Supporting Statement – Part A
Medicare and Medicaid Programs: Home Health Facilities (HHAs) and Supporting Regulations (CMS-10539) (OMB Control Number: 0938-1299)

A. Background

This request for reinstatement is precipitated by recently published proposed rule: "*Medicare Program; Calendar Year (CY) 2025 Home Health Prospective Payment System (HH PPS) Rate Update; HH Quality Reporting Program Requirements; HH Value-Based Purchasing Expanded Model Requirements; Home Intravenous Immune Globulin (IVIG) Items and Services Rate Update; and Other Medicare Policies,*[1]" published July 3, 2024; proposes to add a new standard § 484.105(i), which sets forth a requirement for HHAs to establish an *acceptance to service* policy.

Currently, approved information collection requirements stem from the following Conditions of Participations: §484.45, Reporting OASIS information; §484.50, Patient rights; §484.55, Comprehensive assessment of patients; §484.58, Discharge planning; § 484.60, Care planning, coordination of services, and quality of care; § 484.65, Quality assessment and performant improvement (QAPI); § 484.70, Infection prevention control; § 484.80, Home Health aide services; 484.100, Condition of participation: Compliance with Federal, State and local laws and regulations related to the health and safety of patient; §484.102, Emergency Preparedness; §484.105, Organization, and administration of services; §484.110, Clinical records

Home health services are covered for the elderly and disabled under the Hospital Insurance (Part 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.
- 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 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

1 CMS-1803-P

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.

The preceding information collection which expired on June 30, 2024, estimated the total annual hourly burden as 6,442,694 hours as cost of $183,421,668. We revise this to 870,000 hours at a cost of 76,460,000. A reduction in hours by 642% and cost by 140%. The reduction is largely due to removing the one-time burden estimates that no longer apply.
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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) 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.

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 of Efforts

There is no duplication of information.

5. Small Businesses

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

There are no special circumstances for collecting this information.

8. Federal Register/Outside Consultation

A 60-day notice published in the Federal Register on 10/1/2024 (89 FR 79929). A single comment was received. The Agency has reviewed this comment in Attachment A. No comments

were received in response to the 30-day FR Notice which published on July 21, 2025 (90 FR 34276).

9. Payments/Gifts 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 & Wages)

This section is broken out into the following three parts, Part 12-A, 12-B, and 12-C. Part 12-A explains the general assumptions we use to estimate hourly burden and costs. Part 12-B explains the CoPs in detail and describes the methodology used to estimate the hourly burden and cost. Part 12-C summaries the information.

Part 12-A: General Assumptions and Estimates

The hourly burden and cost estimated is the hourly burden and cost we anticipate HHAs will experience in the next three years. At the time of this writing, the burden is estimated for years 2024 (year 1), 2025 (year 2), and 2026 (year 3).

To estimate the annual average hourly burden and cost to *existing* and *new* HHAs in year 1 (2024), year 2 (2025), and year 3 (2026), we first determine the number of HHA that will exist in year 1 (2024), year 2 (2025), and year 3 (2026) and the number of *new* HHAs we anticipate will open in the same years.

To predict this number, we use historical data from CASPER[2] and project forward the number of HHAs we anticipate will be in existence in year 1 (2024), year 2 (2025), and year 3 (2026).

We find between calendar years 2014 to 2023, there were approximately 12,014 HHAs per year with an average reduction of 153 HHAs or 1% per year, see Table 1.

Using CASPER data, we project the number of HHAs in year 1 (2024), year 2 (2025), and year 3 (2026) to be 11,353; 11,200, and 11,047, respectively. This results in an annualized average

2 Centers for Medicare and Medicaid: Quality Safety and Oversight Group (QSOG).
August 4, 2024. Home Health Agency Provider Reports. https://qcor.cms.gov/hha_wizard.jsp?which=1&report=active.jsp
Data Accessed: 8/13/2024.

of 11,200 existing HHAs per year.

To find the number of new facilities, CASPER data shows there is a persistent decrease in the number of HHAs by 153 on average per year, see Table 2. As a result of this decrease, we assume 0 new HHA providers per in years, 2024, 2025, 2026. As a result of 0 new HHAs, we do not estimate a one-time burden that usually impacts new HHAs.

Table 1. Number of HHA by Year (Historical)

	Row Number	Year	Number of HHAs by Year	Change in the Number of HHAs by Year	Percent Change
	1	2014	12,882		
	2	2015	12,646	-236	-2%
	3	2016	12,514	-132	-1%
	4	2017	12,128	-386	-3%
	5	2018	11,869	-259	-2%
	6	2019	11,732	-137	-1%
	7	2020	11,725	-7	0%
	8	2021	11,629	-96	-1%
	9	2022	11,506	-123	-1%
	10	2023	11,506	0	0%
Average	**11**	**-**	**12,014**	**-153**	**-1%**

Table 2. Number of HHA by Year (Projection)

	Row Number	Burden Estimate Year	Year	Number of HHAs by Year (Projected)	Number of HHAs Increased or Decreased by Year (Projected)	Percent Change (Projected)
	1	Year 1	2024	11,353	-153	-1%
	2	Year 2	2025	11,200	-153	-1%
	3	Year 3	2026	11,047	-153	-1%
Average	**4**	**-**	**-**	**11,200**	**-153**	**-1%**

In Part 12-B we identify HHA staff that we assume would be responsible for associated information collections. We match these staff positions with the Occupational Employment and Wages, May 2023, data from the Department of Labor. We show how we estimate staff hourly wages in table 3.

Table 3. Labor and Hourly Wages

BLS (NAICS) Occupation Code	BLS Occupation Title	Mean Hourly Wage *(a)*	Mean Hourly Wage *(b), rounded*	Fringe Benefit (c= b* 100%) ($/hr) *)*	Adjusted Hourly Wage *(d = b + c)*
29-1141	Registered Nurses	$45.42	$45	$45	$90
11-1000	Top Executives	$65.43	$65	$65	$130
43-0000	Office and Administrative Support Occupations	$23.05	$23	$23	$46
13-2011	Accountants and Auditors	$43.65	$44	$44	$88
29-1141	Registered Nurses**	$41.38	$41	$41	$82
29-1229	Physician	$119.54	$120	$120	$240
46-6013	Medical Administrative Assistant	20.85	$21	$21	$42
**Note the hourly rate used in the proposed rule to estimate the wage cost for Registered at § 484.105(i) are different then the Registered Nurses hourly rate used to estimate all other provision in this PRA. For consistency we keep the Registered Nurses rate as used in the prosed rule, for the § 484.105(i) calculation.					

Part 12-B: Information collections as laid out by Home Health Conditions of participation.

The information collections under ***§484.45, Condition of participation: Reporting OASIS information,*** are the following:

- The HHA must transmit patient assessment data. Assessment data is laid out in the conditions of participation requirements at ***§*** 484.55(a) through (d).
- As described in ***§*** 484.55(a) through (d), Patient assessment data includes the following:
    - Information on the initial assessment visit data such as immediate care needs and homebound status, see ***§*** 484.55(a).
    - The patient's status such as current health, psychosocial, functional, and cognitive status; the patient's strengths, goals, and care preferences, including information that may be used to demonstrate the patient's progress toward achievement of the goals identified by the patient and the measurable outcomes identified by the HHA, see ***§*** 484.55(c).
    - The patient's continuing need for home care; The patient's medical, nursing, rehabilitative, social, and discharge planning needs(c).;
    - A review of all medications the patient is currently using in order to identify any potential adverse effects and drug reactions, including ineffective drug therapy, significant side effects, significant drug interactions, duplicate drug therapy, and noncompliance with drug

therapy, see § 484.55(c).
- The patient's primary caregiver(s), if any, and other available supports, including their willingness and ability to provide care; and their availability and schedules, see § 484.55(c).
- The patient's representative (if any), see § 484.55(c).
- And clinical record items such as: demographics and patient history, living arrangements, supportive assistance, sensory status, integumentary status, respiratory status, elimination status,
- neuro/emotional/behavioral status, activities of daily living, medications, equipment management, emergent care, and data items collected at inpatient facility admission or discharge only see § 484.55(c).

- As described in ***§*** 484.55 (b), the patient assessment data must be timely.
- As described in ***§*** 484.55 (d), the patient assessment data must be updated and revised as frequently as the patient's condition warrants due to a major decline or improvement in the patient's health.

The reporting of ***OASIS*** data is included in the information collection supporting statement, "OASIS Collection Requirements as Part of the COPs for HHAs," with assigned OMB Number: 0938-0760 and corresponding CMS Number: CMS-R-209.

The information collections under ***§484.50, Condition of participation: Patient rights,*** are listed below. This CoP states: the patient and the representative (if any), have the right to be informed of the patient's rights in a language and manner the individual understands, and that the HHA must protect and promote the exercise of the rights.

- *484.50(a) Standard: Notice of rights*
  - As described in paragraph 484.50(a)(1) the HHAs must provide the patient and the patient's legal representative (if any) the following information during the initial evaluation visit, in advance of furnishing care to the patient:
    - A written notice of the patient's rights and responsibilities and the HHA's transfer, and discharge policies as described at paragraph 484.50(d), see 484.50(a)(1)(i).
    - Contact information for the HHA administrator, including the administrator's name, business address, and business phone number in order to receive complaints, see 484.50(a)(1)(ii).
    - An OASIS privacy notice to all patients for whom the OASIS data is collected. 484.50(a)(1)(iii).
  - As described in paragraph 484.50(a)(2), The HHA must obtain the patient's or legal representative's signatures confirming that he or she has received their notice of rights and responsibilities.
- *484.50(c) Standard: Rights of the patient.*
  - HHAs patients must be advised in writing the extent to which payment for HHA services may be expected from Medicare,

Medicaid, or any other federally funded or federal aid program known to the HHA, see § 484.50(7)(i).

- HHAs patients must be advised in writing the extent to which charges for services that may not be covered by Medicare, Medicaid, or any other federally funded or federal aid program known to the HHA, see § 484.50(7)(ii).
- HHA patients must be advised in writing the charges the individual may have to pay before care is initiated, see § 484.50(7)(iii).
- HHAs patients must receive proper written notice, in advance of a specific service being furnished, if the HHA believes that the service may be non-covered care; or in advance of the HHA reducing or terminating on-going care, see § 484.50(8).
- HHA patients must be advised of the state toll free home health telephone hot line, its contact information, its hours of operation, and that its purpose is to receive complaints or questions about local HHAs, see § 484.50(9).
- HHA patients must be advised of the names, addresses, and telephone numbers of the following Federally-funded and state-funded entities that serve the area where the patient resides.
- Be informed of the right to access auxiliary aids and language services as described in paragraph 484.50(f), and how to access these services.

- *484.50(d) Standard: Transfer and discharge*
  - Should the HHA discharge patient under a policy set by the HHA, the HHA must document problem(s) and efforts made to resolve the problem(s), and enter this documentation into its clinical records.
- *484.50(e) Standard: Investigation of complaints.*
  - The HHA 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; (IC-11).

The burden associated with the information collection referenced above, specifically, § 484.50(a) and § 484.50(c), we continue to anticipate that HHAs have already developed standardized notifications that meet the above requirements and have incorporated these notifications into their business processes, thus we do not include a burden estimation.

Regarding the information collection at § 484.50(d), we continue to assume are usual and customary business practices and thus do not include a burden estimation.

Regarding the information collection § 484.50(e), we continue to estimate a burden. We estimate to meet this obligation, requires an HHA to document both the existence of a patient complaint regarding care provided (or not provided) or inappropriate treatment by HHA staff and those working on behalf of the HHA, and the resolution of the complaint. We continue to estimate to burden to meet this requirement would be the time and effort necessary to document

a patient complaint and its resolution. We continue to estimate that, in a 1-year period, an HHA would need to document complaints involving about 5 percent, of the 3,000,000 HHA patients covered[3]. We estimate that the documentation would require 5 minutes per investigation. In addition, approximately a little over half of the HHAs are accredited by the Joint Commission, the Community Health Accreditation Partner, and the Accreditation Commission for Health Care. These accrediting bodies also require patient rights violation investigation and record-keeping standards. Therefore, we continue to assume accredited HHAs are not burdened by this standard. If there is a total of 11,200 annual HHAs, then 5,600 are not accredited (11,200 HHAs × 0.50 = 5,600 non accredited HHAs). Each non-accredited HHA has approximately 268 patient (3,000,000 HHA patients / 11,200 = 268 patients per HHA). If 5% of an HHAs result in investigations, then each non-accredited HHA investigates 13 per year. If each investigation 5 (0.08 hours) minutes to document, then each HHA has a burden of (13 investigations × 0.08 hours = 1 hour per year). If there are 5,600 non accredited HHAs and each has a burden of 1 hour per year, then the total burden is 5,600 hours per year. We assume an HHA secretary at $42 an hour would be responsible for this information collection. Thus, the total burden cost is $235,200 ($42 ×5,600 = 235,200) per year.

The information collections under ***§484.55, Condition of participation: Comprehensive assessment of patients,*** are listed below. This CoP states: Each patient must receive, and an HHA must provide, a patient-specific, comprehensive assessment. For Medicare beneficiaries, the HHA must verify the patient's eligibility for the Medicare home health benefit including homebound status, both at the time of the initial assessment visit and at the time of the comprehensive assessment.

- The requirements at 484.55(a)through (d) are listed under ***§484.45 Condition of participation: Reporting OASIS information.*** The burden for information collections under paragraph §484.55 are included in information collection, "OASIS Collection Requirements as Part of the COPs for HHAs," OMB Number: 0938-0760 (CMS-R-209).

The information collections under ***§484.58 Condition of participation: Discharge planning,*** are listed below:

- 484.58(a) The HHA must develop and implement an effective discharge planning process
- 484.58(b)(1) the HHA must send all necessary medical information pertaining to the patient's current course of illness and treatment, post-discharge goals of care, and treatment preferences, to the receiving facility or health care practitioner to ensure the safe and effective transition of care.
- 484.58(b)(2) the HHA must comply with requests for additional clinical information as may be necessary for treatment of the patient made by the receiving facility or health care practitioner.

The burden associated with the information collection referenced above, specifically, §

3 Centers for Medicaid and Medicare. (2024). *Home Health Quality Reporting Program*. https://www.cms.gov/medicare/quality/home-health

484.58(a) we continue to state[4] this requirement corresponds to the requirements of the IMPACT Act and are exempted from the application of the PRA pursuant to section 1899B(m) of the Act. Therefore, we are not required to estimate the public reporting burden for information collection requirements for that specific element of the final rule in accordance with chapter 35, title 45 of the United States Code. Nor are we required to undergo the specific public notice requirements of the PRA.

Regarding the information collection specifically, § 484.58(b)(1) and (2) we continue to estimate to meet both these requirements, will take an HHA approximately 10 minutes (0.167 hours) per patient. Thus, for the 12,200 HHAs, we estimate that complying with this requirement will require 501,000 burden hours (3 million patients × 0.167 hours = 501,000 burden hours) at an approximate cost of $45,090,00 (501,000 burden hours × $90 average hourly salary for a registered nurse = $45,090,00).

The information collections under ***§ 484.60 Condition of participation: Care planning, coordination of services, and quality of care***, are list below. This CoP states Patients are accepted for treatment on the reasonable expectation that an HHA can meet the patient's medical, nursing, rehabilitative, and social needs in his or her place of residence. Each patient must receive an individualized written plan of care, including any revisions or additions. The individualized plan of care must specify the care and services necessary to meet the patient-specific needs as identified in the comprehensive assessment, including identification of the responsible discipline(s), and the measurable outcomes that the HHA anticipates will occur, as a result of, implementing and coordinating the plan of care. The individualized plan of care must also specify the patient and caregiver education and training. Services must be furnished in accordance with accepted standards of practice. The information collections under ***§484.100 Condition of participation: Compliance with Federal, State and local laws and regulations related to the health and safety of patients*** are listed below. This CoP states staff, must operate and furnish services in compliance with all applicable federal, state, and local laws and regulations related to the health and safety of patients. If state or local law provides licensing of HHAs, the HHA must be licensed.

- §484.100(a), under the Standard "Disclosure of ownership and management of information," the HHA must disclose to the State Survey Agency, at the time of the HHA's initial request for certification, for each survey, and at the time of any change in ownership or management the following information: 1) the name(s) and address(s) of all persons with an ownership or control interest in the HHA, 2) the name(s) and address(s) of each person who is an officer, director, an agent, or a managing employee of the HHA; 3) the names and business address of the corporation, association, or other company that is responsible for the

4 See Final Rule, "Medicare and Medicaid Programs; Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies, and Hospital and Critical Access Hospital Changes to Promote Innovation, Flexibility, and Improvement in Patient Care," published September 30, 2019. 84 FR 51836.

management of the HHA, and the names and addresses of the chief executive officer and the chairperson of the board of directors of that corporation, association, or other company responsible for the management of the HHA.

Regarding the information collection referenced above, specifically, § 484.100(a), we anticipate HHAs have already developed standardized disclose statement that meet the above requirements and have incorporated these updates into their business processes, thus we do not include a burden estimation.

We do however estimate a burden for modifying the current disclosure document. We estimate this modification would require 5 minutes (0.083 hours) per HHA, and be updated 1 time per year. This results in a total of 930 hours for the HHA industry as a whole on a one-time basis (0.083 hours per modification × 11,200 existing HHAs × 1 per year = 930 hours) and cost $42,780.

The information collections under ***§484.102 Condition of participation: Emergency Preparedness*** are listed below. This CoP states the Home Health Agency (HHA) must comply with all applicable Federal, State, and local emergency preparedness requirements and the HHA must establish and maintain an emergency preparedness program.

The information collections associated with the required emergency preparedness program is included in the information collection supporting statement, “Emergency Preparedness

Requirements for Medicare and Medicaid Participating Providers and Suppliers, ”with assigned OMB Number: 0938-1325 and corresponding CMS Number: CMS-10578.

The information collections under ***§484.105 Condition of participation: Organization, and administration of services*** are listed below. This CoP states the HHA must organize, manage, and administer its resources to attain and maintain the highest practicable functional capacity, including providing optimal care to achieve the goals and outcomes identified in the patient's plan of care, for each patient's medical, nursing, and rehabilitative needs. The HHA must assure that administrative and supervisory functions are not delegated to another agency or organization, and all services not furnished directly are monitored and controlled. The HHA must set forth, in writing, its organizational structure, including lines of authority, and services furnished.

- § 484.105(a) Standard: Governing body.
- § 484.105(b) Standard: Administrator.
- § 484.105(c) Standard: Clinical manager.
- § 484.105(d) Standard: Parent-branch relationship.
- § 484.105(e) Standard: Services under arrangement.
- § 484.105(f) Standard: Services furnished.
- § 484.105 (g) Standard: Outpatient physical therapy or speech-language pathology services

- § 484.105 (h) Standard: Institutional planning, including 1) annual operating budget and 2) Capital expenditure plan, 3) budget preparation, and 4) annual review of the plan and budget.

To add, recently published proposed rule: "*Medicare Program; Calendar Year (CY) 2025 Home Health Prospective Payment System (HH PPS) Rate Update; HH Quality Reporting Program Requirements; HH Value-Based Purchasing Expanded Model Requirements; Home Intravenous Immune Globulin (IVIG) Items and Services Rate Update; and Other Medicare Policies*,[5]" published July 3, 2024; proposes to add a new standard § 484.105(i), which sets forth a requirement for HHAs to establish an *acceptance to service* policy.

The *acceptance to service* policy at § 484.105(i)(1) would require HHAs to develop, consistently apply, and maintain an acceptance to service policy, including specified factors, that would govern the process for accepting patients to service. In addition, the proposed requirement at § 484.105(i)(2) would require HHAs to make specified information about their services and service limitations available to the public.

The proposed provision also requires that the policy be reviewed annually and address, at minimum, the following criteria related to the HHA's capacity to provide patient care: the

anticipated needs of the referred prospective patient, the HHA's case load and case mix, the HHA's staffing levels, and the skills and competencies of the HHA staff.

As stated in this proposed rule, it is our understanding, based on information provided by HHA accrediting organizations and the largest HHA trade association, that HHAs typically have *acceptance to service* policies that are categorical in nature, meaning that the policies address entire categories of diagnosis or service types that they are or are not capable of providing care for.

This proposed rule would not prevent HHAs from maintaining these existing policies and is intended to complement them. We also understand that an HHA's case load, case mix, and staffing levels may change over time, and that an HHA may choose to pre-establish methodologies that consider such fluctuations as part of their *acceptance to service* policy to ensure consistency and minimize administrative efforts in maintaining the policy.

As stated in the proposed rule we expect the HHA to utilize a physician and nurse to create and update the HHA's policies. We estimate there are 9,565 Medicare-certified HHAs[6] and that this proposed new requirement would take 1 hour each of a physician and a registered nurse's time on a one-time basis, for an HHA to develop an *acceptance to service* policy. at a cost of $322 per HHA ($82+ $240) and $3,078,400 for all HHA's ($791,599 + $2,286,800).

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5 CMS-1803-P

6 Note the number of HHAs and the hourly rates used in the proposed rule to estimate the requirements at § 484.105(i) are different then the number of HHA and the hourly rates used to estimate all other provision in this PRA. For consistency with the prosed rule, we keep the estimates for § 484.105(i) the same.

We also estimate the HHA nurse would review the *acceptance to service* policy on an annual basis. This annual review would take 5 minutes for an HHA nurse at a cost of $7 per HHA ($82 × 5/60 minute = $7) or $65,999 for all HHAs ($7 × 9,565 = $65,999) to fulfill this requirement.

In addition, we estimate this proposed new requirement would take 15 minutes on a one-time basis for an HHA to the specified information public at a cost of $10.43 per HHA or $99,763 for all HHA's, based on the assumption that the HHA administrative professional will process this task. The average hourly rate for an administrative employee is $41.70, therefore it is $10.43 per HHA ($41.70 hour × 15/60 minutes = $10.43) or $99,763 for all HHA's ($10.43 × 9,565) to fulfill the requirement. We also estimate the HHA administrative professional would review this website annually to assure the continued accuracy of the posted information. This annual review would take 5 minutes at a cost of $3.48 per HHA ($41.70 × 5/60 minute = $3.48) or $33,286 for all HHA's (3.48 × 9,565 = $33,286) to fulfill this requirement.

Regarding the information collection referenced above, specifically, the a forementioned § 484.70(a) through (g) we continue to state constitute usual and customary business practice and will not impose a burden.

The information collections associated with § 484.70(h) are as follows. We anticipate HHAs have already developed their financial plans that meet these requirements and have incorporated these updates into their business processes, thus we do not include a burden to create these documents. We do however estimate the burden for reviewing and revising their existing plans annually. We estimate each plan will take 30 minutes per review and be reviewed annually. Accredited HHAs are required by their accrediting bodies to engage in institutional planning efforts that exceed these minimum federal requirements; therefore, this requirement would not impose a burden upon accredited agencies. The estimated annual burden for non-accredited HHAs is 2,800hours (5,600 existing non-accredited HHAs × 0.50 hours × 1 update per year = 2,800 hours). The estimated annual burden cost is $246,405 (2,800 hours per HHA × $88 per hour = $246,405).

The information collections under ***§484.110 Condition of participation: Clinical records*** are listed below. The CoP states the HHA must maintain a clinical record containing past and

current information for every patient accepted by the HHA and receiving home health services. Information contained in the clinical record must be accurate, adhere to current clinical record documentation standards of practice, and be available to the physician(s) or allowed practitioner(s) issuing orders for the home health plan of care, and appropriate HHA staff. This information may be maintained electronically.

- § 484.110 (a) Standard: Contents of clinical record.
- § 484.110 (b) Standard: Authentication.
- § 484.110 (c) Standard: Retention of records.
- § 484.110 (d) Standard: Protection of records
- § 484.110 (e) Standard: Retrieval of clinical records

The aforementioned documentation and record retention requirements are considered usual and customary business practices; therefore, we do not associate a burden for the clinical records requirement.

Part 12-C: Information collections Summary

We anticipate the HHA industry will face a burden of approximately 890,000 hours at a cost of $79,540,000 in years 2024, 860,000 hours at a cost of $75,430,000 in year 2025 and, 850,000 hours at a cost of $74,400,000 in year 2026, see Table 5. This results in a total annualized hourly of burden of 870,000 hours at a cost of 76,460,000, see table 4.

Table 4. Annualized Average Hourly Burden and Cost by Requirement

		Annualized		
		Average Number of Respondents	Average Hourly Burden	Average Hourly Burden Cost
IC-484.45	new	*	*	*
	existing	*	*	*
IC-484.50(e)	new	0	0	$-
	existing	5,600	5,600	$235,208
IC-484.55	new	*	*	*
	existing	*	*	*
IC-484.58(b)(1) &(2)	new	0	0	$-
	existing	11,200	501,277	$45,114,943
IC-484.60(c)	new	0	0	$-
	existing	11,200	249,138	$22,422,397
IC-484.65(a)(d) & (e)	new	0	0	$-
	existing	5,600	5,600	$ 728,014
IC-484.65(b) & (c)	new	0	0	$ -
	existing	560	2,240	$ 201,604
IC-484.70	new	0	0	$ -
	existing	11,200	44,801	$ 4,032,080
IC-484.80(a)	new	0	0	$ -
	existing	11,200	11,200	$ 515,210
IC-484.80(b)	new	0	0	$ -
	existing	11,200	11,200	$ 515,210

IC-484.80(c)	new	0	0	$ -
	existing	11,200	11,200	$ 515,210
IC-484.80(d)	new	0	0	$ -
	existing	11,200	11,200	$ 515,210
IC-484.100(a)	new	0	0	$-
	existing	11,200	930	$ 42,762
IC-484.105(h)	new	0	0	$ -
	existing	11,200	5,600	$ 492,810
IC-484.105(i)(1)	new	0	0	$ -
	existing	9,565	6,906	$ 1,070,043
IC-484.105(i)(2)	new	0	0	$ -
	existing	9,565	1,326	$ 55,707

Total	existing	-	868,218	$ 76,456,409

Per HHA	existing	-	78	$ 6,826

Table 5. Annualized Average Hourly Burden and Cost by Requirement and Year

		Year 1 (2024)			Year 2 (2025)			Year 3 (2026)		
		Respondents	Hourly Burden	Hourly Burden Cost	Respondents	Hourly Burden	Hourly Burden Cost	Respondents	Hourly Burden	Hourly Burden Cost
IC-484.45	new	*	*	*	*	*	*	*	*	*
	existing	*	*	*	*	*	*	*	*	*
IC-484.50(e)	new	0	0	$-	0	0	$-	0	0	$-
	existing	5,677	5,677	$ 238,415	5,600	5,600	$235,200	5,524	5,524	$232,008
IC-484.55	new	*	*	*	*	*	*	*	*	*
	existing	*	*	*	*	*	*	*	*	*
IC-484.58(b)(1) & (2)	new	0	0	$-	0	0	$-	0	0	$-
	existing	11,353	508,120	$45,730,786	11,200	501,277	$45,114,943	11,047	494,434	$44,499,101
IC-484.60(c)	new	0	0	$-	0	0	$-	0	0	$-
	existing	11,353	252,539	$22,728,474	11,200	249,138	$22,422,397	11,047	245,737	$22,116,319
IC-484.65(a)(d) & (e)	new	0	0	$ -	0	0	$-	0	0	$-
	existing	5,677	5,677	$737,952	5,600	5,600	$728,014	5,524	5,524	$ 718,077
IC-484.65(b) & (c)	new	0	0	$-	0	0	$-	0	0	$ -
	existing	568	2,271	$204,356	560	2,240	$201,604	552	2,209	$198,852
IC-484.70	new	0	0	$-	0	0	$-	0	0	$ -
	existing	11,353	45,412	$ 4,087,120	11,200	44,801	$4,032,080	11,047	44,189	$3,977,040
IC-484.80(a)	new	0	0	$-	0	0	$-	0	0	$-
	existing	11,353	11,353	$522,243	11,200	11,200	$515,210	11,047	11,047	$508,177
IC-484.80(b)	new	0	0	$-	0	0	$-	0	0	$ -

	existing	11,353	11,353	$522,243	11,200	11,200	$515,210	11,047	11,047	$508,177
IC-484.80(c)	new	0	0	$-	0	0	$-	0	0	$ -
	existing	11,353	11,353	$522,243	11,200	11,200	$515,210	11,047	11,047	$508,177
IC-484.80(d)	new	0	0	$-	0	0	$-	0	0	$ -
	existing	11,353	11,353	$522,243	11,200	11,200	$515,210	11,047	11,047	$508,177
IC-484.100(a)	new	0	0	$-	0	0	$-	0	0	$ -
	existing	11,353	942	$43,346	11,200	930	$42,762	11,047	917	$42,179
IC-484.105(h)	new	0	0	$-	0	0	$-	0	0	$ -
	existing	11,353	5,677	$99,537	11,200	5,600	$492,810	11,047	5,524	$486,083
IC-484.105(i)(1)	new	0	0	$-	0	0	$-	0	0	$-
	existing	9,565	19,130	$3,079,930	9,565	794	$ 65,099	9,565	794	$65,099
IC-484.105(i)(2)	new	0	0	$-	0	0	$-	0	0	$-
	existing	9,565	2,391	$100,433	9,565	794	$33,344	9,565	794	$33,344
Total	existing	-	893,247	$79,539,322	131,692	861,574	$75,429,095	130,156	849,836	$74,400,810
Per HHA	existing	-	80	$7,102	12	77	$6,735	12	76	$6,643

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 currently approved information collection estimated the total annual burden hours to be 7,394,066 hours. We revise this to 870,000 hours a decrease of -6,524,066. The reduction is largely due to removing the one-time burden estimates that no longer apply.

16. Publication/Tabulation Dates

There are no publication or tabulation dates.

17. Expiration Date

The expiration date is displayed.

18. Certification Statement

There is no exception to the certification.