Supporting Statement For Paperwork Reduction Act Submission – Part A
"Home Health Quality Measures and Data Analysis"

A. Background

Medicare-certified home health agencies (HHAs) must meet the Conditions of Participation (COPs) as set forth at 42 CFR Part 484 and 488. Since 1999, the COPs have mandated that HHAs use the "Outcome and Assessment Information Set" (OASIS) data set when evaluating adult, non-maternity patients receiving skilled services.[1] The OASIS is a patient-specific, comprehensive assessment that identifies each patient's need for home care and that meets the patient's medical, nursing, rehabilitative, social and discharge planning needs. CMS sees the OASIS as 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." [2]

HHAs are required to collect OASIS data at specific time points (admission, resumption of care after inpatient stay, recertification every 60 days that the patient remains in care, transfer, and at discharge). HHAs are also required to encode and transmit patient OASIS data to the state OASIS repositories. State survey agencies are responsible for collecting OASIS data from HHAs and making OASIS-based outcome reports available to HHAs. Through the state system, an HHA is able to obtain online outcome reports based on its own OASIS data submissions, and comparative state and national aggregate reports. Individual HHAs thus have on-line access to case mix reports, adverse event reports and annualized risk-adjusted outcome reports based on their own reported OASIS data. CMS regularly collects OASIS data from the states for storage in the national OASIS repository, and measures of patient outcomes are made available to consumers and the general public through the Home Health Compare website maintained by CMS.

Since 2000, elements of the OASIS data have also served as the basis for the Prospective Payment System (PPS) that determines home health reimbursement for Medicare patients. Using the same data elements for both quality monitoring and payment allows CMS to ensure that HHAs are not

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1 In meeting the Conditions of Participation, HHAs are expected to collect OASIS data on all of the patients served by the agency with the following exceptions: 1) maternity patients; 2) those under 18; and, 3) those receiving only personal care services, e.g., housekeeping, chore services. In 2003, Section 704 of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) temporarily suspended OASIS collection for non-Medicare/non-Medicaid patients until the outcome of an OASIS Study is presented to Congress. This study was completed in December 2005 and has been submitted to Congress.

2 Medicare and Medicaid Programs: Use of the OASIS as Part of the Conditions of Participation for Home Health Agencies, 42 CFR Part 484 [Final Rules], *Federal Register*, Volume 64, Number 15, January 25, 1999, Pages 3747-3784.

maximizing profits at the expense of beneficiary outcomes while realizing the efficiency of using a single data source. [3]

OASIS is also instrumental in assisting CMS to address the new challenges presented by Pay for Reporting (as mandated in the Dec. 2005 Deficit Reduction Act). Specifically, section 5201(c)(2) of the DRA added section 1895 (b)(3)(B)(v)(II) to the Social Security Act, requiring that "every home health agency [HHA] shall submit to the Secretary [of Health and Human Services] such data that the Secretary determines are appropriate for the measurement of health care quality. Such data shall be submitted in a form and manner, and at a time, specified by the Secretary for purposes of this clause." In addition, section 1895 (b)(3)(B)(v)(I), as also added by 5201 (c)(2) of the DRA, dictates that "for 2007 and each subsequent year, in the case of a home health agency that does not submit data to the Secretary in accordance with subclause (II) with respect to such a year, the home health market basket percentage increase applicable under such clause for such year shall be reduced by 2 percentage points."

Need for revision of the OASIS Data Set

Since OASIS data collection was mandated in 1999, CMS has been systematically collecting input on ways to improve the OASIS instrument and reduce the burden of the collection effort. In 2002, CMS introduced the "reduced-burden" OASIS that was a product of the Secretary's Regulatory Reform Advisory Committee to help guide HHS' broader efforts to streamline unnecessarily burdensome or inefficient regulations that interfere with the quality of health care. The Advisory Committee studied OASIS and recommended deleting those items and assessments not used for payment, quality measurement or survey purposes in an effort to ease paperwork burden on HHAs and their clinicians. This resulted in a burden reduction of 28% and the revised OASIS was implemented in December 2002.

Since the 2002 revision, CMS has continued to solicit input on potential refinements and enhancements of the OASIS instrument from HHAs, industry associations, consumer representatives, researchers and other stakeholders. Work carried out under a previous contract by University of Colorado Health Sciences Center (UCHSC) included gathering suggestions for OASIS revisions, synthesizing and consolidating suggestions for review by a technical expert panel and CMS staff, data analysis to inform the review process, and development of a series of potential OASIS enhancements for consideration by CMS.

Proposed revisions to OASIS items to address issues raised by stakeholders include removing items that are not currently used by CMS for payment or quality, adding items to address clinical domains not currently covered, and modifying item wording or response categories for selected items. These changes and item deletions are and considered to be high priority by CMS and will have implications for outcome measurement, risk adjustment of outcome reports, case mix adjustment for prospective

3 Sections 4602 and 4603 of the Balanced Budget Act require the implementation of a home health prospective payment system (PPS) to replace an interim payment system. In defining PPS for home health agencies (HHAs), the statute requires the Secretary to consider an appropriate unit of service, the number, type and duration of visits provided within that unit of service, and their cost. Payment for a unit of service was modified by a case-mix adjustor, set by the Secretary, to explain a significant amount of the variation in the cost of different units of services. The home health PPS was implemented October 1, 2000.

payment, data submission procedures and specifications, reporting systems, and provider paperwork burden.

In addition, adopting measures of efficient and high-quality care is central to the direction that CMS would like to take in its Quality Initiative. In concordance with long-standing federal objectives, CMS ultimately plans to create a standard patient assessment instrument that can be used across all post-acute care settings. We see the upcoming revision of the OASIS instrument as an opportunity to consider various components of quality care and how patients might be better served as they (and information about them and their care) move among health care settings. For this reason, there is a need for development of process measures that support evidence-based practices across the post-acute care spectrum that have been shown to prevent exacerbation of serious conditions, can improve care received by individual patients, and can provide guidance to agencies on how to improve care and avoid adverse events. Various panels of technical experts, stakeholders, industry associations, MedPAC, and the National Quality Forum (NQF) have offered insights and suggestions on what processes of care reflect best practices for patients receiving care in their homes. Emphasis on incorporating NQF recommendations, advancing standardization of OASIS with various tools (including MDS) and promoting use of evidence-based strategies that improve health are all integral to OASIS instrument revisions to be tested in the upcoming phase.

The revised OASIS instrument

Abt Associates and their subcontractor UCHSC were awarded a contract by CMS in September 2006 to continue the process of refining the OASIS data set, as well as for the testing of the instrument and analysis of the impact of proposed changes. Under this contract, researchers from Abt Associates, UCHSC, and Case Western Reserve University have assisted CMS in carrying out the revisions based on the input described in the previous section. Changes to the OASIS instrument include the following removal and revision of items:

- Elimination of 7 original OASIS items not required for payment, quality or risk adjustment;

- Replacement of 44 original OASIS items with items that are revised and/or simplified to respond to industry concerns by increasing clarity and user-friendliness, and/or reducing complexity and burden (e.g., removal of "prior status" assessment for all Activity of Daily Living (ADL) and Instrumental Activity of Daily Living (IADL) items).

The revised OASIS also includes the addition of the following process items to support evidence-based practices:

- A total of 7 process items to be collected only at Start of Care/Resumption of Care, 4 of which are to be asked seasonally (e.g.; flu vaccine);

- A total of 10 process items to be collected only at Follow-up, Transfer or Discharge, either seasonally or on a small subpopulation;

- A total of 13 process items to be collected at all OASIS time points, 6 of which are to be collected on a small subpopulation.

We estimate the elimination, simplification and revision of existing OASIS items will have a burden impact equivalent to the complete elimination of 19 items. Since many of the process items will be collected only on small subpopulations or during specific months of the year, we estimate the impact of the addition of these items on burden to be equivalent to the addition of 20 items. Therefore, total impact of proposed OASIS revisions, including both elimination, revision and addition of items, changes the estimated burden of the OASIS very little while incorporating process measures needed to support evidence-based practices across the post-acute care spectrum. A revised OASIS instrument incorporating the changes described here is included as Attachment A to this document.

B. Justification

1 . Need and Legal Basis

CMS wants to ensure that the revised OASIS instrument incorporates clinically relevant elements that exhibit the highest degree of validity and reliability – individually, as part of any composite measure, and within a revised patient assessment/data collection instrument. In light of the highly variable kappa values that have been documented across OASIS measures in previous studies[4], CMS is particularly interested in testing proposed OASIS changes and additions not only for reliability but also for agreement corrected for chance. The degree of precision with which elements of interest can be accurately assessed (i.e., specificity as well as sensitivity) is a key criterion.

In addition, CMS places a high priority on designing a home health assessment instrument with refinements that are responsive to industry concerns. Although we have estimated that proposed changes to OASIS items will create an instrument that does not create additional burden, there is no way to validate this without testing the instrument in a home health environment. Similarly, although OASIS changes have been based on stakeholder input, testing of new and revised items with actual users in a home health environment and obtaining their feedback is critical to assess the impact of these changes.

2. Information Users

The information collected will form the basis for CMS's decisions on how best to refine the OASIS data collection instrument. Where appropriate, CMS may also share lessons learned from the survey with HHA industry representatives and other interested parties. This information will be at an aggregate level; no individually identifiable HHA data will be released to the public.

4 Brown University; Reliability Report Medicare Home Health Case Mix Project, January 2000; HCFA Contract #500-96-0003/TO2, Draft: Final Report on Reliability of OASIS-PLUS, Berg, Katherine, PhD, PT.

3. Use of Information Technology

The revised OASIS instrument is not currently available in electronic format. Development of information technology for data collection and submission would not be cost effective since data collection for the testing process will be completed over a period of 3 months or less. Also, the study will require the full revised OASIS instrument to be employed only 180 times in one of 4 versions (Start of Care, Recertification, Transfer and Discharge), with a "mini-assessment" consisting of only new and revised items to be used 320 times in one of the 4 aforementioned versions.

4. Duplication of Efforts

Testing of the revised OASIS instrument for time burden and reliability does not duplicate any other known data collection, and will provide unique information unavailable from any other source. As stated above, the specificity and sensitivity with which proposed OASIS items can be accurately assessed, as well as the burden involved in their collection, are key criteria for determining whether they should ultimately be considered for inclusion in a revised version of OASIS. For this reason, testing of new and revised items with actual users in a home health environment is necessary to ensure that the resulting OASIS instrument is the most valid and the least burdensome instrument possible.

5. Small Businesses

It is not anticipated that the testing of the revised OASIS instrument will impose any larger burden on small HHAs than on larger sized HHAs. Testing of the revised OASIS instrument will be restricted to five or fewer HHAs, participation is voluntary, and a decision not to participate will not affect HHA status with Medicare/Medicaid programs. Also, the Technical Expert Panel that recommended the OASIS revisions included representatives of small HHAs, whose input was sought during the design of the item changes. The data collection timetable will be flexible to minimize burden and to help ensure that an adequate number of responses is obtained from these HHAs, so that burden estimates resulting from the testing will include representation of smaller HHAs.

6. Less Frequent Collection

Limited testing of the revised OASIS instrument is proposed to occur over one 3-month period in the fall of 2007. In order to test the revised OASIS items, the minimum amount of data collection will be performed that also allows statistical accuracy. To assess the time burden of the full revised OASIS, a minimum of 180 complete assessments to ensure statistical accuracy will be required. Data collection to test inter-rater reliability will require a minimum of 160 paired assessments to ensure statistical accuracy. Verification and validation of process measures will be performed on data collected for the tests of burden and inter-rater reliability; no further data collection is needed.

7. Special Circumstances

There are no special circumstances in the data collection for the testing of the revised OASIS instrument.

8. Federal Register/Outside Consultation

INSERT: provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, required by 5 CFR 1320.8 (d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken by the agency in response to these comments. Specifically address comments received on cost and hour burden. (PRA staff is responsible for preparing the appropriate Federal Register Notice(s) for publication in the Federal Register. In this section, PRA staff will put in the date the Federal Register notice published).

Since August 2002, CMS has consulted with various industry associations such as the National Association for Home Care, the American Federation of Home Health Agencies, and the Visiting Nurses Association of America to solicit input on proposed changes to the OASIS instrument. A CMS Technical Evaluation Panel composed of home health agency professionals, experts in quality measurement, payment indicators, and systems, and a beneficiary representative also provides advice on OASIS refinement. Researchers from UCHSC, Case Western Reserve University and Abt Associates have assisted CMS in designing the study and will be conducting the testing of the revised OASIS instrument and analyzing the results.

9. Payments/Gifts to Respondents

Payments to Clinicians for Field Test Data Collection:
Home health clinicians from the volunteer HHAs participating in the data collection will receive compensation for their time spent on study-related activities outside of their regular working hours. Compensation will include $25 per hour for attending eight hours of training on proper administration of the revised OASIS instrument; $60 for each of the revised OASIS assessments they conduct for the burden estimate analysis; $50 for each of the "mini-assessments" they conduct for the inter-rater reliability analysis; and $25 for participating in a one hour debriefing interview.

Payments to Agencies for Office-based Activities:
In order to ~~provide an incentive for~~compensate volunteer HHAs ~~to participate, and to compensate them~~ for their involvement in assisting in identifying and scheduling patient assessments, collecting and delivering the paper OASIS assessments to the researchers, ~~and~~ pulling patient charts for review by research nurses, and participating in weekly telephone consultation with researchers, each agency will receive $1000.

10. Confidentiality

All patient-level data are protected from public dissemination in accordance with the Privacy Act of 1974, as amended. The information collected is protected and held confidential in accordance with 20 CFR 401.30. Data will be treated in a confidential manner, unless otherwise compelled by law.~~We pledge confidentiality of patient-specific data as provided by the Privacy Act of 1974 (5 U.S.C. 552a). We do not pledge confidentiality of aggregate data.~~

11. Sensitive Questions

There are no sensitive questions.

12. Burden Estimates (Hours & Wages)

Since data collection for this project will be confined to one 3-month period, and since data collections will be conducted by research and volunteer HHA nurses who will be compensated by the project for their time, we anticipate that the hour and wage burden for the participating volunteer agencies will be minimal. The following narrative describes the data collection to be conducted between December 2007 and March 2008. Table 1 provides a summary of hour and wage burden estimates associated with the proposed data collection.

Assessing burden of revised OASIS instrument

For the burden estimate, the revised OASIS instrument will be conducted by home health clinicians at volunteer HHAs on a total of 180 home health patients. This data collection will be done within the time period normally scheduled for the agency's COP mandated OASIS collection. Clinicians from volunteer agencies will complete a paper version of the revised OASIS, and will record in-home time spent conducting the assessment as well as separately recording additional time spent coding or collecting additional information outside the home. We anticipate no cost or burden to agencies for this activity, as the home health clinicians will be compensated by the project for time spent collecting data for the revised OASIS instrument. [Note: As discussed in #9, clinicians will be receive $60 per assessment for the collection of the revised OASIS.]

Once the revised OASIS assessment has been completed, clinicians will conduct any additional data collection required to complete their agencies' current assessment process, including the OASIS data set as required under the existing COP. This will include collecting data on the OASIS items that are eliminated from the revised OASIS, as well as information on deleted items such as prior ADL/IADL status and any other data their HHA collects as part of their comprehensive assessment.

We anticipate no cost or burden to agencies for the data collection associated with this activity, as it will be done with volunteer nurses outside of their normal working hours. HHA burden will be restricted to office-based activities, i.e. an on-site study coordinator (administrative RN or equivalent) assisting with the identification and recruitment of 180 patients to participate in the burden study, scheduling the clinicians and patients for the burden assessments, and collecting and delivering the paper OASIS assessments to the researchers, ~~-~~Estimated time burden for participating agencies for this activity is ~~30~~ 40 minutes per patient, plus 6 hours per agency (one half hour per week of the 12-week data collection period) for telephone consultation with researchers to review sample fulfillment and discussion of any issues that may arise during the course of the study. Based on a Bureau of Labor Statistics mean hourly wage rate of $27.31 per hour for a Registered Nurse~~s~~ plus a 37.17% benefits for a total estimated employer cost per hour worked of $37.46, total ~~cost~~ burden for all volunteer agencies for this task would be $4,491.00 (119.88 hours) for patient recruitment plus $2,472.36 (66 hours) for telephone consultation. ~~$3,371.40, or~~ This equals a total of $6,963.36 (185.88 hours) for all sites, or $633.03 (16.9 hours) ~~$306.49~~ per agency if 11 agencies participate equally in the data collection.

Reliability testing of new/revised OASIS items and process items

Two research nurses (either agency home health nurses or hired research nurses) will conduct an inter-rater reliability test with 160 purposively selected patients, divided roughly equally among the volunteer home health agencies. Each patient will be assessed by one nurse and then will be independently assessed by a second nurse within 24 hours. Only the revised OASIS items and minimal identifying information will be collected during these "mini-assessments." Some items will be collected only at discharge/transfer and some only of patients with certain clinical conditions, so the sample will be designed to include patients and assessment points meeting those criteria. [Note: as discussed in #9, clinicians will receive $50 per mini-assessment.]

We anticipate no cost or burden to agencies for the data collection associated with this activity, as it will be done with volunteer nurses outside of ~~normal working~~ hours worked for the agency. ~~A~~ For the inter-rater reliability testing, agencies will, however, have responsibility for office-based activities, i.e., the time of the on-site coordinator to assist with the identification and recruitment of the 160 patients to participate in the inter-rater reliability study, scheduling the clinicians and patients for the inter-rater assessments, and collecting and delivering the paper OASIS assessments to the researchers. Estimated time burden for volunteer agencies for this activity is ~~30~~ 40 ~~-~~minutes per patient. Based on a Bureau of Labor Statistics mean hourly wage rate of $27.31 per hour for a Registered Nurses, plus 37.17% for benefits, for a total estimated employer cost per hour worked of $37.46, total ~~wage~~ burden for all ~~the~~ volunteer agencies for this task would be $3,991.74 (106.56 hours) ~~$599.36 per agency~~, or ~~$54.49~~ $362.91 (9.6 hours) per agency if 11 agencies participate equally in the data collection.

Process item verification and descriptive analysis

To verify the process items in the revised OASIS, a research clinician will visit each volunteer agency to review patient charts for evidence that may support or contradict the process item data reported for 80 of the assessments completed as part of the burden and reliability testing. The process item data collected for each of the selected assessments will be encoded by the research

nurse and the full OASIS assessment data will be obtained for the corresponding patient care episodes.

Participating agencies will be asked to pull patient clinical records and OASIS data on the sample of 80 patients. Total time burden on volunteer agencies is estimated to be 5 minutes per record. Based on a Bureau of Labor Statistics mean hourly wage rate of $27.31 per hour for a Registered Nurses plus a 37.17% benefits for a total estimated employer cost per hour worked of $37.46, total wage burden for all volunteer agencies for this task would be $249.73~~48~~ or $22.70~~68~~ per agency if 11 agencies participate equally in the data collection.

Additional activities associated with field testing of revised OASIS instrument

- Training research nurses - Agency and research nurses will receive training in the correct collection of the new and revised OASIS items. We anticipate no cost or burden to agencies for this activity as training will be done outside of normal working hours. [Estimated project costs as noted in #9: $25/hr x 8 hrs x 45 nurses = $9,000]

- Semi-structured interviews with clinicians - In addition to the quantitative testing of assessment and process measure data collection, clinicians at the volunteer home health agencies will be asked to provide feedback concerning the usability, burden, and usefulness of the revised data set, incorporating process as well as assessment items. This information will be gathered at the conclusion of data collection through semi-structured interviews with the clinicians providing the data. We anticipate no cost or burden to agencies for this activity, as interviews will be done outside of normal working hours. [Estimated project costs as noted in #9: $25/hr x 1 hr x 45 nurses = $1,125]

Total hours and cost burden for participating volunteer agencies

Based on the above calculations, Table 1 displays estimated cost and hour burdens to agencies for ~~the proposed data collection~~ office-based activities. (Note that the payments to clinicians for field data collection are not included here.)

Table 1 Total hours and cost burden for participating volunteer agencies

Office-based Activities~~y~~	**Hour burden per participating volunteer agency[1]**	**Wage burden per participating volunteer agency[2]**
Identifying and recruiting patients, and scheduling assessments for burden ~~assessment~~ testing, weekly telephone consultation with study coordinators	~~8.18~~ 16.9	~~$306.49~~ $633.03

Identifying and recruiting patients and scheduling assessments for reliability testing of new/revised OASIS items and process items	~~7.27~~ 9.6	~~$54.49~~ $362.91
Pulling medical records and OASIS data for process measure verification	~~0.33~~ .61	~~$22.68~~ $22.70
Total burden per participating volunteer agency	**~~15.78~~ 27.11 hours**	**~~$383.76~~ $1,018.64**
Total burden	**~~173.58~~ 298.2 hours**	**~~$4,221.36~~ $11,205.04**

[1] Assumes 11 agencies participate equally in the data collection.
[2] As discussed in #9, volunteer agencies will be compensated $1000 for their participation in the study.

13. Capital Costs

This is a one-time data collection for research purposes that will not be repeated. No capital costs will accrue to respondents related to the collection of information for this survey.

14. Cost to Federal Government

The total cost of this data collection activity has been funded by the Centers for Medicare and Medicaid Services through the contract "Home Health Quality Measures and Data Analysis" with Abt Associates (Contract Number HHSM 500-2005-00018I T.O.#2). Colorado's Center for Health Services Research (UCHSC) Costs to revise, expand and enhance the OASIS instrument (Task 1 of the contract) and testing and analysis of revised instrument and impact on the system (Task 2) have been budgeted for a total of $571,135. This includes the cost of compensating research nurses and home health clinicians for training, data collection activities and participation in follow-up interviews, and compensating volunteer agencies for their participation.

15. Changes to Burden

Because this is a one-time only data collection for research purposes, the testing of the revised OASIS instrument will not result in any annual reporting or recordkeeping costs or time burden.

16. Publication/Tabulation Dates

Abt Associates and their subcontractor UCHSC were awarded the contract in September 2006. Work on the contract began at that time on the revision, enhancement, and expansion of the OASIS items. Data collection activities associated with the testing of the revised OASIS instrument are scheduled to occur December 2007 through March 2008. Analysis of the data and impact on existing systems is scheduled to go through June 2008. Results of this data collection and analyses will be tabulated by contractors Abt Associates and UCHSC and

included in a written report to CMS due September 2008.

As described in # 12, data will be collected and analyzed to support the following 3 tasks:

Burden Analysis
The revised OASIS instrument will be conducted on 180 home health patients by HHA clinicians to assess the time burden of the complete revised OASIS. For this analysis, completion times will be averaged across all 180 patients to obtain an estimate of the average completion time for the revised OASIS assessment. The 180 patients will be selected to include sufficient variability of clinical conditions to ensure inclusion of a minimum number of patients for whom condition-specific items are applicable.

Inter-rater reliability
The revised OASIS instrument will be conducted by 2 different home health clinicians within 24 hours on 160 patients in order to test inter-rater reliability of the revised OASIS items. Inter-rater reliability measures the number of times the 2 RNs provide the same response for the same patient out of the 160 patients assessed. The 160 patients will be selected to include sufficient variability of health states to adequately cover all items in the revised OASIS.

Process item verification and analysis
As described previously, a research clinician will visit each volunteer agency within 60 days after the last patient is admitted to the study, to carry out the verification protocol, reviewing patient charts for evidence that may support or contradict the process data reported for 80 of the assessments completed as part of the burden and reliability testing. Stratified sampling may be used to ensure inclusion of a minimum number of patients for whom condition-specific items are applicable. The process item data collected for each selected assessment will be encoded and the full OASIS assessment data will be obtained for the corresponding patient care episodes.

We will then examine the relationship between process items and relevant information in the OASIS, such as level of pain experienced during the home health stay, development of new pressure ulcers, wound healing status and adverse events leading to emergent care or hospitalization. We will produce a descriptive analysis of our findings, including the frequency of responses selected for each process item and whether information that could be used to calculate patient outcomes for the process items could be located in the OASIS.

17. Expiration Date

This is a “One Time Only” survey. CMS would like to display the expiration date.

18. Certification Statement

There are no exceptions to the certification statement.