Supporting Statement for the Paperwork Reduction Act Submission,
Medicare and Medicaid Programs: Conditions of Participation for Home Health Agencies

A. Background

The purpose of this package is to request Office of Management and Budget (OMB) approval of the collection of information requirements for the final conditions of participation (CoPs) that home health agencies (HHAs) are required to meet to participate in the Medicare program. This is a new information collection, and it replaces the existing collection (OMB control number 0938-0365), which will be discontinued. The existing information collection will be discontinued because the CoPs have been completely revised and reorganized, rendering the existing collection obsolete.

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, skilled nursing facilities (SNFs), or rehabilitation centers when they involve equipment too cumbersome to bring to the home.

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 HHA safely and effectively delivers care to all patients. The information collection requirements described herein are needed to implement the Medicare CoPs for Medicare- and Medicaid-participating HHAs. We believe many of the requirements applied to these HHAs would impose no burden since a prudent institution would self-impose them in the course of doing business. Additionally, these particular standards reflect comparable standards developed by industry organizations such as The Joint Commission and the Community Health Accreditation Program.

Section 1861(o) of the Act (42 U.S.C. 1395x) specifies certain requirements that an HHA 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.

2. Information Users

The primary users of this information will be State agency surveyors, Medicare payment and program integrity contractors, CMS, and HHAs for the purpose of ensuring compliance with Medicare CoPs as well as ensuring the quality of care provided to HHA patients. For example, HHAs are required to develop a standard notice of rights (§484.50) that is used to notify individuals and their representatives of their rights and responsibilities as an HHA patient. HHAs provide this notice to each patient and obtain a signature to demonstrate compliance with this regulatory requirement. Upon routine survey for re-certification purposes, a surveyor may request from the HHA a copy of the standard notice of rights to confirm its existence and to confirm that it contains all specified elements as set forth in the regulation. A surveyor may also conduct a patient home visit and examine the information provided by the HHA to the patient to confirm that patients are actually provided a copy of the standard notice of rights. Additionally, a surveyor may examine a sample of patient clinical records to determine whether or not the HHA has obtained a signature to confirm that patients have received a copy of the notice of rights. CMS conducts oversight of state survey agencies by performing validation surveys, and may examine the same information as the state surveyor. Medicare payment and program integrity conduct targeted reviews, and may request a copy of the patient's plan of care (§484.60) and other documentation from the patient's clinical record (§484.110) in order to verify the accuracy of claims that have been submitted or Medicare payments that have been made for home health care.

3. Use of Information Technology

HHAs may use various information technologies to store and manage records as long as they are consistent with the existing confidentiality in record-keeping regulations at 42 CFR 485.638. This regulation in no way prescribes how the HHA should prepare or maintain these records. HHAs are free to take advantage of any technological advances that they find appropriate for their needs.

4. Duplication of Efforts

There is no duplication of information.

5. Small Business Impact

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

6. Less Frequent Collection

CMS does not collect information directly from home health agencies on a scheduled basis. Rather, HHAs are expected to maintain their own records in a timely fashion. These records are inspected on an as needed basis during the routine 3-year HHA re-certification survey. With less frequent collection, CMS would not be able to ensure compliance with HHA CoPs.
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7. Special Circumstances Leading to Information Collection

There are no special circumstances for collecting this information.

8. Federal Register Notice/Outside Consultation

This information collection request is associated with Home Health Agency Conditions of Participation (0938-AG81) which published January 13, 2017 (82 FR 4504).

9. Payments 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 associated with this information collection.

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.

Assumptions and Estimates Used Throughout

Number of Medicare-participating HHAs nationwide	12,602
Number of Medicare-participating HHAs that are accredited	4,972
Number of HHA patients in Medicare- participating HHAs nationwide	17,751,840
Number of HHA patients in Medicare-participating, accredited HHAs	7,005,548
Number of Medicare beneficiaries in HHAs	3,475,730
Average number of new HHAs per year	455
Average number of new, non-accredited HHAs per year	14
Average number of patients per HHA per year	1,409
Hourly rate of HHA office employee*	$26
Hourly rate of administrator*	$98
Hourly rate of QAPI coordinator**	$63

*Estimate from the Bureau of Labor Statistics Occupational Outlook Handbook, 2014-2015 edition; includes 100 percent benefits and overhead package.
**Based on a registered nurse fulfilling this role.

§484.45 Reporting OASIS Information

Section 484.45 states that HHAs must electronically report all OASIS data in accordance with §484.55. Specifically, an HHA would have to encode and electronically transmit each completed OASIS assessment to the QIES ASAP System or the CMS OASIS contractor within 30 days of completing an assessment of a beneficiary. The burden associated with this requirement is the time and effort necessary to conduct the OASIS assessment on a beneficiary and encode and transmit the information to the QIES ASAP System or the CMS OASIS contractor. While this requirement is subject to the PRA, the burden is currently approved under the following OMB control number, 0938-0760.

§484.50 Patient Rights

Section §484.50 implements the patient rights provisions of section 1891(a)(1) of the Act. The purpose is to recognize certain rights to which home health patients are entitled, and protect their rights. HHAs are required to inform each patient of their rights. In §484.50, we require HHAs to inform patients about the expected outcomes of treatment and the factors that could affect treatment. The HHAs are asked to devote efforts to improve patient's health literacy which lead to an increased comprehension of diagnosis and treatment for both patients and family. Increased comprehension allows patients to remain active and make the best possible decisions for their medical care. We require the following:

- An HHA must provide the patient and representative (legal or patient-selected) with an oral and a written notice of the patient's rights in a manner that the individual can understand. The HHA must also document that it has complied with the requirements of this section.
- An HHA must document the existence and resolution of complaints about the care furnished by the HHA that were made by the patient, representative, and family.
- An HHA must advise the patient in advance of the disciplines that will furnish care, the plan of care, expected outcomes, factors that could affect treatment, and any changes in the care to be furnished.
- An HHA must advise the patient of the HHA's policies and procedures regarding the disclosure of patient records.
- An HHA must advise the patient of his or her liability for payment.
- An HHA must advise the patient of the number, purpose, and hours of operation of the state home health hotline.
- An HHA must advise the patient of the names, addresses, and telephone numbers of specified State-funded and federally-funded entities.
- An HHA must advise the patient of the right to access auxiliary aids and language services, and how to access these services.

We foresee that HHAs will develop a standard notice of rights to fulfill the requirements contained in §484.50(a) of this section. A copy of the signed notice would serve as documentation of compliance. We estimate that an HHA will utilize an administrator to develop the patient rights form. All newly established HHAs would need to develop a notice of patient rights document. In order to speed up the process of becoming Medicare-approved, the majority of new HHAs are choosing to become accredited by a national accrediting organization for Medicare deeming purposes. The patient rights standards and patient notification requirements of the national accrediting organizations would meet or exceed those proposed in this rule; therefore this rule would not impose a burden upon those new HHAs that choose to obtain accreditation status for Medicare deeming purposes. We estimate that it would take 8 hours for each new non-accredited HHA to develop the form. The total annual burden for new HHAs is 112 hours (8 hours per HHA x 14 HHAs). The estimated cost associated with this requirement is $784 per HHA and $10,976 for all new non-accredited HHAs, annually. In addition, we estimate that it would take each existing HHA 1 hour to update its existing patient rights form, for a one-time total of 12,602 hours and a cost of $1,234,996.

The burden associated with §484.50(e) would be the time and effort necessary to document a patient complaint and its resolution. We estimate that, in a 1 year period, an HHA would need to document complaints involving about 5 percent (70) of its patients. We estimate that the documentation would require 5 minutes per investigation. Accredited HHAs are already required by their accrediting bodies to adhere to stringent patient rights violation investigation and record-keeping standards; therefore accredited HHAs would not be burdened by this new standard. The total annual burden per non-accredited HHA (7,630) would be 6 hours (70 investigations x 5 minutes per investigation / 60).

We believe that the requirements of standard (f), "Accessibility," related to providing information to patients in a manner that can be understood would not impose a burden because all HHAs have already attested to CMS that they are in compliance with the requirements of Title VI of the Civil Rights Act of 1964, the Americans With Disabilities Act, and section 504 of the Rehabilitation Act. Since HHAs have already attested that they are in compliance with these longstanding requirements, and since the requirements of this rule are not intended to go beyond these statutes, no new burden would be imposed.

§484.55 Comprehensive Assessment of Patients

Section 484.55 requires the HHA to conduct, document and update, within a defined timeframe, a patient-specific comprehensive assessment that identifies the patient's need for HHA care and services, and the patient's need for physical, psychosocial, and emotional care. The information collection burden associated with the OASIS data set, which comprises the core of the patient assessment, is currently approved under OMB control number 0938-1279. The current expiration date is December 31, 2019.

§484.60 Care Planning, Coordination of Services, and Quality of Care

Section 484.60 requires that each patient's written plan of care specify the care and services necessary to meet the patient-specific needs identified in the comprehensive assessment. Additionally, the written plan of care is required to contain the measurable outcomes that the HHA anticipates will occur as a result of implementing and coordinating the plan of care. This requirement consists of longstanding requirements that implement statutory provisions found in §1835, §1814, and §1891(a) of the Act. Additionally the plan of care must also specify the patient and caregiver education and training specific to the patient's care needs. We believe compliance with certain plan of care requirements, such as addressing each patient's psychosocial status and interventions to address readmission risk factors, will impose a new burden of 10 minutes per patient, per plan of care. A typical HHA patient will have one plan of care. We believe that most HHAs are already addressing these areas during the care planning process as they are usual and customary practices in delivering high quality care. For purposes of this analysis only, we assume that 90 percent of HHAs are already complying with these requirements, and that 10 percent will need to comply. We estimate that the 1,260 HHAs that are not already addressing these new factors in their care planning process will use 296,482 hours (1,409 patients per HHA x 0.167 hours per patient x 1,260 HHAs) at a cost of $18,678,366 for a nurse to document the new required information in the plan of care.

Section 484.60(a) requires that each patient's written plan of care be established and periodically reviewed by a doctor of medicine, osteopathy, or podiatry. While HHAs average 1,409 home health patient admissions per year, 276 of those are Medicare patients. Having a doctor of medicine, osteopathy, or podiatry establish and periodically review the HHA plan of care is also a requirement for Medicare payment; therefore HHAs would do this in the absence of this requirement. This requirement would not impose a burden for those 276 Medicare patients per HHA. The anticipated burden associated with this requirement involves a member of the office support staff who would facilitate interaction with the physician. We estimate that this would take 5 minutes per admission for a total estimated burden of 94 hours per HHA ([1,133 non-Medicare admits per year x 5 minutes] / 60 minutes per hour).

Sections 484.60(a)(4) and (b)(1) require HHAs to conform and fulfill all medical orders issued in writing or telephone (and later authenticated) by a patient's physician or qualified medical professional. We believe compliance with this requirement will constitute a usual and customary business practice and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3 (b) (2). Issuing orders for patient care is one of the most fundamental tasks performed by physicians. Likewise, documenting and adhering to physician orders is one of the most fundamental tasks performed by the physician and all other clinicians within a patient's health care team, including the nurses, therapists, and social workers who are involved in home health care.

Section 484.60(c) requires an HHA to review, revise and document the plan on a timely basis. The burden associated with these requirements is the time and effort associated with reviewing, revising, and maintaining the plan of care. We believe compliance with certain plan of care requirements, such as addressing each patient's psychosocial status and interventions to address readmission risk factors, will impose a new burden of 5 minutes per patient, per updated plan of care. Assuming that a typical HHA patient will have one update to the plan of care, we estimate that all HHAs will use 147,353 hours (1,409 patients per HHA x 0.083 hours per patient x 1260 HHAs) at a cost of $9,283,329 for a nurse to document the new required information in the plan of care.

Section 484.60(e) requires the HHA to provide written instructions to the patient and care giver outlining visit schedule including frequency of visits, medication schedule/instructions, treatments administered by HHA personnel and personnel acting on the behalf of the HHA, pertinent instructions related to patient care, and the name and contact information of the HHA clinical manager. Giving written instruction to the patient and care giver outlining the medication schedule/instructions, visit schedule, pertinent instruction related to the patient's care and treatments and contact information of the HHA has been a long standing practice in the home health industry and is one of the most fundamental elements in patient education. For purposes of this analysis only, we assume that 90 percent of HHAs are already providing this information and 10 percent are not. We estimate that it would take 20 minutes to provide a patient with this written information and that each patient will receive written information twice while under the HHA's care. Based on these assumptions, we estimate that this provision will impose 1,182,376 hours of burden at a cost of $74,489,688 for a nurse to provide the written information.

§484.65 Quality Assessment and Performance Improvement (QAPI)
Section 484.65 requires HHAs to develop, implement, maintain and evaluate an effective, data-driven quality assessment and performance improvement program. We have not prescribed the structures and methods for implementing this requirement and have focused the condition toward the expected results of the program. This provides flexibility to the HHA, as it is free to develop a creative program that meets the HHA's needs and reflects the scope of its services.

The first standard under §484.65 requires that an HHA's quality assessment and performance improvement program include, but not be limited to, the use of objective measures to demonstrate improved performance. The second standard requires the HHA to track its performance to assure that improvements are sustained over time. The third standard requires that the HHA set priorities for performance improvement, consider prevalence and severity of identified problems, and give priority to improvement activities that affect clinical outcomes. Lastly, the fourth standard requires the HHA to conduct performance improvement projects that reflect the scope, complexity, and past performance of the HHA's services and operations, and document these projects.

We believe the writing of internal policies governing the HHA's approach to the development, implementation, maintenance, and evaluation of the quality assessment and performance improvement program, as described in §484.65, will impose a burden. We want HHAs to utilize maximum flexibility in their approach to quality assessment and performance improvement programs. Flexibility is provided to HHAs to ensure that each program reflects the scope of its services. We believe that this requirement provides a performance expectation that HHAs will set their own QAPI plan and goals and use the information to continuously strive to improve their performance over time. Given the variability across HHAs and the flexibility provided, we believe that the burden associated with writing the internal policies governing the approach to the development, implementation, and evaluation of the quality assessment and performance improvement program will reflect that diversity. We estimate that the burden associated with writing the internal policies would be an average of 4 hours annually per HHA, for an industry-wide total of 30,520 hours. (4 hours per HHA x 7,630 non-accredited HHAs), and an industry-wide cost of $1,922,760 (30,520 hours x $63/hour).

HHAs accredited by the Joint Commission, the Community Health Accreditation Partner, and the Accreditation Commission for Health Care are already required by their accrediting bodies to undertake and document performance improvement projects. In the absence of accreditation requirements, we believe that most HHAs already document the quality projects that they have undertaken as part of standard business practice. For purposes of this analysis only, we assume that 10 percent of non-accredited HHAs would use additional resources to document their quality projects. We estimate that the affected HHAs would use 1 hour per quarter to document performance improvement project activities and that the QAPI coordinator would perform this function, for a total of 3,052 hours (0.1 x 7,630 non-accredited HHAs x 1 hour per quarter x 4 quarters per year) at a cost of $192,276.

§484.70 Infection Prevention and Control

Section 484.70 requires an HHA to maintain and document an infection control program with the goal of preventing and controlling infections and communicable diseases. Specifically, §484.70(b) states that the HHA must maintain a coordinated agency-wide program for the surveillance, identification, prevention, control, and investigation of infectious and communicable diseases that is an integral part of the HHA's QAPI program. Section 484.70(c) also requires that each HHA provide infection control education to staff, patients, and caregivers. Since health care-acquired infections have been a source of significant research, education, and training efforts by both the public and private health care sectors for more than a decade, we believe that all HHAs already have infection prevention and control programs. The burden associated with the infection prevention and control program would be the time necessary to document the program. We estimate that each HHA will spend 1 hour per quarter documenting its infection prevention and control program, for a total of 50,408 hours at a cost of $3,175,704 for a nurse to complete the documentation.

§484.75 Skilled Professional Services

Section 484.75 requires skilled professionals who provide services to HHA patients as employees or under arrangement to participate in all aspects of care. This includes, but is not limited to, participation in the on-going patient assessment process; development and maintenance of the interdisciplinary plan of care; patient, caregiver, and family counseling; patient and caregiver education; and communication with other health care providers. Section 484.75 also requires skilled professionals to be actively involved in the HHA's QAPI program and participate in HHA in-service trainings. Furthermore, §484.75 requires skilled professional services to be supervised. Clinician involvement in patient care, quality improvement efforts, and continuing education are all commonly accepted as good medical practice and typically part of state licensure requirements. The supervision of clinician services is also standard medical practice to ensure that patient care is delivered in a safe and effective manner. Therefore, the burden associated with the requirement is not subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2). In addition, the aforementioned requirements would in all likelihood exist in the absence of federal regulations.

§484.80 Home Health Aide Services

This section governs the requirements for home health aide services. Many requirements in this section directly mirror the statutory requirements of sections 1891 and 1861 of the Act and include the following requirements: (1) The HHA must maintain sufficient documentation to demonstrate that training requirements are met; (2) The HHA's competency evaluation must address all required subjects; (3) The HHA must maintain documentation that demonstrates that requirements of competency evaluation are met; and (4) a registered nurse or appropriate skilled professional prepares written instructions for care to be provided by the home health aide.

All home health aide services must be provided by individuals who meet the personnel requirements and training criteria as specified. An HHA is required to maintain documentation that each home health aide meets these qualifications as specified in §484.80(a). The burden associated with these standards is the time required to document that each new aide meets the

qualification requirements. We estimate that it will take 5 minutes per newly hired home health aide per year to document the information. We assume that the average HHA would replace 30 percent of its home health aides in a given year, or roughly two home health aides a year based an average of six home health aide FTEs (Basic Statistics About Home Care Updated 2010, National Association for Home Care, http://www.nahc.org/assets/1/7/10HC_Stats.pdf). Based on an estimate of 5 minutes per newly hired aide and two newly hired aides per agency, per year, we estimate that there will be 2,100 annual burden hours ([5 minutes per aide x 2 aides per HHA] / 60 minutes per hour x 12,602 HHAs) for the home health industry. We assume that an office employee ($26/hour) would perform this function at a cost of $4 per HHA per year. The total cost for all HHAs is $54,600 (2,100 hours x $26/hour).

Section 484.80(b)(1) through (3) discuss the content and duration of the home health aide classroom and supervised practical training. With respect to the recordkeeping requirements, §484.80(b)(4) states that an HHA is required to maintain documentation that demonstrates that the requirements of this standard have been met. The burden associated with this requirement would be the time and effort necessary to document the information and maintain the documentation as part of the HHAs records. We estimate that it would take each of the 12,603 HHAs 5 minutes per newly hired aide per year to document that the requirements of this standard have been met. The estimated annual burden is 2,100 hours ([5 minutes per aide x 2 aides per HHA] / 60 minutes per hour x 12,602 HHAs). The cost burden associated with this requirement is $54,600, based on an office employee completing the documentation ($26/hour x 2,100 hours).

Section 484.80(c) contains the standard for competency evaluation. An individual could furnish home health services on behalf of an HHA only after that individual has successfully completed a competency evaluation program as described in this section. With respect to the recordkeeping requirements, §484.80(c)(5) states that an HHA would be required to maintain documentation that demonstrates that the requirements of this standard have been met. The burden associated with this requirement is the time and effort necessary to document the information and maintain the documentation as part of the HHAs records. We estimate that it would take each of the 12,603 HHAs 5 minutes per newly hired aide per year to document that the requirements of this standard have been met. The estimated annual burden is 2,100 hours ([5 minutes per aide x 2 aides per HHA] / 60 minutes per hour x 12,602 HHAs). The cost burden associated with this requirement is $54,600, based on an office employee completing the documentation ($26/hour x 2,100 hours).

Section 484.80(d) states that an HHA is required to maintain documentation that all home health aides have received at least 12 hours of in-service training during each 12-month period. The burden associated with this requirement is the time and effort necessary to document and maintain records of the required in-service training. We assume that it would require 5 minutes per aide to document the in-service training, and that these trainings would be conducted on a quarterly basis, for a total of approximately 2 hours per HHA, annually, to meet this requirement ([0.083 hours (aka 5 minutes) per aide per training x 4 trainings per year x 6 aides] / 60 minutes per hour). The estimated total annual burden for this requirement is 25,103 hours (0.083 hours (aka 5 minutes) per aide per training x 4 trainings per year x 6 aides per HHA x 12,602 HHAs).

Section 484.80(g) states that written patient care instructions for a home health aide must be prepared by a registered nurse or other appropriate skilled professional. The burden associated with this requirement is the time and effort necessary for a registered nurse or other skilled professional to draft written patient care instructions for a home health aide. Providing written patient care instructions is a usual and customary business practice in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2). Home health aide licensure standards require aides to practice under the direction of a nurse or other qualified medical professional. Likewise, the scope of practice for nurses and other qualified medical professionals includes the preparation of patient care instructions.

At §484.80(h) we require that HHAs document the supervision of home health aides in accordance with specified timeframes. Supervising employees to ensure the safe and effective provision of patient care is standard business practice throughout the health care community. Likewise, documenting that this supervision has occurred for internal personnel, accreditation, and state and federal compliance purposes constitutes a usual and customary business practice and will not be subject to the PRA in accordance with the implementing regulation of the PRA at 5 CFR 1320.3(b)(2).

§484.100 Compliance with Federal, State, and Local Laws and Regulations Related to the Health and Safety of Patients

At §484.100(a), the HHA is required to 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 1891 of the Act. It imposes a minimal burden of adding the necessary additional information to the current disclosure used by HHAs. We estimate that modifying the current disclosure would require 5 minutes (0.083 hours) per HHA, for a total of 1,046 hours for the HHA industry as a whole on a one-time basis (0.083 hours per modification x 12,602 existing agencies). Additionally, we estimate that it would require new HHAs 1 hour to develop a disclosure statement, for a total of 455 annual hours industry wide each year (1 hour per new HHA x 455 new HHAs).

§484.105 Organization and Administration of Services

We require that 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. Although there are reporting and documentation requirements associated with the proposed requirements, these activities are standard business practice and do not impose a burden on HHAs. For example, §484.105(d)(1) states that the parent HHA is responsible for reporting all branch locations of the HHA to the state survey agency at the time of the HHA's request for initial certification, at each survey, and at the time the parent proposes to add or delete a branch. Similarly, §484.105(e)(2) states that an HHA must have a written agreement with another agency, with an organization, or with an individual when that entity or individual furnishes services under arrangement to the HHA's patients. We

believe the burden associated with the aforementioned will constitute a usual and customary business practice and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

Paragraph (h) of this section, Institutional Planning, imposes a minimal burden of the time required by new HHAs to develop the initial plan and by existing HHAs 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. Accredited HHAs are required by their accrediting bodies to engage in institutional planning efforts that exceed these proposed minimum federal requirements; therefore this requirement would not impose a burden upon accredited agencies. In addition, the vast majority of new HHAs are entering the Medicare program via accreditation from a national accrediting body; therefore this provision would not be imposing a burden upon new agencies as well. The estimated annual burden for existing HHAs is 3,815 hours ([7,630 existing non-accredited HHAs x 30 minutes] / 60 minutes per hour). The estimated annual burden for anticipated new HHAs is 21 hours (1.5 hours per HHA x 14 new HHAs).

§484.110 Clinical Records

This section requires that clinical records contain pertinent past and current findings, and that they be maintained for every patient who is accepted by the HHA for home health services. All entries in the clinical record are authenticated, dated and timed, which is usual and customary clinical practice and does not impose a burden. Clinical records must be retained for 5 years after the month the cost report for the records is filed with the intermediary. HHAs are required to have written procedures that govern the use and removal of records, and the conditions for release of information. This section contains longstanding provisions that are specifically required in section 1861(o) of the Act, and are necessary to preserve the patient's privacy and the quality of care. The aforementioned documentation and record retention requirements are considered usual and customary business practices; therefore the burden associated with those requirements will not be subject to the PRA in accordance with the implementing regulation of the PRA at 5 CFR 1320.3(b)(2).

At §484.110(a)(5) HHAs are required to send a copy of a patient's discharge or transfer summary to the patient's primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA, or the facility, if the patient leaves HHA care to enter a facility for further treatment. We estimate that an HHA would spend 5 minutes per patient sending the discharge or transfer summary to the patient's next source of health care services, for a total of 117 hours per average HHA annually ([5 minutes per patient x 1,409 patients] / 60 minutes per hour) at a cost of $3,042 for an office employee to send the required documentation ($26 per hour x 117 hours).

Furthermore, an HHA must make available a patient's clinical record (whether hard copy or electronic form) must be made available to a patient, free of charge, upon request at the next home visit, or within 4 business days (whichever comes first). The burden associated with this requirement is the time and effort required to disclose a clinical record to an appropriate authority.

Making clinical records available to the appropriate authority is part of the survey and certification process, and we believe compliance with this requirement will constitute a usual and customary business practice. Therefore, the burden associated with this requirement will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2). Furthermore, we do not believe that this requirement would alter the frequency or scope of requests stemming from other appropriate authorities such as law enforcement.

§484.115 Personnel Qualifications

In §484.115, we defer to state certification or state licensure requirements in cases where personnel requirements are not statutory or do not relate to a specific payment provision. As defined in the implementing regulations of the PRA at 5 CFR 1320.3(b)(2), these requirements are usual and customary business practices. In accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(3), we believe this state requirement would exist even in the absence of the federal requirement; therefore, the associated burden is not subject to the PRA.

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 Costs ($)
*§484.50(a)	0938-New	14	14	8	112*	98	10,976	10,976
*§484.50(a)	0938-New	12,602	12,602	1	12,602*	98	1,234,996	1,234,996
§484.50(e)	0938-New	7,630	534,100	0.083	44,330	63	2,792,790	2,792,790
§484.60(a)	0938-New	12,602	14,276,110	0.083	1,184,917	26	30,809,662	30,809,662
§484.60(a)	0938-New	1260	1,775,340	0.167	296,482	63	18,678,366	18,678,366
§484.60(c)	0938-New	1260	1,775,340	0.083	147,353	63	9,283,239	9,283,239
§484.60(e)	0938-New	1260	3,550,680	0.333	1,182,376	63	74,489,688	74,489,688
*§484.65(e)	0938-New	7,630	7,630	4	30,520*	63	1,922,760	1,922,760
§484.65(d)	0938-New	763	3,052	1	3,052	63	192,276	192,276
§484.70	0938-New	12,602	50,408	1	50,408	63	3,175,704	3,175,704
§484.80(a)	0938-New	12,602	25,204	0.083	2,100	26	54,600	54,600
§484.80(b)	0938-New	12,602	25,204	0.083	2,100	26	54,600	54,600
§484.80(c)	0938-New	12,602	25,204	0.083	2,100	26	54,600	54,600
§484.80(d)	0938-New	12,602	302,448	0.083	25,103	26	652,678	652,678
§484.100(a)	0938-New	12,602	12,602	0.083	1,046	98	102,508	102,508
*§484.100(a) §484.105(h)	0938-New	455 7,630	455 7,630	1 0.5	455* 3,815	98 98	44,590 373,870	44,590 373,870
§484.105(h)	0938-New	14	14	1.5	21	98	2,058	2,058
§484.110(a)	0938-New	12,602	17,751,840	0.083	1,473,403	26	38,308,478	38,308,478
Total		**140,189**	**40,135,877**	**19**	**4,462,295**	**1,185**	**182,350,264**	**182,350,264**

*Denotes a one-time information collection requirement.

Total burden hours requested = 4,462,295 hours.

13. Capital Costs

There are no capital costs associated with this information collection because all documentation can be accomplished with equipment that is already owned by HHAs. Some HHAs may choose to upgrade their current equipment to operate more efficiently, but such upgrades are not necessary to meet these minimum standards.

14. Cost to Federal Government

There are minimal costs associated with these requirements that are accrued at the Federal level and especially at the regional office (RO) levels. For example, RO staff is responsible for acting on the information collections requirements discussed in this package as it relates to home health agency compliance. Once state survey agencies have completed their surveys and if a final decision to terminate a home health agency for noncompliance is to be made, such decisions are made by the Central Office and the RO.

15. Changes to Burden

This is a new information collection that is necessary due to the complete reorganization and revision of the CoPs. In 2014 we estimated that 13,577 HHAs would use 6,422,694 hours at a cost of $195,237,759 in 2013 dollars to comply with the former set of HHA CoPs. We estimate that 12,602 HHAs will use 4,462,295 hours at a cost of $182,350,264 in 2016 dollars to comply with the completely revised and reorganized requirements. This represents a reduction of 1,960,399 hours and $12,887,495. The hour and cost decreases are likely due to a reduction in the number of estimated HHAs.

16. Publication and Tabulation Dates

There are no publication or tabulation dates.

17. Expiration Date

CMS will display the expiration date on the website https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.html.