Supporting Statement Part A
Medicare Program/Home Health Prospective Payment System Rate Update for Calendar Year 2010: Physician Narrative Requirement and Supporting Regulation in 42 CFR 424.22
CMS-10311, OCN 0938-1083

Background

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 under a plan of care certified or recertified by the patient's physician, (42 CFR 424.22), and 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.
- Speech Language Pathology, Physical Therapy or Continuing 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 and or rehabilitation centers when they involve equipment too cumbersome to bring to the home.

As described in section 1814(a)(2)(c) of the Act, a physician must certify that a home health patient is homebound and needs or needed skilled nursing care on an intermittent basis, or needs physical or speech therapy or (with certain restrictions) occupational therapy. The Act thus requires that the physician fulfill a role that is sometimes thought of as a "gatekeeper" of Medicare's home health benefit by requiring the physician to sign the patient's individual home health plan of care and certifying or recertifying that the patient is homebound and in need of skilled services, in order for the home health agency to be reimbursed for Medicare covered services. The certification and recertification content requirements are stipulated in 42 CFR 424.22.

The "Home Health Prospective Payment System Rate Update for Calendar Year 2010" published by CMS July 30, 2009 promulgated a change in the physician certification and recertification requirements by requiring the physician to include a brief narrative describing the clinical justification of the need for skilled nursing management and evaluation of the care plan, when this need for skilled oversight of unskilled services is the only reason the home health patient meet the in need of skilled services eligibility requirement for Medicare's home health benefit. CMS finalized a policy that requires the physician to include a brief narrative describing the clinical justification necessitating the need for skilled nursing management and evaluation of a patient's care plan. We are requiring this narrative if a

patient's underlying condition or complication requires a registered nurse to ensure that essential non-skilled care is achieving its purpose. The narrative must be located immediately prior to the physician's signature. If the narrative exists as an addendum to the certification or recertification form, in addition to the physician's signature on the certification or recertification form, the physician must sign immediately following the narrative in the addendum. This change supports Medicare's home health coverage criteria for skilled services as stipulated in the CFR, (see 42 CFR 409.42) Medicare contractors described a program vulnerability associated with patients who meet the home health skilled services eligibility requirement solely because of the need for skilled nursing management and evaluation of the care plan. Additionally, the requirement is a first step in adopting the HHS office of the Inspector General (OIG)'s recommendation that CMS better define the home health eligibility skilled services requirements.

The Home Health Prospective Payment System Rate Update for Calendar Year 2011 published on 11/2/2010 changes the certification requirements for Home Health Agencies. This rule implements a provision of the Affordable Care Act as a condition for payment. The Affordable Care Act mandates that, prior to certifying a patient's eligibility for the HH benefit, the physician must document that the physician or a permitted nonphysician practioner (NPP) has had a face-to-face encounter with the patient. Additionally, the Affordable Care Act allows the Secretary to determine a reasonable timeframe for the encounter to occur. The certifying physician must document the face-to-face encounter regardless of whether the physician himself or herself or one of the permitted NPPs perform the face-to-face encounter. To implement this provision of the Affordable Care Act, we finalized §424.22 (a)(1)(v) requiring the physician responsible for performing the initial certification to document that the face-to-face patient encounter, which is related to the primary reason the patient requires home health services, has occurred no more than 90 days prior to the home health start of care date or within 30 days of the start of the home health care.

Additionally, we finalized documentation requirements associated with the face-to-face encounter by stipulating that the physician responsible for certifying the patient for home care must document on the certification itself or as an addendum to the certification that the condition for which the patient was being treated in the face-to-face patient encounter is related to the primary reason the patient requires home health services and why the clinical findings of such encounter support that the patient is homebound and in need of either intermittent skilled nursing services or therapy services and that the documentation must be clearly titled, dated and signed by the certifying physician and include the dated of the encounter. We also finalized that the non-physician practitioner performing the face-to-face encounter must document the clinical findings of that face-to-face patient encounter and communicate those findings to the certifying physician.

This package is an extension.

A. Justification

1. Need and Legal Basis

Section (o) of the Act (42 U.S.C. 1395 x) specifies certain requirements that a home health agency must meet to participate in the Medicare program. To qualify for Medicare coverage of home health services a Medicare beneficiary must meet each of the following requirements as stipulated in §409.42: be confined to the home or an institution that is not a hospital, SNF, or nursing facility as defined in sections 1861(e)(1), 1819(a)(1) or 1919 of Act; be under the care of a physician as described in §409.42(b); be under a plan of care that meets the requirements specified in §409.43; the care must be furnished by or under arrangements made by a participating HHA, and the beneficiary must be in need of skilled services as described in §409.42(c). Subsection 409.42(c) of our regulations requires that the beneficiary need at least one of the following services as certified by a physician in accordance with §424.22: Intermittent skilled nursing services and the need for skilled services which meet the criteria in §409.32; Physical therapy which meets the requirements of §409.44(c), Speech-language pathology which meets the requirements of §409.44(c); or have a continuing need for occupational therapy that meets the requirements of §409.44(c), subject to the limitations described in §409.42(c)(4).

On March 23, 2010, the Affordable Care Act of 2010 (Pub. L., 111-148) was enacted. Section 6407(a) (amended by section 10605) of the Affordable Care Act amends the requirements for physician certification of home health services contained in Sections 1814(a)(2)(C) and 1835(a)(2)(A) by requiring that, prior to certifying a patient as eligible for Medicare's home health benefit, the physician must document that the physician himself or herself or a permitted non-physician practitioner has had a face-to-face encounter (including through the use of telehealth services, subject to the requirements in section 1834(m) of the Act)", with the patient.

The Affordable Care Act provision does not amend the statutory requirement that a physician must certify a patient's eligibility for Medicare's home health benefit, (see Sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act.

2. Information Users

The CoPs and accompanying requirements specified in the regulations are used by Federal or State surveyors as a basis for determining whether a home health agency qualifies for approval or re-approval under Medicare**.** The Physician's certification and recertification of each patient's need for skilled care services; homebound status and the physician's clinical justification for skilled nursing management and evaluation of the care plan specified in the regulations at 42 CFR 424.22 are to used by contractors and by CMS when reviewing the patient's medical record as a basis for determining whether the patient is eligible for the Medicare home health benefit and whether the medical record meets the criteria for coverage and Medicare payment. CMS and the healthcare industry believe that the availability to the HHA of the type of records and general content of records, which this regulation specifies, is standard medical practice, and is necessary in order to ensure the well-being and safety of patients and professional treatment accountability.

3. Use of Information Technology

HHAs may use various information technologies to store and manage patient medical 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 home health should prepare or maintain these records. Home health agencies are free to take advantage of any technological advances that they find appropriate for their needs.

4. Duplication of Efforts

These requirements are specified in ways that do not require a home health agency to duplicate its efforts. If a home health agency already maintains these general records, regardless of format, they are in compliance with this requirement. The general nature of these requirements makes variations in the substance and format of these records from one HHA to another acceptable.

5. Small Businesses

These requirements will not have a significant impact on most home health agency and other providers that are small entities because the cost of meeting the requirements in this rule is less than 1 percent of total home health agency Medicare revenue. Further, most of the requirements in this rule are part of home health agency standard practices. We understand that there are different sizes of HHAs and that the burden for home health agency of different sizes will vary. A portion of the time and cost burden for providers is directly related to patient care and the staff necessary to provide care. A consistently smaller patient census leads to reduced burden because the smaller HHAs have less staff, complete less data collection and less patient rights orientation, etc.

6. Less Frequent Collection

CMS does not collect information directly from home health agencies. In most cases, the HHA rule does not prescribe the manner, timing, or frequency of the records or information that must be available. Home health agency records are reviewed at the time of a survey for initial or continued participation in the Medicare program and to ensure that the physician certification or recertification is signed and dated by the physician before the HHA bills Medicare. Less frequent information collection would impede efforts to establish compliance with the Medicare CoPs or Medicare coverage requirements.

7. Special Circumstances

Absent a legislative amendment, we are unable to anticipate any circumstances that would change the requirements of this package.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published on October 4, 2013 (78 FR 61848). No comments were received.

Requirements	# of Respondents	Burden Hours	Total Annual Burden Hours Associate with CY 2010 Final Rule
424.22	345,600	1/12	28,800

9. Payments/Gifts to Respondents

There will be no payments/gifts to respondents.

10. Confidentiality

Normal medical confidentiality practices are observed.

11. Sensitive Questions

There are no questions of a sensitive nature associated with this information collection.

12. Burden Estimates (Hours & Wages)

Written Narrative

Section 424.22 states that if a patient's underlying condition or complication requires a registered nurse to ensure that essential non-skilled care is achieving its purpose, and necessitates that a registered nurse be involved in the development, management, and evaluation of a patient's care plan, the physician will include a written narrative describing the clinical justification of this need. The narrative must be located immediately prior to the physician's signature. If the narrative exists as an addendum to the certification or recertification form, in addition to the physician's signature on the certification or recertification form, the physician must sign immediately following the narrative in the addendum.

The burden associated with this requirement is the time and effort put forth by the physician to include the written narrative. Because the physician has always been required to review the clinical information needed for deciding whether or not to certify or recertify the patient for Medicare home health services, we estimate it would take one physician approximately 5 minutes to meet this requirement. We estimate the frequency of such a situation to occur in about 5 percent of episodes (or about 345,600 episodes a year); therefore, the total annual burden associated with this requirement would be 28,800 hours for CY 2010.

Face-to-Face Encounter

The Home Health Prospective Payment System Rate Update for Calendar Year 2011 published on 11/2/2010 changes the certification requirements for Home Health Agencies. This rule implements a provision of the Affordable Care Act as a condition for payment. The

Affordable Care Act mandates that, prior to certifying a patient's eligibility for the HH benefit, the physician must document that the physician or a permitted nonphysician practioner (NPP) has had a face-to-face encounter with the patient. Additionally, the Affordable Care Act allows the Secretary to determine a reasonable timeframe for the encounter to occur. The certifying physician must document the face-to-face encounter regardless of whether the physician himself or herself or one of the permitted NPPs perform the face-to-face encounter. To implement this provision of the Affordable Care Act, we finalized §424.22 (a)(1)(v) requiring the physician responsible for performing the initial certification to document that the face-to-face patient encounter, which is related to the primary reason the patient requires home health services, has occurred no more than 90 days prior to the home health start of care date or within 30 days of the start of the home health care.

Additionally, we finalized documentation requirements associated with the face-to-face encounter by stipulating that the physician responsible for certifying the patient for home care must document on the certification itself or as an addendum to the certification that the condition for which the patient was being treated in the face-to-face patient encounter is related to the primary reason the patient requires home health services and why the clinical findings of such encounter support that the patient is homebound and in need of either intermittent skilled nursing services or therapy and that the documentation must be clearly titled, dated and signed by the certifying physician and include the date of the encounter. We also finalized that the non-physician practitioner performing the face-to-face encounter must document the clinical findings of that face-to-face patient encounter and communicate those findings to the certifying physician.

The burden associated with the documentation requirement for the patient's face-to-face encounter by the certifying physician includes the time for each home health agency to develop simple language stating that a face-to-face patient encounter has occurred and to attach the statements as an addendum or include the statements as part of the certification document. The statement of the patient's face-to-face encounter must also include the patient's name, a designated space for the certifying physician to provide the date of the patient encounter and a designated space for the certifying physician to provide his/her signature and the date signed. There were 9,432 home health agencies that filed claims in CY 2008. We estimate it would take each HHA 15 minutes of the home health administrator's time to design a revised certification form which would enable the recording of this documentation,and 15 minutes of clerical time for each HHA to revise their existing initial certification form or to create an addendum. The estimated total one-time burden for developing the patient encounter form would be 4,716 hours.

The certifying physician's burden for signing and dating the patient's face-to-face encounter is estimated at 5 minutes for each certification. We estimate that there would be 2,926,420 initial home health episodes in a year based on our 2008 claims data. As such, we are finalizing the estimated burden for signing and dating the patient's face-to-face encounter would be 243,868 hours for CY 2011.

Additionally, it has been our longstanding manual policy that physicians must sign and date the certification and any recertifications. Because it has been our longstanding manual policy that physicians sign and date certifications and recertifications there is no additional burden to

physicians.

HH Face-to-Face Assumptions and Estimates

# of Medicare HHAs nationwide	9,432 HHAs in CY 2008
# of initial HH episodes nationwide in one year	2,926,420 in 2008
# of annual certifications	2,926, 420
Hourly rate of Physician	$88.46/hour
Hourly rate of registered nurse	$30.65/hour
Hourly rate of office employee	$12.57/hour

Note: All salary information is from the Bureau of Labor Statistics website at http://www.bls.gov/oes/current/oes_nat.htm#b29-0000 Salary data are from May 2009. No fringe is added to the physician hourly rate because physicians performing this documentation would largely be self-employed.

HH FACE-TO-FACE ENCOUNTER BURDEN ESTIMATE: One Time Only Form Development by HHA & Physician Annual Burden

	Number of HHAs	Time per HHA (minutes)	Time per HHA (hours)	Total time, all HHAs (hours)	Hourly rate	Cost per HHA	Total cost
Assumes 9,432 HHAs							
One Time Only Form Development by HHA							
Form development (Nurse)	9,432	15	0.25	2,358 hrs.	$30.65	$7.66	$72,249
Form development (Clerk)	9,432	15	0.25	2,358 hrs.	$12.57	$3.14	$29,616
Subtotal costs, Form development	9,432	30	0.50	4,716 hrs.	$43.22	$10.80	$101,865
Physician Annual Burden for Verification & Completion of Home Health Initial Certifications							
	Number of certifica-tions	Time per certifica-tion (minutes)	Time per certifica-tion (hours)	Total time (hours)	Hourly rate	Cost per HHA	Total cost,
Physician	2,926,420	5	.0833333	243,868	$88.46	$ $2,287.17	$21,572,563
Total, all hours and costs							
Total all hours and costs,	2,926,420	5	.0833333		$88.46	$2,287.17	

	Number of HHAs	Time per HHA (minutes)	Time per HHA (hours)	Total time, all HHAs (hours)	Hourly rate	Cost per HHA	Total cost
424.22(a)(1)(v)				243,868			$21,572,563

13. Capital Costs

There are no additional capital costs.

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 compliance. The coverage and payment requirements associated with the home health face-to-face physician encounter provision does not create additional federal level costs; payment contractors use the data collected as part of their usual and customary claims processing and review activities.

15. Changes to Burden

This is an extension package. It does not set out any program changes or burden adjustments.

16. Publication/Tabulation Dates

We do not plan to publish any of the information collected.

17. Expiration Date

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

18. Certification Statement

There are no exceptions to the certification statement.

B. Collections of Information Employing Statistical Methods

This section does not apply because statistical methods are not associated with this collection.