Supporting Statement for the Paperwork Reduction Act Submission,
Medicare and Medicaid Programs: Conditions of Participation
for Home Health Agencies and Supporting Regulations in 42 CFR 484.10, 484.12, 484.14, 484.16, 484.18, 484.36, 484.48, and 484.52
(CMS-R-39, OMB Control #: 0938-0365)

A. Background

The purpose of this package is to request Office of Management and Budget (OMB) re-approval of the collection of information requirements for the existing conditions of participation (CoPs) that home health agencies must meet to participate in the Medicare program (CMS-R-39, OMB #0938-0365). On March 10, 1997, we proposed to revise the HHA conditions; however, those revisions have not yet been finalized. Also, on January 25, 1999 we finalized a portion of the CoPs to require the use of the Outcome and Assessment Information Set (OASIS). That request is approved under OMB numbers 0938-0760 and 0938-0761. This submission replaces the version due to expire in June, 2007.

Home health services are covered for the elderly and disabled under the Hospital Insurance (Part A) and Supplemental Medical Insurance (Part B) benefits of the Medicare program, and are described in section 1861(m) of the Social Security Act (the Act) (42 U.S.C. 1395x). These services must be furnished by, or under arrangement with, an HHA that participates in the Medicare program, and be provided on a visiting basis in the beneficiary's home. They may include the following:

- Part-time or intermittent skilled nursing care furnished by or under the supervision of a registered nurse.
- Physical therapy, speech-language pathology, or occupational therapy.
- Medical social services under the direction of a physician.
- Part-time or intermittent home health aide services.
- Medical supplies (other than drugs and biologicals) and durable medical equipment.
- Services of interns and residents if the HHA is owned by or affiliated with a hospital that has an approved medical education program.
- Services at hospitals, SNFs, or rehabilitation centers when they involve equipment too cumbersome to bring to the home.

Section 1861(o) of the Act (42 U.S.C. 1395x) specifies certain requirements that a home health agency must meet to participate in the Medicare program. (Existing regulations at 42 CFR 440.70(d) specify that HHAs participating in the Medicaid program must also meet the Medicare CoPs.) In particular, section 1861(o)(6) of the Act requires that an HHA must meet the CoPs specified in section 1891(a) of the Act and such other CoPs as the Secretary finds necessary in the interest of the health and safety of its patients. Section 1891(a) of the Act establishes specific requirements for HHAs in several areas, including patient rights, home health aide training and competency, and compliance with applicable Federal, State, and local laws.

Under the authority of sections 1861(o), 1871 and 1891 of the Act, the Secretary has established

in regulations the requirements that an HHA must meet to participate in the Medicare program. These requirements are set forth in 42 CFR Part 484 as Conditions of Participation for Home Health Agencies. The CoPs apply to an HHA as an entity as well as the services furnished to each individual under the care of the HHA, unless a condition is specifically limited to Medicare beneficiaries. Under section 1891(b) of the Act, the Secretary is responsible for assuring that the CoPs, and their enforcement, are adequate to protect the health and safety of individuals under the care of an HHA and to promote the effective and efficient use of Medicare funds. To implement this requirement, State survey agencies generally conduct surveys of HHAs to determine whether they are complying with the CoPs.

B. Justification

1. Need and Legal Basis

The information collection requirements for which we are requesting OMB approval are listed below. These requirements are among other requirements classified as (or known as) the CoPs which are based on criteria prescribed in law and are standards designed to ensure that each facility has properly trained staff to provide the appropriate safe physical environment for patients. These particular standards reflect comparable standards developed by industry organizations such as the Joint Commission on Accreditation of Healthcare Organizations, and the Community Health Accreditation Program.

2. Information Users

The primary users of this information will be State agency surveyors, the regional home health intermediaries, CMS and HHAs for the purpose of ensuring compliance with Medicare CoPs as well as ensuring the quality of care provided by HHA patients.

3. Improved Information Technology

The information collection methods here present the most efficient and feasible for HHAs.

4. Duplication

There is no duplication of information.

5. Small Business Impact

This information collection affects small businesses. However, the requirements are sufficiently flexible for facilities to meet them in a way consistent with their existing operations.

6. Less Frequent Collection

With less frequent collection, CMS would not be able to ensure timely compliance with HHA CoPs.

7. Special Circumstances Leading to Information Collection

There are no special circumstances for collecting this information.

8. Federal Register Notice/Outside Consultation

The 60-day Federal Register notice published on April 27, 2007.

9. Payment or Gift to Respondents

There are no payments or gifts to respondents.

10. Confidentiality

We do not pledge confidentiality of aggregate data. We pledge confidentiality of patient-specific data in accordance with the Privacy Act of 1974 (5 U.S.C. 552a).

11. Sensitive Questions

There are no questions of a sensitive nature.

12/13. Burden Estimates (Hours and Wages)/Estimate of Total Annual Cost Burden

The information collection requirements are shown below with an estimate of the annual reporting and record keeping burdens. Included in the estimates is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. As of August 2006 there are approximately 8,997 home health agencies. Based on growth figures for the last three years, we estimate that there will be approximately 357 agencies per year entering the program. According to the Standard Analytical Files of the Health Customer Information System, there were 3.1 million Medicare beneficiaries receiving home health services in calendar year 2006. We define an average-size HHA as having 356 admissions per year and 31 nurses and other clinicians or service providers at an average salary of $26.27 per hour (based on information from the National Association for Home Care 2004-5 *Basic Statistics About Home Care* report).

Many of the following requirements are performed only once by each agency (such as the development of a standard patient rights disclosure) and would normally be performed by an agency in the normal course of responsible business practices in the absence of these requirements (such as the maintenance of personnel records) and therefore represent a minimal, if any, burden on home health agencies.

- §484.10 Condition of participation: Patient rights.

  The requirements under this CoP require that the HHA: (a) must provide the patient with a written notice of the patient's rights in advance of providing care and document that it has complied with this requirement; (b) must document the existence and resolution of

complaints about care furnished by the agency that were made by a patient, the patient's family, or guardian; (c) must advise the patient in advance of the disciplines that will furnish care and the proposed frequency of visits to provide such care as well as any changes in the plan of care before the change is made; (d) must advise the patient of the agency's policies and procedures regarding disclosure of clinical records; (e) must advise the patient of the extent to which payment for their services can be expected from any Federally funded or aided program, as well as what costs will not be covered by Medicare and must be paid by the individual, and must also advise the patient orally and in writing of any changes in this information; (f) must advise the patient of the number, purpose, and hours of operation of the State home health hotline.

New HHAs will need to develop a standard notice of rights that will fulfill the requirements contained in paragraphs (a), (c), (d), (e) and (f). Existing HHAs have already developed this notice. The standard notice will contain a checklist to be completed by the HHA in a manner appropriate to each client being admitted. A copy of the signed notice will impose a minimal burden as estimated below. In the rare circumstances to which paragraph (b) applies, it is already common practice to have this information retained in the medical record. Therefore, the requirement under paragraph (b) imposes no burden. The information collection requirements contained in this section mirror those in section 4021 of OBRA '87, which specify the rights of patients receiving services from Medicare certified and/or approved HHA's. These requirements are necessary to ensure HHA compliance with statutory responsibilities. The total estimated annual burden hours for this CoP is **277,502 hours** (356 admits/yr x 5 minutes per admit x 8997 HHAs + 357 estimated new HHAs / 60 minutes). Total cost burden is estimated as $7, 317,727.74 (277,502 hours x $26.37).

- §484.11 Condition of participation: Reporting OASIS information

  CMS-R-209: Approved by OMB (OMB Control #: 0938-0761)

- §484.12 Condition of participation: Compliance with Federal, State and local laws, disclosure and ownership information, and accepted professional standards and principles.

  The HHA must disclose to the State Survey Agency, at the time of the HHA's initial request for certification, the name and address of all persons with an ownership or control interest in the HHA, the name and address of all officers, directors, agents, and managers of the HHA, as well as the name and address of the corporation or association responsible for the management of the HHA and the chief executive and chairman of that corporation or association. This requirement directly implements section 4021 of OBRA '87 and imposes a minimal burden of the creation of a new disclosure of ownership for newly certified HHAs. The burden imposed by the creation of a new document is estimated at 5 minutes for 357 estimated newly certified HHAs. Existing HHAs have already created this disclosure form, and because it must only be done once, they are no longer burdened by this requirement. The total estimated burden is **29.75 hours** (357 estimated new HHAs x 5 minutes / 60 minutes). Total cost burden is estimated at

$781.53 (29.75 hours x $26.27).

- §484.14 Condition of participation: Organization, services and administration.

  Under this CoP the HHA must organize, manage, and administer its resources to attain and maintain the highest practicable functional capacity for each patient regarding medical, nursing, and rehabilitative needs as indicated by the plan of care. These requirements are necessary to ensure responsible management of participating HHAs as well as an acceptable quality care for beneficiaries. Paragraphs (c), (e), (f) and (g) impose no additional burden as they are good business or medical practices which would otherwise be self-imposed by facilities in the absence of Federal requirements. Paragraph (g), which requires that a written summary report for each patient be sent to the attending physician every 62 days, imposes a burden of 3 minutes per patient. The estimated annual burden for HHAs is **160,146 hours** (3 minutes per patient x 356 admissions per HHA x 8997 HHAs / 60 minutes) at a cost of $4,207,051 (160,146 hours x $26.27).

  Paragraph (i) which relates to the HHA's institutional planning imposes a minimal burden and is the amount of time required to develop the initial plan and to review and revise the existing plan. We estimate the burden for developing a new plan at 1½ hours (90 minutes) and the burden for reviewing and revising an existing plan at 30 minutes. If the anticipated source of financing for such expenditure is Title V, Medicare, or Medicaid, the plan must specify whether a capital expenditure proposal has been submitted to the designated planning agency in accordance with section 1122 of the Act, and specify whether the planning agency has approved or disapproved the proposal. The overall plan and budget is reviewed and updated at least annually. The estimated annual burden for existing HHAs is 4498.5 hours (8997 existing HHAs x 30 minutes / 60 minutes). The estimated annual burden for anticipated new HHAs is 535.5 hours (1½ hours x 357 new HHAs). Therefore, the annual burden for paragraph (i) of this CoP is **5034 hours** (4498.5 hours for existing HHAs + 535.5 hours for estimated new HHAs). The total cost for this requirement is $132,243.18 (5034 hours x $26.27)

- §484.16 Condition of participation: Group of professional personnel.
  Paragraph (a) requires that a group of professional personnel will advise, assist and evaluate the agency. The meetings of this group are documented by dated minutes. This requirement implements statutory provisions of section 1861(o) of the Social Security Act. The burden for this CoP is minimal and is satisfied by recording and dating the minutes of the meeting of professional personnel. We estimate the annual burden at 10 minutes per agency 9354 HHAs (8,997 existing HHAs + 357 estimated new HHAs x 10 minutes / 60 minutes) is a total annual burden of **1559hours** at a cost of $40,954.91 (1559 hours x $26.27).

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

Section §484.18 implements the statutory provisions found in sections 1835 and 1814 of the Act, as well as section 1891(a) as amended by OBRA '87 for non-Medicare patients. Paragraph (a) of this section requires that a plan of care be developed in consultation with agency staff, and cover all pertinent diagnoses. Paragraph (b) requires that a plan of care be periodically reviewed. The written plan of care is established for each patient, and periodically reviewed, by a physician in consultation with agency staff. Paragraph (c) requires that the nurse or therapist to immediately record and sign any verbal orders given by the physician. Recording verbal orders reflects customary and usual medical and business practices. Therefore, this requirement does not impose a burden.

We estimate that HHAs average 356 home health patient admissions per year. The anticipated burden associated with this requirement involves at least one clinician (at $26.27 per hour) who will carry out the establishment and periodic review of plans of care by a physician. The requirements or paragraphs (a) and (b) for a clinicians' involvement in the development and review of plans of care established by a physician is estimated at 5 minutes per admission for a total estimated burden of 29.6 hours per HHA (356 admits per year x 5 minutes / 60 minutes) x (8,997 HHAs) for a total of **266,911 hours**. The cost of this requirement is $7,011,752 (266,911 hours x $26.27).

- §484.20 Condition of participation: Reporting OASIS information.
CMS-R-209: Approved by OMB (OMB Control #: 0938-0761)

The requirements under §484.30, §484.32, §484.34 and §484.38 are intended to ensure quality of care, and are commonly accepted as good medical practice, and therefore impose no burden on HHAs as they would be performed even in the absence of Federal regulations.

- §484.36 Condition of participation: Home health aide services.

The requirements in paragraphs (a) and (b) directly mirror the statutory requirements of section 4021 of OBRA '87. The requirements of paragraph (c) implements supervisory requirements found in section 1861(o) of the Act. Paragraph (a) imposes no additional burden as this documentation will be included in the personnel record as required in §484.14(e).

Paragraph (b) imposes a one-time burden (to develop competency evaluation) on any newly certified agencies. We estimate that it will require approximately 3 hours for each newly certified HHA to formulate this evaluation (although this figure may be much lower in practice if agencies chose to adopt standardized evaluation forms). Maintaining documentation that demonstrates that each aide has met the evaluation requirements imposes no burden as this information will be retained in personnel records. Developing the competency evaluation imposes a burden of **1071 hours** (3 hours x 357 estimated new HHAs). The cost of this requirement is $28,135 (1071 hours x $26.27)

Paragraph (c) imposes a burden of approximately 3 minutes for each newly admitted

patient that receives aide care. 356 admits/year x 3 minutes = 17.8 hours/HHA x 9354 HHAs (8997 existing HHAs + 357 estimated new HHAs) = 166,501 hours annually. The total annual cost burden for this CoP is estimated at $ 444(18 hours per HHA x $26.27/hour = $444 x 9354 = $4,153,176). The total annual burden for this CoP is 167,572 hours (1071 hours + 166,501 hours). The total annual cost burden is $4,181,311 ($28,135 + $4,153,176).

- §484.48 Condition of participation: Clinical records.

  This section contains provisions that are specifically required in section 1861(o) of the Act and are necessary to the preservation of a patient's privacy and quality of care. The requirements of this section state that a clinical record containing pertinent past and current findings is maintained for every patient receiving home health services. Clinical records are retained for 5 years after the month the cost report to which the records apply is filed with the intermediary. The HHA must have written procedures which govern the use and removal of records and conditions for release of information. The requirement that a clinical record be maintained is generally considered to be good medical practice, and therefore, imposes no burden.

  There is a minimal burden associated with the retention of clinical records as this merely entails the filing of a copy of the record. The annual burden associated with this CoP is estimated as 3 minutes per patient for both new and existing HHAs (8997 HHAs + 357 estimated new HHAs). Therefore the estimated annual burden for this requirement is 160,596 hours (9,354 HHAs x 356 patients x 3 minutes / 60 minutes). The cost of this requirement is $4,218,868 (160,596 hours x $26.27)

  The requirement that HHAs develop written procedures governing use of records imposes a one time burden of 15 minutes on any newly certified HHA for an estimated burden of 89.25 hours (357 estimated new HHAs x 15 minutes / 60 minutes) at a cost of $2,344.60 (89.25 hours x $26.27).

- §484.52 Condition of participation: Evaluation of the agency's program.

  The HHA has a written policy requiring an overall evaluation of the agency's total program at least once a year by the professional group, staff, and consumers. The evaluation consists of an overall policy, administration, and clinical record review. The requirements of this section are necessary to ensure responsible management, professional oversight, and quality of care in HHAs. The estimated burdens for this CoP are associated with the following requirements: 1) the development of a written policy; 2) minutes kept of the annual meeting; 3) a mechanism established in writing for the collection of data to assist in the evaluation of the agency's program; and 4) minutes kept of the quarterly review of clinical files when the appropriate health professionals review a sample of open and closed clinical files to determine that established policies are followed.

  The development of a written policy governing the annual program evaluation imposes

as one-time burden of 3 hours on each newly certified HHAs. This meeting can be evidenced by a copy of the minutes of the meeting which we estimate will require 10 minutes for each HHA to develop. Written mechanisms for the collection of program information will impose a one-time burden of 30 minutes on each newly certified HHA. The quarterly review of clinical files can be evidenced by the minutes of the meeting. We estimate that this will impose a quarterly burden of approximately 10 minutes on each HHA. The burden for this CoP is four-fold as indicated below.

1) Development of a written policy:
3 hours x 357 new HHAs = 1071 hours
1071 hours x $26.27 = $28,135.17

2) Annual meeting minutes:
9354 x 10 minutes / 60 (8997 existing HHAs + 357 estimated new ones) = 1,559 hours
1,559 hours x $26.27 = $40,954.93

3) Written mechanisms for the collection of program information:
30 minutes x 357 new HHAs / 60 = 178.5 hours
178.5 hours x $26.27 = $4,689.20

4) Minutes of Quarterly review of clinical files:
9354 HHAs (8997existing HHAs + 357 estimated new ones) x 10 minutes x 4 quarters / 60 = 6236 hours
6236 hours x $26.27 = $163,819.72

Total estimated burden for this CoP = 9044.5 hours,

- §484.55 Condition of participation: Comprehensive assessment of patients.

  CMS-R-245: Approved by OMB (OMB Control #: 0938-0760)

Total Burden Estimate

The total annual hourly burden for the information collection requirements under the existing HHA conditions of participation is estimated to be 1,048,483.5 hours.The differences in the estimates (854,891 hours in the previous estimate and 1,048,483.5 hours in the current estimate) are due to three main factors. First, a increase in the number of Medicare-certified HHAs from 7,422 to 9354; a steady increase in the number of HHA's that are expected to become certified in the next three years; and a predictable increase in the number of Medicare beneficiaries using HHA services have resulted in an overall increase in burden. For example, the Patient rights condition of participation requires that all patients be provided with a notice of their rights and that HHAs document compliance with this CoP. We continue to estimate that such documentation will require 5 minutes per patient. However, the hourly burden estimate has been increased because (1) individual HHAs are caring for more patients than estimated in the previous PRA submission, (2) there are 1922 more Medicare-certified HHAs than when the last PRA was submitted, and (3) we estimate that 357 new HHAs will become Medicare certified on

a yearly basis in the next 3 years. After three years of growth in the number of Medicare certified agencies, we estimate that there will be more agencies than the number that currently existed at the time of the last PRA submission.

Second, we have adjusted the burden estimate to correct a technical error that occurred in the last Paperwork Reduction Act submission. In the Clinical Records Condition of Participation we inadvertently estimated that filing a copy of every patient's clinical record would take 3 minutes per HHA. The burden estimate has since been changed to reflect a burden of three minutes per patient, for a total of 17 hours per HHA.

Finally, we have altered the way we calculate burden for three Conditions of Participation: Compliance with Federal, State and local laws, disclosure and ownership information, and accepted professional standards and principles; Organization, services and administration; and Home health aide services. The compliance Condition of Participation requires HHAs to include certain information in their disclosure statement. All existing Medicare-certified HHAs have already completed this one-time requirement. Therefore this requirement no longer poses a burden to them and they are no longer included in the burden calculation.

A burden in the organization Condition of Participation regarding the distribution of a patient's summary to his or her physician was previously covered under OMB No. 938-0357 for CMS form 486. This form has since been retired and the burden has been added to the general Conditions of Participation burden assessment.

In the home health aide condition, HHAs encountered a one-time burden to develop an aide competency evaluation. Existing providers have already developed this evaluation. Therefore, this requirement no longer poses a burden to them and they have been removed from our burden calculation.

Total burden hours for the existing HHA CoPs = 1,048,483.5 hours
Total hours previously estimated = 854,891 hours

Increase of hours = 193,592.5hours

14. Estimate of Annualized Cost to the Federal Government

We reimburse State agencies to carry out the task of ensuring compliance with these requirements. State agencies generally conduct surveys of home health agencies once every three years. The national average for HHA recertification surveys in 2006 was 70 hours at $82 per hour for a three person survey team. The total estimated cost to the Federal government for HHA initial and recertification surveys is $55,643,560 (70 hours x $82 /hour x 9394 new and existing HHAs).

15. Program or Burden Changes

The total annual hourly burden for the information collection requirements under the existing HHA conditions of participation is estimated to be 1,048,483.5 hours.The differences in the

estimates (854,891 hours in the previous estimate and 1,048,483.5 hours in the current estimate) are due to three main factors. First, a increase in the number of Medicare-certified HHAs from 7,422 to 9354; a steady increase in the number of HHA's that are expected to become certified in the next three years; and a predictable increase in the number of Medicare beneficiaries using HHA services have resulted in an overall increase in burden.

16. Publication and Tabulation Dates

There are no publication or tabulation dates.

17. Expiration Date

These information collection requirements do not lend themselves to an expiration date.

18. Certification Statement

There are no exceptions to the certification statement.

C. Collections of Information Employing Statistical Methods

These information collection requirements do not employ statistical methods.