore, we have determined that providers using clinical records with integrated OASIS items will not need additional time on an ongoing basis for initial care or discharges. We have revised our estimates accordingly.

Based on the above findings, for the purposes of this analysis, it will not take any additional time to complete OASIS for the follow-up and post hospital admission items. In fact, we believe that the burden associated with completing these assessments will diminish with the incorporation of OASIS, after the learning curve.

Finally, as we stated earlier in this preamble, the OASIS will be updated and improved periodically after implementation. We anticipate these changes to be refinements of existing items and the addition and deletion of items depending on their value. We believe the implementation of later iterations of the OASIS will result in a very small one-time cost to HHAs.

3. Summary of Cost and Burden Estimates

The estimated total national start-up costs across all certified HHAs is $32,986,848. (See table 1 below). In this final rule, changes from the proposed rule burden estimates are based on updated data that show an increase in the number of certified HHAs, the addition of clinician involvement in the integration of OASIS into existing assessment forms, the addition of printing costs that research identified, and the inclusion of OASIS coordinator training.

The following 3 tables provide a summary of the statistics for start-up and ongoing costs, burden to the average HHA, and combined cost for all HHAs for the collection of OASIS data. The tables are as follows: (1) National Costs to HHAs for Implementation of the OASIS; (2) Breakdown of Agency Start-Up Costs; and (3) Hourly Breakdown and Computation of the Average OASIS Start-Up Costs per HHA.

1. NATIONAL COSTS FOR IMPLEMENTATION OF THE OASIS

Year FY	Number of agencies incurring start-up costs	Start-up costs @ $3144 per HHA (in millions)	Medicare costs (in millions)	Costs to other sources (in millions)
1999 and 2000[1]	10,492	$32.99	[2] $9.89	[2] $23.10
2001	0	0	0	0
2002	0	0	0	0
2003	0	0	0	0

These costs are based on the following assumptions:

[1] Implementation will be in fiscal years 1999 and 2000.

[2] Medicare will reimburse approximately 30% of HHAs for their reasonable Medicare share of start-up costs, based on the estimate that approximately 30% of HHAs will benefit from the add-on adjustment to per-visit cost limits, published on August 11, 1998 in an Interim Payment System Notice. This estimate is reflected by indicating that 30% of $32.99 million (or $9.89 million) will be reimbursed by Medicare. The remaining 70% of $32.99 million ($23.10 million) will most likely be absorbed by a combination of the Medicaid program, private insurers, and beneficiaries, to whom we expect the balance of HHAs to pass along these start-up costs. Because approximately 23% of HHA patients are Medicaid beneficiaries, we expect HHAs to try to have the Medicaid programs absorb up to 23% of this remaining $23.10 million.

2. BREAKDOWN OF AGENCY START-UP COSTS

Task	Agency costs (in dollars)	National costs (agency costs × 10,492 HHAs in millions of dollars)
Start-Up (One-Time Only) Costs		
Integration of OASIS into existing assessment forms:		
Clinician Input—12 hrs. × $24.05/hr	$289	$3.03
Clerical Input—4 hrs. × $12.50/hr	50	.52
Subtotal	339	3.55
Staff Training:		
Coordinator—		
12 hrs. × $30.00/hr. × 1 coordinator	360	3.78
Clinicians—		
3 hrs. × $24.05/hr. × 18 clinicians	1299	13.63
Subtotal	1659	17.41
Learning Curve:		
8 × .25 hr. × $24.05/hr. × 18 clinicians	866	9.09
Printing Costs	280	2.94
Total Start-Up Costs	3144	32.99

3. HOURLY BREAKDOWN AND COMPUTATION OF THE AVERAGE OASIS START-UP COSTS PER HHA

[Does not include costs for printing]

Task	Hours	Computation of average costs	Average cost (rounded to nearest dollar)
Integration of OASIS into existing assessment forms (revisions):			
Initial assessment forms	8.0	12 hrs. × $24.05/hr. (Avg. Clinician rate)	$289
Clinical forms (57–62 day and 48 hours post-hospital admission).	4.0	4 hrs. × $12.50/hr. (Avg. Clerical rate)	50
Discharge forms	4.0		
Sub-Total	16.0	Sub-Total	339
Staff Training:			
Coordinator Training for data collection at initial assessment, assessment at follow-up, at discharge, and data auditing.	12.0	12 hrs. × $30/hr. × 1 Coordinator	360
Clinical Staff Training for data collection at initial assessment, assessment at follow-up, collection at discharge, and data auditing.	54.0	3 hrs. × $24.05/hr. × 18 Clinicians	1299
Sub-Total	66.0	Sub-Total	1659
Learning Curve:			
Initial and next 7 Uses of the OASIS Data Collection (.25 hr./use).		2 hrs. x $24.05/hr. x 18 Clinicians.	
(8 × .25 hr. × 18 Clinicians).			
Sub-Total	36.0		866
Per HHA Total	118.0	Total	2864
Total National Hours	1,238,056	Total Costs	30,049,088

Note: HCFA has requested OMB approval of the Outcome and Assessment Information Set to support the use of collecting patient information as part of the conditions of participation for HHAs. The average start-up costs per HHA for the first years of implementation (FYs 1999 and 2000) is estimated to require 118.0 burden hours. Subsequent years will require approximately 79 burden hours per year. The average burden over a 3-year period is estimated to be 79 hours per year ((118.0 + 118.0 + 0) ÷3) for a national average of 828,862 burden hours per year (79 hours x 10,492 HHAs). While the overall actual burden has not increased from the proposed rule, the totals have been revised in the tables based on data from the Medicare OASIS demonstration, our reassessment on ongoing burden, and technical corrections to the tables published in the proposed rule. We estimate OASIS implementation will occur in fiscal years 1999 and 2000 at 118.0 hours each. The third year burden estimate is zero by which time the OASIS will have become a common business practice for HHAs. Therefore, we are requesting a three-year OMB approval for an average of 79 burden hours per year.

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,* 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, Attention: John Burke HCFA–3007–F, 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, Attention: Allison Herron Eydt, HCFA Desk Officer, Fax number: 202–395–6974 or 202–395–5167

List of Subjects in 42 CFR Part 484

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

42 CFR chapter IV is amended as follows:

PART 484—CONDITIONS OF PARTICIPATION: 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 484.18 is amended by revising paragraph (c) to read as follows:

§ 484.18 Condition of participation: Acceptance of patients, plan of care, and medical supervision.

* * * * *

(c) *Standard: Conformance with physician orders.* Drugs and treatments are administered by agency staff only as ordered by the physician. Verbal orders are put in writing and signed and dated with the date of receipt by the registered nurse or qualified therapist (as defined in § 484.4 of this chapter) responsible for furnishing or supervising the ordered services. Verbal orders are only accepted by personnel authorized to do so by applicable State and Federal laws and regulations as well as by the HHA's internal policies.

Subpart C—Furnishing of Services

3. Section 484.55 is added to subpart C to read as follows:

§ 484.55 Condition of participation: Comprehensive assessment of patients.

Each patient must receive, and an HHA must provide, a patient-specific, comprehensive assessment that accurately reflects the patient's current health status and includes information that may be used to demonstrate the patient's progress toward achievement of desired outcomes. The comprehensive assessment must identify the patient's continuing need for home care and meet the patient's medical, nursing, rehabilitative, social, and discharge planning needs. For Medicare beneficiaries, the HHA must verify the patient's eligibility for the Medicare home health benefit including homebound status, both at the time of the initial assessment visit and at the time of the comprehensive assessment. The comprehensive assessment must also incorporate the use of the current version of the Outcome and Assessment Information Set (OASIS) items, using the language and groupings of the OASIS items, as specified by the Secretary.

(a) *Standard: Initial assessment visit.* (1) A registered nurse must conduct an initial assessment visit to determine the immediate care and support needs of the patient; and, for Medicare patients, to determine eligibility for the Medicare home health benefit, including homebound status. The initial assessment visit must be held either within 48 hours of referral, or within 48 hours of the patient's return home, or on the physician-ordered start of care date.

(2) When rehabilitation therapy service (speech language pathology, physical therapy, or occupational therapy) is the only service ordered by the physician, and if the need for that service establishes program eligibility, the initial assessment visit may be made by the appropriate rehabilitation skilled professional.

(b) *Standard: Completion of the comprehensive assessment.* (1) The comprehensive assessment must be completed in a timely manner, consistent with the patient's immediate needs, but no later than 5 calendar days after the start of care.

(2) Except as provided in paragraph (b)(3) of this section, a registered nurse must complete the comprehensive assessment and for Medicare patients, determine eligibility for the Medicare home health benefit, including homebound status.

(3) When physical therapy, speech-language pathology, or occupational therapy is the only service ordered by the physician, a physical therapist, speech-language pathologist or occupational therapist may complete the comprehensive assessment, and for Medicare patients, determine eligibility for the Medicare home health benefit, including homebound status. The occupational therapist may complete the comprehensive assessment if the need for occupational therapy establishes program eligibility.

(c) *Standard: Drug regimen review.* The comprehensive assessment must include a review of all medications the patient is currently using in order to identify any potential adverse effects and drug reactions, including ineffective drug therapy, significant side effects, significant drug interactions, duplicate drug therapy, and noncompliance with drug therapy.

(d) *Standard: Update of the comprehensive assessment.* The comprehensive assessment must be updated and revised (including the administration of the OASIS) as frequently as the patient's condition warrants due to a major decline or improvement in the patient's health status, but not less frequently than—

(1) Every second calendar month beginning with the start of care date;

(2) Within 48 hours of the patient's return to the home from a hospital admission of 24 hours or more for any reason other than diagnostic tests;

(3) At discharge.

(e) *Standard: Incorporation of OASIS data items.* The OASIS data items determined by the Secretary must be incorporated into the HHA's own assessment and must include: clinical record items, demographics and patient history, living arrangements, supportive assistance, sensory status, integumentary status, respiratory status, elimination status, neuro/emotional/behavioral status, activities of daily living, medications, equipment management, emergent care, and data items collected at inpatient facility admission or discharge only.

(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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