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, OMB 0938-1083

A. Background

This is a revision to OCN 0938-1083 to remove the face-to-face encounter narrative requirement at §424.22(a)(1)(v), which was finalized in the CY 2015 Home Health Prospective Payment System (HH PPS) final rule (79 FR 66032).

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 a home health agency (HHA) that participates in the Medicare program, be provided under a plan of care certified or recertified by the patient's physician, (42 CFR 424.22), and performed 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 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.

As described in section 1814(a)(2)(c) and section 1835(a) (2)(A) 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, 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. The physician is required to sign the patient's individual home health plan of care and to certify or recertify that the patient is homebound and in need of skilled services, in order for the HHA to be reimbursed for providing Medicare covered services. The certification and recertification content requirements are stipulated in 42 CFR 424.22.

Section 6407(a) of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111-148, enacted March 23, 2010) as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152, enacted March 30, 2010), collectively referred to as the "Affordable Care Act" amended 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 tele-health services, subject to the requirements in section 1834(m) of the Act)", with the patient. In addition, as part of the certification of eligibility, the certifying physician must document the date of the encounter and include an explanation (narrative) of why the clinical findings of such encounter support that the patient is homebound, as defined in subsections 1814(a) and 1835(a) of the Act, and in need of either intermittent skilled nursing services or therapy services, as defined in § 409.42(c).

In order to simplify the face-to-face encounter regulations, reduce burden for HHAs and physicians, and to mitigate instances where physicians and HHAs unintentionally fail to comply with certification requirements, in the CY 2015 HH PPS final rule (79 FR 66032), we eliminated the face-to-face encounter narrative requirement at §424.22(a)(1)(v). The certifying physician is still required to certify that a face-to-face patient encounter, which is related to the primary reason the patient requires home health services, 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 and was performed by a physician or allowed non-physician practitioner as defined in §424.22(a)(1)(v)(A), and to document the date of the encounter as part of the certification of eligibility. In addition, due to confusion regarding when the certifying physician is required to document that a face-to-face encounter occurred with the patient, we clarified that a face-to-face encounter is only required for certifications, meaning any time a new start of care assessment is completed to initiate care. Documentation of the face-to-face encounter is not required for re-certifications.

B. Justification

1. Need and Legal Basis

Sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act require a physician to certify that home health services are or were required because the patient:

1. Is or was confined to his/her home;
2. Needs or needed skilled nursing care (other than solely venipuncture for the purpose of obtaining a blood sample) on an intermittent basis or physical or speech therapy or continues or continued to need occupational therapy;
3. A plan for furnishing such services has been established and is periodically reviewed by a physician; and
4. Such services are or were furnished while the individual was under the care of a physician.

Effective for certifications after January 1, 2010, the Affordable Care Act requires that prior to certifying the patient's eligibility for home health services as outlined above, the physician must document that:

5. A physician, nurse practitioner, clinical nurse specialist, certified nurse-midwife, or a physician assistant had a face-to-face encounter with the patient within a reasonable timeframe as determined by the Secretary.

Sections 1814(a) and 1835(a) of the Act state that the certification and recertification requirements are deemed satisfied only where such certification is accompanied by such medical and other evidence as may be required by such regulations.

Similarly, as outlined in sections 1814(a)(2) and 1835(a)(2) of the Act, material that appropriately supports their certification and recertification of Medicare home health beneficiaries is to accompany certifications/re-certifications, as provided by regulations.

The statutory requirements listed above are also outlined in regulation at 42 CFR 424.22.

2. Information Users

This revised information collection approach will allow CMS to limit burden to providers by removing the written narrative requirement, previously at §424.22(a)(1)(v), while still obtaining the required information for the face-to-face requirement used for determining patient eligibility for home health care. As such, CMS will continue to require HHAs and physicians to meet the face-to-face requirements at 42 CFR 424.22(a)(1)(v).
CMS and CMS contractors use the information in the patient's medical record, supplied from the certifying physician and/or the acute/post-acute care facility to the HHA, as the basis for determining whether the patient was eligible for the Medicare home health benefit and whether the medical record meets the criteria for coverage and Medicare payment. Additionally, HHA records are reviewed at the time of a State survey of the provider for initial or continued participation in the Medicare program and by CMS and /or its contractors during medical review as a basis for determining whether the patient was eligible for the Medicare home health benefit and whether the services provided met the criteria for coverage and Medicare payment. Thus, compliance with the requirements at 42 CFR 424.22 continue to be mandatory and are subject to review to verify compliance with program regulations.

3. Use of Information Technology

HHAs and other providers 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 HHA or other providers should prepare or maintain these records. HHAs and other providers

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 HHA or other providers to duplicate their efforts. If a HHA or other provider 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 or other provider to another acceptable.

5. Small Businesses

These requirements will not have a significant impact on most HHAs and other providers (such as physicians, physician practices, or acute/post-acute care hospitals or facilities) that are small entities because the cost of meeting the requirements in this rule is less than 1 percent of total HHA Medicare revenue and these requirements reduce the cost of compliance for other providers. Further, most of the requirements in the CY 2015 final rule are part of HHA and other provider standard practices. We understand that there are different sizes of HHAs and other providers and that the burden for HHAs and other providers 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 due to less data collection and less patient rights orientation, etc.

6. Less Frequent Collection

In most cases, the CY 2015 HH PPS final rule does not prescribe the manner, timing, or frequency of the records or information that must be available. The revised information collection only removes the physician narrative requirement. HHAs and physicians are still required to satisfy the criteria at 42 CFR 424.22 when determining patient eligibility for home health care. 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 final rule published on July 29, 2016 (81 FR 49985). The 30-day Federal Register notice published on October 31, 2016 (81 FR 75409).

We received 29 comments during the 60-day comment period and 0 comments during the 30-day comment period.

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)

In eliminating the face-to-face encounter narrative requirement, we assumed there will be a one-time burden for the HHA to modify the certification form, which the HHA provides to the certifying physician. The revised certification form must allow the certifying physician to certify that a face-to-face patient encounter, which is related to the primary reason the patient requires home health services, 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 and was performed by a physician or allowed NPP as defined in §424.22(a)(1)(v)(A). In addition, the certification form must allow the certifying physician to document the date that the face-to-face encounter occurred.

We estimate that it will take a home health clerical staff person 15 minutes (15/60 = 0.25 hours) to modify the certification form, and the HHA administrator 15 minutes (15/60 = 0.25 hours) to review the revised form. The clerical time plus administrator time equals a one-time burden of 30 minutes or (30 / 60) = 0.50 hours per HHA. For all 11,327 HHAs, the total time required will be (0.50 x 11,327) = 5,664 hours. At $34.76 per hour for an office employee, the cost per HHA will be (0.25 x $34.76) = $8.69. At $117.40 per hour for the administrator's time, the cost per HHA will be (0.25 x $117.40) = $29.35. Therefore, the total one-time cost per HHA will be $38.04, and the total one-time cost for all HHAs will be ($38.04 x 11,327) =$430,879.

In the CY 2011 HH PPS final rule (75 FR 70455), we estimated that the certifying physician's burden for composing the face-to-face encounter narrative, which includes how the clinical findings of the encounter support eligibility (writing, typing, or dictating the face-to-face encounter narrative), signing, and dating the patient's face-to-face encounter, was 5 minutes for each certification (5 / 60 = 0.0833 hours).

Although we finalized elimination of the narrative, the certifying physician will still be required to document the date of the face-to-face encounter as part of the certification of eligibility. We estimate that it will take no more than 1 minute for the certifying physician to document the date that the face-to-face encounter occurred (1 / 60 = 0.0166 hours). The estimated burden for the

certifying physician to continue to document the date of the face-to-face encounter will be 0.0166 hours per certification or 54,084 hours total (0.0166 hours x 3,258,095 initial home health episodes). At $193.08 per hour for a certifying physician, the estimated cost for the certifying physician to continue to document the date of the face-to-face encounter will be $3.21 per certification (0.0166 x $193.08) or $10,458,485 total ($3.21 x 3,258,095) for CY 2016. Therefore, in eliminating the face-to-face encounter narrative requirement, we estimate that burden and costs will be reduced for certifying physicians by 217,315 hours (271,399 – 54,084) or $34,014,511 ($44,472,996 - $10,458,485).

To determine when documentation of a patient's face-to-face encounter is required under sections 1814(a)(2)(C) and 1835 (a)(2)(A) of the Act, in the CY 2015 HH PPS final rule (79 FR 66032), we finalized a clarification that the face-to-face encounter requirement is applicable for certifications rather than initial episodes. A certification (versus recertification) is generally considered to be any time that a new start of care OASIS is completed to initiate care.

We estimate that of the 6,276,792 home health episodes in CY 2015, 3,258,095 start of care assessments were performed on initial home health episodes. An additional 602,418 episodes will require documentation of a face-to-face encounter for subsequent episodes that were initiated with a new start of care OASIS assessment. We estimate that it will take no more than one minute for the certifying physician to document the date that the face-to-face encounter occurred (1 / 60 = 0.0166 hours). The estimated burden for the certifying physician to document the date of the face-to-face encounter for each certification (any time a new start of care OASIS is completed to initiate care) will be 0.0166 hours or 10,000 total hours (0.0166 hours x 602,418 additional home health episodes). The estimated cost for the certifying physician to document the date of the face-to-face encounter for each additional home health episode will be $3.21 per certification (0.0166 x $193.08) or $1,933,762 total ($3.21 x 602,418).

Table 1
HH Face-to-Face Assumptions and Estimates

# of Medicare-billing HHAs, from CY 2016 claims with matched OASIS assessments	11,327
Hourly rate of an office employee (Executive Secretaries and Executive Administrative Assistants, 43-6014)	$34.76
Hourly rate of an administrator (General and Operations Managers, 11-1021)	$117.40
Hourly rate of Family and General Practitioners (29-1062)	$193.08

All salary information is from the Bureau of Labor Statistics website at http://www.bls.gov/oes/current/naics4_621600.htm and includes a fringe benefits package worth 100 percent of the base salary. The mean hourly wage rates are based on May 2016 BLS data for each discipline, for those providing "home health care services."

Table 2
HH FACE-TO-FACE ENCOUNTER
ONE-TIME ESTIMATED BURDEN: Form Revision by HHA

	Number of HHAs	Time per HHA (minutes)	Time per HHA (hours)	Total time, all HHAs (hours)	Hourly rate	Cost per HHA	Total cost
Assumes 11,327 HHAs							
One Time Only Form Revision by HHA							
Form development (Clerk)	11,327	15	0.25	2,832	$34.76	$8.69	$98,432
Form development (Administrator)	11,327	15	0.25	2,832	$117.40	$29.35	$332,447
Subtotal costs, Form revision	11,327	30	0.50	5,664	$152.16	$38.04	$430,879

Table 3
HH FACE-TO-FACE ENCOUNTER
ESTIMATED BURDEN REDUCTION FOR CERTIFYING PHYSICIANS
(No Longer Drafting a Face-to-Face Encounter Narrative)

Physician Annual Burden for Verification & Completion of Home Health Initial Certifications							
	Number of certifica-tions	Time per certification (minutes)	Time per certification (hours)	Total time, (hours)	Hourly rate	Cost Per certification	Total cost
Physician	3,258,095	(4)	(.0667)	(217,315)	$193.08	($10.44)	($34,014,511)

Table 4
HH FACE-TO-FACE ENCOUNTER
ANNUAL BURDEN ESTIMATE: Physician Certification (for additional certifications)

Physician Annual Burden for Verification & Completion of Home Health Initial Certifications							
	Number of certifica-tions	Time per certification (minutes)	Time per certification (hours)	Total time, (hours)	Hourly rate	Cost Per certification	Total cost
Physician	602,418	1	.0166	10,000	$193.08	$3.21	$1,933,762

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

The CY 2015 HH PPS final rule implemented policy changes to the face-to-face encounter requirements at §424.22(1)(1)(v) that result in an estimated net reduction in burden of 217,315 hours or $32,080,749 for certifying physicians (see Tables 3 and 4). The finalized policy changes to the face-to-face encounter requirements at §424.22(a)(1)(v) will result in a

one-time burden of 5,664 hours or $430,879 for HHAs to revise the certification form (see Table 2).

16. Publication/Tabulation Dates

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

17. Expiration Date

Upon receiving OMB approval, CMS will publish a notice in the Federal Register to inform the public of both the approval as well as the 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.