Home Health Conditions of Participation (CoPs) and Supporting Regulations

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 were not 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. This submission replaces the prior version.

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 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. Use of Information Technology

CMS does not require a specific format for maintaining the documentation required in this information collection. HHAs are free to select the most efficient and effective documentation format for their needs, including the maintenance of electronic records in accordance with their unique technical capabilities.

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 July 12, 2013.

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. Burden Estimates (Hours and Wages)

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.

In 2011 there were 11,930 home health agencies. Based on growth figures for the last three years, we estimate that there will be approximately 549 agencies per year entering the program, for a total of 13,577 home health agencies at the close of the three year PRA approval period. In 2010 7,015 freestanding HHAs had 10,729,763, for an average of 1,488 admissions per HHA. Based on this average, we estimate that all 11,930 HHAs had 17,751,840 admissions in 2011 and that all 13,577 projected HHAs will have a total of 20,202,576 admissions at the close of the three year PRA approval period. We define an average-size HHA as having 1,488 admissions per year and 56 clinicians or service providers.(based on information from the National Association for Home Care 2010 *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 many 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). The total estimated burden hours for developing the notice of rights is 1 hour per HHA, and 549 hours in any given year for all new HHAs at a cost of $32,940 for an administrator earning $60/hour to perform this task (based on salary data from the Bureau of Labor Statistics and including a 48 percent benefits and overhead adjustment). Existing HHAs have already developed this notice, and would therefore not be affected by this requirement. 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 disclosing the notice of rights is 1,479,320 - 1,683,548 (1,488 admits/yr x 5 minutes per admit x 11,930 -13,577 HHAs / 60 minutes). Total cost burden is estimated as $68,048,720 - 77,443,208, based on a nurse earning $46/hour to complete this task (1,479,320- 1,683,548 hours x $46/hr, salary estimate includes 48 percent benefits and overhead adjustment). We believe that retaining the signed copy of the notice of rights is standard business practice.

- §484.11 Condition of participation: Reporting OASIS information

  CMS-R-209: Approved by OMB (OMB Control #: 0938-0760)

- §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 549 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 46 hours in any given year (549 estimated new HHAs x 5 minutes / 60 minutes). Total cost burden is estimated at $2,760 (46 hours x $60/hr). We believe that the act of sending information to the State Survey Agency as part of the application process is standard business practice.

- §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 887,592 – 1,010,129 hours (3 minutes per patient x 1,488 admissions per HHA x 11,930- 13,577 HHAs / 60 minutes) at a cost of $16,864,248 – 19,192,451 for an office assistant to complete this task (887,592 - 1,010,129 hours x $19/hour, salary estimate includes 48% benefits and overhead adjustment).

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 5,965 – 6,514 hours (11,930 - 13,028 existing HHAs x 30 minutes / 60 minutes, Note: The estimated 13,028 existing HHAs do not include the estimated 549 new HHAs that would be joining the Medicare program in the third and final approval year for this package). The estimated annual burden for anticipated new HHAs is 824 hours (1½ hours x 549 new HHAs) in any given year. Therefore, the annual burden for paragraph (i) of this CoP is 6,789 – 7,338 hours (5,965 - 6,514 hours for existing HHAs + 824 hours for estimated new HHAs). The total cost for this requirement is $407,340 – 440,280 for an administrator to complete the task (6,789 - 7,338 hours x $60).

- §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 to be 10 minutes per agency for a total annual burden of 1,988 – 2,263 hours (11,930 - 13,577 HHAs x 10 minutes / 60 minutes) at a cost of $37,772 – 42,997 (1,988 – 2,263 hours x $19).

- §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 1,488 home health patient admissions per year. The anticipated burden associated with this requirement involves at least one staff member (at $19 per hour) who will facilitate the establishment and periodic review of plans of care by a physician. The burden for paragraphs (a) and (b) is estimated at 5 minutes per admission for a total estimated burden of 124 hours per HHA (1,488 admits per year x 5 minutes / 60 minutes) for a total of 1,479,320 – 1,683,548 hours (1,488 admits per year x 5 minutes / 60 minutes x 11,930 – 13,577 HHAs). The cost of this requirement is $28,107,080 – 31,987,412 (1,479,320 - 1,683,548 hours x $19).

- §484.20 Condition of participation: Reporting OASIS information.
  CMS-R-209: Approved by OMB (OMB Control #: 0938-0760)

  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 1,647 hours (3 hours x 549 estimated

new HHAs) in any given year. The cost of this requirement is $98,820 (1,647 hours x $60)

Paragraph (c) imposes a burden of approximately 3 minutes for each newly admitted patient that receives aide care, for a total of 887,592 – 1,010,129 hours annually. (1,488 admits/year x 3 minutes x 11,930 – 13,577 HHAs/ 60). The total annual cost burden for this CoP is estimated at $40,829,232 – 46,465,934 (887,592 -1,010,129 hours x $46/hour).

The total annual burden for all provisions within this CoP is 889,239 – 1,011,776 hours (1,647 hours + 887,592 – 1,010,129 hours). The total annual cost burden is $40,928,052 – 46,564,754 ($98,820 + $40,829,232 – 46,465,934).

- §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. Therefore the estimated annual burden for this requirement is 887,592 – 1,010,129 hours (1,488 patients x 3 minutes x 11,930 – 13,577 HHAs / 60 minutes). The cost of this requirement is $16,773,580 – 19,192,451 (882,820 - 1,010,129 hours x $19).

  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 137 hours (549 estimated new HHAs x 15 minutes / 60 minutes) at a cost of $8,220 (137 hours x $60) in any given year.

- §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 HHA. The annual 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 549 new HHAs = 1,647 hours
1,647 hours x $60 = $98,820

2) Annual meeting minutes:
11,930-13,577 HHAs x 10 minutes / 60 = 1,988 – 2,263 hours
1,988 - 2,263 hours x $19 = $37,772 – 42,997

3) Written mechanisms for the collection of program information:
30 minutes x 549 new HHAs / 60 = 275 hours
275 hours x $60 = $16,500

4) Minutes of Quarterly review of clinical files:
11,930-13,577 HHAs x 10 minutes x 4 quarters / 60 = 7,953- 9,051 hours
7,953 – 9,051 hours x $19 = $151,107 - 171,969

Total estimated burden for this CoP = 11,863 – 13,236 hours
Total estimated cost for this CoP = $304,199 – 330,286

- §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 5,644,430 - 6,422,694 hours. The differences in the estimates (1,048,483.5 hours in the previous estimate and 5,644,430 - 6,422,694 hours in the current estimate) are due to three main factors. An increase in the number of Medicare-certified HHAs from 9,354 to 11,930; a steady increase in the number of HHA's that are expected to become certified in the next three years; and a significant increase in the number of patients 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 2,576 more Medicare-certified HHAs than when the last PRA was submitted, and (3) we estimate that 549 new HHAs will become Medicare certified on a yearly basis in the next 3 years.

Second, we have adjusted the burden estimate to account for patients from all payer sources. Due to data limitations, previous Paperwork Reduction Act calculations have only included HHA patients who received services through the Medicare home health benefit. With improved data we are now able to reasonably estimate the total number of HHA admissions from all payer sources, thus increasing our estimate of the total number of patients served.

Table 1: Burden and Cost Estimates Associated with Information Collection Requirements

Regulation Section	OMB Control No.	Respondents	Responses	Burden per Response (in hours)	Total Annual Burden (in hours)	Hourly Labor Cost of Reporting ($)	Total Cost of Reporting ($)	Total Capital/ Maintenance Costs ($)	Total Costs ($)
§484.10		549	549	1	549	60	32,940	0	32,940
§484.10		11,930-13,577	17,751,840-20,202,576	.083	1,479,320-1,683,548	46	68,048,720-77,443,208	0	68,048,720-77,443,208
§484.12		549	549	.083	46	60	2,760	0	2,760
§484.14(g)		11,930-13,577	17,751,840-20,202,576	.05	887,592-1,010,129	19	16,864,248-19,192,451	0	16,864,248-19,192,451
§484.14(i)		11,930-13,028	11,930-13,028	.5	5,965- 6,514	60	357,900-390,840	0	357,900- 390,840
§484.14(i)		549	549	1.5	824	60	49,440	0	49,440
§484.16(a)		11,930-13,577	11,930-13,577	.167	1,988- 2,263	19	37,772-42,997	0	37,772- 42,997
§484.18(a) & (b)		11,930-13,577	17,751,840-20,202,576	.083	1,479,320-1,683,548	19	28,107,080-31,987,412	0	28,107,080-31,987,412
§484.36(b)		549	549	3	1,647	60	98,820	0	98,820
§484.36(c)		11,930-13,577	17,751,840-20,202,576	.05	887,592-1,010,129	46	40,829,232-46,465,934	0	40,829,232-46,465,934
§484.48(a)		11,930-13,577	17,751,840-20,202,576	.05	887,592-1,010,129	19	16,864,248-19,192,451	0	16,864,248-19,192,451
§484.48(b)		549	549	.25	137	60	8,220	0	8,220
§484.52		549	549	3	1,642	60	98,820	0	98,820
§484.52		11,930-13,577	11,930-13,577	.167	1,988- 2,263	19	37,772-42,997	0	37,772- 42,997
§484.52(a)		549	549	.5	275	60	16,500	0	16,500
§484.52(b)		11,930-13,577	47,720-54,308	.167	7,953- 9,051	19	151,107-171,969	0	151,107- 171,969
Total		549-13,577	549-20,202,576		5,644,430-6,422,694		171,605,579-195,237-759	0	171,605,579-195,237-759

Total burden hours for the existing HHA CoPs = 5,644,430 - 6,422,694 hours
Total hours previously estimated = 1,048,483.5 hours
Increase of hours = 4,595,946.5 – 5,374,210.5 hours

13. Capital Costs

There are no capital costs associated with this information collection.

14. Cost to 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. A survey normally requires approximately 70 hours at $138 per hour for a three person survey team. The total potential cost to the Federal government for HHA initial and recertification surveys is $131,153,820 every 3 years (70 hours x $138 /hour x [11,930 existing + 1,647 new HHAs]), provided that all HHAs are surveyed by CMS. However, a significant number of HHAs are deemed providers, and responsibility for surveying these providers is that of the accrediting bodies through which the HHAs seek their deemed status. Thus, in practice, the total cost to the Federal government is significantly lower than the total potential cost.

15. Changes to Burden

The total annual hourly burden for the information collection requirements under the existing HHA conditions of participation is estimated to be 5,644,430 - 6,422,694 hours. The differences in the estimates (1,048,483.5 hours in the previous estimate and 5,644,430 - 6,422,694 hours in the current estimate) are due to three main factors. First, the number of Medicare-certified HHAs increased from 9,354 to 11,930. Second, we expect a larger volume of HHA's to become certified in each of the next three years. And third, an improvement in our data has allowed us to improve our estimate of the total number of HHA admissions rather than being limited to only estimating the number of Medicare HHA admissions.

The total annual cost burden has also increased sue to these same factors. Furthermore, the total annual cost burden has increased due to changes in both the way that the salary estimates are calculated and increases in base salaries over time. Rather than using a single averaged salary estimate to assess the burden for each provision, we have chosen to use specific salary amounts for specific disciplines (e.g. nurses, administrators, and office staff) depending on the discipline that is most likely to be responsible for implementing the requirement at hand. We have also increased salary estimates to reflect recent Bureau of Labor Statistics wage data, and have

incorporated a benefits and overhead package worth 49% of base salary into our estimates to better reflect the true costs of employment. We believe that these adjustments more accurately reflect the impact of these requirements.

16. Publication and Tabulation Dates

There are no publication or tabulation dates.

17. Expiration Date

This collection does not lend itself to the displaying of an expiration date.