or university approved by a State department of education; or

(iii) Has 2 years of appropriate experience as a physical therapist, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking qualification as a physical therapist after December 31, 1977; or

(iv) Was licensed or registered prior to January 1, 1966, and prior to January 1, 1970, had 15 years of full-time experience in the treatment of illness or injury through the practice of physical therapy in which services were rendered under the order and direction of attending and referring doctors of medicine or osteopathy; or

(v) If trained outside the United States—

(A) Was graduated since 1928 from a physical therapy curriculum approved in the country in which the curriculum was located and in which there is a member organization of the World Confederation for Physical Therapy;

(B) Meets the requirements for membership in a member organization of the World Confederation for Physical Therapy,

(5) *Physical therapist assistant.* A person who—

(i) Has graduated from a 2-year college-level program approved by the American Physical Therapy Association; or

(ii) Has 2 years of appropriate experience as a physical therapy assistant, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that these determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as a physical therapy assistant after December 31, 1977.

(6) *Public health nurse.* A registered nurse who has completed a baccalaureate degree program approved by the National League for Nursing for public health nursing preparation or postregistered nurse study that includes content approved by the National League for Nursing for public health nursing preparation.

(7) *Registered nurse.* A graduate of a school of professional nursing.

(8) *Social work assistant.* A person who—

(i) Has a baccalaureate degree in social work, psychology, sociology, or other field related to social work, and has had at least 1 year of social work experience in a health care setting; or

(ii) Has 2 years of appropriate experience as a social work assistant, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that these determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as a social work assistant after December 31, 1977.

(9) *Social worker.* A person who has a master's degree from a school of social work accredited by the Council on Social Work Education, and has 1 year of social work experience in a health care setting.

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

Dated: July 15, 1996.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

Dated: August 16, 1996.

Donna E. Shalala,

Secretary.

[FR Doc. 97–5316 Filed 3–5–97; 9:45 am]

BILLING CODE 4120–01–P

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42 CFR Part 484

[HSQ–238–P]

RIN 0938–AH74

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

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would add additional requirements to the proposed revision to the conditions of participation for home health agencies (HHAs) which also appear in this issue of the Federal Register. Specifically, this proposed rule would require that HHAs use a standard core assessment data set, the ''Outcomes and Assessment Information Set'' (OASIS), when evaluating adult, non-maternity patients.

This proposed rule is an integral part of the Administration's efforts to achieve broad-based, measurable improvement in the quality of care furnished through Federal programs. It is a fundamental component in the transition to a quality assessment and performance improvement approach that focuses on stimulating measurable improved outcomes of care and patient satisfaction in the Medicare and Medicaid home health benefit while at the same time reducing burdens on providers.

DATES: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5:00 p.m. on June 9, 1997.

ADDRESSES: Mail written comments (one original and three copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HSQ–238-P, P.O. Box 7518, Baltimore, MD 21207–0519.

If you prefer, you may deliver your written comments (one original and three copies) to one of the following addresses:

Room 309-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW, Washington, DC 20201, or

Room C5–09–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Comments may also be submitted electronically to the following e-mail address: hsq238phcfa.gov. E-mail comments must include the full name and address of the sender and must be submitted to the referenced address in order to be considered. All comments must be incorporated into the e-mail message because we may not be able to access attachments. Electronically submitted comments will be available for public inspection at the Independence Avenue address below.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HSQ–238–P. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309–G of the Department's offices at 200 Independence Avenue, SW, Washington, D.C., on Monday through Friday of each week from 8:30 a.m. to 5:00 p.m. (phone (202) 690–7890).

For comments that relate to information collection requirements, mail a copy of the comments to: Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Allison Herron Eydt, HCFA Desk Officer.

Copies: To order copies of the Federal Register containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 37194, Pittsburgh, PA 15250–7954.

Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512–1800 or by faxing an order to (202) 512–2250. The cost for each copy is $8.00. As an alternative, you can view and photocopy the Federal Register document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the Federal Register.

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FOR FURTHER INFORMATION CONTACT: Mary Vienna, (410) 786–6940.

SUPPLEMENTARY INFORMATION:

I. Background

A. Purpose of Proposed Regulation

Separately in this issue of the Federal Register, we are publishing a notice of proposed rulemaking that would revise the current conditions of participation that HHAs must meet to participate in the Medicare program, the Medicaid program, or both programs. Those proposed regulations would make the conditions of participation more patient-centered and outcome-oriented and provide the HHAs with more flexibility to operate their programs. As an important part of those proposed revisions, we are introducing the proposed requirement that each HHA develop, implement, and manage an outcome-based quality assessment and performance improvement program. Such a program would provide a foundation for enabling an HHA to monitor the impact of its care on its customers' health status and satisfaction. The information that the HHA derives from this program will enable the HHA to implement real and lasting change to enhance outcomes of care.

In this proposed rule, we are proposing that Medicare-approved HHAs and those HHAs that are required to meet Medicare conditions of participation (which, by definition, includes Medicaid HHAs and managed care organizations providing home health services to Medicare and Medicaid beneficiaries) be required to incorporate the core standard assessment data set included in this proposal, called the ''Outcomes and Assessment Information Set'' (OASIS), into their comprehensive assessment process. (The use of the term ''HHA'' will be used throughout this discussion as a generic term to apply to all environments in which this regulation would apply.)

We intend that the OASIS become one of the most important aspects of the HHA's quality assessment and performance improvement efforts. 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, and service delivery, as well as to build a strong and effective quality assessment and performance improvement program.

B. Background of the OASIS

1. How HHA Quality Indicators Were Developed

We have long been interested in the development of outcome measures in health care. In 1988, we entered into a contract with the Center for Health Policy Research and the Center for Health Services Research at the University of Colorado Health Sciences Center to develop, test, and refine a system of outcome measures that could be used for outcome-based quality improvement in HHAs. The Robert Wood Johnson Foundation provided funding to support work on additional, related tasks. The system is intended to form the foundation for continuous quality improvement (which we call in the proposed conditions of participation published elsewhere in this issue of the Federal Register ''quality assessment and performance improvement'') that could be used to enhance care in agencies where quality is lacking, and to reinforce and further improve patient outcomes and satisfactory in HHAs where care is already exemplary.

Before the system could be constructed, numerous definitional and methodological issues had to be addressed. We are presenting a brief summary of those issues as part of this preamble. Anyone wishing a more detailed explanation of the work that was necessary to develop this system may request one of the publications referenced in this preamble.

We adopted the consensus definition of ''quality'' developed by the Institute of Medicine that states ''quality is the degree to which health services to individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.'' The usefulness of this definition is threefold. First, it recognizes that ''quality'' can occur in varying amounts, not simply in an all-or-nothing manner. Second, this definition encompasses the beneficiary's desires and expectations for outcomes, and not just what the ''professional'' decides. Third, it does not guarantee the desired outcome will be achieved. Rather, quality care ''increases the likelihood'' that needed or desired outcomes will be achieved. In this regard, the implied relationship between quality care or quality of services and outcomes highlights the fact that higher quality care should produce better outcomes. Consequently, the most effective indicator of the quality of care is the actual, consistent attainment of desired health outcomes. As a result, we regard outcomes as central to ensuring and improving care.

Overall, we define an ''outcome'' as a ''change in health status over time.'' In using this definition, we recognize that ''health status'' is a broad term, encompassing physiologic, functional, cognitive, social, and mental health. To properly measure a specific outcomes in any of these areas, it is necessary to collect precise information on the health status indicator of interest at the start of care and at followup points. Satisfaction, however, need only be measured at discharge, though it can be measured at interim points as well.

For our purposes, a patient- or consumer-level outcome can be thought of as a change in health status that occurs during the timespan that begins with the start of care and ends with either the discharge from the HHA or some other followup point after the start of care. Thus, changes in the status of a wound, ability to ambulate, shortness of breath (dyspnea), or ability to manage oral medications are outcomes when such changes are assessed between the start of care and followup time points. Hospitalization and use of emergency care during the home care interval can also be regarded as outcomes, since these events usually occur as a result of a change in health status, typically of an untoward nature. Indicators of consumer satisfaction are also outcomes in that they may represent changes in

cognitive or emotional status in response to home health care. Nonetheless, we sometimes speak of outcomes *and* satisfaction in this proposal to emphasize the importance of beneficiary satisfaction as a particular type of outcome.

A critical element of any quality assessment and performance improvement program in home health care is precise information about performance, particularly consumer outcomes. Such information must be available to the HHA so it can identify and remedy poor outcomes, identify and reinforce exemplary outcomes, and evaluate progress resulting from remedied or reinforced actions. The most efficient way in which HHAs can gather such information is by maximizing the overlap between items needed to measure patient outcomes and those routinely used for purposes of patient assessment, care planning, and service delivery.

The terms ''quality indicators,'' ''performance measures,'' and ''outcome measures'' are often used interchangeably, though technically they can vary somewhat in meaning. Regardless, they all refer to attributes of care and satisfaction that can be used to gauge quality in specific areas. For example, the degree of improvement in a functional area (such as ability to walk after a hip replacement) is a quality indicator. However, defining and quantifying that improvement results in a ''performance measure'' or ''outcome measure'' that assigns a numeric value to the attribute being evaluated. So, while it is accurate to say that improvement in ambulation is a ''quality indicator,'' the improvement becomes a precise and usable quantity measurement when we assign numbers to the patient's performance.

The first step in the development of quality indicators was to agree on outcomes that can be used as valid and reliable indicators of quality care. In dealing with such issues as payment and utilization, the outcomes of care and level of satisfaction the patient experiences can be overlooked. Although outcomes are not yet being measured systematically, we often assume that the care provided accomplishes what we expect. Home health care is no exception. While we recognize that patients have a strong preference for home care over most alternatives, we know little about the effectiveness of home care. Interest in the outcomes of home care, therefore, was arising from payers, accrediting bodies, consumers, and the home care industry itself. This interest provided impetus and credibility to the search for outcomes that can be used a valid and reliable indicators of quality care.

The way in which well-tested and established quality indicators are developed is straightforward, although time consuming and resource intensive. Clinical experts (especially those who actually deliver home care services to people), researchers, patients, and others (for example, administrators) ''nominate'' aspects of the total care process and the outcomes of care across a variety of patient conditions and problems. The list of candidate quality indicators can be very long, including relevant indicators from research, applied literature, and current use. From this list, expert panels group the nominees and specify them more precisely as workable representations of attributes of care, outcomes, or satisfaction that can be measured.

Once the set of nominated quality indicators (outcome indicators in this case) is refined and defined, it is further tested for validity, utility and reliability. When we test for validity and utility, we consider such issues as whether or not the indicators actually reflect what they purport to reflect in terms of patient outcomes, the ability to detect differences among patient groups or types of agencies which are expected to vary in terms of outcomes, utility for examining the effectiveness of care, and acceptance among clinicians. When we test for reliability, we consider such issues as whether or not the information collected on the same patient by different evaluators yields similar judgments about the performance indicators being measured.

As an illustration, we know that improvement in ability to ambulate is a quality indicator. During development of performance measures based on the nominated quality indicators, the specific definition of ''ambulation/locomotion status,'' that was used in testing for validity and reliability, included a six-level scale (0–5). This scale described ambulation from completely bedfast to independence by using specific and precise terminology associated with each of the six levels on the scale. The wording for each level was carefully chosen and refined through both expert review and empirical testing. For example, the one-level in the scale states: ''Chair fast, unable to ambulate even with assistance but is able to wheel self independently.'' The wording for this particular level was specified, reviewed, and then tested by having different care providers collect this information on the same patients to assess the extent of agreement and reliability among different raters. Appropriate changes were made and further testing was conducted in terms of utility and clinical acceptability, with additional refinements occurring as needed.

To properly measure outcomes as changes in health status between two time points, reliable and precise health status scales such as the ambulation scale are needed to render the outcome measures themselves reliable and precise. All health status items in the OASIS underwent such testing since these items will be used for either measuring outcomes or for risk-adjusting outcomes for potential differences in agency risk factors or case mix. The OASIS also contains items relating to independence of functioning and available family and environmental support. While not directly ''health status items,'' they are vital measurements of the context in which a person's health status exists. For example, people with the same health status but with different supports may experience different outcomes.

The criteria the researchers used for selecting the outcome measures included:

(1) Clinical meaningfulness in terms of perceived importance of the measure for outcome-based quality improvement;

(2) Interrater reliability of the data items needed to compute the measures as reflected by two or more reviewers rating a patient's condition similarly;

(3) Diversity of the measures in terms of the different dimensions of health status including functional, physiological, behavioral/emotional, and cognitive status;

(4) Minimal redundancy in terms of clinical information content within the entire measure set;

(5) Validity as reflected by the abilities of the measures to detect agency-level differences in quality of care;

(6) Validity as indicated by the abilities of the measures to detect differences between patient groups or types of agencies expected to vary in terms of outcomes;

(7) Validity in terms of the clinical meaningfulness of relationships among outcome measures;

(8) Validity as reflected by the clinical meaningfulness of the relationships between outcome measures and risk factors or case mix variables;

(9) Sufficient prevalence from a statistical perspective so that the outcome measures would not signify extremely rare or extremely common events;

(10) Minimal statistical redundancy among measures, so that individual measures each can be shown to convey unique information; and

(11) Utility of the data items employed to define and compute outcome measures in terms of the meaningfulness and face validity of such items for assessment and care planning for home care patients.

As we discuss in detail in section I.B.2 of this preamble, the individual items of the OASIS are valid and reliable in computing those outcome measures of patient health status shown to be useful ''quality indicators'' for home care. When the HHA staff who complete the comprehensive assessment use the OASIS as part of the process, they are, in fact, laying the groundwork for planning an effective course of care for an individual patient and for a set of comparable performance data aggregated across patients that can help to shape the agency's agenda for continuous improvement.

We intend to require that HHAs use the OASIS exactly as specified. This requirement is a necessary predicate to building a valid, reliable, comparable data set of outcomes. The items on the OASIS underwent rigorous validity and reliability testing, as discussed in section I.B.2. of this preamble. Consequently, trained individuals can have confidence in using the data items as part of their comprehensive assessment of patients. This confidence extends, then, to the comparability of the data acquired using the same items to amass information from other patients, either in the same HHA or others, as long as the assessments are conducted accurately, using the measurement criteria spelled out for each item. Altering the items or using a different tool and transposing the data onto the OASIS destroys the essential validity and, therefore, the comparability of the data collected. The HHA can rearrange and/or distribute the OASIS items within the agency's comprehensive assessment system as long as the items themselves remain exactly as written and specified by the Secretary.

While this explanation of how the quality indicators were developed is brief, the actual work to develop more than 150 indicators took most of 5 years using expert clinical panels and volunteer HHAs for empirical field testing. Further details on how the home health quality indicators were developed, including validity and reliability testing, are included in the final report of *A Study to Develop Outcome-Based Quality Measures for Home Care*, available from the Center for Health Policy Research and Center for Health Services Research, University of Colorado, Health Sciences Center, 1355 S. Colorado Blvd., Suite 306, Denver, CO 80222. Additional information on outcome-based quality improvement can also be found in ''Measuring and Assuring the Quality of Home Care,'' *Health Care Financing Review*, 16(1):35–67, Fall 1994, and *Outcome Based Quality Improvement: A Manual for Home Care Agencies on How to Use Outcomes*, August 1995, National Association for Home Care, 228 South Street, SE., Washington, DC 20003.

2. Evolution of Medicare's Core Standard Assessment Data Set (OASIS)

As part of the Medicare Home Health Initiative started in 1994, we began discussions with the industry, professional and consumer groups, and enforcement agencies. These discussions articulated our desire that the new conditions of participation serve both the clinical needs of the agency and our emerging quality assessment and performance improvement agenda.

In late 1994, we convened a workgroup of clinical assessment experts representing HHAs and national associations of home care providers along with other experts in assessment, including a representative from the University of Colorado, to help shape the development of an assessment tool. The group suggested it was unnecessary to mandate a comprehensive assessment tool since the majority of agencies are already using such tools. The understandable diversity in such tools that arises from caring for special types of patients (for example, pediatric, chronic, high technology, or Human Immunodeficiency Virus patients) would render a single mandated comprehensive tool unwieldy. The group agreed that the required assessment set should be parsimonious, have maximal overlap with the types of information agencies are already collecting at assessment (to the extent possible), and be shorter and less complicated than the Resident Assessment Instrument, another Federal assessment instrument mandated for use by nursing homes.

The group recommended that we use the data items developed by the University of Colorado for computing risk-adjusted patient outcomes. The precision of the individual items in this data set makes them particularly useful in patient assessment and care planning in addition to their intended use in measuring outcomes. The workgroup recommended the addition of a small number of assessment items for a total of 79 (plus 10 patient identifier items, for example Medicare number, that are commonly used already for billing and other administrative purposes), and the core standard assessment data set was completed. We wish to make it clear that this data set is not, therefore, intended to constitute a complete comprehensive assessment instrument. Rather, the data set comprises items that are a necessary part of a complete comprehensive assessment and are essential to uniformly and consistently measuring patient outcomes. These items are already used in one form or another by virtually all HHAs, and many more are usually used by HHAs that conduct thorough assessments. Likewise, the OASIS comprises fewer items than the Resident Assessment Instrument, another Federal assessment instrument mandated for use by nursing homes.

The workgroup recommended that HCFA determine: (1) How the core standard assessment data set could be incorporated into HHAs' patient assessment processes (HHAs would need to include additional items for the purpose of ''comprehensive'' patient assessment); and (2) if the tool was effective in assisting home health clinical staff to assess certain aspects of patient health and functional status, thus providing information necessary for effective and efficient care planning and service delivery. As the workgroup was concluding its work on the core standard assessment data set in early 1995, the University of Colorado was embarking on a new HCFA-funded project to demonstrate how the quality indicators developed during the previous 5 years could be used. The primary goal of the new project was to assess whether the data set would be of value in targeting and guiding improvements in outcomes and satisfaction for HHA patients. The researchers agreed to use the data set as modified by HCFA and to pilot its effectiveness as the core standard assessment data set. It was at this point that the data set was named the *O*utcomes and *AS*sessment *I*nformation *S*et, or OASIS.

The demonstration currently underway involves the voluntary participation of 50 HHAs distributed across the country. They have been trained to use the OASIS and have begun collecting and transmitting data to the Research Center at the University of Colorado. (The Research Center is also testing a telephone satisfaction questionnaire that is being administered to patients after HHA discharge. The results will help assess the relationship between outcomes and satisfaction.) Data are returned to the HHA as outcome reports, so that the HHA can see how it is performing in terms of

patient outcomes compared with other HHAs in the project. As each data reporting period passes, the database builds, providing additional comparative data back to agencies for use in planning and implementing performance improvement activities. Subsequent outcome reports can assist in evaluating the effectiveness of such activities.

For example, a particular HHA receives an outcome report that shows that 20 percent of its orthopedic patients improved in ability to ambulate by either the 60th day of treatment or the date of discharge, depending upon which came first. The HHA's 20-percent outcome compares with a 40-percent aggregated outcome of the orthopedic patients from all demonstration agencies. Because this 20-percent outcome finding is significantly less than the 40-percent aggregated outcome, the staff makes a determination that this is an outcome that should be investigated further. Using record review, team evaluation and other quality improvement techniques, the HHA staff determines that a potential reason for the low rate of improvement is lack of coordination between physical therapists and other care providers. This lack of coordination, in turn, results in minimal reinforcement of patient exercise programs by others on the care delivery team. The agency staff, therefore, develops and implements a precise action plan or performance improvement plan that strengthens team coordination of specific and relevant caregiving actions. The next outcome report indicates that the number of orthopedic patients improving in ability to ambulate is 35 percent, suggesting that the performance improvement activities resulted in better patient care, thereby producing improved outcomes.

Thus, collection of OASIS data can be used not only in patient-level applications (assessment, care planning, and care delivery) but also for agency-level performance improvement. As an HHA improves over time across various outcome dimensions, the aggregated data will show improvement as well, and average agency performance will likewise continue to improve. Not only will this be advantageous for Medicare beneficiaries and other home care clients, but it will be of value to the home care industry in demonstrating its effectiveness. We want to stress, however, that in order for the OASIS data to be helpful for *all* its purposes, the OASIS items must be filled out accurately. As they begin to collect the OASIS items, HHAs should set up procedures to monitor data accuracy such as conducting validation visits to verify accuracy, interdisciplinary comparisons and record reviews. In fact, data entry accuracy can, and should be, an essential part of the HHA's quality assessment and improvement program, since data accuracy is a fundamental building block of an effective program.

We are aware that large numbers of HHAs are using the OASIS in an informal environment, without direction or guidance from HCFA or the University of Colorado. While we are looking to the Medicare demonstration to answer operational questions regarding the aggregation of OASIS data and their use to improve patient outcomes, we are interested in the experience of those HHAs that are using the OASIS under their own initiative. We are seeking public comments from those HHAs on the following questions:

- How is the OASIS helpful in determining changes in patient health status between two points in time?
- How is the OASIS useful for measuring the outcomes of patients who are prescribed physical therapy, occupational therapy, speech therapy, skilled nursing services, or aide services? How is the OASIS useful for patient evaluation and management?
- How is the OASIS useful for care planning and prescribing services? Could the OASIS be made more useful and, if so, how?
- How is the data in the OASIS useful for identifying and interpreting differences in both the severity and complexity within agency caseloads? Could the OASIS be made more useful and, if so, how?
- What level and type of support (for example, training, monitoring of staff) is required to generate information from the OASIS for use in assessment, care planning, and quality assessment and performance improvement?
- If you have used the OASIS data to produce agency-level reports, are they useful in identifying negative and positive patient outcomes?
- Are there specific domains in which the OASIS is particularly strong or particularly weak?
- Are there other data items that produce information that may be more useful in measuring outcomes in a particular domain?

3. Content and Planned Evolution of the OASIS

For purposes of public comment, we are reprinting the current version of the OASIS in section II of this preamble. The Center for Health Policy Research at the University of Colorado has granted permission for this sample OASIS survey to be published and reproduced. HCFA will provide HHAs with copies of the OASIS and instructions for its use as a manual issuance when the final rule is published. All OASIS data items were developed for outcome measurement, risk adjustment, or patient identifiers. Data items address 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 information. While some data items do not directly address health status, they are vital measurements of the context in which a person's health status exists. For example, people with the same health status but with different supports (financial, caregiver, etc.) may experience different health outcomes. These characteristics should be part of a comprehensive patient assessment, but we again emphasize that the OASIS was not developed to be a comprehensive assessment instrument. HHAs must supplement the OASIS items to comprehensively assess the health status and care needs of patients. For example, the OASIS does not include vital signs, which are a common part of a patient's assessment.

Most OASIS items require the same information that the majority of care providers currently gather in patient assessment, but the OASIS requires the information on a more precise scale. For example, many care providers assess each patient's ability to bathe, but only use three levels, independent, needs moderate assistance, or dependent. The OASIS items ask the care provider to assess the same functional ability (bathing) on a more precise six-level scale. This greater precision results in items that are more descriptive for clinical purposes and more reliable and valid statistically and, thereby, improves their utility in an outcomes improvement, database environment. Consequently, items in clinical records that have analogues in the OASIS should be replaced by the corresponding OASIS items so that all certified agencies will be collecting information using precisely the same items to ultimately measure and risk adjust outcomes.

When the final rule has been promulgated, we will include the instructions and definitions necessary to use the OASIS in the notification to the HHAs. At the present time, however, we wish to clarify several items in the current OASIS. These are:

- Overall Progress, Rehabilitative Prognosis, and Life Expectancy

While these are common assessment items, they are included in this version of the OASIS with the expectation that they will be a part of the data we intend to collect. They have been shown, thus, far, to be highly predictive of health status outcomes. In the controlled environment of the reliability and validity testing of these items where data accuracy is verified, these items correlated well with other items that track functional status. In other words, patients judged to have low rehabilitation potential tend to show less change in health status between two points in time. If these items retain their predictive power through the demonstration and are retained in later versions of the OASIS, they will be useful items for ''sorting'' performance or analysis and for searching for opportunities for improvement. For example, if an HHA reports many patients with high rehabilitation potential, but functional status measures of these patients (risk-adjusted) show poorer results than other high rehabilitation potential patients in other HHAs, an opportunity to improve is presented to the HHA. We want to emphasize that this item adds little or no new burden, since HHAs routinely use assessment items similar to, or the same as, this item.

- Current Residence

We have included this item because it is closely related to the sustainability of an individual in community-based care and, possibly, institutional services. For example, a frail person who is able to live successfully in the home of a family member may not be able to do so if the same person were living alone in a rented room. The performance of the HHA in relationship to such variables as type of residence can make the difference between staying out of a nursing home and getting in to a nursing home. Having this information in the system enables the HHA (and HCFA) to measure patient success in relationship to residence.

- Supportive Assistance

The items in this section are intended to sort out and distinguish among the various types of caregiving that family and others provide, and with what frequency. As these items continue to be analyzed for utility and predictive power during the demonstration, they may be consolidated or shortened. Their importance, though, relates directly to the balance that should be achieved between the service the HHA provides and the help family and others provide to ensure the patient has the best chance to remain at home for as long as possible and to improve as much as possible.

To measure outcomes, OASIS data are collected at uniformly defined time points: start of care, every 57 to 62 days until and including discharge, and within 48 hours after return to home from a hospital admission for any reason other than diagnostic testing. We are using a time frame of 57 to 62 days to provide the HHA flexibility, and to ensure that the reassessment will be completed in time for the 62-day patient recertification. We are requiring that the OASIS be administered within 48 hours of the patient's return from a hospital admission (except when the hospital admission was for diagnostic tests) because we believe hospital admissions are predictive of likely changes in patient status and, therefore, important to capture for care planning and quality assessment and performance purposes.

When HCFA asks HHAs to report OASIS data, some information about the patient at the time of admission to a hospital may be included and, if so, would be related to reasons for the admission to the hospital. If home health care is resumed after the hospital admission and regardless of whether the patient was formally discharged from the HHA, the standard start-of-care OASIS is completed, with supplemental information on the length of hospital stay. Under these circumstances, if the patient was not formally discharged, followup data collection continues at 57 to 62 day intervals in accord with the original start-of-care date. If the patient was formally discharged from the HHA, the data collection proceeds on the basis of the new start-of-care date that followed the inpatient stay.

Some data items are unique to only one time point (for example, discharge information is only collected at patient discharge), while other data are collected at every time point. By collecting data using uniform data items and time points, individual patient data are comparable. The data can be aggregated to form agency-level outcomes and to be used for comparisons to a larger reference group of agencies. As a result, uniformity of data items and times points allows us to compare ''apples to apples.'' Again, this is why we are requiring as a condition of participation that the HHA use the OASIS exactly as specified by the Secretary. The most current version of the OASIS is published in this proposed rule. It reflects minor adjustments to various items that further testing in the field has shown to increase the precision and utility of the OASIS. This version does not change the workload associated with its use and there is some indication it requires less administration time than the earlier version. We urge that agencies currently using various versions of the OASIS, including ''partial'' versions, now focus on the use of the version of the OASIS contained in this proposed notice.

As health care delivery is constantly evolving, so will the OASIS continue to evolve. Although the data set has undergone extensive testing to date, it will be necessary to test and refine the data set on an ongoing basis. Further reliability and validity testing is occurring in the context of the national demonstration noted above. As experience is gained and as home care continues to change, so too must the OASIS. Modifications in items on the OASIS or the addition or deletion of data items from the OASIS as a result of additional testing will be released to HHAs periodically in manual updates, so that HHAs will make the necessary modifications and the OASIS can continue to represent the best data set for home health care outcome measurement.

C. Expectations Regarding the Use of the OASIS

We plan to implement full use of the OASIS in stages. The first step, which will begin when these proposed regulations are published as a final rule, is to require that all HHAs incorporate the exact use of the OASIS into their current comprehensive assessment process. This requirement will help to organize the assessment process around a set of agreed-upon, valid and reliable health status items that are known to be of value in measuring quality outcomes for patients. After HHAs have begun to use the OASIS as specified by the final rule, we intend to publish another proposed rule that would require HHAs to report OASIS data electronically into a national database. We believe this step will bring the use of the OASIS to its full potential as described in section I.C.2. ''The Longer Run Use of the OASIS'' of this preamble.

1. The Near Future

The comprehensive needs of home health patients are currently determined in a wide variety of ways, using numerous assessment tools. The utility and effectiveness of the many ways of completing a comprehensive assessment also vary widely, from highly sophisticated systems to little more than general notes on the plan of care submitted for payment. The first critically important advantage of requiring HHAS to incorporate the exact use of the OASIS within their current approach to a comprehensive assessment process is that it helps to organize the assessment process around

a set of agreed-upon, valid, and reliable health status items that are known to be of value in measuring quality outcomes for patients.

The ease with which the items on the OASIS can be assimilated into a comprehensive assessment process is apparent because all the items must be accounted for in any effective, relevant, comprehensive assessment. Hence, the information that is derived from the OASIS is useful and essential to assessment and care planning, and to internal performance improvement efforts. This fact is central to the rationale for asking that each HHA use the OASIS exactly as specified as part of its comprehensive assessment when the new home health conditions of participation become effective. (Recall that the OASIS items can be rearranged and distributed throughout an HHA's comprehensive assessment, as long as the items are used exactly as written.)

Once the OASIS has been administered as part of the comprehensive assessment, the results help to organize care planning with greater precision than is currently possible, especially in HHAs that lack a carefully structured approach to comprehensive assessment. The increased specificity in patient assessment (in critical areas of health and functional status) will assist agency staff to uniquely tailor a treatment plan to each individual patient.

Once the assessment and care planning process has been completed, and the provision of services has commenced for a specific patient, the OASIS is readministered on a periodic basis. Since OASIS items have been shown to be valid and reliable indicators of several dimensions of health status, the results of accurately administering the OASIS provide an effective measure of progress over time. As such, the OASIS can contribute significant information that helps in reassessing patient status, guiding changes in the plan of care, and developing approaches to solving care problems.

In the day-to-day effort to competently deliver effective services to a wide variety of patients with a panoply of needs, the HHA can easily lose sight of the ''big picture'' or how the agency is performing overall from the standpoint of effectiveness, efficiency, and patient satisfaction. We would require HHAs to begin to use the OASIS before final implementation of our request for HHAs to report OASIS data that can be aggregated in a national database and fed back to each HHA for use in its quality assessment and performance improvement program. In fact, each HHA can collect and use OASIS data on its own to compare the outcomes of similar patients to each other and to compare its performance from one year to the next.

To implement OASIS data collection as part of the quality assessment and performance improvement process, a HHA would ideally proceed with three steps, all of which should occur under the leadership of a team whose focus is to modify current assessment forms and documentation. Because most HHAs are accustomed to revising patient assessment instruments periodically as new clinical protocols become known or as new requirements by accrediting bodies or regulators are implemented, formation of teams or task forces often occurs at the agency level. Clinical supervisors or managers, staff members of various disciplines, and clerical staff are usually included on such teams.

First, the team would review current clinical documentation, comparing assessment items with similar OASIS data items. In some cases (for example, start-of-care date, gender, date of birth, Medicare number), minimal or no change to the current data item is needed. In other situations (for example, dyspnea scale, bathing scale) the precision of the OASIS item requires the HHA to substitute the OASIS item for its current documentation. Next, the documentation team would determine whether to adapt its current form, using a cut-and-paste approach or to develop an entirely new form. Finally, the team would take action. If the team chooses to develop a new form, sample clinical forms are available from several sources to facilitate this development, since this form is usually the most detailed document used by the HHA. HHA documentation for recertification and discharge assessments seldom are standardized, so these forms typically are developed anew rather than modified. Once the forms are developed, the implementation team oversees their pilot testing, modification, finalization, and printing.

Any change in HHA forms, paper flow, and related activities requires staff training to implement. The extent of the changes will affect the amount of training required. Nearly all HHAs make some modification to existing paperwork or internal procedures on approximately an annual basis for reasons such as modifying forms, internal paper flow, or current data entry processes. Consequently, the HHAs are familiar with training staff to accomplish this task. In addition, staff inservice, orientation, and training are routine parts of ongoing HHA activities for both clinical and clerical personnel.

HHAs should also plan for two types of data accuracy checks. The first check is for completeness of data; that is, whether all OASIS items have been completed. This check can be done through a visual check of clinical documentation submitted for data entry or through a programmed data entry check. Other data accuracy checks can be incorporated into a data entry program to examine logical inconsistencies in the documentation (for example, a bedbound patient who is independent in housekeeping, a patient with no pressure ulcers whose pressure ulcers are not healing).

Software is becoming available from vendors and other sources for this purpose. Clinical supervisory personnel are often alerted to incomplete or logically inconsistent documentation, similar to what occurs for HCFA–485 data which is the routine Medicare billing form.

To facilitate internal agency performance improvement activities, it currently is possible for HHAs to create outcome reports for their own patient populations using informal methods. Guidance in doing this is provided in the aforementioned manual published by the National Association for Home Care. For small HHAs or larger HHAs over a shorter time interval, producing preliminary reports of this nature requires only a paper-and-pencil data entry approach and a calculator. However, we encourage computerization as soon as it is possible to do so. The nearly universal move toward electronic information systems, including the health care industry for areas such as billing and payment, suggests that the sooner organizations learn how to use electronic information systems for patient care and quality assessment and performance improvement, the better positioned they will be to respond when HCFA proposes to require electronic reporting of OASIS data in the future.

If the HHA can be part of a reference database group or project, participate in a reference data consortium, or is part of a multiprovider company, such data can be collected and used as a comparison database to assess performance among HHAs in the group, and to search for opportunities that could contribute to improved outcomes and satisfaction for patients. In this case, an individual HHA will be considered relative to all HHAs in the group or database in terms of the extent to which various outcome measures are indicative of high or low quality of care relative to the standard represented by the mean for all HHAs. Case-mix adjustment is necessary for outcome

comparisons across agencies or groups. The OASIS contains tested and reliable data items that can be used for risk factor adjustment.

For example, an HHA generates an outcome report based on OASIS data that indicates that 30 percent of all of the HHA's patients had improved in ability to manage oral medications, compared with 45 percent of its patients from the previous time period. The HHA is concerned about this decline in this outcome because a patient's ability to manage oral medications is often critical to managing his or her medical condition at home. An investigation into care processes reveals that several of the HHA's care providers are not adequately assessing fine motor ability and thus not addressing possible deficits in fine motor skills when planning care. For a number of patients, this appears to be resulting in inadequate assessment of the need for occupational therapy involvement and teaching medication management. The HHA develops a plan of action to improve care by incorporating a more detailed fine motor evaluation into its comprehensive assessment at the start of care, integrating findings from that evaluation into the medication teaching guide, and enhancing nurse-occupational therapy coordination with interdisciplinary care conferences on patients with impaired fine motor function. The HHA's outcome report for the following time period shows that 48 percent of discharged patients improved in ability to manage oral medications. Thus, changes in care processes resulting from an analysis of outcome findings subsequently have a positive impact on patient outcomes.

While we recognize that some HHAs already are using fairly sophisticated computer systems to collect and manage clinical as well as financial data, we realize that many HHAs have not begun, or are just beginning, to utilize electronic means of managing clinical and programmatic information. We believe the contributions the OASIS can make to the assessment, care planning, and implementation of performance improvement activities will stimulate more HHAs to move to an electronic format for managing patient clinical information. In fact, we do not envision how an HHA can successfully move to a continuous quality improvement approach without developing and using a computer-based system to manage and use organizational and patient-based data. In this regard, the OASIS will help guide the multiple clinical record systems and electronic management information systems under development at the present time, providing a foundation for uniformity and precision in assessment, care planning, and outcome monitoring. When we publish these requirements as a final rule, we are committed to sharing data system specifications for the OASIS with the HHA community.

A number of vendors have developed and are marketing various types of software, including electronic clinical recordkeeping, to the home care industry. We encourage such development because as information technology continues to improve, it will increase the efficiency with which the requisite information can be collected for home health care administration, billing, assessment, and outcome monitoring. Incorporating OASIS into electronic clinical records, including the capability to adapt software to modest revisions of the OASIS periodically is both a challenge and an opportunity. It is a challenge because changes have to be made to current electronic clinical record systems, replacing analogous items so that the total length of the start-of-care assessment process for agencies is no greater (or only marginally greater) in terms of time expended by the care providers. Such changes will be reasonably straightforward for some vendors and complex for others.

In many ways, the opportunities for software vendors serve to offset the challenges because as we move toward national use of the OASIS data set and subsequent updates as the OASIS evolves (as explained in section I.C.2. of this preamble) nearly all HHAs will require some type of software system. Such a system, at a minimum, will be needed to perform initial computerization, those editing functions necessary to ensure accurate OASIS and file development so that OASIS data can be submitted to a central location for Medicare system processing. Software conversion and marketing processes will, of course, naturally accompany the increased demand for electronic clinical recordkeeping in the home health care field. In all, we expect there will be substantial opportunities to expand software applications over the next few years.

We are also aware that some companies already exist that provide both software management of assessment and other data as well as data analysis and management services for quality improvement. We believe the implementation of the proposed HHA conditions of participation, published elsewhere in this issue of the Federal Register, which focus on quality assessment and performance improvement, and this proposed rule, which introduces the OASIS to the process, will only expand the opportunities for quality management firms to flourish. While many HHAs already have sophisticated quality improvement management programs, we know a significant number do not. Since we encourage maximum flexibility and creativity in these programs, we believe the requirement that HHAs use the OASIS in no way inhibits these companies from marketing their quality management services.

We are considering the possibility of using the OASIS in our monitoring of managed care organizations in the future. For example, if the OASIS were used, HCFA, HHAs, and managed care organizations would be able to evaluate overall effectiveness of managed care home care and make decisions and improvements based on beneficiary outcomes.

Another advantage of implementing the OASIS as part of the comprehensive assessment at the time the new conditions of participation become effective is that it provides HHAs with time to learn how to use the OASIS effectively and accurately. HHAs can begin to experiment with using OASIS data. This provides opportunities to focus on specific areas for enhancing outcomes of care, patient satisfaction, and organizational efficiencies. Such a learning period would take place prior to HCFA implementing additional rule making that would require HHAs to provide OASIS data electronically to a national database.

2. The Longer Run Use of the OASIS

For informational purposes, we are discussing our long-range goals for the use of the OASIS. While this proposed rule would not require HHAs to report OASIS data to a national database, we intend to publish such a rule when the system is developed. A national database would allow HCFA to make these data available in the form of standardized, risk-adjusted outcome reports. Aggregate OASIS-derived HHA outcome reports that contain no patient-specific data will be in the public domain, and consumers, purchasers, HHAs, and HCFA will be able to use such information in a variety of ways. Additionally, HCFA as a purchaser of managed care services is interested in the quality oversight of home health services delivered by managed care organizations.

When outcome reports become available, each HHA will be able to use the outcome reports in its quality assessment and performance improvement program. The HHA will be able to examine specific care domains,

types of patients, or both and to compare present performance to past performance and national performance norms. For example, the HHA could compare its performance with other HHAs, locally, regionally, and nationally. When these quality indicators are implemented and evaluated, agency profiles could be used in the survey process to compare the HHA's results with past performance. Objective data of this nature can be an important validator of the HHA's improvement efforts and also serve as a flag to the agency in terms of where to focus its quality improvement priorities. The data will allow the HHA to focus its quality improvement resources more efficiently by concentrating on specific outcomes that require attention rather than investing in systematic improvements in a broad range of areas that might presently be satisfactory or even superior relative to other agencies throughout the country. The ability of the HHA to efficiently and effectively improve its individual performance would have the cumulative result of the industry improving services to Medicare and Medicaid beneficiaries at the same or lower cost. It may also further justify and highlight the strengths of home care, thereby enhancing access for other types of patients in the longer run.

An individual HHA can use the outcome reports to evaluate the effectiveness of care provided to specific types of patients and, in the context of investigating processes of care, to individual patients. In order to investigate outcomes that might be judged inadequate by agency staff, an individual patient's clinical records can be reviewed in the context of a process-of-care screen that investigates the circumstances and processes leading to outcomes. Such an investigation can, in turn, lead to a plan of action that focuses on specific changes in care behaviors at the individual patient level. This enables an HHA to identify and apply ''lessons learned'' to its agency operations to improve the outcomes of the agency as a whole. Analogously, the HHA can examine circumstances and processes that produced superior or exemplary outcomes to reinforce care behaviors that produce such outcomes, promulgating information on such care behaviors within the agency.

Data from outcome reports not only can be used by the HHA for continuous quality improvement by monitoring outcomes over time, but also can be used to objectively assess the agency's strengths and weaknesses in the clinical services it provides. Outcome reports can inform the HHA what patients and clinical conditions it best serves, what areas of HHA-care behaviors or activities correlate with patient satisfaction, and what services need improvement. Such information will be of value to the HHA in its strategic planning, financial planning, and marketing.

Aggregate HHA outcome reports that contain no patient-specific data may be used by the industry for comparative performance assessment. The home care industry can identify those agencies regarded as industry leaders in quality of care for comparable services, care domains, and/or patient populations. Identified quality leaders can market their services accordingly and can serve as a reservoir of expertise for other agencies in their efforts to improve performance in selected areas.

The results of outcome measurement also can provide useful information to purchasers and consumers of home care services. Such organizations and individuals will be able to examine reports of industry outcomes and identify those agencies that will best provide the services to meet the needs of individual consumers or the population needs of particular purchasers. Improved access to objective information on quality of care for consumers and purchasers will also drive quality improvement in the industry as a whole. HHAs with records of poor performance will be motivated to improve their performances to compete with better-performing HHAs.

Our managed care partners, as purchasers of home health services, would also be interested in such outcome-based comparative performance measurements of HHAs. A standardized industry-wide instrument would allow plans as purchasers to make value-based purchasing decisions of home health care. The ability to use outcome measurement data is especially important to us as a purchaser of services on behalf of eligible beneficiaries. For example, in addition to comparing an HHA's performance to its own past performance, HCFA and State survey agencies will be able to use industry-wide performance data on a continuous basis to identify HHAs that are not performing to the norm, thereby suggesting the possibility that poor quality of care is occurring. This information can trigger on-site inspections to assess performance. At the same time, the data can be used to look for patterns of exemplary performance that can be shared with others to help improve outcomes of care and satisfaction overall. Having these data on a flow basis frees us up from rigid survey schedules and enables us to use scarce inspection resources more productively. Of course, we would still conduct initial inspections to ensure an HHA is ready for participation. We would also follow up, usually with an on-site visit, on all complaints that suggest quality of care problems. Additionally, State survey agencies and HCFA could use performance data to identify opportunities for improvement in national or local priority areas, such as a project to improve medication management for beneficiaries generally, or to shorten the time necessary to achieve a clinically important patient outcome.

The availability of performance data will also enable State survey agencies and HCFA to evaluate more effectively the HHA's performance of its own quality assessment and performance improvement program. For example, an HHA is receiving objective feedback data that show that the HHA is performing less well than other HHAs in a particular clinical outcome area. The HHA is not using the quality assessment and performance improvement program to address why its results are divergent and to develop interventions to improve its performance. Consequently, the surveyors will have evidence that the HHA is not responding the way it could or should to improve outcomes of care and satisfaction for patients.

Initially, since we are not yet requiring HHAs to submit OASIS data, surveyors will look at how the HHA has used OASIS data internally, and ideally, informally with other HHAs (for example, either within its own company, or through consortia of HHAs in its geographic area). Likewise, accreditation organizations with deemed status can use the information as part of their accreditation processes. As we stated earlier in this preamble, the Department of Health and Human Services will, at a later date, issue a separate notice of proposed rulemaking identifying the specific data elements that would be required to be reported to HCFA, the timetable, and the intended use of these data elements. At this time, it has not been determined how extensive or limited these requirements will be. There will be extensive public comment when the draft is issued. In the meantime, however, we welcome public comment on the question of what would constitute appropriate reporting requirements for the purposes of monitoring progress toward meeting performance outcome measures.

3. Other Potential Applications of OASIS Data

We are presently investigating the potential of the OASIS and information on which clinical outcomes are based to

assist in developing selected features of a Medicare prospective payment system for home health services. Specifically, we have found that in identifying factors that might be valuable in developing case-mix adjustors for payment purposes, traditional characteristics such as patient diagnosis account for little of the variation in home health utilization. Our Office of Research and Demonstrations is currently researching home health case-mix, including an investigation of the use and applicability of the data items contained within the OASIS for developing a home health case-mix adjustor for payment purposes. If such data items are found to be a valid basis for home health case-mix, the potential of the OASIS would be further maximized. At the same time, the burden on HHAs in providing health status information for purposes of measuring outcomes, assessing patient needs, care planning, and measuring case mix would be minimized.

We believe the OASIS data have the potential to be of significant benefit to health professionals and professional organizations. Objective, well-specified data on home health outcomes can assist professionals to determine those practice areas needing improvement, and help to identify inefficient or ineffective practice standards or services which do not contribute to improved patient outcomes. Thus, the OASIS data can inform and improve professional practice standards and ultimately assist in the development of clinical practice guidelines and critical pathways. On a broader scale, we are interested in developing a capability of linking beneficiary information across provider settings with other administrative data (for example, payment and utilization data). Beneficiaries may have very complex service delivery histories, moving among various services and benefits.

In order to effectively track outcomes and to facilitate the administrative tasks involved in integrating the care for individuals, our data systems, including the OASIS, minimum data set (MDS), and others that may emerge, must be able to be integrated. Since mandated data sets have been implemented or are being considered in other domains of health care for which HCFA is responsible (for example, the MDS for nursing homes, and the Uniform Needs Assessment instrument for hospital discharge), we anticipate the evolution of data items and data sets to occur so that the degree of commonality among such data sets can be maximized over the course of time. Data sets have been developed for selected fields such as home care and nursing home care so that the unique needs of patient and Medicare beneficiaries that pertain to each provider type can be adequately taken into consideration in the context of an initial data set such as OASIS or MDS. Because of these unique needs, it is unlikely that we can collectively attain perfect overlap among the different data sets. It is our goal ultimately to 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.

Finally, we expect that the OASIS data will help us in promoting more efficient regulations and policies that encourage good performance in the home care industry. We will be able to objectively examine the home health industry in all its complexity, using outcome data to support or refute anecdotal information, unsubstantiated opinion, or conjecture, thereby facilitating consensus building and more objective policy decisions. Most important, home health outcomes information will aid in shaping and even creating the home health benefit of the future. As we identify those practices and services that contribute to enhanced patient outcomes, the patient populations that should be served by home care can be better specified, and the capacity of the home health industry to provide the requisite services can be strengthened, expanded, or refined in keeping with beneficiary outcomes.

II. Sample OASIS Survey

BILLING CODE 4120–01–P

Medicare Home Health Care Quality Assurance and Improvement Demonstration Outcome and Assessment Information Set (OASIS-B)

This data set should not be reviewed or used without first reading the accompanying narrative prologue that explains the purpose of the OASIS and its past and planned evolution.

OASIS Items to be Used at Specific Time Points

Start of Care (or Resumption of Care Following Inpatient Facility Stay): 1-69

Follow-Up: 1, 4, 9-11, 13, 16-26, 29-71

Discharge (not to inpatient facility): 1, 4, 9-11, 13, 16-26, 29-74, 78-79

Transfer to Inpatient Facility (with or without agency discharge): 1, 70-72, 75-79

Death at Home: 1, 79

Note: For items 51-67, please note special instructions at the beginning of the section.

CLINICAL RECORD ITEMS

a. Agency ID: __ __ __ __ __ __ __ __

b. Patient ID Number: _____

c. Start of Care Date: __ __/__ __/__ __ __ __
month day year

d. Patient's Last Name:

__ __ __ __ __ __ __ __ __ __ __ __

e. Patient State of Residence: __ __

f. Patient Zip Code: __ __ __ __ __

g. Medicare Number:

__ __ __ __ __ __ __ __ __ __ __ __
(including suffix if any)

☐ NA - No Medicare

h. Birth Date: __ __/__ __/__ __ __ __
month day year

i. Discipline of Person Completing Assessment:

☐ 1-RN ☐ 2-LPN ☐ 3-PT
☐ 4-SLP/ST ☐ 5-OT ☐ 6-MSW

j. Date Assessment Information Recorded:

__ __/__ __/__ __ __ __
month day year

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DEMOGRAPHICS AND PATIENT HISTORY

1. **This Assessment is Currently Being Completed for the Following Reason:**

   ☐ 1 - Start of care
   ☐ 2 - Resumption of care (after inpatient stay)
   ☐ 3 - Discharge from agency - not to an inpatient facility **[Go to *Question 4*]**
   ☐ 4 - Transferred to an inpatient facility - discharged from agency **[Go to *Question 70*]**
   ☐ 5 - Transferred to an inpatient facility - not discharged from agency **[Go to *Question 70*]**
   ☐ 6 - Died at home **[Go to *Question 79*]**
   ☐ 7 - Recertification reassessment (follow-up) **[Go to *Question 4*]**
   ☐ 8 - Other follow-up **[Go to *Question 4*]**

2. **Gender:**

   ☐ 1 - Male
   ☐ 2 - Female

3. **Race/Ethnicity** (as identified by patient):

   ☐ 1 - White, non-Hispanic
   ☐ 2 - Black, African-American
   ☐ 3 - Hispanic
   ☐ 4 - Asian, Pacific Islander
   ☐ 5 - American Indian, Eskimo, Aleut
   ☐ 6 - Other
   ☐ UK - Unknown

4. **Current Payment Sources for Home Care: (Mark all that apply.)**

   ☐ 0 - None; no charge for current services
   ☐ 1 - Medicare (traditional fee-for-service)
   ☐ 2 - Medicare (HMO/managed care)
   ☐ 3 - Medicaid (traditional fee-for-service)
   ☐ 4 - Medicaid (HMO/managed care)
   ☐ 5 - Workers' compensation
   ☐ 6 - Title programs (e.g., Title III, V, or XX)
   ☐ 7 - Other government (e.g., CHAMPUS, VA, etc.)
   ☐ 8 - Private insurance
   ☐ 9 - Private HMO/managed care
   ☐ 10 - Self-pay
   ☐ 11 - Other (specify) _____
   ☐ UK - Unknown

5. **Financial Factors** limiting the ability of the patient/family to meet basic health needs: **(Mark all that apply.)**

   ☐ 0 - None
   ☐ 1 - Unable to afford medicine or medical supplies
   ☐ 2 - Unable to afford medical expenses that are not covered by insurance/Medicare (e.g., copayments)
   ☐ 3 - Unable to afford rent/utility bills
   ☐ 4 - Unable to afford food
   ☐ 5 - Other (specify) _____

6. From which of the following **Inpatient Facilities** was the patient discharged during the past 14 days? **(Mark all that apply.)**

   ☐ 1 - Hospital
   ☐ 2 - Rehabilitation facility
   ☐ 3 - Nursing home
   ☐ 4 - Other (specify) _____
   ☐ NA - Patient was not discharged from an inpatient facility **[If NA, go to *Question 9*]**

7. **Inpatient Discharge Date** (most recent):

   __ __/__ __/__ __ __ __
   month day year

   ☐ UK - Unknown

8. **Inpatient Diagnoses** and three-digit ICD code categories for only those conditions treated during an inpatient facility stay within the last 14 days (no surgical or V-codes):

Inpatient Facility Diagnosis	7ICD
a. _____	(__ __ __)
b. _____	(__ __ __)

9. **Medical or Treatment Regimen Change Within Past 14 Days:** Has this patient experienced a change in medical or treatment regimen (e.g., medication, treatment, or service change due to new or additional diagnosis, etc.) within the last 14 days?

   ☐ 0 - No **[If No, go to *Question 11*]**
   ☐ 1 - Yes

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10. List the patient's **Medical Diagnoses** and three-digit ICD code categories for those conditions requiring changed medical or treatment regimen (no surgical or V-codes):

Changed Medical Regimen Diagnosis	ICD
a. _____	(_ _ _)
b. _____	(_ _ _)
c. _____	(_ _ _)
d. _____	(_ _ _)

11. **Conditions Prior to Medical or Treatment Regimen Change or Inpatient Stay Within Past 14 Days:** If this patient experienced an inpatient facility discharge or change in medical or treatment regimen within the past 14 days, indicate any conditions which existed prior to the inpatient stay or change in medical or treatment regimen **(Mark all that apply.)**

- ☐ 1 - Urinary incontinence
- ☐ 2 - Indwelling/suprapubic catheter
- ☐ 3 - Intractable pain
- ☐ 4 - Impaired decision-making
- ☐ 5 - Disruptive or socially inappropriate behavior
- ☐ 6 - Memory loss to the extent that supervision required
- ☐ 7 - None of the above
- ☐ NA - No inpatient facility discharge and no change in medical or treatment regimen in past 14 days
- ☐ UK - Unknown

12. **Diagnoses and Severity Index**: List each medical diagnosis or problem for which the patient is receiving home care and ICD code category (no surgical or V-codes) and rate them using the following severity index. (Choose one value that represents the most severe rating appropriate for each diagnosis.)

0 - Asymptomatic, no treatment needed at this time
1 - Symptoms well controlled with current therapy
2 - Symptoms controlled with difficulty, affecting daily functioning; patient needs ongoing monitoring
3 - Symptoms poorly controlled, patient needs frequent adjustment in treatment and dose monitoring
4 - Symptoms poorly controlled, history of rehospitalizations

Primary Diagnosis	ICD	Severity Rating				
a. _____	(_ _ _)	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4

Other Diagnoses	ICD	Severity Rating				
b. _____	(_ _ _)	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
c. _____	(_ _ _)	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
d. _____	(_ _ _)	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
e. _____	(_ _ _)	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
f. _____	(_ _ _)	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4

13. **Therapies** the patient receives at home: **(Mark all that apply.)**

- ☐ 1 - Intravenous or infusion therapy (excludes TPN)
- ☐ 2 - Parenteral nutrition (TPN or lipids)
- ☐ 3 - Enteral nutrition (nasogastric, gastrostomy, jejunostomy, or any other artificial entry into the alimentary canal)
- ☐ 4 - None of the above

14. **Overall Prognosis:** BEST description of patient's overall prognosis for recovery from this episode of illness.

- ☐ 0 - Poor: little or no recovery is expected and/or further decline is imminent
- ☐ 1 - Good/Fair: partial to full recovery is expected
- ☐ UK - Unknown

15. **Rehabilitative Prognosis:** BEST description of patient's prognosis for functional status.

- ☐ 0 - Guarded: minimal improvement in functional status is expected; decline is possible
- ☐ 1 - Good: marked improvement in functional status is expected
- ☐ UK - Unknown

16. **Life Expectancy:** (Physician documentation is not required.)

- ☐ 0 - Life expectancy is greater than 6 months
- ☐ 1 - Life expectancy is 6 months or fewer

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17. **High Risk Factors** characterizing this patient: **(Mark all that apply.)**

- ☐ 1 - Heavy smoking
- ☐ 2 - Obesity
- ☐ 3 - Alcohol dependency
- ☐ 4 - Drug dependency
- ☐ 5 - None of the above
- ☐ UK - Unknown

LIVING ARRANGEMENTS

18. **Current Residence:**

- ☐ 1 - Patient's owned or rented residence (house, apartment, or mobile home owned or rented by patient/couple/significant other)
- ☐ 2 - Family member's residence
- ☐ 3 - Boarding home or rented room
- ☐ 4 - Board and care or assisted living facility
- ☐ 5 - Other (specify) _____

19. **Structural Barriers** in the patient's environment limiting independent mobility: **(Mark all that apply.)**

- ☐ 0 - None
- ☐ 1 - Stairs inside home which must be used by the patient (e.g., to get to toileting, sleeping, eating areas)
- ☐ 2 - Stairs inside home which are used optionally (e.g., to get to laundry facilities)
- ☐ 3 - Stairs leading from inside house to outside
- ☐ 4 - Narrow or obstructed doorways

20. **Safety Hazards** found in the patient's current place of residence: **(Mark all that apply.)**

- ☐ 0 - None
- ☐ 1 - Inadequate floor, roof, or windows
- ☐ 2 - Inadequate lighting
- ☐ 3 - Unsafe gas/electric appliance
- ☐ 4 - Inadequate heating
- ☐ 5 - Inadequate cooling
- ☐ 6 - Lack of fire safety devices
- ☐ 7 - Unsafe floor coverings
- ☐ 8 - Inadequate stair railings
- ☐ 9 - Improperly stored hazardous materials
- ☐ 10 - Lead-based paint
- ☐ 11 - Other (specify) _____

21. **Sanitation Hazards** found in the patient's current place of residence: **(Mark all that apply.)**

- ☐ 0 - None
- ☐ 1 - No running water
- ☐ 2 - Contaminated water
- ☐ 3 - No toileting facilities
- ☐ 4 - Outdoor toileting facilities only
- ☐ 5 - Inadequate sewage disposal
- ☐ 6 - Inadequate/improper food storage
- ☐ 7 - No food refrigeration
- ☐ 8 - No cooking facilities
- ☐ 9 - Insects/rodents present
- ☐ 10 - No scheduled trash pickup
- ☐ 11 - Cluttered/soiled living area
- ☐ 12 - Other (specify) _____

22. **Patient Lives With: (Mark all that apply.)**

- ☐ 1 - Lives alone
- ☐ 2 - With spouse or significant other
- ☐ 3 - With other family member
- ☐ 4 - With a friend
- ☐ 5 - With paid help (other than home care agency staff)
- ☐ 6 - With other than above

SUPPORTIVE ASSISTANCE

23. **Assisting Person(s) Other than Home Care Agency Staff: (Mark all that apply.)**

- ☐ 1 - Relatives, friends, or neighbors living outside the home
- ☐ 2 - Person residing in the home (EXCLUDING paid help)
- ☐ 3 - Paid help
- ☐ 4 - None of the above **[If None of the above, go to *Question 27*]**
- ☐ UK - Unknown **[If Unknown, go to *Question 27*]**

24. **Primary Caregiver** taking lead responsibility for providing or managing the patient's care, providing the most frequent assistance, etc. (other than home care agency staff):

- ☐ 0 - No one person **[If No one person, go to *Question 27*]**
- ☐ 1 - Spouse or significant other
- ☐ 2 - Daughter or son
- ☐ 3 - Other family member
- ☐ 4 - Friend or neighbor or community or church member
- ☐ 5 - Paid help
- ☐ UK - Unknown **[If Unknown, go to *Question 27*]**

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25. How Often does the patient receive assistance from the primary caregiver?

- ☐ 1 - Several times during day and night
- ☐ 2 - Several times during day
- ☐ 3 - Once daily
- ☐ 4 - Three or more times per week
- ☐ 5 - One to two times per week
- ☐ 6 - Less often than weekly
- ☐ UK - Unknown

26. Type of Primary Caregiver Assistance: (Mark all that apply.)

- ☐ 1 - ADL assistance (e.g., bathing, dressing, toileting, bowel/bladder, eating/feeding)
- ☐ 2 - IADL assistance (e.g., meds, meals, housekeeping, laundry, telephone, shopping, finances)
- ☐ 3 - Environmental support (housing, home maintenance)
- ☐ 4 - Psychosocial support (socialization, companionship, recreation)
- ☐ 5 - Advocates or facilitates patient's participation in appropriate medical care
- ☐ 6 - Financial agent, power of attorney, or conservator of finance
- ☐ 7 - Health care agent, conservator of person, or medical power of attorney
- ☐ UK - Unknown

SENSORY STATUS

27. Vision with corrective lenses if the patient usually wears them:

- ☐ 0 - Normal vision: sees adequately in most situations; can see medication labels, newsprint.
- ☐ 1 - Partially impaired: cannot see medication labels or newsprint, but can see obstacles in path, and the surrounding layout; can count fingers at arm's length.
- ☐ 2 - Severely impaired: cannot locate objects without hearing or touching them or patient nonresponsive.

28. Hearing and Ability to Understand Spoken Language in patient's own language (with hearing aids if the patient usually uses them):

- ☐ 0 - No observable impairment. Able to hear and understand complex or detailed instructions and extended or abstract conversation.
- ☐ 1 - With minimal difficulty, able to hear and understand most multi-step instructions and ordinary conversation. May need occasional repetition, extra time, or louder voice.
- ☐ 2 - Has moderate difficulty hearing and understanding simple, one-step instructions and brief conversation; needs frequent prompting or assistance.
- ☐ 3 - Has severe difficulty hearing and understanding simple greetings and short comments. Requires multiple repetitions, restatements, demonstrations, additional time.
- ☐ 4 - Unable to hear and understand familiar words or common expressions consistently, or patient nonresponsive.

29. Speech and Oral (Verbal) Expression of Language (in patient's own language):

- ☐ 0 - Expresses complex ideas, feelings, and needs clearly, completely, and easily in all situations with no observable impairment.
- ☐ 1 - Minimal difficulty in expressing ideas and needs (may take extra time; makes occasional errors in word choice, grammar or speech intelligibility; needs minimal prompting or assistance).
- ☐ 2 - Expresses simple ideas or needs with moderate difficulty (needs prompting or assistance, errors in word choice, organization or speech intelligibility). Speaks in phrases or short sentences.
- ☐ 3 - Has severe difficulty expressing basic ideas or needs and requires maximal assistance or guessing by listener. Speech limited to single words or short phrases.
- ☐ 4 - Unable to express basic needs even with maximal prompting or assistance but is not comatose or unresponsive (e.g., speech is nonsensical or unintelligible).
- ☐ 5 - Patient nonresponsive or unable to speak.

30. Frequency of Pain interfering with patient's activity or movement:

- ☐ 0 - Patient has no pain or pain does not interfere with activity or movement
- ☐ 1 - Less often than daily
- ☐ 2 - Daily, but not constantly
- ☐ 3 - All of the time

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31. **Intractable Pain:** Is the patient experiencing pain that is not easily relieved, occurs at least daily, and affects the patient's sleep, appetite, physical or emotional energy, concentration, personal relationships, emotions, or ability or desire to perform physical activity?

☐ 0 - No
☐ 1 - Yes

INTEGUMENTARY STATUS

32. Does this patient have a **Skin Lesion** or an **Open Wound**? This excludes "OSTOMIES."

☐ 0 - No **[If No, go to *Question 36*]**
☐ 1 - Yes

33. Does this patient have a **Pressure Ulcer**?

☐ 0 - No **[If No, go to *Question 34*]**
☐ 1 - Yes

33a. **Current Number of Pressure Ulcers at Each Stage:** (Circle one response for each stage.)

Pressure Ulcer Stages	Number of Pressure Ulcers				
a) Stage 1: Nonblanchable erythema of intact skin; the heralding of skin ulceration. In darker-pigmented skin, warmth, edema, hardness, or discolored skin may be indicators.	0	1	2	3	4 or more
b) Stage 2: Partial thickness skin loss involving epidermis and/or dermis. The ulcer is superficial and presents clinically as an abrasion, blister, or shallow crater.	0	1	2	3	4 or more
c) Stage 3: Full-thickness skin loss involving damage or necrosis of subcutaneous tissue which may extend down to, but not through, underlying fascia. The ulcer presents clinically as a deep crater with or without undermining of adjacent tissue.	0	1	2	3	4 or more
d) Stage 4: Full-thickness skin loss with extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structures (e.g., tendon, joint capsule, etc.)	0	1	2	3	4 or more
e) In addition to the above, is there at least one pressure ulcer that cannot be observed due to the presence of eschar or a nonremovable dressing, including casts? ☐ 0 - No ☐ 1 - Yes					

33b. **Stage of Most Problematic (Observable) Pressure Ulcer:**

☐ 1 - Stage 1
☐ 2 - Stage 2
☐ 3 - Stage 3
☐ 4 - Stage 4
☐ NA - No observable pressure ulcer

33c. **Status of Most Problematic (Observable) Pressure Ulcer:**

☐ 1 - Fully granulating
☐ 2 - Early/partial granulation
☐ 3 - Not healing
☐ NA - No observable pressure ulcer

34. Does this patient have a **Stasis Ulcer**?

☐ 0 - No **[If No, go to *Question 35*]**
☐ 1 - Yes

34a. **Current Number of Observable Stasis Ulcer(s):**

☐ 0 - Zero
☐ 1 - One
☐ 2 - Two
☐ 3 - Three
☐ 4 - Four or more

34b. Does this patient have at least one **Stasis Ulcer that Cannot be Observed** due to the presence of a nonremovable dressing?

☐ 0 - No
☐ 1 - Yes

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34c. Status of Most Problematic (Observable) Stasis Ulcer:

- ☐ 1 - Fully granulating
- ☐ 2 - Early/partial granulation
- ☐ 3 - Not healing
- ☐ NA - No observable stasis ulcer

35. Does this patient have a **Surgical Wound**?

- ☐ 0- No **[If No, go to *Question 36*]**
- ☐ 1- Yes

35a. Current Number of (Observable) Surgical Wounds: (If a wound is partially closed but has more than one opening, consider each opening as a separate wound.)

- ☐ 0 - Zero
- ☐ 1 - One
- ☐ 2 - Two
- ☐ 3 - Three
- ☐ 4 - Four or more

35b. Does this patient have at least one **Surgical Wound that Cannot be Observed** due to the presence of a nonremovable dressing?

- ☐ 0 - No
- ☐ 1 - Yes

35c. Status of Most Problematic (Observable) Surgical Wound:

- ☐ 1 - Fully granulating
- ☐ 2 - Early/partial granulation
- ☐ 3 - Not healing
- ☐ NA - No observable surgical wound

RESPIRATORY STATUS

36. When is the patient dyspneic or noticeably **Short of Breath**?

- ☐ 0 - Never, patient is not short of breath
- ☐ 1 - When walking more than 20 feet, climbing stairs
- ☐ 2 - With moderate exertion (e.g., while dressing, using commode or bedpan, walking distances less than 20 feet)
- ☐ 3 - With minimal exertion (e.g., while eating, talking, or performing other ADLs) or with agitation
- ☐ 4 - At rest (during day or night)

37. Respiratory Treatments utilized at home: **(Mark all that apply.)**

- ☐ 1 - Oxygen (intermittent or continuous)
- ☐ 2 - Ventilator (continually or at night)
- ☐ 3 - Continuous positive airway pressure
- ☐ 4 - None of the above

ELIMINATION STATUS

38. Has this patient been treated for a **Urinary Tract Infection** in the past 14 days?

- ☐ 0 - No
- ☐ 1 - Yes
- ☐ NA - Patient on prophylactic treatment
- ☐ UK - Unknown

39. Urinary Incontinence or Urinary Catheter Presence:

- ☐ 0 - No incontinence or catheter (includes anuria or ostomy for urinary drainage) **[If No, go to *Question 41*]**
- ☐ 1 - Patient is incontinent
- ☐ 2 - Patient requires a urinary catheter (i.e., external, indwelling, intermittent, suprapubic) **[Go to *Question 41*]**

40. When does **Urinary Incontinence** occur?

- ☐ 0 - Timed-voiding defers incontinence
- ☐ 1 - During the night only
- ☐ 2 - During the day and night

41. Bowel Incontinence Frequency:

- ☐ 0 - Very rarely or never has bowel incontinence
- ☐ 1 - Less than once weekly
- ☐ 2 - One to three times weekly
- ☐ 3 - Four to six times weekly
- ☐ 4 - On a daily basis
- ☐ 5 - More often than once daily
- ☐ NA - Patient has ostomy for bowel elimination
- ☐ UK - Unknown

42. Ostomy for Bowel Elimination: Does this patient have an ostomy for bowel elimination that (within the last 14 days): a) was related to an inpatient facility stay, or b) necessitated a change in medical or treatment regimen?

- ☐ 0 - Patient does not have an ostomy for bowel elimination.
- ☐ 1 - Patient's ostomy was not related to an inpatient stay and did not necessitate change in medical or treatment regimen.
- ☐ 2 - The ostomy was related to an inpatient stay or did necessitate change in medical or treatment regimen.

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NEURO/EMOTIONAL/BEHAVIORAL STATUS

43. Cognitive Functioning: (Patient's current level of alertness, orientation, comprehension, concentration, and immediate memory for simple commands.)

- ☐ 0 - Alert/oriented, able to focus and shift attention, comprehends and recalls task directions independently.
- ☐ 1 - Requires prompting (cuing, repetition, reminders) only under stressful or unfamiliar conditions.
- ☐ 2 - Requires assistance and some direction in specific situations (e.g., on all tasks involving shifting of attention), or consistently requires low stimulus environment due to distractibility.
- ☐ 3 - Requires considerable assistance in routine situations. Is not alert and oriented or is unable to shift attention and recall directions more than half the time.
- ☐ 4 - Totally dependent due to disturbances such as constant disorientation, coma, persistent vegetative state, or delirium.

44. When Confused (Reported or Observed):

- ☐ 0 - Never
- ☐ 1 - In new or complex situations only
- ☐ 2 - On awakening or at night only
- ☐ 3 - During the day and evening, but not constantly
- ☐ 4 - Constantly
- ☐ NA - Patient nonresponsive

45. When Anxious (Reported or Observed):

- ☐ 0 - None of the time
- ☐ 1 - Less often than daily
- ☐ 2 - Daily, but not constantly
- ☐ 3 - All of the time
- ☐ NA - Patient nonresponsive

46. Depressive Feelings Reported or Observed in Patient: (Mark all that apply.)

- ☐ 1 - Depressed mood (e.g., feeling sad, tearful)
- ☐ 2 - Sense of failure or self reproach
- ☐ 3 - Hopelessness
- ☐ 4 - Recurrent thoughts of death
- ☐ 5 - Thoughts of suicide
- ☐ 6 - None of the above feelings observed or reported

47. Patient Behaviors (Reported or Observed): (Mark all that apply.)

- ☐ 1 - Indecisiveness, lack of concentration
- ☐ 2 - Diminished interest in most activities
- ☐ 3 - Sleep disturbances
- ☐ 4 - Recent change in appetite or weight
- ☐ 5 - Agitation
- ☐ 6 - A suicide attempt
- ☐ 7 - None of the above behaviors observed or reported

48. Behaviors Demonstrated <u>at Least Once a Week</u> (Reported or Observed): (Mark all that apply.)

- ☐ 1 - Memory deficit: failure to recognize familiar persons/places, inability to recall events of past 24 hours, significant memory loss so that supervision is required
- ☐ 2 - Impaired decision-making: failure to perform usual ADLs or IADLs, inability to appropriately stop activities, jeopardizes safety through actions
- ☐ 3 - Verbal disruption: yelling, threatening, excessive profanity, sexual references, etc.
- ☐ 4 - Physical aggression: aggressive or combative to self and others (e.g., hits self, throws objects, punches, dangerous maneuvers with wheelchair or other objects)
- ☐ 5 - Disruptive, infantile, or socially inappropriate behavior (**excludes** verbal actions)
- ☐ 6 - Delusional, hallucinatory, or paranoid behavior
- ☐ 7 - None of the above behaviors demonstrated

49. Frequency of Behavior Problems (Reported or Observed) (e.g., wandering episodes, self abuse, verbal disruption, physical aggression, etc.):

- ☐ 0 - Never
- ☐ 1 - Less than once a month
- ☐ 2 - Once a month
- ☐ 3 - Several times each month
- ☐ 4 - Several times a week
- ☐ 5 - At least daily

50. Is this patient receiving **Psychiatric Nursing Services** at home provided by a qualified psychiatric nurse?

- ☐ 0 - No
- ☐ 1 - Yes

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ADL/IADLs

For Questions 51-67, complete the "current" column for all patients. For these same items, complete the "prior" column only at start of care; mark the level that corresponds to the patient's condition 14 days prior to start of care. In all cases, record what the patient is *able to do*.

51. Grooming: Ability to tend to personal hygiene needs (i.e., washing face and hands, hair care, shaving or make up, teeth or denture care, fingernail care).

Prior Current
- ☐ ☐ 0 - Able to groom self unaided, with or without the use of assistive devices or adapted methods.
- ☐ ☐ 1 - Grooming utensils must be placed within reach before able to complete grooming activities.
- ☐ ☐ 2 - Someone must assist the patient to groom self.
- ☐ ☐ 3 - Patient depends entirely upon someone else for grooming needs.
- ☐ UK - Unknown

52. Ability to Dress Upper Body (with or without dressing aids) including undergarments, pullovers, front-opening shirts and blouses, managing zippers, buttons, and snaps:

Prior Current
- ☐ ☐ 0 - Able to get clothes out of closets and drawers, put them on and remove them from the upper body without assistance.
- ☐ ☐ 1 - Able to dress upper body without assistance if clothing is laid out or handed to the patient.
- ☐ ☐ 2 - Someone must help the patient put on upper body clothing.
- ☐ ☐ 3 - Patient depends entirely upon another person to dress the upper body.
- ☐ UK - Unknown

53. Ability to Dress Lower Body (with or without dressing aids) including undergarments, slacks, socks or nylons, shoes:

Prior Current
- ☐ ☐ 0 - Able to obtain, put on, and remove clothing and shoes without assistance.
- ☐ ☐ 1 - Able to dress lower body without assistance if clothing and shoes are laid out or handed to the patient.
- ☐ ☐ 2 - Someone must help the patient put on undergarments, slacks, socks or nylons, and shoes.
- ☐ ☐ 3 - Patient depends entirely upon another person to dress lower body.
- ☐ UK - Unknown

54. Bathing: Ability to wash entire body. **Excludes grooming (washing face and hands only).**

Prior Current
- ☐ ☐ 0 - Able to bathe self in shower or tub independently.
- ☐ ☐ 1 - With the use of devices, is able to bathe self in shower or tub independently.
- ☐ ☐ 2 - Able to bathe in shower or tub with the assistance of another person:
  (a) for intermittent supervision or encouragement or reminders, OR
  (b) to get in and out of the shower or tub, OR
  (c) for washing difficult to reach areas.
- ☐ ☐ 3 - Participates in bathing self in shower or tub, but requires presence of another person throughout the bath for assistance or supervision.
- ☐ ☐ 4 - Unable to use the shower or tub and is bathed in bed or bedside chair.
- ☐ ☐ 5 - Unable to effectively participate in bathing and is totally bathed by another person.
- ☐ UK - Unknown

55. Toileting: Ability to get to and from the toilet or bedside commode.

Prior Current
- ☐ ☐ 0 - Able to get to and from the toilet independently with or without a device.
- ☐ ☐ 1 - When reminded, assisted, or supervised by another person, able to get to and from the toilet.
- ☐ ☐ 2 - Unable to get to and from the toilet but is able to use a bedside commode (with or without assistance).
- ☐ ☐ 3 - Unable to get to and from the toilet or bedside commode but is able to use a bedpan/urinal independently.
- ☐ ☐ 4 - Is totally dependent in toileting.
- ☐ UK - Unknown

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56. **Transferring:** Ability to move from bed to chair, on and off toilet or commode, into and out of tub or shower, and ability to turn and position self in bed if patient is bedfast.

Prior Current

- ☐ ☐ 0 - Able to independently transfer.
- ☐ ☐ 1 - Transfers with minimal human assistance or with use of an assistive device.
- ☐ ☐ 2 - Unable to transfer self but is able to bear weight and pivot during the transfer process.
- ☐ ☐ 3 - Unable to transfer self and is unable to bear weight or pivot when transferred by another person.
- ☐ ☐ 4 - Bedfast, unable to transfer but is able to turn and position self in bed.
- ☐ ☐ 5 - Bedfast, unable to transfer and is unable to turn and position self.
- ☐ UK - Unknown

57. **Ambulation/Locomotion:** Ability to SAFELY walk, once in a standing position, or use a wheelchair, once in a seated position, on a variety of surfaces.

Prior Current

- ☐ ☐ 0 - Able to independently walk on even and uneven surfaces and climb stairs with or without railings (i.e., needs no human assistance or assistive device).
- ☐ ☐ 1 - Requires use of a device (e.g., cane, walker) to walk alone or requires human supervision or assistance to negotiate stairs or steps or uneven surfaces.
- ☐ ☐ 2 - Able to walk only with the supervision or assistance of another person at all times.
- ☐ ☐ 3 - Chairfast, unable to ambulate but is able to wheel self independently.
- ☐ ☐ 4 - Chairfast, unable to ambulate and is unable to wheel self.
- ☐ ☐ 5 - Bedfast, unable to ambulate or be up in a chair.
- ☐ UK - Unknown

58. **Feeding or Eating:** Ability to feed self meals and snacks. **Note: This refers only to the process of eating, chewing, and swallowing, not preparing the food to be eaten.**

Prior Current

- ☐ ☐ 0 - Able to independently feed self.
- ☐ ☐ 1 - Able to feed self independently but requires:
  (a) meal set-up; OR
  (b) intermittent assistance or supervision from another person; OR
  (c) a liquid, pureed or ground meat diet.
- ☐ ☐ 2 - Unable to feed self and must be assisted or supervised throughout the meal/snack.
- ☐ ☐ 3 - Able to take in nutrients orally and receives supplemental nutrients through a nasogastric tube or gastrostomy.
- ☐ ☐ 4 - Unable to take in nutrients orally and is fed nutrients through a nasogastric tube or gastrostomy.
- ☐ ☐ 5 - Unable to take in nutrients orally or by tube feeding.
- ☐ UK - Unknown

59. **Planning and Preparing Light Meals** (e.g., cereal, sandwich) or reheat delivered meals:

Prior Current

- ☐ ☐ 0 - (a) Able to independently plan and prepare all light meals for self or reheat delivered meals; OR
  (b) Is physically, cognitively, and mentally able to prepare light meals on a regular basis but has not routinely performed light meal preparation in the past (i.e., prior to this home care admission).
- ☐ ☐ 1 - Unable to prepare light meals on a regular basis due to physical, cognitive, or mental limitations.
- ☐ ☐ 2 - Unable to prepare any light meals or reheat any delivered meals.
- ☐ UK - Unknown

60. **Transportation:** Physical and mental ability to safely use a car, taxi, or public transportation (bus, train, subway).

Prior Current

- ☐ ☐ 0 - Able to independently drive a regular or adapted car; OR uses a regular or handicap-accessible public bus.
- ☐ ☐ 1 - Able to ride in a car only when driven by another person; OR able to use a bus or handicap van only when assisted or accompanied by another person.
- ☐ ☐ 2 - Unable to ride in a car, taxi, bus, or van, and requires transportation by ambulance.
- ☐ UK - Unknown

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61. **Laundry:** Ability to do own laundry -- to carry laundry to and from washing machine, to use washer and dryer, to wash small items by hand.

Prior Current

☐ ☐ 0 - (a) Able to independently take care of all laundry tasks; OR
(b) Physically, cognitively, and mentally able to do laundry and access facilities, but has not routinely performed laundry tasks in the past (i.e., prior to this home care admission).

☐ ☐ 1 - Able to do only light laundry, such as minor hand wash or light washer loads. Due to physical, cognitive, or mental limitations, needs assistance with heavy laundry such as carrying large loads of laundry.

☐ ☐ 2 - Unable to do any laundry due to physical limitation or needs continual supervision and assistance due to cognitive or mental limitation.

☐ UK - Unknown

62. **Housekeeping:** Ability to safely and effectively perform light housekeeping and heavier cleaning tasks.

Prior Current

☐ ☐ 0 - (a) Able to independently perform all housekeeping tasks; OR
(b) Physically, cognitively, and mentally able to perform all housekeeping tasks but has not routinely participated in housekeeping tasks in the past (i.e., prior to this home care admission).

☐ ☐ 1 - Able to perform only light housekeeping (e.g., dusting, wiping kitchen counters) tasks independently.

☐ ☐ 2 - Able to perform housekeeping tasks with intermittent assistance or supervision from another person.

☐ ☐ 3 - Unable to consistently perform any housekeeping tasks unless assisted by another person throughout the process.

☐ ☐ 4 - Unable to effectively participate in any housekeeping tasks.

☐ UK - Unknown

63. **Shopping:** Ability to plan for, select, and purchase items in a store and to carry them home or arrange delivery.

Prior Current

☐ ☐ 0 - (a) Able to plan for shopping needs and independently perform shopping tasks, including carrying packages; OR
(b) Physically, cognitively, and mentally able to take care of shopping, but has not done shopping in the past (i.e., prior to this home care admission).

☐ ☐ 1 - Able to go shopping, but needs some assistance:
(a) By self is able to do only light shopping and carry small packages, but needs someone to do occasional major shopping; OR
(b) Unable to go shopping alone, but can go with someone to assist.

☐ ☐ 2 - Unable to go shopping, but is able to identify items needed, place orders, and arrange home delivery.

☐ ☐ 3 - Needs someone to do all shopping and errands.

☐ UK - Unknown

64. **Ability to Use Telephone:** Ability to answer the phone, dial numbers, and effectively use the telephone to communicate.

Prior Current

☐ ☐ 0 - Able to dial numbers and answer calls appropriately and as desired.

☐ ☐ 1 - Able to use a specially adapted telephone (i.e., large numbers on the dial, teletype phone for the deaf) and call essential numbers.

☐ ☐ 2 - Able to answer the telephone and carry on a normal conversation but has difficulty with placing calls.

☐ ☐ 3 - Able to answer the telephone only some of the time or is able to carry on only a limited conversation.

☐ ☐ 4 - Unable to answer the telephone at all but can listen if assisted with equipment.

☐ ☐ 5 - Totally unable to use the telephone.

☐ ☐ NA - Patient does not have a telephone.

☐ UK - Unknown

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MEDICATIONS

65. **Management of Oral Medications:** Patient's ability to prepare and take all prescribed oral medications reliably and safely, including administration of the correct dosage at the appropriate times/intervals. **Excludes injectable and IV medications. (NOTE: This refers to ability, not compliance or willingness.)**

Prior Current

☐ ☐ 0 - Able to independently take the correct oral medication(s) and proper dosage(s) at the correct times.

☐ ☐ 1 - Able to take medication(s) at the correct times if:
(a) individual dosages are prepared in advance by another person; OR
(b) given daily reminders; OR
(c) someone develops a drug diary or chart.

☐ ☐ 2 - Unable to take medication unless administered by someone else.

☐ ☐ NA - No oral medications prescribed.

☐ UK - Unknown

66. **Management of Inhalant/Mist Medications:** Patient's ability to prepare and take all prescribed inhalant/mist medications (nebulizers, metered dose devices) reliably and safely, including administration of the correct dosage at the appropriate times/intervals. **Excludes all other forms of medication (oral tablets, injectable and IV medications).**

Prior Current

☐ ☐ 0 - Able to independently take the correct medication and proper dosage at the correct times.

☐ ☐ 1 - Able to take medication at the correct times if:
(a) individual dosages are prepared in advance by another person, OR
(b) given daily reminders.

☐ ☐ 2 - Unable to take medication unless administered by someone else.

☐ ☐ NA - No inhalant/mist medications prescribed.

☐ UK - Unknown

67. **Management of Injectable Medications:** Patient's ability to prepare and take all prescribed injectable medications reliably and safely, including administration of correct dosage at the appropriate times/intervals. **Excludes IV medications.**

Prior Current

☐ ☐ 0 - Able to independently take the correct medication and proper dosage at the correct times.

☐ ☐ 1 - Able to take injectable medication at correct times if:
(a) individual syringes are prepared in advance by another person, OR
(b) given daily reminders.

☐ ☐ 2 - Unable to take injectable medications unless administered by someone else.

☐ ☐ NA - No injectable medications prescribed.

☐ UK - Unknown

EQUIPMENT MANAGEMENT

68. **Patient Management of Equipment (includes ONLY oxygen, IV/infusion therapy, enteral/parenteral nutrition equipment or supplies):** Patient's ability to set up, monitor and change equipment reliably and safely, add appropriate fluids or medication, clean/store/dispose of equipment or supplies using proper technique. **(NOTE: This refers to ability, not compliance or willingness.)**

☐ 0 - Patient manages all tasks related to equipment completely independently.

☐ 1 - If someone else sets up equipment (i.e., fills portable oxygen tank, provides patient with prepared solutions), patient is able to manage all other aspects of equipment.

☐ 2 - Patient requires considerable assistance from another person to manage equipment, but independently completes portions of the task.

☐ 3 - Patient is only able to monitor equipment (e.g., liter flow, fluid in bag) and must call someone else to manage the equipment.

☐ 4 - Patient is completely dependent on someone else to manage all equipment.

☐ NA - No equipment of this type used in care **[If NA, go to *Question 70*]**

69. **Caregiver Management of Equipment (includes ONLY oxygen, IV/infusion equipment, enteral/parenteral nutrition, ventilator therapy equipment or supplies):** Caregiver's ability to set up, monitor, and change equipment reliably and safely, add appropriate fluids or medication, clean/store/dispose of equipment or supplies using proper technique. **(NOTE: This refers to ability, not compliance or willingness.)**

☐ 0 - Caregiver manages all tasks related to equipment completely independently.

☐ 1 - If someone else sets up equipment, caregiver is able to manage all other aspects.

☐ 2 - Caregiver requires considerable assistance from another person to manage equipment, but independently completes significant portions of task.

☐ 3 - Caregiver is only able to complete small portions of task (e.g., administer nebulizer treatment, clean/store/dispose of equipment or supplies).

☐ 4 - Caregiver is completely dependent on someone else to manage all equipment.

☐ NA - No caregiver

☐ UK - Unknown

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EMERGENT CARE

70. **Emergent Care:** Since the last time OASIS data were collected, has the patient utilized any of the following services for emergent care (other than home care agency services)? **(Mark all that apply.)**

- ☐ 0 - No emergent care services **[If No emergent care and patient discharged, go to *Question 72*]**
- ☐ 1 - Hospital emergency room (includes 23-hour holding)
- ☐ 2 - Doctor's office emergency visit/house call
- ☐ 3 - Outpatient department/clinic emergency (includes urgicenter sites)
- ☐ UK - Unknown

71. **Emergent Care Reason:** For what reason(s) did the patient/family seek emergent care? **(Mark all that apply.)**

- ☐ 1 - Improper medication administration, medication side effects, toxicity, anaphylaxis
- ☐ 2 - Nausea, dehydration, malnutrition, constipation, impaction
- ☐ 3 - Injury caused by fall or accident at home
- ☐ 4 - Respiratory problems (e.g., shortness of breath, respiratory infection, tracheobronchial obstruction)
- ☐ 5 - Wound infection, deteriorating wound status, new lesion/ulcer
- ☐ 6 - Cardiac problems (e.g., fluid overload, exacerbation of CHF, chest pain)
- ☐ 7 - Hypo/Hyperglycemia, diabetes out of control
- ☐ 8 - GI bleeding, obstruction
- ☐ 9 - Other than above reasons
- ☐ UK - Reason unknown

DATA ITEMS COLLECTED AT INPATIENT FACILITY ADMISSION OR DISCHARGE ONLY

72. To which **Inpatient Facility** has the patient been admitted?

- ☐ 1 - Hospital **[Go to *Question 75*]**
- ☐ 2 - Rehabilitation facility **[Go to *Question 78*]**
- ☐ 3 - Nursing home **[Go to *Question 77*]**
- ☐ 4 - Hospice **[Go to *Question 78*]**
- ☐ NA - No inpatient facility admission

73. **Discharge Disposition:** Where is the patient after discharge from your agency? **(Choose only one answer.)**

- ☐ 1 - Patient remained in the community (not in hospital, nursing home, or rehab facility)
- ☐ 2 - Patient transferred to a noninstitutional hospice **[Go to *Question 78*]**
- ☐ 3 - Unknown because patient moved to a geographic location not served by this agency **[Go to *Question 78*]**
- ☐ UK - Other unknown **[Go to *Question 78*]**

74. After discharge, does the patient receive health, personal, or support **Services or Assistance**? **(Mark all that apply.)**

- ☐ 1 - No assistance or services received
- ☐ 2 - Yes, assistance or services provided by family or friends
- ☐ 3 - Yes, assistance or services provided by other community resources (e.g., meals-on-wheels, home health services, homemaker assistance, transportation assistance, assisted living, board and care)

Go to *Question 78*

75. If the patient was admitted to an acute care **Hospital**, for what **Reason** was he/she admitted?

- ☐ 1 - Hospitalization for emergent (unscheduled) care
- ☐ 2 - Hospitalization for urgent (scheduled within 24 hours of admission) care
- ☐ 3 - Hospitalization for elective (scheduled more than 24 hours before admission) care
- ☐ UK - Unknown

76. **Reason for Hospitalization: (Mark all that apply.)**

- ☐ 1 - Improper medication administration, medication side effects, toxicity, anaphylaxis
- ☐ 2 - Injury caused by fall or accident at home
- ☐ 3 - Respiratory problems (SOB, infection, obstruction)
- ☐ 4 - Wound or tube site infection, deteriorating wound status, new lesion/ulcer
- ☐ 5 - Hypo/Hyperglycemia, diabetes out of control
- ☐ 6 - GI bleeding, obstruction
- ☐ 7 - Exacerbation of CHF, fluid overload, heart failure
- ☐ 8 - Myocardial infarction, stroke
- ☐ 9 - Chemotherapy
- ☐ 10 - Scheduled surgical procedure
- ☐ 11 - Urinary tract infection
- ☐ 12 - IV catheter-related infection
- ☐ 13 - Deep vein thrombosis, pulmonary embolus
- ☐ 14 - Uncontrolled pain
- ☐ 15 - Psychotic episode
- ☐ 16 - Other than above reasons

Go to *Question 78*

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77. For what **Reason(s)** was the patient **Admitted** to a **Nursing Home? (Mark all that apply.)**

- ☐ 1 - Therapy services
- ☐ 2 - Respite care
- ☐ 3 - Hospice care
- ☐ 4 - Permanent placement
- ☐ 5 - Unsafe for care at home
- ☐ 6 - Other
- ☐ UK - Unknown

78. **Date of Last (Most Recent) Home Visit:**

__ __ / __ __ / __ __ __ __
month day year

79. **Discharge/Transfer/Death Date:** Enter the date of the discharge, transfer, or death (at home) of the patient.

__ __ / __ __ / __ __ __ __
month day year

- ☐ UK - Unknown

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III. Provision of the Proposed Regulations

This proposed rule would add further requirements to the proposed regulations regarding conditions of participation for HHAs published elsewhere in this issue of the Federal Register. We would require that HHAs incorporate the use of the OASIS in their comprehensive assessment of their patients, and that they use data from the OASIS in their internal quality assessment and performance improvement programs. As we stated previously in this preamble, we are not yet proposing to require that HHAs collect and report OASIS data to a national data system or to use national comparative OASIS data as a part of their quality assessment and performance improvement programs.

- We would revise proposed § 484.55 ''Conditions of participation: Comprehensive assessment of patients'' by adding language to the introductory paragraph so that it would read as follows: ''Each patient must receive, and an HHA must provide, a patient-specific, comprehensive assessment * * * that incorporates the exact use of the current version of the Outcomes and Assessment Information Set (OASIS), as specified by the Secretary.'' We believe that this is the only added regulatory language necessary to require an HHA to incorporate the OASIS into its already existing comprehensive assessment process. While not stated explicitly in the language of the regulation, the OASIS is inappropriate for use with individuals under 21 years of age and is not intended for use with maternity cases. Information about the OASIS'' clinical applicability is part of the dataset procedures so we do not believe it is necessary to state in the proposed regulations that the use of the OASIS is not applicable to maternity cases and individuals under 21 years of age.
- We would also add language at proposed § 484.55(d)(1) to state that the comprehensive assessment must be updated and revised as frequently as the condition of the patient requires, but not less frequently than every 62 days. These updates must include the administration of the OASIS within every 57 to 62 days after the start of care. We are proposing to add this requirement to ensure that reassessments would be completed in time for the 62-day patient recertification.
- We would revise proposed § 484.55(d) to require that an HHA administer the OASIS ''within 48 hours of the patient's return to the home from a hospital admission for any reason except diagnostic testing. (This update includes the administration of the OASIS.)'' We are proposing to add the requirement that an assessment using the OASIS be administered after a hospital admission for any reason except diagnostic testing because we know that, typically, such a hospital admission can indicate a significant change in a patient's functional status.

We believe that the use of the OASIS upon the patient's return to the home would be useful from a care planning standpoint as part of the comprehensive assessment and as a significant functional status ''data point'' for comparative purposes. This event will trigger reporting of OASIS data as well in the future.

- We would add new § 484.55(e) to provide that the HHA must incorporate into its own assessment instrument, exactly as the OASIS is written, OASIS data items that 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.
- We would add language to § 484.65(a) ''Conditions of participation: Quality assessment and performance improvement'' to indicate that the HHA's quality assessment and performance improvement program must include at a minimum, quality indicator data derived from patient assessments, that must be included in data derived from the use of the OASIS.

While we are not yet proposing to require that HHAs collect and report OASIS data to a national data set, the incorporation of the OASIS into the comprehensive patient assessment would provide the HHA with a rich, internal database that it can begin to use for its internal quality assessment and performance improvement programs. For a home health company or a managed care organization, the availability of OASIS data for company-wide or organization-wide use would be helpful in measuring performance and identifying both those areas that need improvement and those areas where performance is exemplary. This information can be shared by HHAs throughout the company or organization to improve performance. Small HHAs can enter into arrangements with other HHAs to share data into a larger pool for the same purposes as larger organizations. The net result of this rulemaking, then, would be to require each HHA to use the OASIS as part of its comprehensive assessment of patients and to use that information not only for care planning and service delivery, but as a part of the HHA's quality assessment and performance improvement program.

While we believe we have accurately summarized the history of the development of quality indicators for home care, the potential uses of them in the near and longer-term future, and our planned regulatory approach to incorporating their use into the HHA conditions of participation, we welcome comments on all aspects of both this discussion and our regulatory approach to incorporating the use of quality indicators into the Medicare HHA benefit. As with any system of measurement, there are limitations to the home health care quality indicators (and the OASIS), and we have tried to be sensitive to those limitations. Commenters are urged to help us ensure that we have struck the proper balance between what our proposed approach can and likely cannot achieve.

IV. Impact Statement

A. Impact on HHAs

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 proposed rule such as this would 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.

All HHAs are considered small entities for the purposes of the RFA. Consequently, we are including a statement of impact on the effect that this proposed rule would have on HHAs. This impact statement reflects *only* the impact of the provisions of this proposed rule. There are no costs in this impact analysis that stem from the proposed regulations regarding the HHA conditions of participation published elsewhere in this issue of the Federal Register. Only the costs associated with the introduction of the OASIS into the HHA conditions of participation are included in this impact statement and in the Collection of Information Requirements section of this preamble.

We anticipate that HHAs will incur some additional costs from implementation of this proposed rule. These costs are Medicare and Medicaid allowable costs and will be paid on a reasonable costs basis subject to the applicable Medicare and Medicaid rules. A chart projecting the costs to HHAs for the first five years of implementation of the use of the OASIS

is included at Section VI.C.1. We strongly believe that the benefits associated with the use of OASIS data will far outweigh its costs. As discussed in detail 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 their care planning. The increased specificity in patient assessment will assist agency staff to uniquely tailor a treatment plan to each individual patient.

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 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 the State survey agencies will be able to use the data on a continuous basis to identify providers that are not performing to the norm. This use will allow us to further progress in our efforts to develop a more efficient and targeted survey approach.

As we discussed above, these proposed regulations would require that each HHA use a standard core assessment data set as part of its assessment of most adult patients. The impact of these proposed regulations would 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 and is discussed in detail in the ''Collection of Information Requirements'' section of this preamble. There are no other requirements that would impact HHAs in these proposed regulations.

B. Rural Impact Statement

Section 1102(b) of the Social Security Act (the Act) requires us to prepare a regulatory impact analysis for any proposed 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 proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

C. Review by the Office of Management and Budget

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

V. Response to Comments

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

VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, agencies are required to provide 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, 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. Therefore, we are soliciting public comment on each of these issues for the proposed information collection requirements discussed below.

The proposed regulations at § 484.55 and § 484.65 would require HHAs to use the OASIS as part of a comprehensive assessment of the patient. The burden from requiring HHAs to collect the OASIS data can be divided into two categories. The first category encompasses activities that are required for startup. These activities include incorporating the OASIS data into an HHA's clinical records, initial acclimation to the OASIS, and training agency staff to use the OASIS data. After these initial startup activities, the second burden arises from the collection of the OASIS data on an ongoing basis.

A. Startup Activities: Time and Cost

We expect HHAs to incorporate the OASIS data into their clinical records both to minimize the documentation burden (for example, 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 followup time point (that is, every 57 to 62 days; within 48 hours after the return home from a hospital admission; and at discharge).

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. Most HHAs are accustomed to revising patient assessment instruments periodically, as new assessment protocols become available or as new requirements by accrediting bodies or regulators are implemented. Once OASIS items are included in clinical record forms, HHAs should have only minor subsequent revisions to make with any future OASIS releases. The following estimates are based on the actual experience of the HHAs that participated in the development of the home health quality indicators.

1. Inclusion of OASIS Elements Into Assessment Forms

We define an average-size HHA as having 18 nurses and other service providers and 486 admissions per year. We estimate that the time required by an average-size HHA to revise assessment forms to accommodate the OASIS is approximately 8 hours for revision of the initial assessment forms. The HHA will also require an additional 4 hours for revision of clinical record forms at the 57 to 62 day assessment, and for the assessment within 48 hours after a return to home from a hospital admission. Many items in the discharge follow up are identical to these 2 follow up points, but there are several additional data elements associated with discharge that will result in an additional 4 hours for revisions of discharge forms. Thus, the total impact for clinical record forms revision is estimated to be 16 hours per agency for integration of OASIS items for all data collection time points. This estimate includes time associated with pilot testing the revised forms and subsequent revisions as necessary.

We do not believe that nursing staff need to complete the integration of OASIS data elements into an HHA's assessment forms. Therefore, we estimate that the cost for an average-size HHA to revise the clinical records will be $200, based on an hourly rate of $12.50 of clerical time. The total national hours for revisions of patient assessment forms is projected to be 146,992 hours for 9,187 HHAs (the number of certified facilities as of March 1996), with an associated national cost of $1.8 million.

2. Staff Training

We are assuming a total of 3.5 hours per nurse or other service provider within each HHA for purposes of estimating staff training time for the new OASIS recordkeeping. The Center for Health Services Research at the University of Colorado has written a guide, ''Item-by-Item Tips,'' for HHA use in training staff. This guide includes responses for frequently asked questions about OASIS items, and should be helpful to HHAs in the training of staff. Based on research conducted by the University of Colorado, training for data collection for initial assessments will require about 2 hours. Training for data collection for recertification assessments at the follow up points (that is, 57 to 62 day data collection and assessments within 48 hours after the return home from a hospital admission for any reason except diagnostic testing, includes a subset of admission items, but will require an additional 20 minutes of training. Collecting patient status data at discharge is likely to require the most significant modification of current HHA practice. This training will require about 40 minutes of training and will encompass both an introduction to a few specific data items and a discussion of revised agency procedures.

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 utilized by the agency to monitor data accuracy (including follow-behind visits, interdisciplinary comparisons, record reviews) require training as they are implemented. Several approaches to data auditing could be included in training of approximately 30 minutes. The projected 3.5 hours of training time is expected to cost an average HHA with 18 care providers about $1,515, based on an average hourly rate of $24.05 for a registered nurse. The total national training burden is projected to be 578,781 hours across all certified HHAs, at a cost of $13.9 million.

Once care providers are familiar with the OASIS items, OASIS data collection imposes a minimal burden above what care providers are currently doing to assess their patients. 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 care providers 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, after using the OASIS approximately 5 times, the time required beyond the routine patient assessment to complete the OASIS decreases to approximately 2.5 minutes. Thus, the total ''startup'' or transitional burden until familiarity with OASIS for an average HHA is estimated to be 22.5 hours and to cost about $541, based on an average hourly rate of $24.05 for a registered nurse. This results in a national burden of 206,708 hours for all HHAs, at a cost of $5 million.

B. Ongoing Data Collection

Most items included in the OASIS require information that the majority of care providers currently gather during patient assessments. However, the OASIS employs a more precise scale. For instance, most care providers assess a patient's ability to bathe in the course of an assessment, but only using three levels (independent, needs moderate assistance, or dependent). The OASIS item for bathing requires that the care provider assess 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 57 to 62 days, within 48 hours after return to the home from a hospital admission for any reason except diagnostic testing, and at discharge). Some data items are unique to only one time point (for example, selected items are only collected 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 (for example, a given HHA's patients relative to a national reference sample.)

OASIS data collection on an ongoing basis imposes a minimal burden above the routine patient assessment. We estimate that providers using clinical records with integrated OASIS items will need an additional 2.5 additional minutes for both start of care and for the followup assessment at the 57 to 62 day interval. Therefore, when collecting OASIS data, HHAs will spend an additional 2.5 minutes beyond what they currently use to complete the patient assessment at start of care. Similarly, at 57 to 62 day intervals, care providers currently conduct detailed assessments in order to review any needed changes in the plan of care for recertification. OASIS items are expected to require an additional 2.5 minutes above the routine assessment currently performed by home health agencies at 57 to 62 day intervals.

For home health episodes that began in 1992, HCFA billing data indicate that 42 percent of HHA patients would have had at least one 60-day follow up. Data from 1992 also indicate that 26 percent of patient home health episodes lasted more than 120 days requiring a second follow up, while 17 percent had episodes lasting 180 days or longer requiring a third follow up. Since the average HHA has 486 admissions per year, in conjunction with the episode length information from 1992, we estimate an impact per HHA of 20.3 hours per year for start-of-care assessments, and 17.2 hours per year for the 57 to 62 day intervals.

Factoring in an additional 2.5 minutes beyond what agencies currently do, we also estimate an additional burden of 5.1 hours per HHA for assessments conducted within 48 hours after a patient's return to home from a hospital admission for any reason except diagnostic testing. This assumes that 25 percent of patients are admitted to hospitals per year and require the resumption of home health services upon return to the home.

At discharge, care providers currently conduct a fairly brief assessment, only documenting significant changes in patients and the reason for discharge. However, OASIS requires that care providers conduct a more thorough patient assessment. This provides the information necessary to measure changes in patient health status over time and permits statistical analysis of patient outcomes (including aggregation of patient data to produce agency-level outcome reports). Therefore, while some additional burden is imposed on care providers, data collection at discharge is necessary to measure outcomes. Based on 486 admissions for an average HHA, and applying an incremental time increase of 8 minutes, the estimated total time necessary to complete the OASIS items at patient discharge is

projected to be 64.8 hours per year per agency.

Finally, as we stated earlier in this preamble, the OASIS will be updated and improved from time to time after implementation. We anticipate these changes to be refinements of existing items and the addition and deletion of items depending on utility or ineffectiveness. On balance, we believe the implementation of later iterations of the OASIS will result in a very small cost to HHAs. However, when such revisions are made, we will detail the related costs.

In total, we project that the total incremental ongoing time for an average HHA to complete OASIS data will be about 107.3 hours per year, with an associated cost of $2,583. Nationally, this will result in 1,077,721 hours of incremental time based on historical growth rates of 9.3 percent for HHAs, at an estimated cost of $25.9 million.

Again, we welcome comments on all aspects of the above material. Written comments on the information collection and recordkeeping requirement should be mailed directly to the following:

Health Care Financing Administration, Office of Financial and Human Resources, Management Planning and Analysis Staff, Room C2–26–17, 7500 Security Boulevard, Baltimore, MD 21244–1850; and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

Attention: Allison Herron Eydt, HCFA Desk Officer.

Any comments submitted on the collection of information requirements set forth in § 484.55 and § 484.65 must be received by these two offices on or before May 9, 1997, to enable OMB to act promptly on HCFA's information collection approval request.

C. Summary of Cost and Burden Estimates

The following tables summarize the total burden from the collection of the OASIS items:

1. NATIONAL COSTS TO HHAS FOR IMPLEMENTATION OF THE OASIS

Year*	Number of agencies incurring start-up costs	Start-up costs @ $2256 per HHA (in millions)	Ongoing costs @ $2583 per HHA (in millions)	Total costs (in millions)	Medicare costs (in millions)
1	9,187	$20.73	$23.73	$44.46	$22.23
2	864	1.93	25.94	27.86	13.93
3	934	2.11	28.35	30.46	15.23
4	1,021	2.30	30.99	33.29	16.64
5	1,006	2.52	33.87	36.38	18.19

*These costs are based on the assumption that date of implementation will be in fiscal year 1997.

2. BREAKDOWN OF AGENCY START UP AND ONGOING COSTS

Task	Agency costs (in dollars)	National costs—historic growth rate of 9.3% (Agency costs × 9,187 HHAs) (in millions of dollars)
Startup (one-time only) costs:		
Integration of OASIS into existing assessment forms	$200	$1.8
Staff training	1515	13.9
Learning curve	541	5.0
Total start up costs	2256	20.7
Ongoing costs:		
Initial care	488	4.5
Follow up (57–62 days)	414	3.8
Post-hospital admission	120	1.1
Discharges	1558	1.4
Total ongoing costs	2583	25.9
Total combined costs	4839	46.6

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

Task	Hours	Computation of average costs	Average cost
Intergration of OASIS into existing assessment forms:			
Revision of intial assessment forms	8		
Revision of clinical forms (57–62 day assessment)	4		
Revision of clinical forms (48 hours post-hospital admission)	4		
Total	16	16 hrs × $12.50 per hr (avg. clerical rate)	$200
Staff training:			
Data collection for initial assessment	2		

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

Task	Hours	Computation of average costs	Average cost
Data collection for recertification assessment at follow-up	0.3		
Data collection at discharge	0.7		
Data auditing	0.5		
Total	3.5	3.5 hrs × $24.05 per hr × 18 providers	1,515
Learning curve:			
Initial use of the OASIS data collection	0.25		
Next 4 uses of the OASIS data collection (4 × .25 hrs)	1		
Total	1.25	1.25 hrs × $24.05 per hr × 18 providers	541
Total	19.75		2,256

4. HOURLY BREAKDOWN AND COMPUTATION OF ONGOING OASIS COST BURDENS PER HHA

Task	Computation of hours	Total hours	Computation of average cost	Average cost
Initial care	486 admissions×2.5 min per admissions÷60 min.	20.3	20.3 hrs×$24.05 per hr	$488
Followup (57–62 days)	(42 percent of HHA patients×first follow-up×486 admissions) + (26 percent of HHA patients×second follow-ups×486 admissions)+(17 percent×third follow-up×486 admissions)=413 follow-ups—413 follow-ups×2.5 min per followup÷60 min.	17.2	Hrs×$24.05 per hr	414
Post-hospital admission	(486 admissions×.25 of HHA patients×2.5 min per admission)÷60 min.	5.1	5.1 hrs×$24.05 per hr	123
Discharge	(486 admissions×8 min per admission)÷60 min.	64.8	64.8 hrs×$24.05 per hr	1,558
Total		107.4		2,583

42 CFR Chapter IV would be amended as follows:

List of Subjects in 42 CFR Part 484

Health facilities, health professions, Medicare, Reporting and record keeping requirements.

Note to readers: The following proposed regulations text reflects changes to proposed regulation text published elsewhere in this issue of the Federal Register and not to regulations text in the existing Code of Federal Regulations.

HCFA proposes to amend 42 CFR Part 484 would be amended as set forth below.

PART 484—CONDITIONS OF PARTICIPATION: HOME HEALTH AGENCIES

A. 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)).

B. In § 484.55, the introductory paragraph and paragraph (d) are revised and new paragraph (e) is added 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 identifies the patient's need for home care, that meets the patient's medical, nursing, rehabilitative, social, and discharge planning needs, and that incorporates the exact use of the current version of the Outcomes and Assessment Information Set (OASIS), as specified by the Secretary.

* * * * *

(d) *Standard: Update of comprehensive assessment.* The comprehensive assessment must include information on the patient's progress toward clinical outcomes, and must be updated and revised—

(1) As frequently as the condition of the patient requires, but not less frequently than every 62 days. These updates must include the administration of the OASIS within every 57 to 62 days after the start of care;

(2) When the plan is revised for physician review;

(3) Within 48 hours of the patient's return to the home from a hospital admission for any reason except diagnostic testing (This update includes the administration of the OASIS.); and

(4) At discharge. (This update includes the administration of the OASIS.)

(e) *Standard: Incorporation of OASIS data items.* The OASIS data items must be incorporated into the HHA's own assessment instrument and must include, exactly as the OASIS is written, 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 information.

C. In § 484.65, paragraph (a)(1) is revised to read as follows:

§ 484.65 Condition of participation: Quality assessment and performance improvement.

* * * * *

(a) * * *

(1) Quality indicator data derived from patient assessments, including, at a minimum, data derived from the use of the OASIS, to determine if individual and aggregate measurable outcomes are achieved compared to a specified previous time period.

* * * * *

(Catalog of Federal Domestic Assistance Programs No 93.774, Medicare—Supplementary Medical Insurance, and No. 93,778, Medical Assistance Program)

Dated: January 21, 1997.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

Dated: January 30, 1997.

Donna E. Shalala,

Secretary.

[FR Doc. 97–5315 Filed 3–5–97; 9:45 am]

BILLING CODE 4120–01–P